

### UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 10, 2022

Alexander Hamm, Supervisor Radiation Control Program Center for Health Facilities Regulation Rhode Island Department of Health 3 Capitol Hill Providence, RI 02908-5097

Dear Mr. Hamm:

We have reviewed the proposed revisions to the Rhode Island regulations 216-RICR-40-20, Radiation, received by our office on January 25, 2022. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules and Regulation Amendment Tracking System Identification Numbers (RATS IDs) 2018-1, 2018-1, 2018-3, 2019-1, 2019-2, 2020-1, 2020-2, 2020-3, 2021-1, 2021-2, and 10 CFR Parts 32, 37, 40, and 150 as identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Bill Dundulis on February 8, 2022.

As a result of our review, we have three comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Rhode Island regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Rhode Island regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in NMSS Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes and provide a copy to Division of Material Safety, State, Tribal, and Rulemaking Programs, NMSS.

The SRS Data Sheet summarizes our knowledge of the status of other Rhode Island regulations, as indicated. Please let us know if you note any inaccuracies,or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the NMSS State Communication Portal: <a href="https://scp.nrc.gov/rulemaking.html">https://scp.nrc.gov/rulemaking.html</a>.

A. Hamm -2-

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Michelle Beardsley, State Regulation Review Coordinator, at (301) 415-0275 (Michelle.Beardsley@nrc.gov) or Monica Ford at (610) 337-5214 (Monica.Ford@nrc.gov).

Sincerely,
Signed by Anderson, Brian on 02/10/22

Brian C. Anderson, Chief State Agreement and Liaison Programs Branch Division of Materials Safety, Security, State and Tribal Programs Office of Nuclear Material Safety and Safeguards

#### Enclosures:

- 1. Compatibility Comments
- 2. RI SRS Data Sheet

A. Hamm -3-

SUBJECT: RHODE ISLAND PROPOSED REGULATIONS TO RATS IDS 2018-1,

2018-2, 2018-3, 2019-1, 2019-2, 2020-1, 2020-2, 2020-3, 2021-1, AND

2021-2 DATE February 10, 2022

DISTRIBUTION: SP[05]
DIR RF (Tracking number)
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ADAMS Accession No. ML22026A084 pkg and ML22040A317 letter

OFFICE	RI/DRSS	NMSS/MSST	OGC	NMSS/MSST
NAME	MFord	MBeardsley	NA	BAnderson
DATE	02/10/202	02/10/2022		02/10/2022

OFFICIAL RECORD COPY

### COMPATIBILITY COMMENTS ON RHODE ISLAND PROPOSED and REVISED FINAL REGULATIONS

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SIA	TE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	216-RICR- 40-20-7.2.5B	40.60(a), (b), (c)(1), and (c)(2)	2020-3	C	Reporting requirements  Rhode Island includes this regulation in the group of regulations not incorporated by reference.  Additionally, Rhode Island does not incorporate equivalent regulation text in 26 RICR 40-20-7.  Rhode Island needs to delete the reference to 40.60 from 26 RICR 40-20-7.2.5B in order to meet the compatibility category C designation assigned to 10 CFR 40.60 (a), (b), (c)(1) and (c)(2).
2	216-RICR- 40-20-7.2.5B and 7.6.4	40.36(f)	Part 40	H&S	Financial assurance and recordkeeping for decommissioning  Rhode Island does not adopt by reference 10 CFR 40.36(f) in 7.2.5B. However it does adopt this section by reference in 7.6.4. Therefore Rhode Island needs to remove the reference to 10 CFR 40.36(f) from 7.2.5B.  Rhode Island needs to make the above change in order to meet the compatibility category H&S designation assigned to 10 CFR 40.36(f).  Comment modified from NRC letter dated November 2, 2018.
3	216-RICR- 40-20- 7.6.19B	40.56	Part 40	NRC	Restrictions on the use of Australian-obligated source materials  Rhode Island lists an incorrect regulation in Section 7.6.19 B., i.e., 10

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					CFR 40.56. Rhode Island should cite 10 CFR 40.55 in section 7.6.19 B.
					Rhode Island needs to make the above change in order to meet the compatibility category NRC designation assigned to 10 CFR 40.56.
					Comment stands from NRC letter dated November 2, 2018.

#### **STATE REGULATION STATUS**

**Tracking Ticket Number:** Date: February 10, 2022

required to be adopted for purposes of

Compatibility.

State: Rhode Island

[ # amendment(s) reviewed identified by a \*at the beginning of the equivalent NRC requirement.]

for Departures from Manufacturer's Instructions

Parts 30 and 35

57 FR 45566

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Not Required	Not Required	Rhode Island has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	Rhode Island has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183	01/01/1994	Final	No Comments 10/16/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, and 70 56 FR 64980	10/15/1994	Final	No Comments 09/22/1999	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final	No Comments 09/22/1999	Rhode Island has adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements	none	Not Required	Not Required	These regulation changes are not

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30 and 40 58 FR 39628	10/25/1996	Final	No Comments 03/27/2000	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable <sup>1</sup>	Not Applicable	Rhode Island does not have any licensees subject to these regulations. (See SECY-95-112)
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable <sup>1</sup>	Not Applicable	Rhode Island does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40 and 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Rhode Island does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40 and 70 59 FR 36026	08/15/1997	Final	No Comments 03/27/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32 and 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final Final ML18054A337	Comments 03/27/2000 No Comments 11/02/18 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 03/27/2000	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20 and 61 60 FR 15649; 60 FR 25983	03/01/1998	Final	No Comments 03/27/2000	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final	No Comments 03/27/2000	Rhode Island has adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19 and 20 60 FR 36038	08/14/1998	Final	Comments 03/27/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40 and 70 60 FR 38235	11/24/1998	Final	No Comments 03/27/2000	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20 and 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Final	No Comments 03/27/2000	Rhode Island has adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	04/01/1999	Final ML042520322	Comments 10/25/2004 ML043010048	Rhode Island has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40 and 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61 and 70 61 FR 24669	06/17/1999	Final	No Comments 03/27/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML042520322	No Comments 10/25/2004 ML043010048	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML073040203	No Comments 11/28/2007 ML073320009	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20 and 35 62 FR 4120	05/29/2000	Final	No Comments 03/27/2000	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1)	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71 and 150 62 FR 28947	06/27/2000	Final	No Comments 03/27/2000	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40 and 70 62 FR 39057	08/20/2000	Final ML093420277	No Comments 01/14/2010 ML093630121	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final	No Comments 03/27/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71 and 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML042520322	No Comments 10/25/2004 ML043010048	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40 and 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 (Superceded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Rhode Island has adopted Final Regulations equivalent to RATS ID: 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final	No Comments 03/27/2000	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36 and 39 63 FR 39477; 63 FR 45393	10/26/2001	Final	No Comments 03/27/2000	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final	No Comments 03/27/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Rhode Island does not have the authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML042520322	No Comment 10/25/2004 ML043010048	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML042520322	No Comment 10/25/2004 ML043010048	
2000-2	New Dosimetry Technology Parts 34, 36 and 39 65 FR 63750	01/08/2004	Final ML042520322	No Comment 10/25/2004 ML043010048	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31 and 32	02/16/2004	Final ML062700535	Comments 10/27/2006 ML063030281	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	65 FR 79162		Final ML18054A337	Comments 11/02/2018 ML18054A313	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML042520322	No Comment 10/25/2004 ML043010048	
2002-2	Medical Use of Byproduct Material Parts 20, 32 and 35 67 FR 20249	10/24/2005	Final ML042520322	No Comment 10/25/2004 ML043010048	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40 and 70 68 FR 57327	12/03/2006	Final ML062700535	No Comments 10/27/06 ML063030281	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71	10/01/2007	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	69 FR 3697		Final ML18054A337	No Comments 11/02/2018 ML18054A313	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML062700535	No Comments 10/27/2006 ML063030281	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML062350571	No Comments 09/01/2006 ML062490383	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052570551	No Comments 09/15/2005 ML052630170	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML14126A173 Final ML18054A337	Comments 07/03/2014 ML14113A571 Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML14126A173	No Comments 07/03/2014 ML14113A571	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML14126A173	No Comments 07/03/2014 ML14113A571	
			License Condition ML082840230	No Comments 10/21/2008 ML082880140	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	72 FN 43147, 34207		Final ML18054A337	Comments 11/02/2018 ML18054A313	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements	12/17/2010	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	Parts 30, 31, 32 and 150 72 FR 58473		Final ML18054A337	Comments 11/02/2018 ML18054A313	
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61 and 150 72 FR 55864	11/30/2010	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference except for Part 61 <sup>1</sup>
	/2 FN 33004		Final ML18054A337	Comments 11/02/2018 ML18054A313	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML080800494	No Comments 04/09/2008 ML080990804	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19 and 20 72 FR 68043	02/15/2011	Final ML14126A173 Final ML18054A337	Comments 07/03/2014 ML14113A571 No Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Final ML14126A173 Final ML18054A337	Comments 07/03/2014 ML14113A571 No Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2011-1	Decommissioning Planning Parts 20, 30, 40 and 70 76 FR 35512	12/17/2015	Final ML14126A173 Final ML18054A337	No Comments 07/03/2014 ML14113A571 Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70 and 150	11/14/2014	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	76 FR 56951		Final ML18054A337	Comments 11/02/2018 ML18054A313	
2012-1	Change of Compatibility of Parts 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	77 113040		Final ML18054A337	No Comments 11/02/2018 ML18054A313	
2012-2	Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194	08/10/2015	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
	77 FR 34194		Final ML18054A337	No Comments 11/02/2018 ML18054A313	
2012-3	Technical Corrections Part 30, 34, 40 and 71 77 FR 39899	08/06/2015	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
			Final ML18054A337	Comments 11/02/2018 ML18054A313	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2012-4	Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40 and 70 77 FR 43666	10/23/2015	Final ML14126A173	Comments 07/03/2014 ML14113A571	Rhode Island submitted final regulations incorporating NRC regulations by reference.
			Final ML18054A337	Comments 11/02/2018 ML18054A313	
2013-1	Physical Protection of Byproduct Material, Parts 20, 30, 32, 33, 34, 35, 36, 37, 39 and 71 78 FR 16922	03/19/2016	License Condition ML15301A131 Final ML18054A337	No Comments 11/13/2015 ML15301A125 Comments 11/02/2018 ML18054A313	Part 37 only  Rhode Island submitted final regulations incorporating NRC regulations by reference except for Parts 36 <sup>1</sup> and 61 <sup>1</sup> .
2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, Parts 30, 40 and 70 78 FR 32310	08/27/2016	Final ML18054A337	Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2015-1	Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 79 FR 57721, 80 FR 143	01/26/2018	Final ML18054A337	No Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2015-2	Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150 79 FR 58664, 80 FR 3865	01/28/2018	Final ML18054A337	Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2015-3	Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71 80 FR 33987	07/13/2018 *extended to 08/15/2020 See STC 17-060	Final ML18054A337	No Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2015-4	Miscellaneous Corrections, Parts 37 and 40 80 FR 45841	09/02/2018	Final ML18054A337	Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
2015-5	Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71 and 150 80 FR 74974	12/31/2018	Final ML18054A337	Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference except for Part 61 <sup>1</sup>
*2018-1	Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments, 10 CFR Parts 30, 32 and 35	01/14/2022	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2018-2	Miscellaneous Corrections - Organizational Changes 10 CFR Parts 37, 40. 70 and 71	12/21/2021	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2018-3	Miscellaneous Corrections 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140	07/30/2022	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
*2019-1	Miscellaneous Corrections 10 CFR Parts 2, 21, 37, 50, 52, 73, and 110	12/18/2022	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2019-2	Organizational Changes and Conforming Amendments 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150	12/30/2022	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2020-1	Individual Monitoring Devices 10 CFR Parts 34, 36, and 39	06/16/2023	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2020-2	Social Security Number Fraud Prevention 10 CFR Parts 9 and 35	08/17/2023	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2020-3	Miscellaneous Corrections 10 CFR Parts 1, 2, 19, 20, 21, 30, 34, 35, 40, 50, 51, 52, 60, 61, 62, 63, 70, 71, 72, 73, 74, 75, 76, 110, and 140	11/16/2023	Proposed ML22026A093	Comment 02/10/2022 ML22026A084	
*2021-1	Miscellaneous Corrections 10 CFR Parts 2, 11, 20, 25, 32, 35, 37, 50, 52,55, 70, 72, 73, 95, and 110	09/08/2024	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	
*2021-2	Miscellaneous Corrections 10 CFR Parts 9, 37, 40, 50, 51, 52, 55, 71, 73, and 110	12/30/2024	Proposed ML22026A093	No Comments 02/10/2022 ML22026A084	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
*N/A	Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150	*see applicable RATS IDs	Proposed ML18054A337	Comments 4/12/2018 ML18054A313	Rhode Island submitted proposed regulations incorporating NRC regulations by reference.
			Final ML18054A337	Comments 11/02/2018 ML18054A313	Rhode Island submitted final regulations incorporating NRC regulations by reference.
			Revised Final ML22026A093	Comments 02/10/2022 ML22026A084	Comments re: Part 40

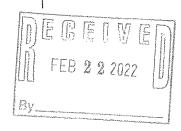
<sup>&</sup>lt;sup>1</sup> IMPEP Team: verify that Rhode Island does not have any licensees subject to these regulations during each review.



18 Feb 2022

Paula Pullano
Department of Health
3 Capitol Hill
Room 410
Providence, RI 02908-5097
Paula.Pullano@health.ri.gov

RE: Public Comments for 216-RICR-40-20



Dear Paula

As part of the public submission process, I have two comments regarding the amending of all Parts Subchapter 20 (Radiation) of Chapter 40.

As a frequent user of the Regulations, I use Abode Acrobat to merge all 15 Parts into a single document.

At the start of 2019, the State of Rhode Island amended all Parts of Subchapter 20 (Radiation) of Chapter 40. Later in 2019, the State made a correction to Part One (Chapter 40, Subchapter 20). Based on the protection that was assigned to Part One (post correction), Adobe Acrobat now cannot combine Part 1 with the other 14 Parts.

I would therefore request that you please make sure the "Combine (PDF) files' function in Adobe Acrobat will work for <u>all</u> Parts (Chapter 40, Subchapter 20). In addition, please verify that Part 14 of Chapter 40, Subchapter 20 will not have an 'old' protection setting assigned to it.

2. Bring up-to-date the Rhode Island RCA-3 form, with new "SI" units of measurement (record Intake in megabecquerel and Dose in millisievert). https://health.ri.gov/forms/reporting/radiation/OccupationalExposureForAMonitoringPeriod.pdf

Thank you for your consideration.

Best-Regards

Mark Dirksen Brown University

cc: Stephen Morin

# NOMAD PRO 2

## Handheld X-ray System

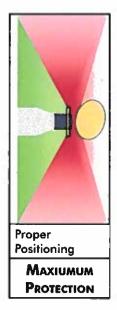
for Intraoral Radiographic Imaging

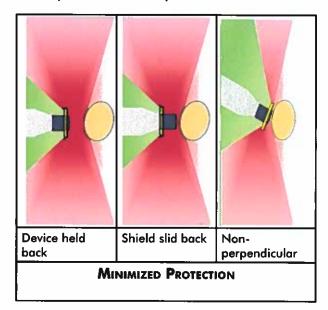


**OPERATOR MANUAL** 

MANUFACTURED BY ARIBEX

- An exposure can be terminated for any reason by prematurely releasing the depressed trigger (for more information, see Section 4.0, Operation).
- As shown in graphic representations, maximum protection (green area)
  from backscatter radiation (red area) exists when the NOMAD Pro 2 is
  positioned near the patient, is perpendicular to the operator (with the
  patient's head tilted if needed), and the backscatter shield is fully
  extended toward the patient and parallel to the operator.





- Operation outside the protection zone (or with a diminished protection zone) requires proper precautions such as the use of a lead apron and thyroid collar, according to requirements of local jurisdictions.
- Do not operate if the backscatter shield or collimator cone is broken!



In implementing a radiation protection program, consult all applicable regulations governing radiation protection and the use of X-ray equipment, and ensure full compliance with any such regulations.



#### **Community College of Rhode Island**

**Dental Health Programs** 

February 4, 2022

To whom it may concern,

Please accept this letter as public testimony for the proposed changes to <u>216-RICR-40-20-4</u>, section: 4.3.3 Individuals Operating X-ray Systems for Healing Arts Use. I have been educating and training dental health students in all aspects of oral radiography for more than 22 years at the Community College of Rhode Island. I have some concerns about the inconsistencies among existing regulations, the proposed regulations, and RI General Law, Title 5, Businesses and Professions, Chapter 68.1, Radiologic Technologists.

There are discrepancies among the regulations for *Dentists, Dental Hygienists, and Dental Assistants* (216-RICR-40-05-2), RI General Law 5-68.1-4 (3) and the proposed changes to *Medical Diagnostic and Interventional X-Ray, Imaging Systems* (216-RICR-40-20-4) that I would like to address. Dental hygienists and dental assistants who have graduated from Commission on Dental Accreditation (CODA) accredited programs offered at CCRI and other CODA-accredited institutions take a 5-credit course in Oral Radiology, have 45 hours of didactic education and 30 hours of lab and clinical practice. These programs meet and exceed the recommendations listed in 216-RICR-40-20-4, section: 4.3.3 (H) for Individuals Operating X-ray Systems for Healing Arts Use. My concern is that the proposed language in 216-RICR-40-20-4, section: 4.3.3 (H) might be misconstrued and affect the training of dental assistants trained on the job, with no minimum education requirements.

In the regulations for Dentists, Dental Hygienists, and Dental Assistants (216-RICR-40-05-2) it states:

2.10 Delegable Procedures/Duties to Dental Hygienists, Public Health Dental Hygienists, DANB-Certified Assistants, DAANCE-Certified Maxillofacial Surgery Assistants and Dental Assistants with Specific Type of Supervision:

2.10.3 Non-Delegable (Exclusionary) Procedures/Duties

(11) Exposure of radiographs without successful completion of a course in dental radiography which is offered by an education institution with a program accredited by the Commission on Dental Accreditation, and which fulfills institutional requirements as set forth in R.I. Gen. Laws § 40-20-1.

CCRI has been offering a course for dental assistants who are trained on the job to allow for certification to operate and expose dental radiographs on patients since at least the 1980s. The most recent revision of this course requires students to participate in 14 hours of didactic training and 12 hours of lab and clinical training (see attachment 1. Syllabus for training requirements and schedule). Candidates who successful complete this training, receive a certificate of completion (see attachment 2. Certificate of Completion). The understanding has been that this course, that is offered through a CODA accredited institution, satisfied RI General Laws § 5-68.1-4:



#### **Community College of Rhode Island**

#### **Dental Health Programs**

§ 5-68.1-4. License required.

- (a) No individual shall practice radiologic technology or shall represent himself or herself as practicing radiologic technology, unless he or she is licensed under this chapter. The provisions of this section do not apply to:
- (3) A dentist, licensed dental hygienist, or certified dental assistant when practicing within his or her field of expertise.

In the proposed regulations for: *Medical Diagnostic and Interventional X-Ray, Imaging Systems* (216-RICR-40-20-4), it states:

#### Proposed Change:

Rationale: 4.3.3(H) Clarifies required training that must be completed before an individual is allowed to operate dental X-ray equipment.

H. A dental facility registrant shall provide initial training and annual evaluations of X-ray operators to include but not limited to: positioning of the X-ray tube, image processing, operator location during X-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency for three (3) years.

As a dental health professional, who has researched and studied this subject for many years, I believe the best course of action, in regards to patient and operator safety and to be consistent with the regulations for Dentists, Dental Hygienists, and Dental Assistants ( $\underline{216-RICR-40-05-2}$ ), RI General Law  $\underline{5-68.1-4}$  (3) is to amend 4.3.3(H) to read:

H. A dental facility registrant shall provide initial training and a shall ensure that x-ray operators have completed a course in dental radiography offered by an educational institution with a program accredited by the Commission on Dental Accreditation (216-RICR-40-05-2.10.3(11)). Annual evaluations of X-ray operators to include but not limited to: positioning of the X-ray tube, image processing, operator location during X-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency for three (3) years.

Thank you for your consideration. If additional information or clarification is needed, do not hesitate to reach out to me.

Sincerely,

Kerri H. Friel, RDH, CDA, MA

Professor, Dental Health Programs

kfriel@ccri.edu

Keni Trie

401-301-8135



CCRI
Community College of Rhode Island

**Dental Health Programs** 

#### **Community College of Rhode Island**

#### **Dental Health Department**

#### **Introduction to Dental Radiography**

#### February 2022

#### **COURSE SYLLABUS**

**COURSE** 

**DIDACTICS:** Blackboard: <a href="https://blackboard.ccri.edu/">https://blackboard.ccri.edu/</a>

**LAB LOCATION:** Room 1163a, Flanagan Campus

Phone in dental radiography lab: 333-7338

**PREREQUISITE:** It is strongly recommended that participants have a minimum of six

months of full-time chairside dental assisting experience.

**COURSE** 

**DESCRIPTION:** This intensive two-week course educates dental assistants in the

basic fundamentals of dental radiography. Successful course completion satisfies the Rhode Island Department of Health requirement for exposure of radiographs in the dental office setting.

Students are required to complete online coursework and attend

both laboratory sessions. Students will be awarded with a

certificate upon successful completion of all course requirements.

Online Component: 12 hours Clinical Component: 14 Hours

**COURSE** 

COORDINATOR & Kerri H. Friel, RDH, COA, CDA

LAB INSTRUCTOR: Email: kfriel@ccri.edu

LAB INSTRUCTORS: Sarah Luther, RDH, CDA, PHDH

Email: <u>sluther@ccri.edu</u> **Joanna Popolla, CDA**Email: <u>jpopolla@ccri.edu</u>

RECCOMENDED

**TEXTBOOK:** Iannucci and Howerton, Dental Radiography Principles and

Techniques, 6 ed. Elsevier, 2022. ISBN:978-0-323-69550-3

May be purchased online through Amazon or other online retailers.

### UNIFORM & PPE REQUIREMENTS:

All students are expected to attend lab sessions in professional scrubs. In additional, please bring 1 lab coat, 1 box of non-latex gloves, 10 Level 3 or N95 (student preference) masks, safety glasses and a face-shield.

#### SUGGESTED LEARNING SCHEDULE:

Schedule	Торіс	Suggested Reading
Wednesday before 1st lab	MODULE	
-	Dental X-Ray Equipment	Chapter 7
A - 2/9/22	Physics of X-Radiation	Chapter 2
or	Radiation Biology	Chapters 3
D 0/00/0000	Radiation Protection	Chapters 4
$B - \frac{2}{23}/2022$	Radiation Characteristics	Chapter 6
	Infection Control	Chapter 16
	Quiz #1	
Friday before 1st lab	MODULE 2	
•	Digital Imaging	Chapters 8
A - 2/11/22	Intraoral Imaging Techniques and Other	Chapters 18 - 21
or	Radiographic Techniques	
D 2/25/22	Special Needs of Patients	Chapter 24
B - 2/25/22	Panoramic Imaging	Chapter 25
	Exposure and Technique Errors	Chapter 22
	Quiz #2	
Wednesday before 2 <sup>nd</sup> lab	MODULE 3	
A – 2/16/22	Anatomical Landmarks	Chapters 27, 29
A - 2/10/22	Identification of Restorative Materials	Chapter 32
or	Radiographic Interpretation of Decay &	Chapters 33, 234
B - 3/2/22	Periodontal Disease	
B - 3/2/22	Quiz #3	
Friday before 2 <sup>nd</sup> lab	MODULE 4	
$A - \frac{2}{18/22}$	Technique Errors	Chapter 20
H = L/10/2L	Patient Management	Chapter 13
or	Legal Issues, State and Federal Law	Chapter 14
B - 3/4/22	Quality Assurance	Chapter 10
D - 3/4/22	Quiz #4	

### LAB SCHEDULE:

Date	Торіс
Lab 1 (8-3) A - 2/12/22 or B - 2/26/22	<ul> <li>Lab Experience:</li> <li>The Dental X-Ray Machine components &amp; functions</li> <li>Generation of the X-ray beam</li> <li>Radiation Safety</li> <li>Digital Imaging – Sensor Functioning and Care</li> <li>Bitewings – Manikin</li> <li>Anterior &amp; Posterior Periapicals – Manikin</li> <li>Panoramic Radiography – Partner Placement</li> <li>Clinical Experience:</li> <li>Infection Control in the dental operatory</li> <li>Patient Placement – Full Mouth Series</li> </ul>
Lab 2 (8-3) A - 2/19/22 or B - 3/5/22	Lab Practice: <ul> <li>FMX on manikin</li> <li>Partner Placement pan</li> </ul> <li>Skill Assessments:         <ul> <li>Panoramic Assessment – Partner Placement</li> <li>Full Mouth Series Assessment – Manikin</li> <li>Remediation as Needed</li> </ul> </li> <li>Clinical Proficiency:         <ul> <li>Placement of a Full Mouth Series on a Partner</li> </ul> </li> <li>Final Exam</li>

<sup>\*</sup> must pass skill assessments with a 75 or better

#### **COURSE**

#### **REQUIREMENTS: Blackboard online content:**

There are no required times to log in for this course. All didactic instruction will be online and will be accessible 24 hours a day seven days a week. Course Modules consist of a PowerPoint with suggested reading assignment, short video and corresponding quiz.

**Quizzes:** There is one required quiz after the completion of each module on Blackboard. You must earn of grade of 70 and are allowed two attempts. If you are not successful on the first attempt, review the material prior to repeating the quiz. The quizzes are due according to the lecture syllabus schedule.

**Final Examination:** The final will cover material from the course modules and lab. All coursework must be complete before a student is eligible to sit for the final exam.

**Skill Assessments:** Laboratory proficiencies are scheduled during lab time as indicated on the lab schedule. These must be completed during the assigned lab session.

#### **Lab Requirements:**

- one panoramic radiograph manikin \*
- one paralleled full series manikin \*

\*A grade of 75 or better is required for each of these assessments

If a student earns a grade of less than 75, the student must repeat the proficiency to achieve 75 level competency. Only one repeat attempt will be allowed. If 75 level competency is not achieved on the second attempt the student will not be able to continue in the course but may retake the course on a space available basis.

### PROOF OF COURSE COMPLETION:

Upon successful course completion a certificate will be given to the student. The student is encouraged to make of copy of this certificate, as no duplicate certificates will be issued.

### GRADING STANDARDS:

#### Lecture

 Quizzes:
 10%

 Final Exam
 20%

 Lab:
 70%

Grading is Pass/Fail. Students must earn a minimum grade of 70 in order to pass the course.

#### **POLICIES:**

Attendance is required for lab. There will be no make-up of missed time. A student must attend all scheduled lab hours to receive a passing grade in the course.

### COVID-19 PROTOCOL:

All CCRI Workforce students and visitors to all CCRI campuses will be required to wear a mask AND provide proof of Covid vaccination OR proof of a negative Covid test. Proof of Covid testing must be within 24 hours for Rapid Tests OR within 72 hours for PCR tests. Original paperwork OR a photo/screenshot is acceptable proof of both vaccination and dated negative Covid test.

Free no-appointment-needed Covid testing is available on CCRI campuses – RAPID TESTING IS VERY LIMITED. Planning for PCR testing is strongly recommended.

CCRI Covid testing schedule can be found here. Or you may schedule a COVID test at a state-run test site, visit portal.ri.gov or call 401-222-8022.

1/2022



### Dental Radiography Certificate of Completion

This is to certify that

Xxxxx Xxxxx

successfully completed

Introduction to Dental Radiography 12 Hours Online Course Work 14 Hours Laboratory/Clinical

This course fulfills the necessary requirements for exposure of dental radiographs as set forth in the State of Rhode Island Rules and Regulations.

Kerri H. Friel, CDA, RDH, MA

Professor, Dental Health Programs Dental Assisting Program, Director December 2021

#### **Rhode Island Dental Association**

875 CENTERVILLE RD • BLDG. 4, SUITE 12 • WARWICK, RI 02886 P: (401) 825-7700 • F: (401) 825-7722 WWW.RIDENTAL.ORG

February 23, 2022

Paula Pullano Rhode Island Department of Health 3 Capitol Hill Providence, RI 02908-5097 Paula.Pullano@Health.ri.gov

In re: Rules and Regulations on Medical Diagnostic and Interventional X-Ray and Imaging Systems (216-RICR-40-20-4)

Dear Ms. Pullano:

Please accept the below written comments regarding the proposed revisions to the Rules and Regulations on Medical Diagnostic and Interventional X-Ray and Imaging Systems (216-RICR-40-20-4.) These comments are submitted on behalf of the Rhode Island Dental Association (RIDA) based on feedback from our membership.

#### • Section 4.3.9 (F)

#### COMMENT:

- For clarification purposes, is the list of protective garments only intended to provide examples or to suggest that each of the items listed are required?
- (1) It is stated that "All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labelled with their lead equivalence.
  - Do the evaluations have to be performed by a specific individual?

#### • Section 4.13 (A)(1)(b)

• Indicates that when operating a hand-held intraoral dental radiographic unit, operators shall wear a one quarter of one (0.25) mm lead equivalent apron, unless otherwise authorized by the Agency or recommended by

a health physicist or Qualified Medical Physicist.

#### · COMMENT:

This is contrary to manufacturers guidelines which indicate that so long as the operator is within the protection zone than an apron is not required. One purpose of the hand-held portable unit is its increased safety to the operator and patient. We would suggest amending the language to read "the operator shall be shielded according to manufacturer recommendations."

Thank you for your attention to this matter. Should you have any questions please do not hesitate to reach out.

Respectively,

Christy B. Durant, Esq. cdurant@ridental.org

#### Hi Lauren

Mark

Another correction for Regulations.

Please make sure the RCA-3 form is updated with SI units

<a href="https://health.ri.gov/forms/reporting/radiation/OccupationalExposureForAMonitoringPeriod.pdf">https://health.ri.gov/forms/reporting/radiation/OccupationalExposureForAMonitoringPeriod.pdf</a>

1
"DOSES" reported in mSv.
2
"INTAKE IN" reported in MBq.
thanks

Hi Lauren
A comment
Please consider as part of Subchapter 20 (Radiation) being amended.
Be sure that I will be able to use the "combine files' function within Adobe Acrobat for all the Parts. I like to combine all Parts into one document.
FYI – A few years back, after Part One was amended the protection that was assigned to it, after the amendment, did not allow for it to be combined with the other 14 Parts.
Best Regards

Mark

Alexander Hamm
Supervising Radiological Health Specialist
Center for Health Facilities Regulation – Radiation Control Program
Three Capitol Hill Room 305
Providence, Rhode Island 02908

Re: Public Comments Regarding Proposed Amendments to Subchapter 20 (Radiation) of 216-RICR-40

Dear Mr. Hamm,

Thank you for allowing the public to offer comments regarding the proposed amendments to Subchapter 20 (Radiation) of 216-RICR-40.

I provided testimony at the February 7<sup>th</sup> hearing specific to item numbers 2, 5, 6, and 9 below, however, I've outlined multiple additional comments and concerns.

- 1. 216-RICR-40-20-4.3.3(E) "The training required §§ 4.3.3(C) and (D) of this Part shall be provided by a Qualified Medical Physicist or another individual approved by the Agency."
  - a. It is unlikely that a Qualified Medical Physicist (QMP) will regularly provide this training especially the 1 hour of hands-on training required by 216-RICR-40-20-4.3.3(D)(4). The qualifications of [other] "individual[s] approved by the Agency" must therefore be defined.
- 2. 216-RICR-40-20-4.3.7
  - a. I commend the Agency for proposing to delete this regulation. This deletion is perfectly in line with the April 2019 Position Statement (PP 32-A) put forth by the American Association of Physicists in Medicine (AAPM) and endorsed by such organizations as the American College of Radiology (ACR), the Health Physics Society (HPS), and the Radiological Society of North America (RSNA), among others.
- 3. 216-RICR-40-20-4.5.13(C) "The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e., a cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads)). This evaluation shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee. If the registrant does not have a Radiation Safety Committee, the review shall be conducted by the Radiation Safety Officer and the registrant's medical physicist."

- a. I commend the Agency for proposing to delete this regulation. The 1 Gy threshold is arbitrarily low and unduly burdensome.
- 4. 216-RICR-40-20-4.10.1(A)(2)(b) "Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR). (1) Facilities shall establish and follow an image quality control program in accordance with the recommendations of a Qualified Medical Physicist, the system manufacturer, or a nationally recognized organization; (2) Facilities other than dental, podiatric and veterinary, shall quarterly complete phantom image evaluation using a phantom approved by a Qualified Medical Physicist, system manufacturer, or the Agency. At a minimum the analysis shall include: artifacts, spatial resolution, contrast/noise, workstation monitors, and exposure indicator constancy."
  - a. Please consider including the time investment requirements of staff to comply with this regulation in the Benefit-Cost Analysis. I recommend referencing the International Atomic Energy Agency's (IAEA) Human Health Report No. 15, entitled *Medical Physics Staffing Needs in Diagnostic Imaging and Radionuclide Therapy: An Activity Based Approach*, which states that 2 hours are spent per year per QMP per CR cassette and 8 hours are spent per year per QMP per digital radiology detector.
- 5. 216-RICR-40-20-4.3.15(A) "A registrant shall report any dose to an embryo/fetus that is greater than fifty (50) mSv (5 rem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring prescribing physician. 1. A registrant shall report any dose to a nursing child that is a result of an administration of radiation to a breast-feeding individual that is greater than fifty (50) mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician."
  - a. The addition of language relating to nursing children is not scientifically necessary or valid. Assuming the nursing child is not nursing during the imaging procedure, no nursing child will receive any radiation dose from any dose to a breast-feeding individual from an x-ray imaging procedure. This proposed change will only create unnecessary confusion.
  - b. Please also specify between the "referring" and the "prescribing" physician. It seems the "referring prescribing" physician is a typographical error. I recommend changing "referring physician" to "prescribing physician."
- 6. 216-RICR-40-20-4.3.15 and 216-RICR-40-20-5.3.12
  - a. Again, assuming the nursing child is not nursing during the imaging procedure or radiation treatment, the addition of language relating to nursing children is not scientifically necessary or valid. No nursing child will receive any radiation dose from any external dose to a breast-feeding individual. These proposed changes will only create unnecessary confusion.
  - b. Please consider keeping the more gender-inclusive language of "pregnant individual" and "breast-feeding individual" versus "mother."
- 7. 216-RICR-40-20-4.5.3(C) "A medical resident or radiologic technology student in training shall not be allowed to operate fluoroscopic x-ray systems unless in the physical presence of a licensed practitioner of the healing arts and a radiologic technologist, as specified in § 4.3.3(C) of this Part."

- a. There are situations where medical residents are currently trained directly by licensed practitioners of the healing arts without the presence of a radiologic technologist. I believe the Agency is unintentionally disallowing for this possibility with this regulation, which requires a radiologic technologist be additionally present.
- 8. 216-RICR-40-20-4.5.13 and 216-RICR-40-20-4.7.5
  - a. Please consider including the time investment requirements of staff to comply with this regulation in the Benefit-Cost Analysis. I recommend referencing the International Atomic Energy Agency's (IAEA) Human Health Report No. 15, entitled *Medical Physics Staffing Needs in Diagnostic Imaging and Radionuclide Therapy: An Activity Based Approach*, which states that 100 hours are spent per year per QMP per protocol, and consider that a single FGI system and a single CT system might each individually employ on the order of 10<sup>2</sup> protocols.
- 9. 216-RICR-40-20-4.1.1(C) "The requirements of NCRP Report 168, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures (2010) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part."
  - a. NCRP 168's definition of a Qualified Medical Physicist (QMP) conflicts with 216-RICR-40-20-3.14.
- 10. At this time, I ask the Agency to consider deleting 216-RICR-40-20-5.7.1 "Each facility location authorized to use a therapeutic radiation machine in accordance with § 5.7 of this Part shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten (10) μSv (one (1) mrem) per hour to ten (10) mSv (one thousand (1,000) mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with § 5.8 of this Part."
  - a. There is no longer a scientific basis for this regulation. This regulation was put in place when therapeutic radiation machines were constructed with radioactive depleted uranium for shielding purposes. Modern equipment no longer contains depleted uranium so there is no reason for a survey meter onsite.
- 11. The Benefit-Cost Analysis indicates that the Medical Physicist's hourly rate is \$66.74 per hour. However, the 2020 Professional Survey Report published by American Association of Physicists in Medicine (AAPM) indicates the typical hourly rate is much closer to \$150-\$250 per hour. For example, the median reported hourly charges for retesting diagnostic imaging equipment is reported to be \$200 per hour. This alone indicates that some costs in the Benefit-Cost Analysis are significantly underestimated.
- 12. The Benefit-Cost Analysis estimates the time investments of Radiologic Technologists, Medical Physicists, Dental Assistants, and Dentists for § 4.10. However, the Benefit-Cost Analysis is completely silent on the expected time investments of staff for other proposed changes such as those in § 4.3, § 4.5, and § 4.7.
- 13. At this time, I also ask the Agency to consider changing all references of "misadministrations" to "medical events." The Nuclear Regulatory Commission (NRC) and many agreement states made this change in terminology sometime around 2008.
- 14. The rationale/summary of change for § 5.5.2 & § 5.5.3 is said to "Synchronize wording with equivalent requirements in 10 C.F.R. 35.3047." This should be "...10 C.F.R. 35.3045."

15. The references to "isotopes" in 216-RICR-40-20-9.4.5(A)(9) and 216-RICR-40-20-9.4.6(A)(5) should be changed to "radioisotope" or "radionuclide."

Thank you again for allowing the public to offer our comments to these proposed amendments as well all work to improve the health and safety of Rhode Islanders.

Please do not hesitate to contact me with any questions or concerns.

Very sincerely and respectfully,

Michael Oumano, PhD, DABR, DABSNM, MRSE, CMLSO

Radiation Safety Officer, Medical Physicist

Rhode Island Dept of Health Registration RPS0189

Phone: 203-598-2683

Email: moumano1@gmail.com

17 Tichael Oumano

#### Comments by Frank Ascoli, MS Medical Physicist RI Registration RPS 0037

February 18, 2022

#### 1. 216-RICR-40-20-4.3.3-H

#### **Individuals Operating X-ray Systems for Healing Arts Use**

Comment: Initial training for a new employee in the taking of dental x-rays is necessary. However yearly re-training with record keeping places an unnecessary management duty on the facility and will not improve patient care. Training by whom? The dental assistant and hygienist are best qualified to take x-rays. Dental x-rays are quickly critiqued by the dentist and feedback on poor technique is immediate. In other words, QA and dentist supervision is on-going with each x-ray.

#### 2. 216-RICR-40-20-4.3.8

#### **Non-Healing Arts Exposure Prohibited**

Comment: This proposed rule would preclude IRB sanctioned research when such research has been approved by a medical doctor. Specifically, women may volunteer as subjects for bone mineral density (DXA) research studies under an IRB. The proposed rule should not restrict or impede IRB sanctioned research.

#### 3. 216-RICR-40-20-4.3.15

#### Report and Notification of a Dose to an Embryo/Fetus and subsequent notifications

Comment: This proposed rule does not make sense. Why report radiation dose to a nursing child at home if the mother has a radiological x-ray exam? I believe the intent was to protect a nursing child from ingesting radioactive breast milk following a nuclear medicine exam of the breast feeding mother.

#### 4. <u>216-RICR-40-20-4.5.3-C</u>

#### **Equipment Operation**

Comment: This proposed rule does not differentiate radiology, cardiology, or orthopedic residents from general medical residents. In practice, residents in radiology and other specialties using ionizing radiation are well trained in the use of the fluoroscope. Having an attendant physician physically present will present undo hardships to the practice of medicine.

#### 5. 216-RICR-40-20-4.9.6-A

#### **DXA Examination requirements**

Comment: See #2 above.

#### 6. 216-RICR-40-20-4.10.1.A.2.b(2)

#### QA Image Processing, Facilities Using QR, DR

Comment: This proposed rule will place undue hardship on free-standing radiographic and urgent care facilities without full-time physics support. It would require the facility to purchase an expensive phantom and do quarterly QA testing on the imaging system while the operator may not be best qualified to do the evaluation. While this rule has merit, the intent would be better served if the QMP was required to do the testing yearly with his or her own phantom as part of the annual safety program.

#### 7. <u>216-RICR-40-20-4.10.1.A.3.c</u>

#### **QA for Radiographic Equipment**

Comment: It is unclear if dental, podiatry, and veterinary facilities are exempt from yearly testing by a QMP.

#### 8. <u>216-RICR-40-20-5.3.12.A</u>

#### Report and Notification of a Dose to an Embryo/Fetus

Comment: Same concern as #3 above. Not applicable to therapeutic radiation machines.

#### 9. 216-RICR-40-20-5.5.2.B (1-3)

#### **Reports and Notifications of Misadministrations**

Comment: The wording limiting dose to non-involved organs is too restrictive and does not conform to the reality of modern radiation therapy treatments. This added wording is attempting to define misadministrations in terms of annual radiation worker permissible doses and has no basis in radiotherapeutic cancer treatments where typical patient doses may exceed 70 Gray. In practice, minor adjustments to radiation portals may be made (sometimes daily with image guidance) without compromising dose to the tumor or uninvolved tissue. These minor spatial adjustments, well within the practice of radiation therapy, could easily exceed the levels in the regulation. (e.g., 5 rem) to parts of skin and other organs.