2009 Rationale

Part X
Therapeutic Radiation Machines

Introduction

Part X of the Suggested State Regulations for Control of Radiation (SSRCR) was previously concerned with the requirements for use of linear accelerators and superficial and orthovoltage X-ray units in the administration of radiation therapy. Section X.10 has been added to address QA/QC requirements for radiation therapy simulators. Section X.11, along with revisions to existing sections, has been added to address regulation of electronic brachytherapy (eBx) devices. Section X.12 has been added to address any new technology that is not readily addressed by the existing Part X. Part X has also been amended to address Intensity Modulated Radiation Therapy (IMRT), as well as the inclusion of various "housekeeping" amendments.

Global Corrections:

All references to "External Beam Radiation Therapy" (units) have been replaced with "Therapeutic Radiation Machine" to include electronic brachytherapy devices within the scope of these requirements.

All references to "1 month", with regard to the interval at which specified checks or calibrations should be conducted, have been replaced with "30 days".

Specific Provisions

Sec. X.2 - Definitions. The definitions of "conventional simulator", "electronic brachytherapy", "electronic brachytherapy device", "electronic brachytherapy source", "intensity modulated radiation therapy (IMRT) ", "mobile electronic brachytherapy service", "Qualified Medical Physicist" and "virtual simulator" have been added. The definitions of "simulator" and "therapeutic radiation machine" have been revised. The definition of "Radiation Therapy Physicist" has been deleted because this designation is no longer utilized.

"Conventional simulator", "simulator" and "virtual simulator". These definitions were added/ revised to address the differences in QA/QC requirements for each simulator type that has been identified in new Section X.10.

"Electronic brachytherapy", "electronic brachytherapy device", "electronic brachytherapy source" and "mobile electronic brachytherapy service". These definitions were added to reflect terminology used in new Section X.11. The definition of "therapeutic radiation machine" was specifically amended to identify electronic brachytherapy (eBx) as a modality included under this definition.

"Intensity Modulated Radiation Therapy (IMRT)". This definition was added because QA/QC for this modality is now specifically addressed under X.7v.

"Mobile Electronic Brachytherapy Service" was added to address the transport of eBx units to multiple locations and/or eBx units configured in self-contained mobile vans. Based on discussions with several state radiation control programs, mobile units are likely to play a significant role for utilizing this treatment modality in their jurisdiction.

"Patient" Minor changes in wording based on peer review comments.

"Periodic quality assurance check" Minor changes in wording based on peer review comments.

"Qualified Medical Physicist" This definition was added to parallel the use of "Authorized Medical Physicist" in SSRCR Part G and 10 CFR 35. However, the SR-X Committee opted to avoid possible confusion by using "Qualified", rather than "Authorized" because the Part X training/experience requirements differ in several key aspects from those in SSRCR Part G and 10 CFR 35. This designation replaces the "Radiation Therapy Physicist" terminology previously used in Part X.

"Therapeutic radiation machine" This definition has been modified to specifically include electronic brachytherapy (eBx) devices.

In addition, minor changes (suggested during peer review) were made for the definitions of "patient", "periodic quality assurance check" and "redundant beam monitoring system".

X.3c. Training for Therapeutic Radiation Machine Authorized User The list of acceptable board certifications has been clarified to address questions concerning board certification in "Radiology" by the American Board of Radiology.

X.3d. Training for Qualified Medical Physicist: The training and experience requirements have been modified to more closely align with what is mandated for therapy AMPs under Part G and 10 CFR 35. However, the training and experience requirements are not identical because physicists supporting therapeutic radiation machines require a "skill set" which differs in certain key areas from those necessary to support therapy devices used pursuant to Part G and 10 CFR 35.

X.6 Therapeutic Radiation Machines of Less Than 500 kV: A footnote has been added at the beginning of this section to indicate that eBx devices are subject to Section X.11 and not Section X.6.

X.7c.i. This section has been modified to address measurement of leakage radiation in those situations where the maximum available field size is less than 100 cm^2.

X.7v. This section has been added to require appropriate QA/QC checks for IMRT-capable therapeutic radiation machines.

Sec. X.10 Quality Assurance For Radiation Therapy Simulation Systems: This section has been added to establish appropriate QA/QC checks for various types of radiation therapy simulators.

Sec. X.11 – Electronic Brachytherapy Devices.

This section has been added to establish radiation safety requirements for proper utilization of eBx devices. [**NOTE:** *X.11 does not contain the "for equipment manufactured after ....." statement that is typically used when new equipment requirements are being introduced. This was intentional. The requirements in X.11 have been developed based on current eBx units, which are "first generation" devices that have no need for a "grandfather" clause to address existing technology that is currently in use. However, individual States may still adopt an effective date, if they believe it to be necessary*.]

X.11a. Applicability: The section is self-explanatory

X.11b. through X.11k.: These sections establish radiation safety requirements that are comparable to those established for other low energy therapy devices in X.6, while recognizing some unique aspects of eBx devices.

X.11l. Therapy-Related Computer Systems: This section establishes requirements for QA/QC of treatment planning systems, similar to those established in X.7. There is no comparable requirement in X.6 because the equipment regulated under this section generally predates utilization of computer-based planning systems.

X.11m. Training: This section establishes training and experience requirements unique to EBT devices. It should be considered as a supplement to the general training and experience requirements in X.3, not a replacement.

X.11n. Mobile Electronic Brachytherapy Service: This section establishes the minimum QA/QC requirements that must be met prior to utilization of an eBx device at non-fixed locations.

X.12 – Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage

The sudden emergence of eBx devices has demonstrated the necessity for a "catch-all" provision, similar to that established by NRC under 10 CFR 35.1000, for regulating new radiation therapy modalities that aren't readily addressed by current regulations.

Appendix A – Shielding Requirements.

This appendix has been amended to reference the most current NCRP documents applicable to shielding requirements for therapeutic radiation machines.

Matters for Future Consideration

At this time the committee has no additional specific charges from CRCPD. However, the committee intends to conduct a review of the CRCPD CyberKnife white paper, as well as current technical literature regarding Tomotherapy and IGRT (e.g., Trilogy) units, to determine if any Part X amendments are needed to specifically address these technologies. The committee also intends to review other emerging therapeutic radiation machine technologies (e.g., proton therapy) for possible inclusion in a future revision of Part X.