ASTRO
TARGETING CANCER CARE

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Margret R. Cooke
Commissioner
Massachusetts Department of Health
250 Washington St.
Boston, MA 02108

Dear Ms. Cooke,

The American Society for Radiation Oncology[1] (ASTRO) respectfully submits this petition for rulemaking by requesting the Massachusetts Department of Health to amend 105 CMR 120.409, *Computed Tomography (CT) X-Ray Systems* to distinguish between accreditation for CT used for diagnosis and CT used for radiation therapy simulation and consider aligning with suggested state regulations for radiation therapy accreditation.

Suggested Regulatory Change

ASTRO recommends the following change to the regulations (changes are underlined and in red):

> Any facility offering diagnostic CT services after April 30, 2011, shall have ACR accreditation.

This change will distinguish between accreditation for diagnostic CT services and non-diagnostic CT services, such as dedicated radiotherapy simulators, cone beam CT systems on linear accelerators, or any other system that is not used for medical diagnosis.

In an email exchange with Karen Farris, Supervisor, Healing Arts/Mammography, Bureau of Environmental Health, MA Dept of Public Health, Radiation Control Program, asking for clarification of whether the requirement applied to diagnostic or simulation CT, she stated that "today, many facilities are performing a diagnostic CT during the CT simulation because it's easier and convenient for the patient."

While radiation oncologists strive to make treatments more convenient for patients, the reasons for a diagnostic CT scan differ from those of a CT simulation. The two involve different protocols, on different machines, and at different times during cancer treatment. CT simulation machines are designed to mimic a linear accelerator, which means that they can accommodate sizeable immobilization devices or other equipment needed to ensure reproducibility for treatment. Additionally, CT simulation uses a set

[1] ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

protocol to allow for standardization of images to allow for treatment planning calculations; therefore, the images are of a different quality than those found in a diagnostic CT. There could be some circumstances where a facility may use the same machine for diagnosis and simulation; however, in this rare occurrence, they are not done at the same time.

Suggested Regulatory Addition

To complement our first recommendation, we recommend that the Department consider aligning with recently approved suggested state regulations by adding the following provisions to 105 CMR 120.000, *The Control of Radiation*.

External Audits and Accreditation:

1. Each registrant providing radiation therapy with therapeutic radiation equipment shall:
   a. Maintain an external audit as described in Appendix A *(attached)* to 105 CMR 120.000; or
   b. Maintain an accreditation in radiation oncology by the American College of Radiology (ACR), American College of Radiation Oncology (ACRO), American Society for Radiation Oncology (ASTRO), or an accrediting organization that is recognized by the Agency.
2. For a newly registered facility, an initiation for external audit or accreditation shall be no later than 6 months after patient treatment begins.
3. The outcome of the external audit or accreditation survey shall be available for inspection and provided to the Agency upon request.

These provisions are a critical component of the revisions to the Conference of Radiation Control Program Director's (CRCPD) Suggested State Regulations (SSR) Part X, *Therapeutic Radiation Machines* approved by the CRCPD Board of Directors on February 22, 2023. This provision of the SSR would add a requirement for each registrant providing radiation therapy with therapeutic radiation equipment, including CT simulators, to either maintain accreditation or conduct an external audit. ASTRO believes that facilities that obtain practice accreditation have the appropriate systems, personnel, and policies and procedures that are needed for high-quality patient care.

On behalf ASTRO's 280 members in Massachusetts, we urge the Department to pursue rulemaking to amend 105 CMR 120.49 to distinguish between diagnostic CT and simulation CT and change the accreditation requirements to 105 CMR 120.00 to protect patient safety. Thank you for considering this request. Should you have any questions, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs at 703.839.7366 or cindy.tomlinson@astro.org.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

CC: Jack Priest, Director, Radiation Control Program, Massachusetts Department of Public Health
Karen Farris, Supervisor, Healing Arts/Mammography, Radiation Control Program, Massachusetts Department of Public Health

Attachment: Appendix A

APPENDIX A

EXTERNAL AUDIT

Purpose: To provide licensees and registrants with a standard form for documenting compliance with the audit requirements contained in X.7.u.

X.7u.i.(1) requires that each registrant providing radiation therapy with therapeutic radiation equipment shall maintain a program audit. This audit shall be completed by an authorized physician and qualified medical physicist. This audit shall be conducted at intervals not exceeding 36 months and when new technology and/or features are used. The auditing physician and physicist must be external.

The licensee or registrant shall promptly review the audit findings; address the need for modification or improvements, and document actions taken. If recommendations are not acted on, the reason for no action or an alternative will also be documented.

This guidance document contains the suggested minimum expectations of a X.7u.i.(1) audit. Licensees and registrants may need to expand and/or focus on more specific facets of their program.

Documentation: Licensees and registrants are required by X.7u.iii, to maintain the outcome of the external audit and it shall be available for inspection and provided to the Agency upon request.

The physician audit requirement is a review of all the clinical aspects of the practice such as patient management (medical record review), including treatment response seen in follow-up visits if appropriate, and assessment of staffing levels including physician assistants, therapists and nurses based on patient volume and technology and complexity of services provided at the facility. The reviewing physician shall meet the requirements of X.3c.

The physicist audit consists of a review of the QA manual and records, policies and procedures and an assessment of staffing, training and equipment needs. The reviewing physicist shall meet the requirements of X.3d.

Instructions: The audit form is divided into four sections. Section A contains general questions about the practice, including therapy modalities, facility, staffing, patient simulation and treatment. Section B, the review of patient charts and images, must be completed by a physician who is active in the practice and type of radiation therapy offered by the licensee or registrant. Section C, the physics component, must be completed by a physicist who is active in the practice of the technology and modalities in use at the practice under audit. Section D contains the audit summary and recommendations as well as the facility's response.

THERAPEUTIC RADIATION MACHINE PROGRAM AUDIT

A. General Information Section			
Facility Name			
Auditor Name(s)			
Period Reviewed	From:	To:	Date(s) of audit:
Modality/Device/Technology (External Beam only)	**Annual Workload (# patient's/year)**	Type(s):	**Comments**
Treatment Machine			
CT-Sim	NA		
Record and Verify System	NA		
Treatment Planning System	NA		
If necessary, use a separate sheet to list multiple machines/ devices/ technologies			
Comments:			

I.	Facility/ Mechanical/ Electrical Safety/ Data Safety	Yes /No/ NA
1.	Is the facility size adequate for the number of patients treated?	
2.	Are appropriate shielding calculations and radiation surveys available for the treatment and simulation rooms?	
3.	Do therapy rooms have functioning: Door interlocks?	
	Door closing safety interlocks?	
	Machine collision interlocks?	
	Radiation on light?	
	Audio/Video monitors?	
	Multi-device interlock switch?	
4.	Are there plans for any replacements or additions? Comment:	
5.	Is there a Departmental Policy & Procedures Manual?	
6.	Is there a Continuous Quality Improvement (CQI) program in place and does it include the following?	
	Weekly patient chart rounds/ New patient conferences	
	Patient morbidity and mortality rounds	
	Patient satisfaction surveys	
	Individual physician/physicist peer review	
	Clinical studies on patient outcomes (e.g. post-treatment issues, side effects, quality of life, etc.)	
	Facility practice improvement studies (e.g. department improvement activities/projects that are measured)	
7.	Is there an Interdisciplinary Quality Assurance and Safety Committee and do they review and follow-up on following?	
	Departmental CQI program results (see above)	
	Patient/ Staff medical/ safety events (e.g. incident learning systems, Hospital/ department reporting system, etc.)	
	New procedures approval (any new technology/ modalities/ treatment techniques should be reviewed and approved before clinical implementation)	
	Medical Physicist QA/ Machine downtime reports	
8.	Do you have emergency procedures for on-site and weekend/off hour treatments?	
9.	Is there a plan for disaster recovery and continuity of care?	
10.	Is there a protocol that properly addresses the mechanical and safety operation for external beam therapy units and is this protocol being followed?	
11.	Comments:	

II.	**Staffing**
1.	Radiation Oncologists: Board Certified FTE____ Non-Board Certified FTE_____ Resident FTE _____
2.	Physicists: Board Certified FTE____ Non-Board Certified FTE____ FTE Residents _____
3.	Dosimetrists: Board Certified FTE____ Non-Board Certified FTE_____ Student FTE _____
4.	RTTs: Board Certified/ Licensed FTE _____ Non-Board Certified FTE ____ Student FTE _____
5.	Nurses: FTE Nurses _____
6.	Physician Assistants/ Nurse Practitioners: FTE PA/ NP _____
7.	Number of patients on treatment daily _____
8.	Comments:

III.	Simulation and Treatment		
	QA Item	**Yes /No**	**Comments**
1.	Do you have a documented time out policy and procedure for simulation and treatment?		
2.	Is a radiation oncologist within the radiation oncology department during treatment?		
3.	Do you have a policy for patient shift changes?		
4.	Do you have a policy and procedure for overrides of interlocks for patient treatments? (Who, when, documentation etc)		
5.	Do you have a policy and procedure for MD and Physicist attendance for high dose per fraction cases (e.g. SRS/ SBRT)?		
6.	Is a Winston-Lutz test performed and approved prior to each day of use for SRS cases?		
7.	Comments:		

B. Patient Chart Review Section

Although every patient's treatment plan and management may be peer reviewed prior to and during treatment, it is important to conduct chart audits. Medical records of at least 15 patients must be included in the annual audit, if applicable. Patient selection for the audit should include all radiation oncologists who provided service during the audit period, those with treatment completed, those under treatment, different disease/treatment sites, curative/palliative treatment and the different modalities/technology services provided under the license/registration. At least one treatment completed chart of each of the new procedures or technologies added since the last audit should be among the charts selected.

Instructions: Complete one form for each patient chart reviewed. Attach these reviews to the summary form (Summary of chart reviews).

I. Treatment (Select): Curative/Palliative
Treatment completed/current
External beam/Other
Modality/Technology

MR #	Chart Review Item	Yes/No	Comments
1.	Is there a history and physical documented in the chart?		
2.	If appropriate, is the Tumor Staged?		
3.	Is there a Pathology report?		
4.	Have appropriate imaging records and reports been obtained?		
5.	Is there a signed informed consent?		
6.	Is there a documented formal written simulation order by the physician?		
7.	Is there documentation of patient ID and setup photos?		
8.	Is there a signed and dated written directive stating the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, treatment frequency, treatment technique, number of fractions, and patient imaging instructions?		
9.	Does the radiation oncologist review the Organs At Risk (OAR) if someone else contours them?		
10.	Is there documentation of a formal Physician peer review of target volumes and OAR's?		
11.	For SRS/SBRT/IMRT patients, is there a written order for dose volume constraints by the Radiation Oncologist?		
12.	**Prior to start of treatment**, for multiple lesion treatments and high dose per fraction treatments (e.g. SRS/ SBRT) is there a documented formal physician peer review of the target volumes and dose to be delivered?		
13.	Is the plan appropriate for tumor stage & type, plan approved, double-checked, DVH, dose to target organs/OAR's documented?		
14.	For Image guided Radiation Therapy (IGRT) patients, have the images been approved by the physician prior to the next fraction?		
15.	Is there documentation in the patient's chart of weekly on-treatment visits?		
16.	Is there a Physician and Physicist treatment summary?		
17.	Are there follow-up visits documented?		

Comments:

II. Medical Record Review

Patient MR#	Disease/Treatment Site	Treatment Intent/Status Curative/Palliative Completed/Current	Treatment Technique/Modality	Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

III. Other Observations:

IV. Summary and Recommendations:

Physician Reviewer's Signature _____ Date:_____

Print Name _____

C. Physics Review Section

Instructions: This section is to be completed by a qualified medical physicist.			
I.	**Quality Assurance**		**Yes / No**
1.	Is there a Physics QA manual?		
2.	In the Physics QA Manual, is the QA program adequately documented? Including:		
		a. procedure for performing the test?	
		b. frequency of the test?	
		c. acceptable deviation?	
		d. corrective actions to be taken?	
		e. initial and ongoing training for physics staff?	
		f. reviewed by a qualified physicist?	
		Frequency?	
3.	Is there evidence of a new equipment evaluation and assessment policy in the QA manual?		
4.	Is there documentation of initial (acceptance testing and commissioning), daily, weekly, monthly, and annual treatment machine and CT-simulator QA?		
5.	Are appropriate protocols used for treatment machine and CT-simulator QA?	Specify all that are used:	
6.	Does the medical physicist supervise the maintenance and repair of radiation oncology equipment?		
7.	Is there evidence that the medical physicist participates in regular departmental QA meetings and presents documentation of QA activities?		
8.	Is a departmental radiation safety program in place?		
9.	Is there evidence of physics chart checks at least once every 6 fractions?		
	Is there a chart check protocol for short course treatments (less than or equal 5 fractions)?		
10.	Is there evidence of a physicist end of treatment chart check and was it completed within 1 week of the patient finishing?		
11.	Comments:		

II.	Measurement Equipment	Yes / No
1.	Does the facility have appropriate physics equipment to properly evaluate and calibrate the treatment machines?	
2.a	Are dosimetry systems used for linear accelerator beams calibrated according to current approved protocols? If so, list protocol(s) and date(s) below.	
2.b	Protocol(s): Date(s):	
3.a	Are survey meters calibrated by approved laboratories? Current calibration protocols? List meter(s) date(s) of calibration	
3.b	Meter(s): Date(s):	
4.	Comments:	

III.	**Treatment Planning** (Items 2, 3 and 4 below are part of acceptance testing and commissioning of Treatment Planning Systems prior to clinical use)	**Yes / No**
1.	Is there a Treatment Planning Manual/ guidelines?	
	Is the method used for computation of the treatment time or monitor units clearly documented in this manual?	
2.	Are monitor units and time calculations confirmed by data measured for relevant cases (benchmark data)?	
3.	Has dose distribution data used by the treatment planning system been measured and/or verified (reference data)?	
4.	Are the TPS computer algorithms verified against the appropriate measured or published data (benchmark data)?	
5.	Is there a periodic QA program for the treatment planning system?	
	Is this QA program documented?	
6.	Is there is evidence of a double check system and documentation performed prior to the patient commencing treatment?	
	For IMRT patients, is there evidence of patient-specific QA?	
7.	Are all treatment plans and calculations approved by a qualified medical physicist and authorized physician?	
8.	Comments:	

Qualified Medical Physicist Reviewer's Signature _____ Date:_____

Print Name _____

D. Audit Summary Section

I. Recommendations:

Auditor's Signatures:

Qualified Medical Physicist _____ Date:

Authorized Physician _____ Date:

II. Facility's Response and Corrective Actions:

Facility's Signatures:

Qualified Medical Physicist _____ Date:

Authorized Physician _____ Date:

Facility Director _____ Date:

V. References

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

C. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

D. NCRP Report 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities. (2006).