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Safety Considerations for IMRT

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This document was prepared by the IMRT experts invited by the Multidisciplinary Quality Assurance Subcommittee of the Clinical Affairs and Quality Committee of the American Society for Radiation Oncology (ASTRO) as a part of ASTRO's Target Safely Campaign.

The IMRT white paper was reviewed by 8 experts from the field of IMRT. In December 2010, it was posted for public comments for 4 weeks. We received comments from physicians, physicists, therapists, and representatives from radiation therapy manufacturers, including general and specific comments from the American Association of Physicists in Medicine (AAPM). All the comments were reviewed and discussed by the entire writing group and appropriate revisions were incorporated in the paper with group consensus.

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This white paper was prepared on the basis of information available at the time the Writing Group was conducting its research and discussions on this topic. There may be new developments that are not reflected in this white paper and that may, over time, be a basis for ASTRO to consider revisiting and updating the white paper.

Conflict of Interest Notification:

Before initiation of this white paper, all members of the White Paper Writing Group were required to complete disclosure statements. These statements are maintained at ASTRO Headquarters in Fairfax, VA and pertinent disclosures are published with the report. The ASTRO COI Disclosure Statement seeks to provide a broad disclosure of outside interests. Where a potential conflict is detected, remedial measures to address any potential conflict are taken and will be noted in the disclosure statement. Dr. Jean Moran has received a research grant, paid to the University of Michigan, from Varian Medical Systems. Dr. Avraham Eisbruch is a Chair of an independent review committee assessing the complications of investigational protocol at Amgen. Dr. Geoffrey Ibbott has received a research grant, paid to the University of Texas M. D. Anderson Cancer Center, from Varian Medical Systems, and is a consultant with the Young Ricchiuti Caldwell and Heller Law Firm LLC. Dr. Benedick Fraass serves on the Varian Patient Safety Council. He receives no compensation or reimbursement for this work. The Writing Group Chair ensured that the white paper was built by consensus to deliberately minimize any potential conflicts of interest. ASTRO has reviewed these disclosures and determined that they do not present a conflict with respect to these Writing Group members' work on this White Paper.

Safety Considerations for IMRT

1. Introduction

1.1 Scope of this Document on Patient Safety for IMRT

This report on intensity-modulated radiation therapy (IMRT) is part of a series of white papers addressing patient safety commissioned by the American Society for Radiation Oncology's (ASTRO) Target Safely Campaign. The document was approved by the ASTRO Board of Directors on February 14, 2011 and has been endorsed by the American Association of Physicists in Medicine (AAPM), American Association of Medical Dosimetrists (AAMD), and the American Society of Radiologic Technologists (ASRT). The document has also been reviewed and accepted by the American College of Radiology's Commission on Radiation Oncology.

This report is related to other reports of the ASTRO white paper series on patient safety, still in preparation, especially those on peer review and on image-guided radiation therapy (IGRT) since both of these areas have implications on the practice of IMRT. There are sections of this document that defer to guidance that will be published by those groups in future reports. We respectfully acknowledge that there is a larger body of work on quality assurance and quality control principles within the medical community at large [1,2,3] and within radiation oncology [4,5]. In addition, a number of international agencies actively support patient safety such as the World Health Organization (WHO), the International Commission on Radiological Protection (ICRP), the European Society of Therapeutic Radiology and Oncology (ESTRO) and the International Atomic Energy Agency (IAEA). Many of the quality control/assurance issues pertinent for IMRT are also pertinent for broader clinical practice, and will likely be addressed in a later paper. However, because this is the first report in the series, some of these more "generic concerns", that are not limited to IMRT, are herein included.

IMRT provides increased capability to conform isodose distributions to the shape of the target(s), thereby reducing dose to some adjacent critical structures. This promise of IMRT is one of the reasons for its widespread use. However, the promise of IMRT is counterbalanced by the complexity of the IMRT planning and delivery processes, and the associated risks.

The New York Times reported on serious accidents involving both IMRT and other radiation treatment modalities [6,7]. This report provides an opportunity to broadly address safe delivery of IMRT, with a primary focus on recommendations for human error prevention and methods to reduce the occurrence of errors or machine malfunctions that can lead to *catastrophic failures or errors.*

1.2 Background Information on IMRT

Treatment planning and delivery of IMRT require use of specialized software and hardware. Table 1 defines example documentation, software, and hardware that are the key components of an IMRT program.

Regardless of the delivery technique, an institution with an IMRT program requires a full treatment team, proper equipment, and proper procedures to safely care for radiation therapy patients. It is crucial to have individuals with proper credentials and training specific to radiation therapy for the simulation, treatment planning, QA, and delivery processes. For IMRT, the roles of the treatment team members are described in detail in a report from the IAEA.[8] The IMRT team members discussed in this report include radiation oncologists, medical physicists, dosimetrists (or treatment planners), radiation therapists, and administrative staff. Special attention should be paid to the roles of the physician and physicist; both board certified medical specialists who share responsibility for IMRT quality. The physician has the overall responsibility for the IMRT program. The physicist is responsible for commissioning the entire IMRT program (hardware and software), maintaining software/equipment for treatment planning and delivery, overseeing (typically with the help of the equipment manufacturer) training of individuals who use the software and delivery equipment, overseeing treatment planning and quality assurance of individual treatment plans, and monitoring the accuracy of the treatment delivery throughout an individual patient's treatment course.

2. Safety Concerns

This document presents tools and techniques that can be used by individual clinics to reassess and strengthen the safety of their IMRT programs. Due to the complexity of IMRT delivery, we believe it is unsafe for IMRT to be delivered in emergent situations that would encourage staff to skip the needed quality assurance steps. And yet, given the pressures that every clinic is under, and the desire to meet multiple needs, it can be difficult to ensure support for this approach. Hazards within an IMRT program can be broadly categorized as environmental or technical. Environmental concerns, that can affect all patient treatments, include things such as the lack of standard operating procedures, haste (such as inadequate time to perform all steps in a process), habituation, incomplete understanding or misuse of procedures/equipment, an inadequate QA program, and a lack of continuing staff education. While these hazards are not unique to IMRT, their impact may be large due to the complexity of IMRT. Therefore, a portion of this report is also devoted to creating and supporting a culture of safety to address environmental concerns whose affect are not limited to IMRT.

Technical concerns that affect safety include things such as inadequate commissioning of the clinical IMRT

Table 1. Key Components of an IMRT System

Component	Description
Written treatment directive	Clear communication from physician to dosimetrist/physicist regarding desired treatment planning goals including target doses and normal tissue limits.[21]
Treatment planning system (TPS)	Software used to create the representation of the patient, define volumes for treatment and avoidance, position and shape beams for planning, optimize the intensities (weights) of small beamlets, and calculate dose. For IMRT, cost or objective functions (these may be points on a dose-volume histogram) are specified to best meet the written treatment directive. IMRT treatment planning is typically an iterative process that requires interactions between physicians, dosimetrists, and physicists.[18,19] The TPS may use a fluence-based approach by creating larger segments from the small beamlets to achieve more efficient dose delivery.
Conversion of desired fluence into a field consisting of segments	For fluence-based systems, the fluence is converted into a series of segments or sequences as a function of time (and monitor units) which can be delivered by the treatment machine. The number of MLC segments may range from 5 to greater than 100 for a given field. Approximations in the TPS modeling may result in differences between the optimized and actual delivered fluence. This can be a challenging issue during the planning and delivery process.[18,19,20]
Plan transfer to the treatment management system	The treatment data are transferred from the TPS to the TMS for delivery. Verifying the correctness and integrity of all data, as well as confirming the deliverability of the leaf sequences to be used, are among the most critical steps to be confirmed in the IMRT QA process.[18,19,15] Lack of transfer of the MLC files is a known cause of a catastrophic failure.
Treatment management system (TMS)	The TMS is used to deliver the patient treatment. This system has a record of the treatment plan to be delivered, the number of fractions, etc and it also tracks the delivery dates, dose, and other associated information. Use of the patient information stored in the TMS is an important part of a pre-treatment QA program.
Patient specific pre-treatment quality assurance (QA)	Because of the complexity of IMRT planning and delivery, pre-treatment patient-specific quality assurance has been recommended in guidance documents from ASTRO, ACR, and AAPM.[18,19,26,15]
Equipment for pre-treatment QA	Equipment for IMRT typically includes multiple complementary detectors and phantoms to verify the accuracy of the data transfer and dose calculations. Some centers may also have monitor unit check software for treatment field calculations, and this capability is often used in combination with measurements.
Analysis software	Many systems utilize the gamma analysis technique to compare calculations and measurements.[28] Users typically specify the number of points that are expected to satisfy the criteria for dose (in Gy or in %) and distance (in mm) for agreement when they establish their program.
Linear accelerator for treatment delivery	The linear accelerator needs to be capable of accurately delivering intensity modulated treatments. For gantry-based systems using an arc delivery technique (e.g.VMAT), additional information regarding the accuracy of the gantry information at multiple delivery points need to be validated as well. For these systems, derivation of the delivery information as described for leaf sequencing above would also include verification that the gantry sequences, leaf positions, dose delivery, and time information are correct and registered (in time and MU) correctly. Guidelines for commissioning and pre-treatment QA for VMAT treatment plans are currently under development.

Table 2. Example Distribution of Responsibilities in the IMRT Planning and Delivery Process.

	Physician	Dosimetrist*	Physicist	Therapist
Decides to use IMRT Primary	Primary	Advisory	Advisory	
Patient positioning	Supervisory	Supervisory or advisory	Advisory	Primary
Registration of image datasets	Approval	Primary or secondary	Primary or secondary	Primary or secondary
Segmentation of images (e.g. contouring)	Targets, certain structures, also approves/ reviews other's segmentations	Normal tissues, expanded volumes		
Specifies dose constraints	Primary	Advisory	Advisory	
Calculate dose		Primary	Supervisory or advisory	
Review treatment plan and 3D doses	Primary	Primary (compare to physician requests)	Advisory (Final review)	Secondary
Perform and evaluate patient-specific pre-treatment QA†	Advisory		Primary	
Treat patient	Supervisory	Advisory	Supervisory	Primary
Monitor patient for effects to treatment‡	Primary			Advisory
Monitor accuracy of delivery	Primary (review and approve portal images, and pre- treatment dosimetry measurements)		Primary beam parameters, monitor units, doses)	Primary

* This refers to the individual performing the treatment planning.
† See text in section 4 for more detail.
‡ Nurses and mid-level providers also assist in monitoring the patient during the course of therapy and may provide additional information to the physician regarding the patient's progress.

program, inadequate validation of the accuracy of treatment delivery parameters, improper use of one or more parts of the planning and delivery process, and an inadequate investigation of discrepancies between treatment plan parameters and QA results.

One source of increased risk with IMRT is the large number of monitor units per treatment.[9]) Compared to non-IMRT treatments, the monitor units can be increased by about a factor of 3 or more depending on the modulation and delivery efficiency. This may increase the risk of catastrophic dose delivery error in some circumstances. Another potential risk is the shape and orientation of the beams, and the resultant dose distribution, relative to critical structures. If steep dose gradients are placed at the edge of targets and/or normal tissues, the accuracy of set-up may be critical. Proper use and frequency of imaging techniques (e.g. IGRT) are helpful to verify patient positioning and will be presented in the IGRT Safety White Paper.

IMRT treatment planning and delivery involves a full treatment team (see Table 2 with an example distribution of the roles for the team members). Some clinics distribute effort differently; e.g. a physicist may perform IMRT treatment planning instead of a dosimetrist. Regardless of the distribution of effort, care should be taken to have a mechanism in place for independent review of each patient's plan, data transfer, and QA results. For example, a dosimetrist may be responsible for reviewing and downloading the plan before the physicist performs additional pre-treatment quality assurance checks. Clinics with limited physics/dosimetry staff should arrange 1) for peer review of their overall IMRT quality program and 2) especially for independent review of patient-specific IMRT QA. For example, AAPM Task Group Report 103 describes a mechanism for components of peer review.[10])

The process of IMRT treatment planning and delivery is complex (see Appendix 1 for detailed listing of the main process steps for IMRT planning and delivery). All individuals described as part of the IMRT team in this report play a critical role in assuring that each patient receives the correct treatment. Some of the tasks commonly ascribed to the different team members, each with the ability to prevent or detect catastrophic failures for IMRT, are listed below. The tasks listed include broad programmatic issues, as well as patient-specific items.

Attending Physician:

- Oversees the process that guarantees that each patient receives the correct treatment for the correct treatment site, as documented in the patient's chart and verified by imaging. This oversight includes verification of the correct treatment prescription, segmentation of target volumes, image registration, treatment plan, and image guidance strategy (See IGRT White Paper for more details).
- For any IMRT QA failures, oversees decision to delay patient treatment, begin treatment with a simpler plan, or other approach.
- Monitors the patient for any unexpected or early treatment side effects and communicates with the physicist, dosimetrist, and therapists in such situations.

Medical Physicist:

- Responsible for the clinical commissioning and use of the treatment planning, treatment management, and treatment delivery systems.
- Designs the quality assurance system, QA checks, and performs or supervises the routine QA checks of equipment and software. Verifies that equipment and procedures perform within pre-defined tolerance values.
- Oversees or performs the patient-specific pre-treatment IMRT QA measurements, reviews the results, and communicates with the team regarding the results. Defines the criteria for pass vs. failure of the IMRT patient-specific QA. Defines for the team the dosimetric implications of discrepancies between the anticipated and measured beam data.

Medical Dosimetrist:

- Verifies correct patient, treatment site, and correct image datasets from simulation (and other studies if appropriate).
- Creates a treatment plan per the physician-defined clinical goals. This is often an iterative process requiring feedback from physicians and medical physicists.
- Verifies that the treatment plan is reviewed (e.g. for target coverage and normal tissue exposure), and highlights for the physician the areas where the plan failed to meet the desired dose goals.
- Notifies the physicists of any software problems during the planning, data transfer, or review. If this occurs, individuals should stop at that point in the process and further immediate investigation is needed by the physicist.
- Enters the approved plan information into the patient's chart and the treatment management system.

Radiation Therapists:

- Prior to commencing a course of treatment: Review the approved treatment plan information, review instructions and directives for internal consistency and logic, and that the other team members have completed and provided formal approval for their tasks (e.g. patient-specific pre-treatment physics QA).

- Prior to each treatment session: Confirm that the patient prescription is still valid (e.g. physician has not changed the treatment plan or closed the course). The ASRT Radiation Therapy guide recommends the performance of a time-out prior to "beam on" to verify the correct patient and correct isocenter for each treatment delivery.[11]
- Prior to initial treatment and as prescribed thereafter: Obtain and review appropriate images. Seek approval per department standard operating procedure (SOP).
- During treatment: monitor treatment conditions and patient for inconsistencies or irregularities.
- Notifies the physicists of any machine or software problems when they arise during treatment. If a problem occurs, the therapists should stop at that point in the treatment delivery. The physicist should review the machine and software status and determine if it is safe to resume treatment.

Administrators:

- Provide adequate resources for personnel, equipment, and time for commissioning an IMRT system.
- Support the time required for personnel to develop standard operating procedures.
- Support continuing education on IMRT for all personnel.
- Provide support for individuals to be able to halt any procedures that are deemed unsafe.

Additional Personnel:

Other personnel also contribute to the care and safety of IMRT patients, e.g. nurses and physician's assistants working with physicians; physics assistants working with medical physicists; and trainees in all areas working with their corresponding certified or licensed specialist. In addition, good communication between the department's information technology (IT) personnel, the manufacturer's service engineers, and the physicists is crucial for maintaining the correct versions of software and ensuring that necessary upgrades occur and are tested prior to clinical use.[12] The IAEA guidance document on the roles and responsibilities for IMRT also specifies supervision responsibilities and is an excellent reference for each department to use in defining the roles and supervisory requirements for IMRT.[8]

The tasks above are only a sampling of the many tasks required by each team member. Appendix 1 provides a detailed listing of the tasks, by team member, and in approximate chronologic order. When the steps for IMRT are considered sequentially, the process includes 54 process steps and 15 hand-offs between the personnel. This illustrates the critical need for clearly defined roles, and unambiguous/robust hand-offs (and means of communication) between personnel. The amount of work involved also demonstrates the importance of timely peer review at key points in the process. Key items from Appendix 1 (and the list above) were used to create checklists that can be considered for pre-IMRT time-outs (see Appendix 2). These checklists should be customized in accordance with the assignment of tasks and workflow in individual clinics.

3. Supporting a Culture of Safety for IMRT: Environmental Considerations

3.1 Department Environment

This section addresses safety concerns involving the environment in the department. The departmental leadership establishes the foundation for patient safety and teamwork. They can minimize the likelihood of catastrophic failures through a variety of elements. While these elements are not unique to IMRT, we believe that they are crucial for ensuring a safe radiation therapy program, especially since IMRT requires additional equipment, personnel, and procedures for safety.

- **The members of the department must trust each other.[1]**

- **Strong administrative support for safety:**

Administrators help set the tone within the department by openly supporting error-prevention and taking responsibility for supplying necessary resources (e.g. equipment), training, and personnel (e.g. adequate staffing levels) while providing sufficient time to complete necessary quality assurance and controls. At this time, regulations do not specify the training requirements for non-physician personnel involved in IMRT. Efforts are underway by national organizations to update the requirements for staffing for IMRT and other techniques. Until those reviews/documents are available, we recommend that treatment units be staffed with at least two therapists at all times (one to focus on the patient during delivery and one to focus on the treatment console), and that all IMRT plans be independently verified/reviewed by a second physicist/dosimetrist prior to plan export to the machine. For physicians, peer review of treatment volumes and plans (to be addressed in a separate document in the white paper series) is valuable along with continuing education activities such as expert workshops on image segmentation. Administration should also provide funding and time for periodic independent peer review[10] of the quality assurance program.

- **Event tracking, review, investigation:**

To improve error prevention and remediation of events(any unplanned/undocumented deviation from the depart. ment's standard process or the patient's expected treatment), the team should discuss potential and actual sources of errors and document all events that occur. All catastrophic or significant errors, or substantial near misses, should be reviewed in a timely fashion by the team and treatments should be halted if necessary. Additional resources may be required to appropriately document and evaluate such events.

- **Appropriate personnel and training:**

All personnel involved in the process of patient care with IMRT should have adequate training, access to continuing education, and certification (and/or a license or appropriate oversight by a licensed or certified individual as defined in ACR guidance documents).[13,14]Educational programs organized by national and international radiation therapy organizations often include training specific to IMRT. To evaluate the adequacy of commissioning, personnel should have time to 1) read and follow guidance documents such as TG119[15] which describes tests that compare local IMRT QA measurements with published results and [2] participate in an independent evaluation using a phantom test such as those that have been designed by the Radiological Physics Center (RPC) for IMRT. When participating in an independent audit, IMRT tasks should be performed by the same personnel who would perform the task for a patient.

- **Use of Standard Operating Procedures:**

Standard operating procedures (SOPs) that contain a clear description of tasks and checks that are specifically aimed at avoiding catastrophic failures are an essential element of error prevention. Such SOPs should include a time frame for completion of tasks and checks. This report includes example checklists for IMRT that can be adapted to be part of a SOP. Standard operating procedures are discussed in greater detail in Section 3.2.

- **Defined Roles and Responsibilities for Team Members:**

As noted in Section 3.2, each clinic should have policies that clearly define the roles and responsibilities of the personnel involved in IMRT.

- **Strong Communication among Team Members:**

Team members must have the opportunity to regularly interact with each other during the planning and delivery process. For example, a physicist needs to be available immediately for any problems that may arise with the software or equipment during the treatment delivery to review error messages and to verify that the equipment is safe to use before the therapists resume a patient's treatment. Also, there are situations when it is extremely valuable for a dosimetrist or a physicist to be in the treatment room during the initial patient setup to explain the details of the location of the treatment unit isocenter, when photographs and/or drawings may be insufficient. Similarly, locating IMRT-planning and physician-work areas close to each other will facilitate such interactions. Extra caution should be taken with "remote planning" since clear communication is more difficult. Administration should encourage and allow adequate time for open communication among team members who must feel comfortable challenging each other; without reprisals. In addition, individuals must be able to freely question each step of the process. Such open communication is needed for inter-team discussions about problems that may arise during the planning/delivery of IMRT (see Table 3 for examples).

- **ACR/ASTRO Practice Accreditation**

To better support safety in radiation therapy, we recommend that departments become accredited through the joint ACR/ASTRO practice accreditation process, which includes a systematic review of a department's procedures and the adequacy of the training for personnel. During the independent review process, the department's SOPs for each treatment procedure along with sample checklists can serve as an efficient and effective mechanism for determining the facility's ability to mitigate errors such as possible catastrophic patient errors. With respect to IMRT, comprehensive evaluation should include a review of the department's [1] accelerator QA program for IMRT, [2] patient-specific pre-treatment QA program, [3] SOP and timelines for IMRT, [4] communication mechanisms between members of the IMRT team, [5] review of documentation for a randomly chosen patient case (written directive for simulation and treatment planning, prescription, treatment plan, QA, and delivery records) and [6] an assessment of whether or not the procedures and department culture are aimed at avoiding catastrophic errors and supporting patient safety.

Currently, 9% of US radiation oncology departments are accredited by the ASTRO/ACR program. While the number of institutions accredited at this time is low, independent reviews of quality assurance programs that are provided through accreditation and other external peer review methods are invaluable. It will take some time to increase the number of institutions participating in accreditation.

Table 3. Example problems in the planning and delivery process for IMRT and possible remedial actions.

Stage	Example Problem	Example Communication Flow		Possible Action
		From:	To:	
Simulation	Patient not positioned adequately	Dosimetrist upon review of patient setup contacts therapists and physician	Therapist, physician	Adjust positioning and re-simulate; review frequency and type of image guidance; avoid or mitigate with routine dosimetrist participation at simulation
Treatment Planning	Segmentation error	Peer physician	Treating physician	Replanning may be needed. Can reduce the occurrence of error by earlier peer review
Treatment Planning	Treatment plan does not meet constraints	Dosimetrist/ Physicist	Physician, physicist	Physician needs to redefine trade-offs and provide revised prescription information to the dosimetrist; physician may need to consult with the patient regarding trade-offs; physicist may assist in redesigning the plan
Pre-treatment QA	IMRT QA failed	Physicist	Whole team including physician	Review causes for failure: Is it a new technique? Was the technique thoroughly tested? Is anything different? What is the root cause of the problem? Is target volume vs critical structure geometry more challenging than typical cases for this disease site?
During Treatment Course	Patient showing unusual early effects to radiation	Physician; therapist	Other caregivers, dosimetrist and physicist, physician	Review treatment plan and QA; review patient set-up (e.g. positioning, beam placement); verify accuracy of data in RV; review possible confounding clinical factors (e.g. medication use, chemotherapy)
During Treatment Course	Immobilization device no longer fits snuggly (e.g. loose head mask)	Therapist	Physician, dosimetrist	Assess anatomic changes, and dosimetric effects: possible re-simulation/ immobilization

- **Continuous Quality Improvements**

Departments should continually evaluate the adequacy of their programs. Administration should maintain records of staff continuing education credits for IMRT and other procedures and should regularly support individuals in receiving the appropriate education. National organizations should evaluate the formal requirements for IMRT-specific re-education.

3.2 Standard Operating Procedures for IMRT

Part of the foundation of a safe and high quality IMRT program is the creation of standard operating procedures (SOPs). It is important for each institution to customize procedures to reflect their institutional processes and resources when creating a program that explicitly incorporates patient safety.

We believe that SOPs help improve patient safety. In our daily lives, we have become insensitive to situations where software or a device may not work and by habit we simply restart the software or the device and try again. However, in the context of delivery radiation therapy, this approach can be dangerous. For example, if error messages are encountered during transfer of information to the treatment management system, it is critical for the physicist to be called and for a full investigation of the transferred information (and an assessment of the system) to occur. We believe that SOPs that empower individuals to halt treatment or planning when a problem is encountered can be used to empower individuals to stop in the midst of a problem, to take the time to understand the problem, and to decide upon the best course of action. In the midst of a situation where adequate time is not allowed for performing all of the necessary QA steps prior to treatment, time pressures may stand in the way of identifying and resolving problems. One of the root causes of inadequate commissioning of IMRT systems may be tied to the clinical pressures to create an IMRT program as quickly as possible.

A program can be more complex when IMRT is combined with other techniques such as respiratory motion management, dynamic delivery, real-time adaptive techniques and/or daily image guidance. Thus, similar to complex procedures used in many other medical specialties, implementation of and adherence to detailed policies and procedures are necessary to avoid both quality errors and catastrophic failures. The use of a checklist can rigorously enforce adherence to the procedures as documented in the IMRT SOP (see example checklist, Appendix 2).

The IMRT SOP document should:

- Be a written document that requires adherence to the clearly stated procedures for IMRT planning, verification, and delivery.
- Describe the check, double-check, and testing procedures designed to minimize catastrophic failures.
- Explicitly identify at each step the dependence of the work on the quality of the previous step. Figure 1 shows an example IMRT planning and treatment process with communication paths among members of the department.
- Specify the timeline for completion of quality assurance checks as well as actions to be taken when measured values fall outside of tolerances. Patient-specific QA for IMRT plans should be performed before a patient begins treatment with a given treatment plan.
- Specify how the treatment management system will be used and how user rights need to be set. For example, therapists need access permissions to view the treatment plan and prescription information but should not have software permission to edit this information. Special attention should be paid to the user rights for acquiring or over-riding treatment couch (and other) equipment positions since the potential for a catastrophic failure exists if the patient is treated in the wrong position. Tolerance tables should be specified in the system to be sensitive to errors in the patient's position when using indexed immobilization equipment. The function of these features may be specific to the treatment planning and treatment management system vendors and software versions.
- Designate procedures when a change is needed in the plan of a patient already under treatment. These procedures should include the necessary QA processes that are followed for new plans.
- Be specific to the clinic's operations and equipment. Although recommendations are given here, the exercise of developing SOPs tailored to the workflow and organization of each institution is extremely valuable.
- Define a standard process and the necessary documentation for situations where a physician wants to end treatment of a particular plan immediately. Team members should be informed of any changes with respect to a patient's treatment, and adequate time should be allowed for review and performance of necessary QA if a new plan will be generated.
- Be continually evaluated and updated as often as necessary. SOPs require support and engagement from administration, physicians, dosimetrists,theapists, and physicists.

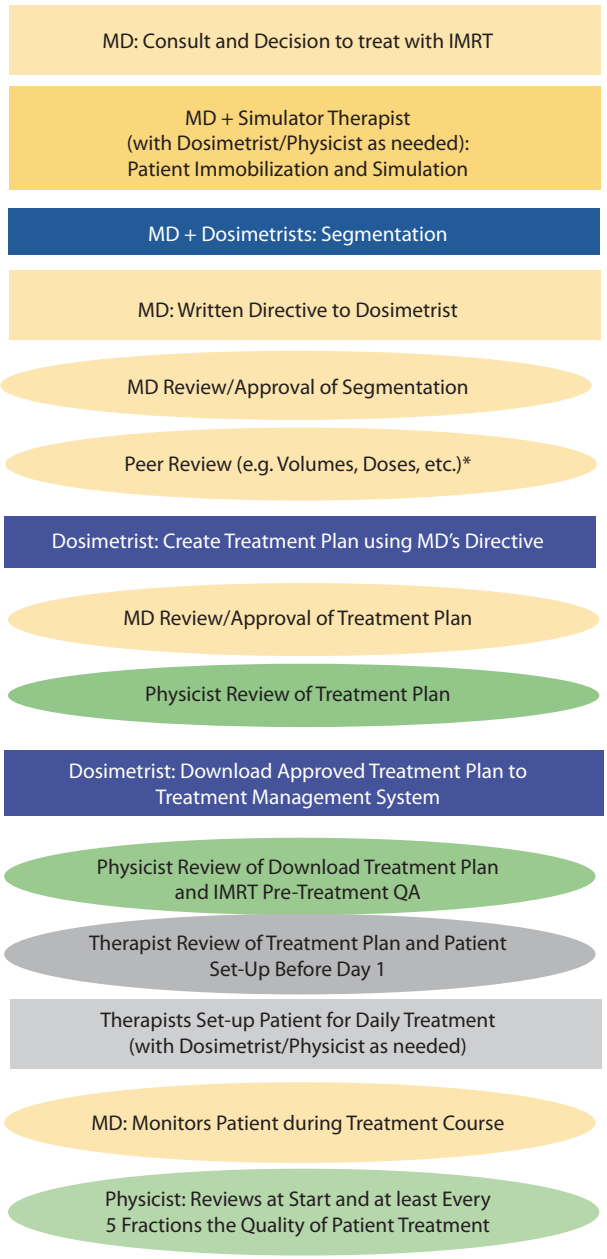

Figure 1. An abbreviated diagram of the process (boxes) and review (ovals) steps for IMRT planning for an individual patient. Each color (or shade) represents member of the treatment team.
*Peer review will be addressed in detail in a report of the white paper series on patient safety.

3.3 Process Time Considerations

Each clinic needs to determine an adequate time for its IMRT process from the time of initial consult through the start of the patient treatment. Figure 1 shows the complexity of the IMRT process (in abbreviated form) as a series of process steps and review steps by members of the IMRT team. It should be noted that if there is a change in the patient geometry that requires a new simulation, the entire process must be restarted.

Risks may also increase if inadequate time is allotted for, and in between, the various steps (e.g. image segmentation, written directive, planning, patient-specific QA). Each clinic should define in its SOP a recommended timeline for the various steps. Image segmentation is a critical, somewhat subjective, and often time consuming, step that is frequently a bottle-neck in this process. Therefore, the timeline should reflect the time needed for radiologist input, image registration, and peer review of image segmentation.[16,17] The time allotted to planning cannot begin until these image-segmentation-related steps are completed. Given the complexities, delays at any step may require that the patient's treatment be rescheduled. Pre-treatment QA should occur at least a day before the commencement of treatment to allow time to investigate potential problems. To the extent possible, the first treatment of new patients should be performed when all members of the IMRT team are readily available, in case questions arise.

4. IMRT: Guidance for Quality Assurance: Technical Considerations

4.1 Existing guidance documents for IMRT QA

The complexity of IMRT planning and delivery has led to the creation of guidance documents on quality assurance aspects of IMRT from radiation therapy organizations (see Table 5 for summary).[18,19,20,15,14] These earlier IMRT QA documents emphasized establishing a quality IMRT program and did not explicitly concentrate on the potential for catastrophic failures in IMRT delivery. Several documents suggested that some QA efforts could be decreased or even eliminated after the accumulation of a stated amount of experience. In this work, we acknowledge that certain types of catastrophic failures resulting from human error and/or equipment (hardware or software) malfunction might not be predictable based on past experience. In some situations, periodic testing alone may be inadequate for identifying these types of problems. Therefore, this report revisits the processes and tasks performed by the IMRT team involved in IMRT with special attention to patient safety and to minimizing the potential for catastrophic failures

4.2 Establishing and Monitoring an IMRT QA Program

The requirements for establishing an IMRT program have been defined by AAPM guidance documents.[18,19] The key elements of these reports that directly affect the safety considerations being addressed here are training, commissioning of an IMRT system, establishing an IMRT program, and monitoring that program.

Table 5 Summary of Guidance Documents on IMRT.

First author (sponsoring organization(s)) Year	Focus	Items of note that are not addressed
Ezzell et al. (AAPM) 2003	Types of IMRT delivery; QA considerations; machine QA and pre-treatment QA; staff training and education	This was an early report; there was limited detail on individual aspects of IMRT.
Galvin et al (ASTRO and AAPM) 2004	Specific to tasks of individuals on the treatment team; included details for commissioning MLC-based IMRT; dose prescriptions; challenges and tradeoffs in IMRT planning.	Permitted changes in IMRT QA program; permitted changes in monitor units for QA, this technique is now discouraged due to implications in leaf sequencing and quality questions in commissioning.
ACR Practice Guideline for IMRT 2007	Describes qualifications and members of the IMRT treatment team; describes elements of QA program	Does not consider potential for data transfer errors; does not provide examples of forms for practice.
ESTRO Guidelines for the Verification of IMRT (ed. Mijnheer, Georg)	Comprehensive review of dosimetry and techniques for pre-treatment quality assurance. Different approaches to QA are described as a function of the hardware and software systems.	It does not address catastrophic failures.
IAEA 2008	Review of transition from 2-D RT to 3D CRT and IMRT; defines personnel training requirements and increased needs for personnel and specialized equipment to support a program; includes a self-assessment questionnaire for institutions.	
Ezzell et al (AAPM Task Group 119) 2009	Describes a series of tests and results for different combinations of software and delivery systems.	These tests are useful for assessing quality once the system is fully commissioned.
Holmes et al (ASTRO) 2009	Recommendations for documenting IMRT treatments	
Low et al (AAPM Task Group 120) [TBD]	Describes dosimeters and analysis techniques for IMRT, including limitations of different techniques.	Describes how to get the proper data for commissioning a system and for doing pre-treatment QA measurements. It does not define what tests need to be done.
This document	Describes standard operating procedures, checklists, and concerns with respect to avoiding catastrophic failures for IMRT.	Lacks detail with respect to specific tests. Reference is made to previous documents with respect to commissioning an IMRT program.
ICRU 83 - 2010	Describes prescribing, recording, and reporting IMRT patient doses	

4.2.1 Training

Administrators should allow time and provide financial support for training with new equipment, prior to the use of the equipment for patient treatments. Personnel who will use the planning and delivery systems should be trained, typically by the vendors. Individuals who receive vendor training can be responsible for training others in the department. They should also follow up with the vendor directly on any questions that came up during this stage. If the systems are provided by multiple vendors, specialized training and testing of the inter-operability of the systems is necessary. Inter-operability tests are frequently conducted by the physicist. The physicist may need additional support from one or more vendors and from the department's IT personnel if there are concerns about the communication pathways for data. When starting a new program, it can be valuable for members of the treatment team to visit an institution that has similar equipment and software and to learn about that institution's implementation of IMRT and standard operating procedures.

Dosimetrists and physicists should be trained in how to use the planning system features for IMRT that include the optimization system, and tools for reviewing IMRT fields and plans. Physicians should provide dosimetrists and physicists with clear guidance on the desired goals for treatment planning on a site-by-site basis. This information can be further developed into a treatment directive for standard treatments.[21] The dosimetrists and physicists should work together in converting this information into a series of cost functions for testing and use of the treatment planning system. The physician should review all plans at this stage to provide feedback on whether or not the plans are acceptable. Dosimetrist, physicists, and physicians should review the output of the system to look at differences from their typical 3DCRT plans.

During training, therapists should learn about how the IMRT delivery technique is different from conformal delivery and should receive instruction on how to verify correct functioning of equipment such as by watching monitor displays of leaf motion during delivery. All personnel should understand the changes in field shaping, motion of leaves for delivery, and the increase in monitor units. Additional safety cues such as differences in the chirping or rapid pulsing sound of the accelerator for conformal compared to IMRT fields and differences in the display in the treatment management system should also be noted and evaluated for each delivery. For individuals with no IMRT experience, the physicist can help support initial training that begins with the setup and irradiation of phantoms using treatment plans that are representative of those the therapists will be using for patient treatments. All personnel should be instructed about the potential hazards in IMRT.

4.2.2 Commissioning an IMRT System

When commissioning the treatment planning part of any delivery system, the guidance of AAPM Task Group 53 should be followed.[22] For example, the fundamental functionality and accuracy of the treatment planning system such as contouring, spatial accuracy, dose volume histograms, and dose calculations should be assessed. The guidance documents by Ezzell et al[18] and Galvin et al[19] describe additional tests that are necessary for IMRT commissioning. For example, the treatment planning system should be tested for a range of field sizes and amounts of modulation (and therefore dose gradients). The commissioning should include the \smallest field allowed for IMRT (e.g. 1x1 cm^2, depending on limitation set in the planning system). For the especially-challenging measurements of small fields, institutions are encouraged to contact the RPC to compare their measurements to the average measurements for other institutions.

Additionally, the departmental administrator should purchase the special dosimetry equipment needed for this task and make sure there is adequate time to commission it for clinical use. The resulting treatment plans should be transferred to the treatment management system for delivery evaluation to better understand approximations made in the leaf sequencing algorithm.

With respect to the machine, the mechanical limits of the delivery equipment need to be determined and baseline values should be measured for tests such as the reproducibility and accuracy of leaf positioning, positioning of the MLC as a function of the gantry angle, etc. [23] Baseline functioning of the mechanical and dosimetric systems should be studied and assessed over time to verify that the system functions correctly.

As part of commissioning, the physicist should determine that quality treatment plans can be created with the IMRT treatment planning system and then successfully verified with the QA program. At this stage, it is appropriate that the accuracy of calculations be evaluated at multiple depths in a phantom and with different detector systems. It is crucial that a comprehensive set of tests are made with the treatment planning system, transferred with the methods to be used clinically, and delivered with the treatment management system (TMS). Plans that are developed by dosimetrists during the training stage can be used for delivery system tests. The commissioning should include measurement of full treatment plans for multiple patients to verify the dose in a phantom.[18] During commissioning, measurements should be made for individual fields and for the composite or full delivery. Tests can also be performed with anthropomorphic phantoms.

The commissioning measurements for the treatment planning and delivery systems must be made with the proper equipment. AAPM TG-120 notes that multiple

measurements systems are required for commissioning and establishing a QA program.[24] For example, ionization chambers are typically used for absolute dose verification whereas diodes or other high resolution detectors are required for measurements in the penumbra region.[24] The highest resolution measurement system should be used for the individual field measurements during commissioning to verify that the planned gradients can be reliably delivered.

During commissioning, institutions should develop methods for handling incomplete IMRT treatments.

- First, the ability of the treatment management system to record an incomplete treatment under a range of scenarios (e.g. beam off through software/hardware failure) should be established.
- Second, the ability of an interrupted treatment to be completed should be evaluated by assessing the delivery on a phantom.
- Third, personnel should be trained on how to handle the situation where a therapist may need to resume treatment shortly after an interruption.
- When a treatment cannot be completed, the institution should have a policy to define who should be notified, and who should determine if/when treatment is to be resumed. Typically, this decision is made by the physician and physicist. For interruptions due to a machine fault, the physicist must verify that the equipment can be used safely prior to the resumption of patient treatments. This may include the performance of necessary QA checks of the affected systems.
- If the patient has moved since the interruption, it may be necessary to re-image the patient before completing the treatment in order to minimize the possibility of an overlap or under-lap of the modulated dose distribution.

It is invaluable to perform these measurements for representative cases as a function of body site prior to clinical release of IMRT. Situations where sub-optimal results were obtained should be documented and corrected if possible. If the problem cannot be corrected, software safeguards should be put in place to prevent the use of the system in a way that may lead to poor agreement between calculations and measurements. The potential limitations of the systems to be used for pre-treatment quality assurance should also be assessed for different types of treatment plans.[24] For example, some treatment plans with targets simultaneously receiving different dose levels may require a different QA approach, detector, and/or phantom shape if it is difficult to identify a region of uniform dose for verification of the distribution.[24] In addition, institutions may want to perform the test suite of TG119 to compare the commissioning results to those obtained in that report.[15] The adequacy of the commissioning can be independently tested by performing an IMRT credentialing test such as using the RPC head and neck phantom (for centers involved in NCI-sponsored trials) or a test from the MD Anderson Dosimetry Laboratory. In addition, institutions may wish to invite another professional to visit their site and review their program.

4.2.3 Establishing a QA Program

As part of clinical implementation, it is necessary to create a periodic quality assurance program for the treatment planning system and the delivery system. Pre-treatment QA measurements should not be used as a substitute for rigorous and periodic equipment QA. The information obtained during commissioning should be used to establish the baseline performance of the treatment planning system and delivery system. For the treatment planning system, monthly tests can include the use of checksums to compare the data files to those of the original commissioned version of the system. A component of the system checks are end-to-end tests which are described in detail in Section 4.3. Elements of the periodic QA required for IMRT delivery systems are described in the report of AAPM Task Group 142.[23] For example, the leaf position accuracy for all leaves can be visually verified by using film or a detector with adequate spatial resolution to measure the results of stepping all leaves across the field with beam delivery for a narrow gap at regular intervals.[25] TG142 recommends that this type of test (also known as the picket fence test) is performed weekly for machines used to deliver IMRT. The leaf position accuracy is critical because of the dependence of the resulting distribution on the accuracy of gap between opposed leaves.[25] The physicist is responsible for creating a QA program that is consistent with the desired accuracy needed for the IMRT program. We believe there is a need for more explicit guidance from professional radiation therapy organizations with respect to IMRT QA methods and criteria for agreement.

During this phase, the clinical tolerance limits for the pre-treatment QA program should be determined and documented in the treatment procedure. There should be clear criteria for a pass or fail of the IMRT patient-specific IMRT QA technique. A procedure should be developed for investigating plans that fail QA, and for documenting identified problems and how they were addressed. When creating the pre-treatment QA program, the QA system should be tested to make sure that errors that would be considered unacceptable can be detected by the program. The initial IMRT commissioning and clinical QA testing must be performed with detailed analysis. In addition, a series of measurements should be repeated to assess the reproducibility of the treatment delivery.

4.2.4 Pre-treatment IMRT QA program

The current guidance from ACR and ASTRO for IMRT patient-specific quality assurance recommends verification of the IMRT treatment plan parameters and the use of dosimetric measurements to verify the accuracy of the dose delivery.[26] Due to safety considerations, these tests for acceptability should always be performed prior to the start of the patient's treatment with any given plan.

The pre-treatment QA program must be appropriate for the treatment planning and delivery systems. The physicist must verify that the IMRT detector, analysis system, and agreement criteria for routine QA are capable of picking up different types of errors such as: incorrect dose per fraction (if doses are scaled, the system will not catch this), incorrect leaf positioning, and other incorrect delivery parameters.[24] For example, Kruse found that some combinations of 2D detectors and criteria were insensitive to clinically-relevant differences.[27] Ideally, the same files to be used for the patient delivery should be used for the quality assurance measurements. When this is not possible due to limitations in the treatment management system, additional checks should be performed such as comparison of the monitor units and resulting fluence distributions at the treatment unit between the QA and patient fields, or recalculation of the beams for the measured field and the patient field.

There is variation in practice among institutions with respect to the content of pre-treatment IMRT QA programs along with the equipment and software used. When creating and/or modifying an IMRT QA program, there are several situations where users should be cautious.

For the measurement component, the program is weakened:

- if the wrong detector is selected such as one with too poor resolution or inadequate spacing for the gradients in the intensity maps;
- if QA failures are approached solely by repeating measurements at multiple different positions in the dose distribution until a point passes rather than identifying the root cause; or
- by the application of too generous dose/distance criteria for agreement.

For calculational methods, users are cautioned that:

- some methods do not check the accuracy of the data transfer to the treatment management system;
- some methods use poor algorithms which make them inadequate for dosimetric verification of complex geometries.

Many institutions use the Gamma-index method to simultaneously evaluate dosimetric and spatial parameters.[28] If the parameters are set too broadly, the QA method may be unable to identify suboptimal plans. With respect to criteria for agreement, for the pre-treatment patient specific IMRT QA checks reported in TG119, institutions defined a region which was either 10% of the maximum dose or delineated by the jaw settings, and a criteria of 3% dose/3^{mm} distance criterion .[15] The criteria that provide adequate safety can depend upon the delivery technique and the capabilities of the measurement equipment (such as the spatial resolution of the detectors). Further, these constraints are all somewhat arbitrary. The impact of failing to meet these constraints on the clinical 3D dose distribution, and the anticipated clinical outcome, is not explicitly addressed with these methods. Until formal guidance is available, we recommend that users establish acceptance criteria that they have determined will identify plans that should fail the QA check. For example, users should deliberately create plans with known errors such as the incorrect fluence for regions of high or low dose across the irradiated volume and/or critical structures, plans with one field with a rotated collimator or an incorrect fluence distribution, and other discrepancies that should be identified by the QA method. For treatment plans that exceed the institution's pass criteria, the QA results should be reviewed and additional investigation such as recalculation of the estimated delivered dose should be done to assess the potential impact on the patient's treatment. In other situations, there may be difficulties with the patient geometry, especially when combined with treatment plans treating multiple regions to different doses. When additional investigation is performed, the physicist and physician should document the review, especially for situations where the treatment plan is used because the discrepancy is not expected to have a clinical impact.

Regardless of the approach used, patient safety requires that the integrity and accuracy of the information used for treatment delivery is verified. The relationship between the delivery segments, fractional monitor units, and total number of monitor units must be verified along with the accuracy of the calculation. The approach and acceptance criteria should be documented in the institution's standard operating procedures and followed for all patients.

Further guidance is needed from national organizations on the content of pre-treatment IMRT QA programs, the appropriate dose/distance criteria (as a function of the QA method), and the role of calculation-based methods in such programs.

4.2.5 Monitoring the IMRT Program

Once an IMRT program is underway, the physicist should review the results for each patient. If failures are identified, the physicist may need to review the commis-

sioning data to determine if there have been any changes in the software or hardware that affect the planning or delivery. For example, the motion of multileaf collimator leaves can be affected by adjustments made to the physical MLC or settings at the treatment unit. The physicist is also responsible for updating the program as new guidance becomes available. When software or hardware changes occur, the physicist is responsible for further testing. Some of these tests are described in Section 4.2.6 on End-to-End Tests. Retraining of personnel may also be needed.

Maintenance on the accelerator should be documented. Prior to release of the equipment for clinical use, service reports should be reviewed by a designated qualified medical physicist and any necessary additional actions such as equipment tests to verify proper functioning should be performed. Periodic tests of the treatment planning system are also required and testing is required prior to clinical use for any software upgrades.

4.2.6 Complete System End-to-End Testing

End-to-end tests are essential to minimize the possibility of catastrophic failures. These tests help to verify the accuracy of the entire chain (from CT simulation to dose delivery), for both conformal and IMRT, and should be performed (at a minimum) during commissioning prior to clinical use of a new technique. Ideally, these tests should use a phantom, with a detector (to measure dose), that is CT-scanned and then imported into the treatment planning system.

The end-to-end tests should be repeated any time a significant hardware component or software version has been changed to confirm that communication paths between systems are intact. The results should be documented and can be used as a reference for system performance. The dose delivered by the plan to an ion chamber and the dose gradient across the individual fields should be documented for IMRT.

Due to the safety concerns of ensuring the right target can be treated with the right dose for a given plan, a localization test from the CT simulation through delivery is described. The simplest phantom for end-to-end tests is a plastic block with a drilled hole designed to hold an ionization chamber. This block phantom should be scanned with the CT-simulator and the isocenter can be set at a reference point that is easily identified on the CT images (e.g. at the end of the drilled hole). Beams can be planned on this phantom, transferred to the treatment management system with associated images for alignment, and then delivered, with the planned dose compared to the delivered dose serving as an overall metric of quality. For delivery, the phantom is positioned on the treatment couch using an IGRT system or reference marks on the phantom, and the ionization chamber is inserted to the very end of the drill hole. After measurement with the ion chamber, the chamber can then be removed to produce images of the end of the drill hole using the treatment beam. This step verifies the positioning of the treatment fields as dictated by the planning process. Skipping the CT-simulation and treatment planning steps and using stored information, the procedure can be easily repeated at any time to verify the integrity of the treatment delivery process.

By copying a patient's treatment plan to the phantom geometry, the end-to-end test approach can be adapted for patient-specific testing. Delivering a treatment plan to a phantom is known as a composite delivery.[15] This test verifies the accuracy of a particular treatment plan in the phantom geometry and can detect data-corruption problems. However, the sensitivity of this approach to detect errors depends on the type, resolution, size of the active volume, and sensitivity of the detectors.[24]

4.3 Need for Additional Guidance

As noted earlier, independent audits (e.g. by peer review or some other mechanisms) are useful to evaluate the adequacy of the commissioned radiation therapy delivery system. This is true for verification of the linear accelerator output under basic calibration conditions (e.g. a fixed 10x10 cm^2 field for a specific setup), specialized techniques (e.g. IMRT, stereotactic approaches), and specialized localization and/or imaging techniques. Independent audits have been provided by the RPC since 1968 for institutions participating in clinical trials funded by the National Cancer Institute (NCI). This independent evaluation of an IMRT planning and delivery system assesses the adequacy of commissioning, the skill set of the personnel, and the institution's QA process for testing the software and delivery systems.

As IMRT was incorporated into clinical trials, the RPC developed an anthropomorphic head and neck phantom, with inserts simulating two targets and an organ at risk, to assess IMRT accuracy.[29] When an institution receives the phantom, personnel fill the phantom with water, place the insert with enclosed dosimeters into the top of the phantom, and then have the phantom go through the radiation therapy department's IMRT process from CT scanning through treatment planning, target localization, pre-treatment quality assurance, and finally delivery. For each part of the process, the tasks should be performed by those individuals who perform those tasks for patient treatments. The phantom is returned to the RPC who determines the actual doses delivered to the phantom via thermoluminescent dosimeters (to measure a point) and film (for two dimensional measurements across the target and organ-at-risk) within the phantom. These measurements are compared to the intended doses as defined by the institution's treatment planning system.

In an RPC analysis of 752 phantom irradiations between 2001 and 2009, approximately 78% of the irradiations met the generous criteria of 7% agreement in dose and/or 4 mm with respect to the dose gradient for the measured points and planes.[30] More than 350 institutions failed to meet the irradiation criteria on the first attempt and were advised to repeat the phantom irradiation. These results show the marked variation in the quality of the individual institution's implementation of IMRT when evaluated independently. The overall failure rate for these tests has been ≈ 20-25%. Failure rates for IMRT based on the thoracic and pelvic phantoms are similarly ≈ 20-30%. There is room for improvement.

An investigation of these IMRT head and neck phantom irradiation failures has shown that some are due to incorrect positioning of the phantom/couch. However, failures were also caused by inadequate commissioning of the treatment planning system that can affect patient treatments.[31] For example, failure was also caused by the use of field segments of small dimensions or small fluence, for which the uncertainty in leaf position or dose delivery can be relatively large.[18] Since a modulated field is composed of multiple smaller fields, errors in the smaller fields can have a cumulative effect in degrading the quality of the IMRT delivery. Other failures have been due to beam modeling errors such as inaccurate penumbra, beam and MLC characterization, as well as inaccurate leaf positioning or leaf movement synchronization. Incorrect entry of output factor or percentage depth dose data into the treatment planning system has been identified as another cause. This demonstrates the importance of assessing the adequacy of commissioning of IMRT and of training that includes understanding and following the published guidance documents on IMRT. Use of an independent assessment of IMRT delivery on a phantom was shown to be effective at highlighting IMRT process implementation errors.

The RPC also noted that many patient-specific IMRT QA procedures may be inadequate to detect some errors. For example, some would obtain multiple measurements with a single ionization chamber in different positions for their composite (or "hybrid") delivery. This is of concern because it may lead to a situation where multiple errors are not detected since they may "cancel each other out." Further, when there was a disagreement between a measurement and the calculation, some simply repeated a single measurement instead of investigating whether the discrepancy was indicative of a deeper problem (as would be prudent). The RPC also found a range of institutional tolerances for IMRT. The TG119-defined criteria of 3% and 3 mm dose and distance values, where the evaluated points were defined as those greater than 10% of the maximum or the region defined by the jaws[15], are not uniformly adhered to. This is a potential concern since different QA techniques have different sensitivities. Further, the TG119 criteria might not be adequate for highly modulated fields.[27] The methods for evaluation and the criteria for acceptability are an area that needs further and more rigorous recommendations to improve the safety and quality of IMRT delivery. We recommend that IMRT QA criteria be established using tests of the most highly modulated fields that are seen in the local clinic, which may be more demanding than those in the TG 119 test suite.

4.4 Checklists for the IMRT Process

There is a growing body of literature on the use of checklists for improving patient safety.[32] For example, in a large study of 3,733 patients in eight hospitals, surgical checklists reduced the rates of post-surgery deaths (from 1.5% to 0.8%) and inpatient complications (from 11.0% to 7.0%).[33] Checklists have been also been used in some radiation therapy procedures. For example, AAPM Task Group 42 on Stereotactic Radiosurgery recommends using a treatment procedure checklist "to minimize the risk of misadministration or injury."[34]

In a team environment, checklists can be used to verify that each team member performed their required roles. Appendix 2 provides example checklists for members of the IMRT team following the flow of a patient from simulation through delivery. It is expected that each institution will need to develop its own checklists, especially since the processes and personnel may vary according to that institution's practice and software and hardware. A sign-off sheet can be used so that it is clear who performed a given step, and that pre-requisite steps are performed before subsequent steps. Table 4 summarizes the primary recommendations, tasks, and assigned personnel to guard against catastrophic failures for IMRT, primarily for MLC-based delivery systems. These recommendations have been compiled from the situations that were considered to be the riskiest points in the IMRT process or where missing information could adversely affect patient care.

5. Collaboration between Users and Manufacturers to Improve IMRT Safety

Improvements in IMRT equipment/methods to enhance patient safety are needed and would be facilitated by collaborative efforts between manufacturers, users, and regulatory agencies such as the Food and Drug Administration. The members of each of these three groups hold important information about RT patient safety, but none of the groups have complete control over solving the problem of catastrophic errors.

Manufacturers should introduce new IMRT treatment delivery equipment, approaches and features only after it is clear that necessary equipment and clinical QA procedures are clearly described for the user. The equipment QA component consists of the testing procedures

Table 4. Recommendations to Guard against Catastrophic Failures for IMRT

Recommended Tests and Procedures	Person who Performs Tasks	Primary Review Responsibility	Second Review
Half a procedure if the operator is unclear about what is being done.	All	All	All
Verify the patient information, treatment site, and prescription	All	All	All
Verify correct positioning of the high dose region of isodose plan relative to targets	Dosimetrist	Physician	Physicist
Verify the recording of reference and shift information from the planning scan in patient chart (electronic or paper)	Dosimetrist	Physicist	Therapist
Assess pre-treatment localization/portal images with respect to corresponding reference images before first treatment; physician determines frequency of IGRT techniques(4)	Dosimetrist exports reference images from treatment planning system	Physician	Therapist
Verify that the correct version of the patient's treatment plan is approved, sent to treatment management system, and used for patient-specific QA	Dosimetrist exports from the treatment planning system	Physicist	Therapists confirm against prescription for each treatment; physician prescription should specify the physician approved plan
Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins	Physicist, dosimetrist, therapist or physics assistant	Physicist	Therapists confirm that only fully approved plans are used for treatment
Perform a complete chart check including review of information in treatment management system prior to the start of any treatment and after any change in treatment before changes are used for treatment.Visually review field apertures in treatment management system Perform a check of dose to verify TPS calculation (measurement or calculation using DICOM export of data from RTP system)	Physicist	Therapist	
Perform a time out prior to treatment delivery.	Therapist	Second therapist	

Perform a check of treatment parameters before start of and during first treatment against a fixed version of the treatment plan Includes visual verification of field apertures during first treatment and after any change in treatment. At each fraction, verify motion of leaves (if MLC delivery) and total monitor units	Dosimetrist exported from TPS; verified by physicist	Therapist	Second therapist
Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (periodically and after any software or hardware changes)	Physicist, therapist or physics assistant	Physicist	Second physicist to review

used for acceptance testing and quality control of the manufacturers' equipment. The clinical QA component consists of the tests used during commissioning and for periodic QA. In some cases it is necessary to devise new approaches for both QA components that are unlike the procedures used for the predicate device upon which FDA 510(k) approval was based. Clinical QA procedures are typically developed by medical physicists, but this task cannot be completed without access to and familiarity with the new equipment. Therefore, successful development of new procedures requires a combined effort of the manufacturer and a team of physicists, typically expert users. Initially, the manufacturer guarantees that the necessary information for QA is available to the early adopters of the new equipment. Then for safe adoption of new technologies in a variety of settings, the manufacturer has the responsibility to test, document, and provide reasonable QA procedures for equipment to users.

This section outlines specific examples of improvement possibilities, grouped into four main categories. Many of these examples are applicable to other methods of radiotherapy in addition to IMRT.

A) Improved methods to directly and independently verify/validate patient plan and treatment data on the treatment machine prior to, during, and after radiation delivery:

1. Pre-treatment QA for IMRT: patient parameters in the treatment management system (not copies) should be used for QA measurements and calculations.
2. Tools/devices should be developed that will make the IMRT QA more efficient, e.g. further development of flat panel detectors to perform pre-treatment QA dosimetry, and possibly daily QA of each treatment delivery. Some centers have developed their own techniques to improve QA efficiency. Vendors should make strong efforts to evaluate and adapt these methods and make them available to their entire user community.
3. Plan QA completion/approval status should be recorded, and automatically demoted if the plan is subsequently modified with the ability to enforce blocking treatment if not approved.
4. Prior to loading a patient's plan for each day's treatment, the software should display the correct patient, target site(s) to be treated, and cumulative dose to a reference point(s) so that the patient's dose target can be explicitly reviewed by the therapists prior to delivering additional dose.
5. Tools should be developed for therapists to verify that treatment fields and monitor units have been reviewed and are correct prior to delivery.
6. Graphics of the motions of all dynamic components (e.g. MLC, gantry etc) should be depicted in real-time during treatment delivery, such that they cannot be minimized or hidden.
7. Creation and storage of trajectory (e.g. MLC) log files during delivery to allow comparison for QA validation including providing access to the log files and making software tools available for associated analysis during a subsequent review.
8. Real-time trajectory information should be used to stop treatment if the delivery is out of an expected range, and provide information to the operator, including an immediate alert if treatment is stopped.
9. Development and implementation of real time methods (such as use of EPIDs) or other detectors to predict/detect potential overdose of a treatment delivery that can be interlocked with the linear accelerator to halt an incorrect treatment.

B) Provision of safety measures in the IMRT workflow such as communication features, checklists, data integration and tracking.

1. Systems should allow incorporation of checklists, time out functions and communication logs within electronic medical records and the treatment management systems. There should be an option of a "forced time out", with customizable items, within the treatment management system.
2. Checklists should be interactive and modifiable such that their utility can be maximized in the environment in which they are being used.
3. Systems should permit the grouping/naming of plans (including descriptions), and especially, a clear designation for an approved plan. Since IMRT planning is often iterative, with multiple beams and plans being generated, some uniform convention (customizable to the institution) to the naming of beams and plans, with automatic naming of items, would be helpful.
4. The physician should be able to specify a final approval of the treatment plan and prescription that sets the treatment plan status to be enabled for delivery.
5. Treatment management systems should have only one approved version of the treatment plan that cannot be changed at the treatment unit, to be used as a reference that is directly traceable to the information reviewed before treatment, used for pre-treatment QA, and approved by the treatment team.
6. Systems should have a robust method of dealing with privileges associated with the modification of couch and other parameters in the treatment plan.
7. The electronic record (including the information in the treatment management system) should retain display and retain information that was demonstrated to be valuable through the earlier paper chart and manual treatment processes used historically.
8. There should be an improved audit trail in the system, and a mechanism for analyzing the data and using that information to refine treatment processes.
9. When a physician needs to change a plan, there should be an automatic communication through the treatment management system to other team members about the change. The plan status should change to unapproved for treatment and all members should be able to easily identify the change in status on the machine schedule.
10. A vendor's maintenance logs or other automatic mechanisms should be routinely used to notify physicists of any and all equipment repairs, replacements, and/or software changes. This could improve communication among team members and reduce the possibility of errors.

C) Integration of IMRT sub-systems and QA procedures

1. There should be improved communication and development between manufacturers of hardware, treatment planning systems, and users. This is especially important for modeling approximations of the hardware system.
2. Improved methods are required between software systems to assure that tumor-targeting based on CT imaging translates to accurate positioning of the patient on the treatment unit. Image guidance is an important component of verifying that the patient is in the correct treatment position. However, the desire for imaging may introduce unintended errors if the table needs to be shifted (away from the correct treatment position) for imaging (e.g. due to clearance). In this setting, the therapist needs to remember to return the patient to correct position before treatment, and systems to automatically assess positioning would be particularly helpful.
3. Patient safety can be enhanced by implementation of safe system defaults (e.g. when data is not present, the software defaults to a "safe setting").
4. The introduction of new IMRT treatment planning methods and treatment delivery approaches may require the development of new QA procedures. Development of such QA procedures should be a shared responsibility and collaborative effort between the end-users and manufacturers. The involvement of the end-user may be in both the concept and development, but definitely in clinical implementation, testing and validation. The manufacturer should collaborate with end-users in such development, and should provide the necessary understanding and knowledge of the new technology so that an effective approach can be developed. Then, manufacturers should update the other users by providing information about newly developed QA methods and providing all users with the newly developed software.

D) Human Factors

Software and hardware that is used for IMRT planning and delivery should be created and structured to maximize the probability that it is used as intended. For example, attention should be paid to human factors engineering principles (e.g. software interfaces should use clear, consistent and unambiguous graphics). Where possible, automation, forcing functions, and standardization should be used to assure that tasks are performed

as desired. Opportunities to "hard-wire" redundancies and double checks might be helpful for particularly-critical steps. IMRT is not performed in a vacuum. Rather, it occurs in the context of diverse clinical practice. Thus, design of IMRT-specific products should at least consider how their implementation might affect, and be affected by, other realities within the existing clinical environment. For example, the user-machine interface of a single system may seem clear and logical when considered in isolation. However, if that interface is fundamentally different from other interfaces that the user is also using, the inconsistency can raise safety concerns.

The preceding list is not meant to be exhaustive, but rather to provide some examples of the broad opportunities for improvements in existing systems. Some of these suggestions are applicable to only specific vendor's products and others are more general. Overall, successful improvements to existing/future systems will require joint efforts by the users, vendors and regulators. The prioritization, implementation, testing and commercial release of any improvements should be a partnership between users, manufacturers, and regulators. Improved methods of communication are required between with users and vendors to facilitate these efforts. Joint educational programs where the users and vendors continue to educate each other might also be helpful.

6. SUMMARY

The many factors noted in this report that can impact IMRT safety can be broadly divided into environmental and technical factors, and are summarized as follows.

6.1 Environmental factors

IMRT is time and resource intensive. Administration needs to provide ample support for the technological tools themselves (e.g. hardware and/or software), as well as the time needed to implement/commission these tools. Resources need to support initial and ongoing efforts towards staff education and maintenance. IMRT requires a team of adequately skilled and credentialed personnel who work well together and who have the support of hospital and departmental leadership.

- The roles of all team members should be adequately defined.
- Guidance documents on IMRT should be followed. All staff should have opportunities and time for training on new equipment and for continuing education on IMRT.
- Clinics must have a culture of safety which administration plays a key role in supporting.
- Standard Operating Procedures are needed to define the tasks, responsible persons, and methods to assure appropriate and timely QA. Examples are provided in this report to be adapted to individual clinics. These should be regularly monitored and reviewed prior to implementation of new techniques.
- Checklists should be developed by each clinic to verify key QA components. (The examples herein are provided as a guide for institutions to create their own checklists.) Each clinic should review its processes, update its procedures, and consider using sign off sheets for the most critical steps of the IMRT planning and delivery process. The examples in this report are for illustration purposes only.
- Timely treatment is important, but undue pressure and real-time changes to the treatment plan can lead to errors. A "forced time out" can be used to assure adequate time to perform reviews/QA at key points in the process. Adequate time needs to be allowed to perform patient-specific pre-treatment QA and verify the treatment plan is acceptable before a plan is used for patient treatment. Team members need to acknowledge that initiation of treatment may need to be delayed to allow time for necessary quality assurance checks and subsequent investigations of problems.

6.2 Technical factors affecting patient safety include:

- A specific QA program is needed to maintain the specialized software and hardware that are required for IMRT planning and delivery.
- The adequacy of the commissioning of a program should be assessed with peer review and independent audits.
- Complete system end-to-end tests play a valuable role in maintaining a safe program. These tests can be part of annual QA for the program, performed any time equipment is upgraded, or more frequently if needed.
- Patient-specific pre-treatment QA is considered necessary for a safe IMRT program (and should be documented in the SOP). The QA methods used should verify the integrity of the data transfer from the treatment planning system to the treatment management system and the accuracy of the dose to be delivered. The physicist is responsible for making sure the correct tools and methods are used.
- More guidance is needed on the essential components of an IMRT QA program, including pre-treatment QA methods and specification of the acceptability criteria for IMRT treatment plans. There is

a wide variation of methods used in practice. The development of new QA tools is an area where future collaboration with manufacturers may be especially beneficial.

The recommendations in this report are intended to provide guidance to aid clinics in avoiding catastrophic errors and to improve the safety and quality of care for patients receiving IMRT. It is expected that there will be further developments with respect to the evaluation of IMRT programs for accreditation, and that new guidance documents, such as the forthcoming report by AAPM on quality assurance approaches (Task Group 100) will continue to enhance the quality and safety of IMRT use.

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Appendix 1.

Table 1: Example Workflow for IMRT. The flow of work and steps may vary by individual clinic.

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
1	Verify the medical necessity of IMRT.				
2	Pre-CT/simulation, provide simulator therapist: a. Patient name and identification number b. Treatment site and laterality c. Instructions for simulation				
3	Oversee simulation process including immobilization, positioning, placement and communication with therapists, dosimetrists, physicists about special requests.				
4	Prior to patient's appointment, review: a. Patient name and identification b. Treatment site and laterality c. Physician directive for simulation and treatment site to assess proper equipment and positioning				
5	Position patient following standard procedures for treated body site: a. Verify patient is comfortable b. Verify positioning is reproducible				
6	Verify isocenter or reference marks are properly placed based per physician guiance.				
7		If there are additional questions regarding the patient setup, communicate with the physician, dosimetrist and/or physicist prior to or during the simulation.			

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
8		Document positioning with photographs and text information (e.g. equipment used and settings if adjustable).			
9	Segmentation (e.g. contouring) of target volumes.				
10	Specify/approve the CTV and PTV expansions. PTV expansion should be consistent with frequency and type of image guidance.				
11	Specify desired doses for targets and limits to normal structures. Clarify priorities where structures overlap (e.g. PTV with normal structure) and where goals will conflict.				
12	Document that risk/benefit trade-offs were discussed with patient.				
13			Prior to patient's appointment, review: a. Patient name and identification; b. Treatment site and laterality; c. Physician directive for simulation and treatment site to assess proper equipment and positioning.		
14			Review datasets for integrity (completeness), dates, and labeling of: a. Primary imaging dataset for treatment planning; b. Secondary imaging datasets.		

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
15			Review treatment planning guidelines from physician, including: a. Prescription (total dose, fraction size, fractionation, bolus, etc.); b. Target volumes; c. Treatment objectives and dose constraints in the treatment directive.		
16			Review patient information from the simulator therapists to assess: a. If positioning/immobilization is reasonable and consistent with anticipated beam orientations b. Position of isocenter or reference marks from simulation		
17			Perform image segmentation (e.g. contouring): a. Normal tissues; b. Create expanded volumes for CTV, PTV, and organs at risk as directed by the physician; c. For regions where normal tissues are not segmented, define areas of unspecified normal tissue if appropriate to minimize doses to other tissues; d. Notify physician, physicist, or other dosimetrist that volumes are ready for review.		
18	Approve segmentation (contours) created by dosimetrist including expanded CTV and PTV if appropriate.				

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapis
19	Have the treatment volumes reviewed by another physician as part of peer review.				
20			Review placement of beams and isocenter. a. Document if the treatment isocenter is identical to the anticipated isocenter at the time of CT simulation; b. If not, document the necessary shift from planning (or reference point) to the treatment isocenter, and create new "set-up beams".		
21			Perform treatment planning and optimization.		
22			Communicate with physicist that the treatment plan is ready for an initial review for plan acceptability and deliverability issues. The physicist should note any concerns regarding: dose gradients, beam modulation, and deliverability of fields.		
23				Perform an initial review of the plan for reasonableness.	
24			Prepare treatment plan for physician review.		
25	Verify that planned dose distribution meets guidance specified in the directive and/or is clinically acceptable (i.e. assesses correctness of trade-offs made in planning.)				

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
26	Write treatment prescription: Review treatment planning guidelines from physician, including: a. Prescription (total dose, fraction size, fractionation, bolus, etc.); b. Target volumes; c. Treatment objectives and dose constraints in treatment directive d. Frequency/type of imaging.				
27			Review: a. Patient name and identification; b. Treatment site and laterality; c. Physician directive for simulation and treatment site to assess proper equipment and positioning.		
28			Review datasets for integrity (completeness), dates, and labeling of: a. Primary imaging dataset for treatment planning; b. Secondary imaging datasets.		
29			Review treatment plan.		
30				Verify that treatment plan meets the physician's dose constraints specified in directive.	
31			Set table, collimator, and gantry tolerances to pre-established level to consider treatment site and immobilization device/technique.		

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
32			Transfer treatment plan and DRRs to treatment management system after physician has approved and signed plan.		
33			Prepare documentation for therapists: e.g. isocenter set-up, and other considerations for delivery of the treatment plan.		
34			Notify the physicist or other personnel that plan is ready for pre-treatment quality assurance.		
35				Prepare/oversee the creation/calculation of the approved treatment plan on the phantom QA geometry. Use the dose per fraction specified for plan delivery.	
36				Verify integrity of information transferred to treatment management system for patient plan and QA plan, including: correct transfer of gantry, collimator, table, and jaw positions, and calculated monitor units etc.	
37				Perform or oversee quality assurance checks of the treatment plan for the full delivery with proper gantry angles and for individual fields. Note any potential concerns for delivery of patient treatment.	
38				Verify the accuracy of monitor units.	
39				Document pre-treatment checks performed in patient chart.	

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
40				Communicate failure of QA at any step to full treatment team. Patient treatment may need to be delayed.	
41				Investigate and document causes of failures.	
42					Prior to patient's appointment review: a. Patient name and identification; b. Treatment site and laterality; c. Physician directive for simulation and treatment site to assess proper equipment and positioning.
43					Verify physician's treatment prescription and treatment plan are signed and match information in treatment management system.
44					Verify patient's pre-treatment QA was performed and approved by physics.
45					At time of treatment appointment, a. Confirm signed treatment plan and prescription are still approved for treatment; b. Position/ immobilize patient as documented; c. Have a second therapist verify that the patient is set-up correctly; d. Perform the specified imaging; e. Have images approved as specified by department protocol.

Task Number	Physician	Simulation Therapist	Dosimetrist	Physicist	Treatment Therapist
46					For each beam, verify treatment parameters in the treatment management system are consistent with the approved treatment plan.
47					Verify patient is always in the proper position before turning the beam on for each field or auto-field sequence.
48					During treatment, each therapist should take on a specific role.
49					Designate a therapist to watch the console for real-time outputs.
50					Designate another therapist to monitor the patient via video/audio devices.
51					If additional devices (e.g. respiratory motion management or other real-time information) are used, determine if a third therapist is needed to do special procedure monitoring.
52					Document the completion of each treatment delivery. Note any deviances from the standard treatment and communicate with full team.
53				At a minimum, on a weekly basis, monitors the accuracy of the treatment including reproducibility of positioning, correct treatment plan information (parameters, monitor units), and use of beam modifiers; e.g. bolus, use of IMRT, etc.	
54	During treatment course, review patient imaging for reproducibility of positioning and monitor patient's progress.				

Appendix 2.

Example Checklists

1. Master Checklist of Overall Process:

- □ Begin with a team that has adequate training and credentials in radiation therapy
- □ Develop standard operating procedures (SOP) for all aspects of program
  - o Criteria for IMRT documented
  - o Create checklists at critical steps where errors could be made that affect the patient's safety or degrade patient quality
- □ Estimate a standard timeline from simulation to planning to QA to patient start
  - o Allow adequate time for all steps without undue pressure
  - o Request additional tools or resources (staff) from administration if there is a lack of resources
- □ Notify team members of problems at any steps
  - o It may be necessary to delay the patient start with an IMRT plan
  - o Halt a procedure if the operator is unclear about what is being done

2. Physician checklist:

1. Review information regarding previous radiation treatment
2. Specify details for simulation
3. Verify image registration
4. Image segmentation: Verify segmentation of target volumes and normal structures (motion considered?)
5. Verify prescription dose and fraction size
6. Target coverage: Verify target DVH's meets/exceeds desired
7. Normal tissue: Verify normal tissue DVH's at/below desired
8. View 3D dose distribution to assess for
   a. Dose in unspecified regions (e.g. beams from unusual orientations)
   b. Assess dose gradients near target/normal-tissue interfaces
   c. Gross target and normal tissue exposures
9. Confirm desired set-up techniques, image guidance, motion control for needed accuracy

3. Simulator therapist checklist:

1. Understand diagnosis and treatment goals as they relate to patient setup
2. Confer with physician, dosimetrist and/or physicist prior to simulation to determine appropriate patient positioning and immobilization
3. Note if patient positioning is comfortable and reproducible
4. Place markers on skin during scanning as needed, including markers denoting previously-irradiated sites
5. Ensure that scanned volume is consistent with that requested
6. View images to verify completeness and that needed anatomy is not "cut off"
7. Provide documentation/imaging to dosimetry and treatment machines

4. Dosimetrist/physicist checklist for treatment planning:

1. Confer with treatment team prior to simulation/treatment planning to understand treatment goals and appropriate patient positioning and immobilization
2. Confirm imported data set(s) with regard to date, modality, and patient
3. Perform image registration/segmentation of normal structures
4. Verify written prescription
5. Create optimal treatment plan while achieving desired dose objectives for both target and organs at risk
6. Evaluate the dosimetric impact of previous treatment on the current treatment
7. Check labeling of all targets and critical structures to avoid ambiguities a possible confusion
8. Designate/name final approved plan according to department criteria
9. Communicate with physicist regarding plan QA
10. Verify plan attributes in treatment management system (pt setup, tx parameters, isocenter placement, reference images)
11. Communicate with radiation therapists regarding approved plan to include image guidance, motion control or other special instructions

5. Example physicist checklist

Pre-treatment:

1. Review
   a. Patient identification number and name
   b. Treatment site and laterality
   c. Diagnosis/ treatment location/intent
2. Review treatment plan to verify that the treatment plan meets the physician's dose constraints as specified in the directive
3. Prepare/oversee the creation/calculation of the approved treatment plan for the QA geometry using the dose per fraction specified for patient delivery
4. Perform or oversee the pre-treatment quality assurance checks including:
   a. Verify integrity of the information transferred to the treatment management system for the patient plan and the QA plan, including correct transfer of gantry, collimator, table, and jaw positions, and calculated monitor units etc.
   b. Verify correctness of MLC leaf positions, sequences, and fractional monitor units
   c. Verify the accuracy of monitor units used for the patient dose calculation
5. If pre-treatment QA fails, communicate to the full treatment team that the treatment plan cannot be used for patient treatment and that the patient treatment may need to be delayed.
6. Investigate and document any causes of failures
7. Review that the patient continues to receive the correct treatment at least on a weekly basis

6. Example treatment therapist checklist:

Pre-RT course

1. Verify written prescription/consent
2. Review patient setup, image guidance and motion control
3. Review approved treatment plan, verify delivery type is IMRT (DMLC/SMLC), and verify documentation of QA
4. Obtain and review appropriate images; seek approval per department SOP
5. Perform time out (correct patient, correct site, correct plan) prior to treatment delivery
6. Alert physicist to unusual machine behavior; pauses/stops treatment if necessary

Prior to/during each fraction

1. Perform time out (correct patient, correct site, correct plan) prior to treatment delivery
2. Verify that imaging is within specified constraints, proceed per department protocol
3. Note changes in patient status, concerns about reproducibility, or intra-fraction motion
4. Verify that machine motions are correct and leaves move for IMRT fields