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TECHNICAL WHITE PAPER: GUIDANCE FOR STATE PROGRAMS THAT REGULATE INTENSITY-MODULATED RADIATION THERAPY

H-25 TASK FORCE ON INTENSITY-MODULATED RADIATION THERAPY (IMRT)

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H-25 TASK FORCE ON IMRT

The CRCPD H-25 Task Force was assigned to develop guidance for state regulators that will ensure safe use of this new modality, intensity-modulated radiation therapy (IMRT). The IMRT manufacturers, as well as the American Society for Radiation Oncology (ASTRO), the American College of Radiation Oncology (ACRO), the American Association of Physicists in Medicine (AAPM), and the American College of Radiology (ACR), have written documents regarding the many areas of concern and covering operational uses of IMRT. These documents may be used in developing the basis on which to establish a state regulatory program for IMRT.

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EXECUTIVE SUMMARY

Intensity-modulated radiation therapy (IMRT) is a cancer treatment modality that is used to treat prostate, head and neck, and other cancers. Treatment delivery equipment, such as stereotactic radiosurgery, for treating cancers using radiation include Cyberknife® and Gamma Knife® (equipment previously addressed by other CRCPD working groups). With the implementation of the multi-leaf collimator, Cyberknife® is now able to deliver IMRT treatment as well. Functionally, IMRT is the delivery of radiation that uses non-uniform beam intensity patterns to achieve a three-dimensional (3D) dose distribution that closely approximates the shape of the tumor. Through the use of inverse treatment planning (an automated optimization technique), IMRT can deliver higher radiation doses within a tumor while minimizing doses to adjoining normal critical organs. This advanced treatment uses computer-aided manipulation of multiple radiation beams to form a 3D dose distribution, and as a result IMRT can achieve greater tumor control and reduction of normal tissue complications. To achieve this complex radiation therapy modality requires a combination of image-guided techniques, patient-specific quality assurance (QA), computer optimization and a beam delivery system to deliver the planned 3D treatments (ACR-ASTRO 2014; IAEA n.d.).

Some of the IMRT treatment approaches currently in use include:

- legacy ARTISTE™ linear accelerator (Siemens Healthineers USA)[1];
- Novalis Tx™ (Varian Medical Systems, Inc. and BrainLab, Inc.)[2];
- Precise Treatment System™ and Versa HD™ (Elekta, Inc.);
- Clinac™ (Varian Medical Systems, Inc.); and
- TomoTherapy™ (Accuray, Inc.).

All of the aforementioned treatment delivery systems are computer controlled; on the other hand, the Cyberknife™ (Accuray, Inc.) is a robotic system with the linac mounted on the robotic arm. Regardless whether a gantry or robot is used in a linear accelerator-based therapy machine in delivery of conformal radiation treatments, improved tumor control is due to the delivery of a higher

[1] Siemens stopped manufacturing this system in 2012. Some legacy systems may still be in use.

[2] Varian is no longer offering Novalis™ and their partnership with BrainLab, Inc. has ended.

radiation dose within the tumor while limiting doses to normal tissues to lower levels. The end result is greater dose sparing on adjacent normal tissues than with conventional external beam radiation treatments restricted by tolerance and sensitivity of those normal tissues.

IMRT has been used for treating prostate cancer, and other clinical trials have reported IMRT's effectiveness in treating head and neck tumors as well as breast cancer; currently, IMRT is used for treatment throughout the body. IMRT helps radiation oncologists to achieve increased precision more than is possible with conventional radiotherapy through a combination of medical linear accelerator (linac) or Co-60 sources (Viewray^{tm}) for production and delivery of radiation, advanced treatment planning and control software, and specialized mechanical devices used to "paint" a precise radiation dose to the shape and depth of the tumor.

IMRT and other conformal radiation therapies can deliver a dose anywhere within the body. As with any conventional radiation therapy, IMRT treatment involves radiation oncologists, dosimetrists, radiation therapists and qualified medical physicists working collaboratively in all phases of treatment planning and delivery. IMRT is a significant advancement in treatment and control of cancerous lesions with the benefit of less biological damage to healthy tissues and overall reduction in complications. IMRT has been developed to achieve that optimal dose distribution.

The purpose of this report is to provide application reviewers and state inspectors with a checklist, the key concepts for reviewing and inspecting IMRT radiotherapy facilities. This report:

- summarizes general IMRT operating principles;
- gives reference internet sites for five examples of clinical IMRT units that are currently in use (Note that upgrades, including software, to the system may change this information and therefore, specific license conditions may have to account for those upgrades.);
- provides a primer for shielding requirements;
- discusses machine registration;
- gives an outline of inspection procedures, and;
- gives examples of state regulatory programs and reference materials that can serve as a guide for program development.

INTRODUCTION

Volumetric modulated arc therapy (VMAT) and intensity modulated radiation therapy (IMRT) produce a higher conformed dose distribution over target volume than that of standard 3D conformal treatment by delivering intensity-modulated dose from several static directions around the patient. The VMAT radiotherapy technology is an advanced form of IMRT that delivers a precisely sculpted dose distribution with a 360º rotation of the gantry with one or more arc treatment, as compared to IMRT treatment with repeated stops and starts at different angles. Regardless of differences in beam delivery, the ability of the two modalities to shape dose distributions is exploited to create sharp dose fall-off near the boundaries between the target volume and healthy tissues. Basically, this means sparing healthy tissues by delivering a much lower dose to them. Since VMAT and IMRT achieve the same goal of precise dose distribution, for the purpose of this guidance document, IMRT will serve as the umbrella nomenclature for both delivery methods. Another major advantage of IMRT is to produce isodose distributions that more closely follow the boundaries of the target volume, as compared to that achievable with conventional 3D conformal radiation therapy (3DCRT) which uses uniform beam intensity. With these advantages, radiation oncologists may prescribe a higher tumor dose for better tumor control, potentially leading to improved patient outcome.

Clinical studies indicate that higher doses delivered with IMRT techniques are improving the rate of local tumor control (IAEA n.d.). Studies in patients with prostate cancer have shown that higher radiation doses (between 13 and 25 percent higher than doses used in standard radiotherapy) increased the rate of local tumor control from 43 to 94 percent. With IMRT, radiation oncologists were able to deliver those higher doses while reducing the rate of side effects in healthy tissue. Due to these improved outcomes for cancer patients, IMRT continues to be developed, refined, and applied to other types of cancers.

The medical linear accelerator (linac) produces high-energy x-rays used for delivering radiotherapy treatments. For IMRT, the linac has a specialized multileaf collimator (MLC) that responds to a computerized treatment program to deliver radiation in a custom-designed intensity pattern in the defined treatment area. IMRT can also be delivered using specially designed compensators, as in the .decimal® compensators for IMRT delivery systems that are often used for pediatric cases. The tungsten leaves of the MLC move

dynamically during dose delivery and modulate the intensity of the emitted radiation beam directly over the treatment area.

The IMRT unit achieves its increased precision through a combination of computer programs and specialized MLC that produce and deliver a shaped or sculpted radiation beam. Each radiation beam delivery is divided into many beamlets with varying intensity, resulting in different doses of radiation deposited within and across the tumor. For example, when a beamlet passes through a tumor, the intensity is programmed to be higher; when a beamlet passes through sensitive normal tissues, the intensity is programmed to be lower (Zelefsky 2000). During treatment, the radiation intensity of each beam is controlled, and the beam shape changes hundreds of times during each treatment session. Most MLC linacs sweep the positions of the leaves during the duration of a beam's delivery, varying the intensity received by each portion of the irradiated tissue (Lee 2002). This allows diseased sections of the irradiated area to receive higher doses than sensitive normal tissues. In some cases, the isodose distribution can achieve a concave shape to avoid sensitive structures.

Planning an IMRT treatment involves several phases. Extended field of view computed tomography (CT) scan showing the interface between the patient's skin and air, and encompassing the tumor location is required. Additional imaging studies, magnetic resonance imaging (MRI) and/or positron emission tomography (PET) scans of the body area to be treated, may be ordered by the doctor to assist in accurate definition of anatomical position of the tumor and adjacent organs/tissues and their dimension in size and shape. The digital information from these preliminary scans is transferred to the radiotherapy planning computer system. Using the treatment planning software, the radiation oncology team plans the course of treatment based on computerized dose calculations.

To aid in stabilizing the patient and improving setup reproducibility of the patient position for the duration of the daily treatments that can span several weeks, a custom immobilization device is often made. A dedicated Styrofoam^{tm} mold or a reusable vacuum cradle are typical examples of such devices. This is done prior to acquiring the planning CT images to make sure the patient's position is consistent throughout planning and treatment, and so that these immobilization devices are accounted for in the treatment planning process. Additionally, for treating cancers in the head or neck a thermoplastic mask may be molded around the patient's cranium and shoulders to further immobilize the treatment area, so that the target will be treated as accurately and consistently as possible from one therapy fraction to the next (Cancer Research UK. n.d.). Note that even small body-part (e.g., respiratory organs and heart) movements can result in significant deviations from the calculated

doses in the treatment plan; therefore for certain applications, patient instructions for breathhold can become important.

As noted previously, IMRT technical development is volumetric modulated arc therapy (VMAT), in which the treatment is delivered using the same linac (Teoh 2011). The VMAT machine continuously rotates the radiation source around the patient during the treatment, while delivering intensity-modulated doses. To do so, the machine continuously reshapes and changes the intensity of the radiation beam as it rotates around the body. In addition, this technique shortens the treatment time to less than 10 minutes per fraction. Other than the continuous arc movement, the ability to modulate dose rate is an important distinction between VMAT and IMRT. Despite both VMAT and IMRT treatment sparing surrounding healthy tissues, the patient can still experience side effects. As with any radiation therapy, the resultant side effects only affect the parts of the body that the radiation beam has traversed on its way to the intended target. Currently, the majority of clinical results on VMAT are limited to planning and feasibility studies; nevertheless, there are some emerging clinical findings that have been reported.

This new capability to modulate the intensities of individual rays within each beamlet provides IMRT gains with greater control of dose distributions. When combined with various imaging techniques to precisely delineate tumor volumes and deliver the planned treatments, IMRT deliveries have resulted in better tumor control and reduction in healthy tissue side effects.

It is important to note that installation of IMRT and VMAT units does not reduce a facility's standard radiation shielding requirements associated with the high-energy radiation used in radiotherapy and can, in fact, increase the amount of shielding required. Shielding of IMRT or VMAT equipment involves the same, or even higher, level of safety requirements, machine performance, and understanding of the principles of radiation therapy as in any other forms of complex radiotherapy. The quality assurance program will be more complex if IMRT is being performed. From a regulator's point of view, the registrant is required to have:

- training and qualification documents for radiation therapists, qualified medical physicists, and radiation oncologists;
- quality assurance reports;
- radiation delivery accuracy tests;
- optimized treatment planning reviews;
- shielding requirement specifications;
- operating and emergency procedures;
- medical events procedures, and;
- annual calibration of imaging and therapy units.

In the report on delivery, treatment planning, and clinical implementation of IMRT, Ezzell, *et.al.*, provides a more detailed guidance to those individuals who are interested (AAPM 2003).

GENERAL OPERATING PRINCIPLES

IMRT is an image-guided radiotherapy because it relies on the use of volumetric image information for accurate determination of tumor boundaries and the adjacent critical organs and tissues. A general IMRT process is shown in Figure 1. The details of the implementation may be vendor- or delivery-system-dependent, but the general flow is similar. The IMRT process consists of four sequential phases:

1. tumor delineation;
2. treatment planning and optimization;
3. quality assurance; and
4. treatment setup and radiation delivery (Dong and Mohan 2003).

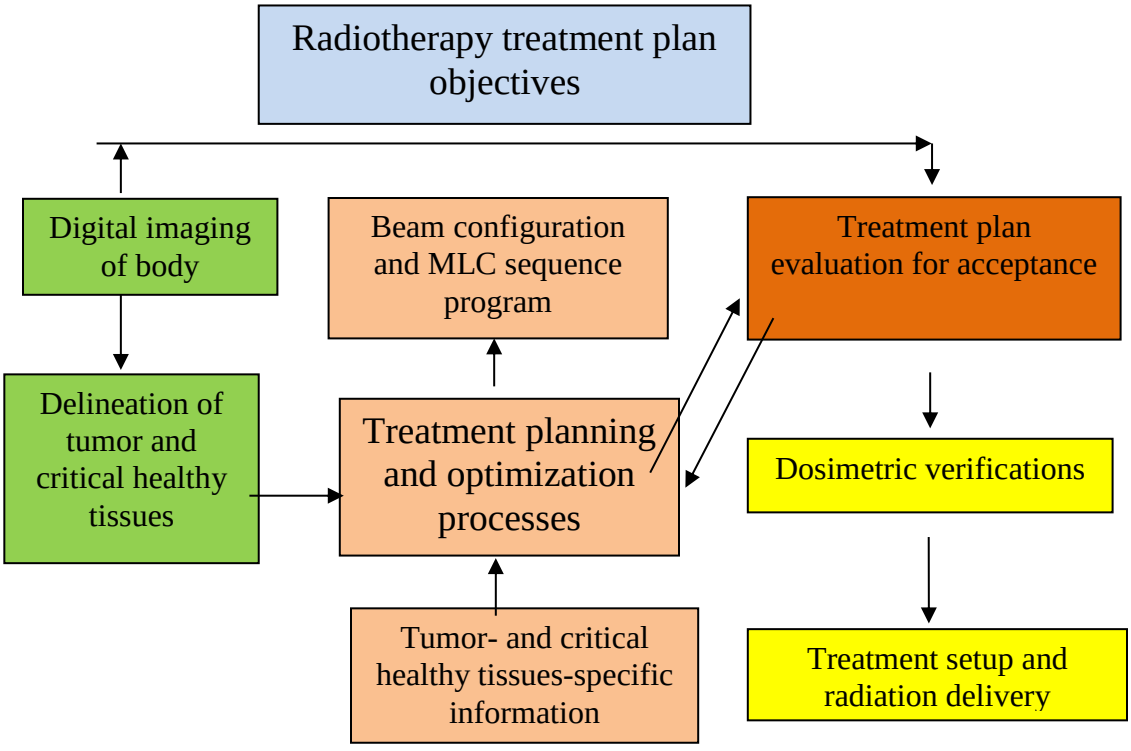

Figure 1. IMRT planning and treatment delivery flow diagram. Redrawn and simplified from original source (Dong and Mohan 2003).

Tumor (Target) delineation

Both the tumor (target) and critical organs are identified and outlined accurately by using one or more digital imaging techniques. As noted previously, body movement during treatment cause dose delivery errors. For example, prostate motion during radiotherapy can lead to under-dosing the tumor within the prostate while overdosing the rectum and bladder. In addition to that, daily variation in bladder and rectum filling can further reduce the curative effects of delivered radiation.

Treatment planning and optimization

These processes translate clinical requirements into computer-controlled commands to the treatment machine.

Quality assurance

When a linac-based MLC is used for IMRT delivery, the MLC computer-controlled leaf movement is complex and synchronized to the specific beam delivery over time. Dose accuracy is paramount, since it is possible for dose error to occur because of a steep dose gradient near the boundaries of the tumor and critical tissues. Other QA requirements are the same as those for conventional 3D conformal radiation therapy; nevertheless, IMRT's intensive computer processing requirements and greater demand for precise control of MLC will require additional QA procedures in order to ensure accuracy and reliability in delivering an optimized treatment. One such QA is end-to-end testing; this should be performed to verify treatment plan delivered the correct target dose.

Treatment setup and radiation delivery as part of QA

Calibration of applicable IMRT dosimetry and measurement equipment is necessary in order to verify dose delivery in accordance with a specific

treatment plan. See reference on treatment verification by B. Mijnheer (2008). As such, there needs to be some form of image-guidance on the machine. IMRT treatments can be made of small radiation fields or a combination of small and large subfields. In those treatments with small fields, it becomes a challenge to do dosimetry because many of the radiation detectors typically employed in radiation oncology departments are too large to accurately measure small radiation fields. It is essential that small pencil chambers be used otherwise, measurements with wrong chamber size can lead to dosimetric errors. It is essential also to ensure proper placement of detectors in steep dose-gradient regions. Other possible sources of measurement error in an IMRT treatment results from the manner in which IMRT beams are delivered at various orientations. The correct selection of radiation detectors depends on the type of IMRT measurements and the delivery characteristics for the particular IMRT system.

The basic requirements for radiation electrometer equipment remain the same as those for non-IMRT measurements, however. The requirements are:

- accuracy;
- linearity;
- stability;
- minimum charge collection;
- high impedance; and
- low leakage.

They all need to be factored in when performing calibration measurements (Low 2011; 38:3). It is important that calibration procedures for ionization chambers and electrometers be done before IMRT measurements are made.

PRIMER FOR SHIELDING REQUIREMENTS

The purpose of shielding is to limit radiation exposure of staff, patients, visitors, and the public to acceptable levels. Shielding plans and calculations must be designed and performed by a qualified radiation expert and checked by a certified expert. The role of the registrant/licensee and the regulator is to verify that assumptions and design criteria are adequate in protecting public and medical staff, approve the design, and receive notification of all modifications.

As with review of any megavoltage radiotherapy facility's shielding design, a reviewer will need to:

- have a good understanding of the underlying principles of the design of a radiotherapy facility;
- be familiar with safety requirements, including interlocks, maze design, and warning postings;
- be able to calculate the shielding thickness required for a particular barrier;
- be familiar with more complicated calculations involving scattered and leakage radiation at various angles;
- understand the required shielding calculated based on the weekly workload of the unit at specific energy, the distance from the target or isocenter from the patient, the fraction of time that the beam is directed at primary barriers, and occupancy of controlled/uncontrolled areas; and
- perform shielding verification and surveys.

Shielding fundamental steps

Fundamental steps for reviewing shielding include the following (NCRP 2008; IAEA 2008).

Obtain a plan/map of the treatment room and surrounding areas that identifies locations of occupancy with respect to primary beam and secondary beam for both scatter and leakage photons (and neutrons for beam energy > 10 MV).

Confirm that the construction of the facility (materials and their thicknesses) are in agreement with the shielding design calculations. Higher radiation

workloads used with IMRT can impact the shielding materials used (*e.g.*, high density concrete, lead, borated polyethylene).

Verify that leakage radiation proportional to the total number of monitor units (MU) the machine produces per week has been taken into consideration. [*n.b.*, IMRT requires increased monitor units/cGy at isocenter, where IMRT ratio equals MU with IMRT/cGy at isocenter (NCRP 2008; IAEA 2008; ACR-AAPM 2015).]

Verify shielding calculation methods were used for scatter radiation arising from patient and barriers.

Ensure all room penetrations are correctly dimensioned and positioned on the plan, e.g., doors, dosimetry, utility conduits, and heating/ventilation/air conditioning ducts.

Obtain information on IMRT linac equipment.

Include basis information:

- workload (Generally, the linac workload, W in Gy/week, is determined, based on the typical patient dose multiplied by the number of patients treatment per week);
- target dose;
- use factor;
- rotational capabilities of the linac equipment;
- distance to area of interest; and
- occupancy of areas to be shielded.

[*n.b.*, Percent workload with IMRT is typically assumed to be 50% and 100% for treatment room dedicated to IMRT (ACR-AAPM 2015).]

Consider complex issues, such as neutrons produced by high-energy linacs (gamma/x-ray, n) (typical threshold of E > 10 MV for neutron activation of materials in the beam line and in the concrete walls of the treatment room).

[Note: Most types of IMRT deliver a radiation field in many field segments; therefore, many more monitor units (MU) are delivered per field than in conventional radiotherapy (AAPM 2014). The total target dose will still be the same, and the primary beam shielding will not be affected. However, the leakage radiation, which comes from the head of the linear accelerator, can be significantly increased and when VMAT is used. The increase is generally in the order of two or three. (In the past a factor of 10 was often assumed (Low 2011). Therefore, the secondary barrier thickness would need to be thicker to attenuate the increased radiation leakage (Rodgers 2011).

Table 1. Example of some of the major relevant shielding calculation parameters to consider. (NCRP 2008, IAEA 2008, ACR-AAPM 2015)

	Shielding design goal of 0.1 mSv/week for controlled areas; Barrier transmission factor; Barrier thickness based on the transmission factor	
	Primary barrier and secondary barrier as dictate by shielding requirements and facility design	
	Equation*, such as $H_o = W_{primary}\ UT/d_S^2$, calculations for determining weekly dose equivalent to be attenuated at location X. [The equation is for calculating the dose behind a primary barrier.]	
	TVL data based on barrier materials used and beam energy for determining barrier transmission factor	
	Equation*, such as $P = B_{primary}\ H_o$, for determining barrier thickness, B.	
	Important consideration of barrier width as determined by the beam divergence with gantry angle plus tolerance as specified in NCRP 151 (NCRP 2008; IAEA 2008)	
	For each primary barrier location it is necessary to verify the transmitted the time-averaged-dose-rate in a week, and the time-averaged dose in-any-one-hour (this value should not be greater than 20 uSv/hr in uncontrolled area).	
	Equation*, such as $P = 10^{-3}B_L W_L T/d_L^2$, used for leakage barrier calculations at a rate of less than 0.1% of the primary beam at 1 m from the x-ray target.	
	Equation*, such as W_L = (average # MU using IMRT/average # MU without IMRT) x $W_{primary}$, used for workload calculations. For TomoTherapy^{tm} , 16 MU/cGy is used to calculate leakage workload. For other linacs with a robotic arm, 15 MU/cGy. Workload for leakage, W_L, will be larger than the $W_{primary}$ when IMRT and stereotactic radiosurgery procedures are being performed. Equation*, such as W_L = W x IMRT Factor, where IMRT Factor = % IMRT x IMRT ratio + (1 - % IMRT).	

* Equations listed are for illustrative purpose only. It is assumed a reviewer would recognize the meaning of the variables.
[Note: Leakage is typically 0.1% of primary and scatter, depending on beam energy and direction is also about 0.1%.]

Table 2. Example of workload assumptions for multi-energy linac.

Energy (MV)	Patients per Day	Workload (Gy/patient)	Workload (Gy/week)	MU/cGy Ratio	Leakage Photons	Workload (Gy/week) Neutron
6 3D						
6 IMRT/VMAT						
6 Flattening-filter free (FFF) beams						
Total						
10 3D						
10 IMRT/VMAT						
10 Flattening-filter free (FFF) beams						
Total						
15 3D						
Total						

RADIATION MACHINE REGISTRATION

For state radiation control programs, the requirements and process of registration/licensing of IMRT linacs should be in accordance with the appropriate state radiation control program for registering/licensing of standard imaging units and linac systems.

Administratively, the application should document the following information:

- assigned individual, such as a Radiation Safety Officer, who is qualified to oversee the radiation safety program;
- qualified medical physicist to ensure proper calibration, machine performance, and treatment planning (ACR-AAPM 2015; AAPM 2013);
- radiation safety committee to oversee the use of IMRT for patients, review written prescription of the radiation doses used in treatments, investigate medical events (variance with established criteria and limits; wrong patient, wrong treatment administered);
- education and training of medical staff (e.g., radiation therapists, qualified medical physicists, radiation oncologists, radiation therapists, and dosimetrists) involved in the radiation therapy (ACR-ASTRO 2014);
- QA documents of activities and procedures for ensuring quality in the processes by which IMRT treatments are developed. QA aims to prevent suboptimal dose delivery from occurring before putting IMRT into clinical use (ACR 2010; Hartford, et.al. 2009).
- Formal QC program that includes (Hartford, et.al. 2009; AAPM 2009a; ACR-ASTRO 2014):
    - documented commissioning process;
    - user training;
    - well-defined acceptance tests;
    - well-defined post-service repair tests;
    - well-defined repeatability checks;
    - appropriate actions taken upon discovery of treatment variance;
    - documents of all measurement results and periodic radiation surveys;
    - documentation of periodic QA according to the report of AAPM Task Group 142 (AAPM 2009b); and
    - protocols dealing with patients.

Table 3. Example parameters relevant to an IMRT application review.

	Make and model of medical linac	
	Photon energy used for IMRT	x MV
	Make and model of MLC used for IMRT	
	Procedures adopted for QA of delivery system (machine specific QA). Describe the parameters, test methods and tools used in detail.	
	Make and model of the treatment planning system	
	Detailed procedures used for QA of IMRT treatment planning system	
	Make and model of the imaging unit(s) used for IMRT	
	QA for patient setup procedures	
	Make and model of dosimetry equipment	
	Frequency of QAs/QCs (List)	D/W/M
	Criteria for accepting IMRT plan	
	Formal risk analysis based on appropriate and accepted method before any significant changes made to the IMRT system	
	Staff shall be clear about their responsibilities for treatment planning and verification	
	Staff training is up-to-date to maintain clinical competencies	
	Regular review of all work instructions, in accordance with policy and procedure manual	

IMRT treatment planning and delivery are difficult to assess. In the words of Gary Ezzell, *et.al.*, on the AAPM Task Group 119 report (AAPM 2009a), "How good is good enough?" and "What is a reasonable and achievable standard for IMRT commissioning?" Their report can serve as a reference for regulatory reviewers to assess an IMRT application. The report's results are summarized in many tables that can be used as a baseline.

A reviewer may gain a working knowledge by evaluating a Varian TrueBeam™ software-based linac system performance for general emulation of other devices for evaluation. An excellent source is the article by Clivio, A., et. al. (Clivio 2015).

INSPECTION PROCEDURES

An inspection process associated with IMRT is conducted in accordance with regulatory standards in effect in the jurisdiction where the inspection is conducted. Due to the complex preparation associated with radiotherapy systems and the potential for significantly large radiation exposure to patients and medical staff directly involved with the linac, the inspection should address the commitments of the machine application in addition to the regulations. The application gives the regulatory agency an indicator of the applicant's readiness, capabilities, and knowledge. The required documentation provides details of all the commitments made during the registration process and contains:

- a diagram and description of all locations of use for the IMRT system;
- emergency procedures;
- training requirements;
- continuing clinical experience;
- procedures for root-cause analysis; and
- radiation safety policy.

Site Inspection Activities

The inspection process associated with an IMRT system is composed of three different activities. The first activity is the safety equipment check; after this verification of operational safety equipment, conduct the radiation survey in and around the therapy suite while the system is in use. The second activity is the inspection of the facility and interviews of the personnel responsible for treatment and safety programs. The third activity is the review of records.

Safety Equipment Check and Radiation Survey

A radiation survey should be performed around the therapy suite to confirm that the shielding calculations and registrant's periodic surveys are adequate. In addition to a general survey, it is recommended that the surveyed locations be matched to the locations identified on the shielding report. Inspection items to be completed prior to conducting a radiation survey:

- Verify operating and emergency procedures are up to date and available in the treatment facility.
- Check the operation of radiation exposure lights, patient viewing and intercom systems, and radiation monitors.
- Verify radiation warning sign postings.
- Verify the emergency contacts of all relevant personnel in accordance with emergency response procedures.

Use an ionization survey meter to check external dose rates using the highest energy and the highest clinical dose rate. Some recommended measurements are:

- Primary barriers: Make dose rate measurements for all primary barriers with maximum field size with the collimator angle that will maximize the diagonal dimension across the barrier.
- Secondary barriers: Put scattering material, e.g., a water tank, at the isocenter to simulate the patient. Make dose rate measurements for all secondary barriers and the maze entrance for gantry angles at 90^{o} increments.
- Measure the neutron dose rate at the maze entrance with a portable neutron monitor for linacs operating at 10 MV or above.
- Compare the results with the calculated values and state radiation safety regulations.

Facility Inspection

What to look for in a work organization:

- excessive workload complaints;
- adequate staffing level (ASTRO 2012);
- proper coordination among the members of the radiation therapy team to reduce the chances of treatment errors (such as, clarity of treatment workflow and procedure documented in policy and procedures manual);

- initial training on new technology, recentness of education credits and professional development for any changes and updates;
- verification of compliance with submitted QA/QC program;
- regular peer review of QA/QC program including QA results;
- training for "unusual situations;" and
- promotion of a "safety culture" or an incident learning system. As an example, ASTRO's *Safety is No Accident* contains very helpful instructions on how to assess staffing levels (ASTRO 2012).

Site Record Review

The third activity is the review of QA/QC test records for compliance with the manufacturer's requirements for QA/QC, of annual medical physicist radiation surveys and calibration reports, of radiation safety committee minutes involving medical events; and of maintenance and service records.

- Review policies and procedures that describe all processes.
- Review QA/QC checklist based on policies and procedures to follow each step of treatment planning and delivery procedures.
- Review checklists for QA/QC tasks assigned to the dosimetrists, therapists, qualified medical physicists, and other staff.
- Review facility service records (renovations, electrical system upgrades, ventilation, etc.) that can compromise shielding of treatment room.
- Review equipment maintenance/service reports.
- Review records of medical events or misadministration for root cause analyses.
- Items for records review and follow-up:
  - no end-to-end test performed before first patient treated;
  - open MLC and open treatment patient anatomy;
  - plan done and approved by the radiation oncologist on record without qualified medical physicist's and dosimetrist's second check;
  - computer system failure during patient treatment;
  - no IMRT QA/QC was done and done timely and did not follow IMRT QA/QC protocol. ASTRO recommends QA be done before the first treatment, but a minimum guideline is before the 3rd fraction (provided that the treatment consists of more than 5 fractions);
  - oncologist failed to verify the treatment port;
  - root cause analyses as reported by the facility;
  - lack of periodic radiation surveys of controlled and adjacent uncontrolled areas for ensuring adequacy of shielding.

Table 4. Example of QA checklist* based on AAPM Task Group 142 recommendations. (AAPM 2009b; ACR-ASTRO 2014; Jones 2012)

Frequency	QA	Procedures	Yes/No
Daily	Dosimetry/Mechanical/Safety	Dosimetry	
		Mechanical	
		Safety	
Daily	Wedge	Check-Out run for one angle	
Daily	Imaging	Collision interlock	
		Position/repositioning and image and treatment coordinate coincidence	
Daily	Laser alignment system	Verify alignment	
Weekly	MLC	MLC Qualitative test	
		Travel speed	
		Leaf position accuracy	
Monthly	Dosimetry	X-ray and electron output	
		Backup monitor chamber	
		Typical dose-rate output	
		Electron beam energy constancy tests	
Monthly	Mechanical	Light/radiation field coincidence	
		Jaw position indicators	
		MLC settings vs. radiation field for two patterns (non-IMRT)	
		Photon beam profile constancy	
		Distance check for lasers compared with front pointers and localizing lasers	
		Gantry/collimator angle indicators	
		Accessory trays QA	
		Cross-hair centering and jaw positioning indicators	

Monthly	Mechanical	Treatment couch position indicators QA	
		Wedge placement accuracy	
		Latching of wedges, blocking tray	
Monthly	Imaging	Planar MV imaging (EPID) and kV imaging	
		Cone-beam CT (kV and MV)	
	Wedge	Wedge factor for all energies	
Annual	Dosimetry	SRS arc rotation mode and arc mode	
		X-ray/electron output calibration	
		Spot check of field-size dependent output factors for x-ray	
		Spot check of output factors for electron applicators	
		Spot check for physical wedge transmission factor constancy	
		X-ray beam quality and electron beam quality	
		X-ray monitor unit linearity	
		Electron monitor unit linearity	
		X-ray output constancy vs. dose rate	
Annual	Mechanical	Collimator rotation isocenter	
		Gantry rotation isocenter	
		Couch rotation isocenter	
		Electron applicator interlocks	

Annual	Mechanical	Coincidence of radiation and mechanical isocenter	
		Table top sag	
		Table angle	
Annual	MLC	MLC transmission	
		Leaf position repeatability	
		MLC spoke shot	
Annual	Imaging	Full range of travel SDD	
Annual	Wedge	Check of wedge angle for 60 degree	

*N.B., Although several sections in this table do not apply to IMRT, their inclusion is for state inspectors auditing of a radiotherapy facility and its treatment machine; therefore, the table will need to be modified accordingly. Please consult AAPM website http://aapm.org/default.asp for tests that are applicable to IMRT.

Another required review involves documents of training and clinical experience involving the use of IMRT. For example, training can be designed in accordance with AAPM Task Group 249 which addresses the clinical rotation for a medical physics resident, who would receive training in areas of external beam, IMRT, brachytherapy, and associated radiation safety under the supervision of qualified medical physicists, dosimetrists, radiation oncologists, at participating cancer centers (AAPM 2013). The American Society for Therapeutic Radiology and Oncology (ASTRO) and the American College of Radiology (ACR) are excellent reference sources for practice guidelines.

REGULATORY GUIDANCE AND REFERENCE MATERIALS

AAPM Task Group 100 analyzed the causes of failure for IMRT, the initiation of error reporting systems and a focus on safety culture (AAPM Forthcoming). The Task Group's recommended changes have been given a great deal of the attention by the regulatory community and the Advisory Committee on Medical Uses of Isotopes of the U.S. Nuclear Regulatory Commission (USNRC). The recommendations will improve safety and quality in clinical applications of radiation; nevertheless, they will pose challenges for state regulatory agencies on writing regulations, reviewing and issuing licenses, and performing inspections.

Although IMRT systems are not regulated by the USNRC, nor specifically regulated by some state public health radiation control departments, many state regulatory agencies have taken up the challenge. Although not specifically written for IMRT, some excellent regulatory examples are:

- *Texas Administrative Code Chapter 289.229, Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices;*
- Texas Board of Licensure for Professional Medical Physicists *(Title 22 Part 26 Chapter 601 Rule 601.21);*
- *Ohio Administrative Code Rule No. 3701:1-67-06, Standards for therapy equipment operating at or above one megavolt (MV), Rule No. 3701:1-67-08* and *Appendix, Shielding design and safety requirements, Appendix: Required Facility Design Information,"* and *Rule No. 3701: 1-67-09, Quality assurance for radiation therapy simulation and image guidance equipment;* and
- Minnesota Department of Health's proposed permanent rules related to radiation therapy, *Chapter 4733, 2015*.

There are many other reference guides available that should be considered when developing state regulations and guidance for registration and inspection of IMRT systems, such as, CRCPD *Publication No. E-13-3* [based on Suggested State Regulations for Control of Radiation (SSRCR) Part X], *Inspection Protocol for Medical Linear Accelerators*, and the checklist (based on Rhode Island regulations), *Rhode Island Radiation Control Agency Therapeutic Radiation Machine Inspection Report.*

An overview of IMRT, definitions and basic concepts, presented by Dr. Thomas R. Mackie is available in pdf format:
http://www.iaea.org/inis/collection/NCLCollectionStore_/_Public/40/003/40003881.pdf

An excellent reference for a more detailed treatment of radiation oncology physics is *Radiation Oncology Physics: A Handbook for Teachers and Students, Podgorsak, E.B., ed., IAEA Publication,* 2005. (Available in pdf format: http://www-pub.iaea.org/MTCD/ publications/ PDF/Pub1196_web.pdf#page=569)

A summary of relevant reference materials is IAEA Training Course Material, *Transition from 2-D RT to 3-D CRT and IMRT.* (Available in pdf format: https://humanhealth.iaea.org/HHW/RadiationOncology/Treatingpatients/Treatment_planning_and_techniques/Training_Course/22_Training_Course_Material_2D_to_3D_and_IMRT.pdf)

INTERNET SITES OF IMRT TREATMENT DELIVERY SYSTEMS AND SOFTWARE

Specific examples of IMRT delivery systems are not listed in this report because the manufacturers' continual upgrades of hardware and software. Therefore, the interested reader is directed to the various vendors for current information.

https://usa.healthcare.siemens.com/clinical-specialities/oncology/breast-care-therapy/therapy-mr

https://www.varian.com/oncology/treatment-techniques/external-beam-radiation/vmat
https://www.varian.com/oncology/products/treatment-delivery/clinac-ix-system

http://www.accuray.com/solutions/treatment-delivery/tomotherapy-treatment-delivery

https://www.elekta.com/radiotherapy/treatment-delivery-systems/precise-treatment-system.html

http://www.usa.philips.com/healthcare/product/HCNOCTN138/pinnacle-smartarc-the-speed-of-vmat-delivery-the-excellence-of-pinnacle

http://mobiusmed.com/mobius3d/

The treatment delivery systems mentioned in this document can be obtained from the respective vendors' internet sites. The selection of those various systems serves as examples only. As noted earlier, the mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Conference or any federal agency supporting the work contained in this document.

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GLOSSARY AND ABBREVIATIONS

3DCRT is a conventional 3D conformal radiation therapy that uses uniform beam intensity in treatment that is shaped to match the tumor.

AAPM is the American Association of Physicists in Medicine.

ACMUI is the Advisory Committee on Medical Uses of Isotopes.

ACRO is the American College of Radiation Oncology.

ACR is the American College of Radiology.

ASTRO is the American Society for Radiation Oncology.

CT is computed tomography that uses x-rays to scan axial sections of the body to create detailed anatomy.

Cyberknife® is a robotic radiosurgery system that delivers accurate beams of high dose radiation to tumors.

Damage as used in context of radiation treatment means cell killing by damaging the cellular DNA beyond the ability of the impacted cells in tumor and healthy tissues to repair and to recover physiological functions.

Dose distribution is a pattern of various radiation doses to a particular target (*e.g.*, a tumor).

Dosimetrist is a trained person who specializes in calculating proper radiation dose for radiotherapy with the aid of treatment planning software.

ESTRO is the European SocieTy for Radiotherapy & Oncology.

Gamma Knife® radiosurgery is a special radiotherapy that focuses close to 200 beams to treat tumors and other lesions in the brain.

Healthy tissue is a physiologically functional part of the body whose functions and interactions with other tissues and organs are under the influence of and responsive to homeostatic control.

IAEA is the International Atomic Energy Agency.

IMRT is a radiotherapy treatment that uses non-uniform beam intensity patterns with computer-aided optimization to achieve specific dose distribution.

Isodose distribution is a pattern of dose depositions that can be graphically illustrated as contour map of region of interest with the same dose (isodose) deposition, usually with the contour map overlaying maps with other regions of interest.

Linac is a linear accelerator that generates high-energy x-rays (or electrons) used in radiation therapy.

MLC is a multileaf collimator device under computer control made up of individual leaves, usually constructed of tungsten, that can move independently in and out of the path of a radiation beam in order to block it or allow it to pass through the beam portal.

MU is monitor unit, a measure of ionization occurring in a treatment beam that will give a quantity of absorbed dose at a specific depth within a patient. [See MU methodologies in the AAPM Task Group 71 report (2014).]

MRI is magnetic resonance imaging modality that uses magnetic fields and pulses of radio waves to image the body to create detailed anatomic slices.

PET is a positron emission tomographic modality. It uses a radioactive tracer that emits positrons that are detected by a scanning device to identify physiological function of organs and tissues.

Qualified Therapeutic Medical Physicist, as defined by AAPM, for the purpose of providing clinical professional services, is an individual who is competent to independently provide clinical professional services in one or more of the subfields of medical physics. See the complete definition at http://www.aapm.org/medical_physicist/fields.asp.

QA means quality assurance, which is the process through which the quality management system gives assurance (*i.e.,* confidence) that existing standards or requirements are met.

QC means quality control, which is the process through which the actual quality performance is measured, as compared with existing standards, and the actions necessary to keep or regain conformance with those standards.

Radiation dose is the amount of radiation absorbed by an irradiated object. This unit is the gray (Gy), defined to be 1 J/kg. (Related to the unit rad, where 1Gy = 100 rad.)

Radiation oncologist is a specialist in the treatment of cancer with radiation.

Radiation therapist is a person who is trained and qualified to operate a radiotherapy unit for clinical treatment.

Radiation treatment planning, in radiotherapy, is the process in which a radiation oncology team consisting of radiation oncologists, radiation therapists, qualified medical physicists and dosimetrists plan the appropriate external or internal beam radiotherapy treatment for a cancer patient. For IMRT, this process involves selecting the appropriate beam energy and radiation deposition within a defined tumor volume, while sparing adjacent healthy tissues.

Radiotherapy is the treatment of disease with ionizing radiation.

Side effects are undesirable complications as a result of treatment.

Treatment planning system (TPS) is used in external beam radiotherapy to generate beam shapes and dose distributions with the intent to maximize tumor control and minimize healthy tissue complications.

USNRC is the United States Nuclear Regulatory Commission.

VMAT is volumetric modulated arc therapy. VMAT radiotherapy technology is an advanced form of IMRT that delivers a precisely sculpted dose distribution with a 360º rotation of the gantry with one or more arc treatment, as compared to IMRT treatment with repeated stops and starts at different angles.

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