STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS (AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to Part 4 and Part 5 of 216-RICR-40-20, *Radiation*.

Regulation	**Rationale/Summary of Change**
§ 4.1.1(A)	Incorporation by reference date changed to reflect most recent revision date of the document being incorporated by reference.
§ 4.2(A)(12)	Definition clarified to show that *barrier* means *primary protective barrier*.
§§ 4.2(A)(39) & 4.2(A)(55)	*Licensed* practitioner added for clarification.
§ 4.3.3(A)	Text modified to reflect current title of cited regulation.
§ 4.3.10(D)(1)	Text modified to correct redundant typo.
§ 4.4.14(A)	*Medical event* definition revised for consistency with most current (April 2015) version of Part F of the *Suggested State Regulations for the Control of Radiation* (*SSRCR*).
§ 4.4.14(D)(3)	*Total* removed as redundant wording.
§ 4.5.6(A)(1(d)	Section modified to fix incorrect cross-reference.
§ 4.7.8(A)	Section modified to delete obsolete cross-reference.
§ 4.8.3	Retention period for mammograms has been changed for consistency with June 2023 amendments to R.I. Gen. Laws § 23-4.9-1.
§ 4.10.3(I)(2) & (3)	Section modified to fix incorrect cross-reference.
§ 4.14.16(B)	Column header modified to fix incorrect cross-reference.
Global-Part 5	*Authorized User* has been changed to *Authorized Physician* in accordance with the January 2023 revisions to Part X of the *Suggested State Regulations for the Control of Radiation* (*SSRCR*).
Global-Part 5	The contents of §§ 5.8 and 5.11 have been interchanged for a more logical organization of regulatory requirements. The requirements for *Electronic Brachytherapy* are now contained in § 5.8 and the requirement for *Instrument Calibration* have been revised and are now in § 5.11. All changes from current regulatory text (except renumbering) are described below.
Global-Part 5	The contents of current § 5.13 has been moved to § 5.14 for a more logical organization of regulatory requirements. A new § 5.13 has been added to address *Emerging and Future Technologies* in accordance with the January 2023 revisions to Part X of the *SSRCR*. All changes from current regulatory text (except renumbering) are described below.
Global-Part 5	All references to *shall* have been changed to *must* for consistency with the style guide used in the January 2023 revisions to Part X of the *SSRCR*.

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Global-Part 5	All sections dealing with record retention requirements have had language added which indicates that required records must be maintained *in an auditable form* in accordance with the January 2023 revisions to Part X of the *SSRCR*.
Global-Part 5	All references to specific calibration procedures in the current regulations have been replaced by reference to *procedures established by a recognized national organization or manufacturer protocols, as appropriate* for consistency with the January 2023 revisions to Part X of the *SSRCR*.
Global-Part 5	All references to compliance with *IEC requirements* have been replaced with *the appropriate manufacturer specifications and perform as intended* for consistency with the January 2023 revisions to Part X of the *SSRCR*
Global-Part 5	Removed all grandfather clauses pertaining to implementation dates. All TRMs currently in use in RI were installed after the previously specified implementation dates.
§ 5.2	Definitions for *Accessible surface*, *Added filtration*, *Dose equivalent Intensity Modulated Radiation Therapy*, *Mobile electronic brachytherapy service*, *nominal treatment distance*, *Practical range of electrons*, *Recordable event*, and *Shadow tray* have been deleted in accordance with the January 2023 revisions to Part X of the *SSRCR*
§ 5.2	Definitions for *Absorbed dose (D)*, *Absorbed dose rate*, *Electronic brachytherapy*, and *Virtual simulator* have been revised in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.2	Definitions for *Dosimetry system*, *Image guided radiation therapy (IGRT)*, *Medical Health Physicist*, *Mobile electronic brachytherapy*, *Mobile therapeutic radiation machine*, *Monitor unit (MU)*, *Patient intervention*, *Primary protective barrier*, *Qualified Medical Physicist*, *Quality management program*, *Radiation oncology safety team*, *Radiation protection program*, *Safety assessment program*, *Survey instruments*, *Treatment frequency*, *Treatment modality*, *Treatment site*, and *Treatment technique* have been added in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.3.2	Section has been modified to clarify that FDA approval is required for all therapeutic radiation machines (TRMs) designated for human use.
§ 5.3.3	Section has been modified to clarify qualification requirements for *Authorized Physicians* in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.3.4	Section has been modified to clarify qualification requirements for *Medical Physicists* in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.3.6	Section has been modified to clarify requirements for development and posting of operating and emergency procedures in accordance with the January 2023 revisions to Part X of the *SSRCR*.

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§ 5.3.8	Section has been modified to clarify qualification requirements for *Visiting Authorized Physician* in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.3.9	Adds additional required items to the quality management training program in accordance with the January 2023 revisions to Part X of the *SSRCR*.
§§ 5.3.10 & 5.3.11	Revises record retention requirements in accordance with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.3.12(D)	Section revised to delete obsolete cross-reference.
§§ 5.4.1(A)-(D)	Current paragraphs §§ 5.4.1(A)-(D) have been redesignated as §§ 5.4.1(B)-(E) respectively.
§ 5.4.1(A)	New § 5.4.1(A) has been added to consolidate shielding and safety design requirements that had previously been scattered throughout the regulations.
§ 5.4.1(B)	Reorganized for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.4.1(D)	Additional required elements for survey records have been added for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.4.3	Existing § 5.4.3 has been deleted and moved to § 5.6.11. New subsection § 5.4.3 has been added to clarify required radiation measurement equipment for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.4.4	Deadline for submitting required reports to the Agency has been extended to 36 days for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.5.1(A)(1)(c)	*Written Directive* now includes additional required elements for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.5.1(A)(1)(e)	*Written Directive* retention requirements have been revised to be the same as other comparable medical records for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.5.1(A)(2)	Procedures for Administration have been revised for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.5.2(B)	The events that would constitute a reportable *medical event* have been revised for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§§ 5.5.2(C) & (D)	Modified to clarify reporting requirements and timelines for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.5.2(F)	Notification timelines have been revised for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.5.2(I)	Required contents of a medical event report record have been revised for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.5.3(A)	Record retention period has been revised for consistency with the January 2023 revisions to Part X of the *SSRCR.*

Regulation	Rationale/Summary of Change
§ 5.5.5	Entire section has been deleted and RESERVED because *Recordable Events* are no longer defined in the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6 (section header)	Language added, for consistency with the January 2023 revisions to Part X of the *SSRCR*, to allow manufacturer's certification to be used to demonstrate compliance with requirements in §§ 5.6.1 through 5.6.13.
§ 5.6.9(A)(5)	Language modified to indicate that some devices used to prevent unauthorized access to a TRM may not be actual *locks*. The term now used is *access control device* for consistency with the January 2023 revisions to Part X of the *SSRCR*
§ 5.6.15(A)(2)	Language added to indicate that a *control panel* does not always have to be outside treatment room as long as radiation levels at the *control panel* are in accordance with applicable regulatory requirements for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.16	Section has been modified to include requirements for *acceptance testing and commissioning* in addition to *full calibrations* for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§§ 5.6.16(B) & (C)	Current paragraph B has been deleted and existing paragraph C has been redesignated as paragraph B for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.17	*Periodic* has been removed from the section title and inserted prior to each occurrence of *quality assurance checks* in the subparagraphs for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.17(B)(1) & (C)	Language has been added to require that *periodic quality assurance checks* be performed in accordance with a *recognized national standard* for consistency with the language in the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.17(D)	Language added to clarify when system recalibration would be required for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.17(E)	Language added to clarify that *periodic absolute dose* is a required measurement for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.6.17(G) & (H)	Performance interval has been extended to 36 days for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7 (section header)	Language added, for consistency with the January 2023 revisions to Part X of the *SSRCR*. to allow manufacturer's certification to be used to demonstrate compliance with requirements in §§ 5.7.2 through 5.7.16.
§§ 5.7.1 & 5.7.23	Current § 5.7.1 has been moved to § 5.7.23 for consistency with the January 2023 revisions to Part X of the *SSRCR,* and has been ***RESERVED*** to avoid renumbering the entire § 5.7.

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§ 5.7.2	Language added to specify that leakage radiation information must be determined or obtained from manufacturer for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.4	Language has been added to specify *if applicable* because some TRMs do not have removable wedge filters (for consistency with the January 2023 revisions to Part X of the *SSRCR*).
§ 5.7.7	Section has been revised to include *beam flatness* requirements and all subparagraphs have been modified appropriately for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.8(C)	The term *dosimeter display* has been changed to *treatment delivery parameters* for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.11	Requirement added for *termination condition* to also be visible in the treatment room for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.13	The section title has been changed to *Irradiation Control Device* to recognize that many TRMs no longer have *timers* in the traditional sense. Section also recognizes that *monitor unit indicator* has replaced *timer* in some applications for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.16(A)(5)	Section reorganized with for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.16(A)(8)	Section has been added to require a quality assurance program for systems where the radiation source is mounted on a ring gantry for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.17(A)(2)	Language added to indicate that a *control panel* does not always have to be outside treatment room as long as radiation levels at the *control panel* are in accordance with applicable regulatory requirements for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.17(A)(8)	Deletes the requirement that an emergency power cutoff switch be located in the control room for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.20(A)	Language has been added to clarify the role of the Qualified Medical Physicist during acceptance testing, commissioning, and full calibration of a TRM for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.20(B)	Description of acceptance testing and commissioning procedures has been expanded for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.20(C)	Description of full calibration procedures has been expanded for consistency with the January 2023 revisions to Part X of the *SSRCR*.

Regulation	Rationale/Summary of Change
§§ 5.7.20(E), (F) and (G)	Current section E has been deleted and existing §§ 5.7.20(F) & (G) have been renumbered as §§ 5.7.20(E) and (F) respectfully for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.7.21	*Periodic* has been removed from the section title and inserted prior to each occurrence of *radiation output quality assurance checks* in the subparagraphs for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§§ 5.7.21(E)-(G)	Current §§ 5.7.21(B) & (C) have been redesignated as §§ 5.7.21(A)(1) & (A)(2) respectively. Current §§ 5.7.21(D)-(G) have been redesignated as §§ 5.7.21(B)-(E) respectively. All changes are for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.7.21(A)(2)	Language has been added to require that *periodic quality assurance checks* be performed in accordance with a *recognized national standard* for consistency with the language in the January 2023 revisions to Part X of the *SSRCR.*
§ 5.7.21(C)	Section has been modified to clarify that QA procedures must be in writing and be in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies for consistency with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.7.21(E)	Section has been expanded and reorganized for consistency with QA checks required by the January 2023 revisions to Part X of the *SSRCR.*
§ 5.7.22	The existing § 5.7.22 has been deleted in entirety because IMRT procedures are now common enough that the previous requirements of this section are now met by *periodic quality control procedures*. A new § 5.7.22 has been added to specifically require either *Accreditation or External Audits* for each registrant providing radiation therapy with TRMs. Both of these changes are consistent with the January 2023 revisions to Part X of the *SSRCR.*
§ 5.8 (section header)	Language added to allow manufacturer's certification to be used to demonstrate compliance with requirements in §§ 5.8.4 through 5.8.6 for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.8.5(A)(5)	Language modified to recognize that some electronic brachytherapy devices no longer have *locks* in the traditional sense. Terminology has been changed to *access control device* for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.8.12(B)(2)	Language has been added to require that *applicator-specific input parameters required by the dose calculation algorithm* also be determined during acceptance testing for consistency with the January 2023 revisions to Part X of the *SSRCR.*

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§ 5.9.2	Language has been added to clarify that installation of a TRM of *different model, different isocenter or higher energy or workload* into a room not previously approved for that energy will require the submission of a new shielding design to the agency for review. This change is consistent with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.10	Section title has been modified to include quality control for *Imaging Systems Used for Guidance During Therapeutic Radiation.* This change is consistent with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.10(B)	Language has been added to require that *Quality Assurance* be performed in accordance with a *recognized national standard* for consistency with the language in the January 2023 revisions to Part X of the *SSRCR*.
§ 5.10(C)	Language has been added to clarify that imaging systems used exclusively for simulation or guidance of therapeutic radiation are exempt from the provisions of Part 4 (diagnostic X-Ray) for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.11.5	Although § 5.11.5 is indicated as being *added* it is actually a consolidation of requirements that had been scattered throughout the existing regulations. There are no significant changes in regulatory requirements and these changes are consistent with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.12(A)(1)(c)	Language has been added to specifically require that *other personnel who will be involved in performing quality assurance tasks and/or setting up patients for treatment or delivering treatment* must also be included in any training for new technology prior to its implementation for consistency with the January 2023 revisions to Part X of the *SSRCR*.
§ 5.13	This is a new section on *Emerging and Future Technologies* which outlines the minimum requirements that a proposed registrant must address prior to implementing newly acquired, FDA-cleared emerging technologies or previously unused features of a future technology system which cannot be effectively regulated under the existing regulations. This new section is consistent with the January 2023 revisions to Part X of the *SSRCR*.
§§ 5.14.2(A)(6), 5.14.3(A)(7) & 5.14.4(A)(3)	Language added to require submission of sample calculations. This is consistent with both other requirements in § 5.14 and the January 2023 revisions to Part X of the *SSRCR*.