CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-20-5

RULE TITLE: Therapeutic Radiation Machines

REASON FOR RULEMAKING: These amendments were proposed because existing regulations were written in the 1990s, with only minor amendments (specifically the inclusion of electronic brachytherapy devices) in 2009. The state-of-the-art for therapeutic radiation machines has evolved over the past thirty years to a point where the radiation control program cannot effectively regulate some of the newer technology. These proposed amendments would allow for effective regulation of all current technology and have provisions to address future technological advances in therapeutic radiation machines. These proposed amendments will allow the program to properly achieve its goals of protecting patients, the general public and occupationally exposed workers from unnecessary exposure to the harmful effects of ionizing radiation. These proposed amendments will bring the regulation into agreement with the revisions to Part X of the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. in January 2023.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS: No public hearing was requested in response to the Notice of Proposed Rulemaking published on 26 September 2023. However, the Department received one written comment which recommended that references to an antiquated radiation measurement unit be removed, and several minor technical errors be corrected in the proposed regulations. The Department concurs with the issues raised in this comment and will make the appropriate changes in the proposed rule.

CHANGES TO THE TEXT OF THE RULE: In addition to the changes contained in the above referenced Notice of Proposed Rulemaking, the following changes were made in response to public comments:

- 1. §§ 5.2(A)(1), 5.2(A)(26), 5.6.1(A)(2), 5.6.4(A)(3), 5.7.9(A)(3), 5.14.2(A)(2), 5.14.3(A)(1), and 5.14.3(A)(2) were revised to eliminate any references to the antiquated radiation measurement unit "rad".
- 2. § 5.3.4(A)(4) was revised to correct the name of one of the certification boards that is acceptable for documenting required training for medical physicists.

- 3. § 5.6.19 was revised to correct the abbreviation used to designate "hour".
- 4. § 5.11.5(A)(2) was revised to correct the units used to express the size of the radiation field.
- All of the above changes are minor/technical in nature and do not impact any of the analyses/conclusions in the Cost Benefit Analysis (CBA) prepared for these proposed regulations.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

- 1) Alternative approaches;
- 2) Overlap or duplication with other statutory and regulatory provisions; and
- 3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.