Benefit-Cost Analysis

Therapeutic Radiation Machines

216-RICR-40-20-5

Rhode Island Department of Health

14 June 2023

Background

The Rhode Island Department of Health ("RIDOH"; "The Department") is proposing to amend *Therapeutic Radiation Machines* [216-RICR-40-20-5] to address several necessary changes.

These regulations were initially promulgated as their own independent regulations on 1 January 2019 when *Rules and Regulations for the Control of Radiation* [R23-1.3-RAD] was repealed and fifteen separate regulations were adopted to replace the repealed rule. *Rules and Regulations for the Control of Radiation* was adopted as a Rhode Island regulation in June 1978. The regulations have been amended twenty-two times over the last forty-five years, approximately once every two years. The most recent amendments were promulgated in May 2022 at which time minor housekeeping changes were made which dealt primarily with administrative reporting requirements but did not revise any of the technical requirements for therapeutic radiation machines. The most recent major revision was in 2009 when the rules were modified to include electronic brachytherapy.

Radiation control regulations are amended when technically necessary based on locally identified issues or to come into compatibility with the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD). CRCPD published a revision to Part X of the SSRCRs in January 2023. These proposed amendments will make the Rhode Island regulations compatible with SSRCR Part X.

The radiation control program was originally created in the 1960s as part of the former Office of Occupational and Radiological Health. The radiation control program in its current form was created with the passage of the Radiation Control Act in 1976. The program created in response to the need to protect the patients, the general public and occupationally exposed workers from unnecessary contact with the harmful effects of ionizing radiation. The radiation control program administers fourteen other sections of Chapter 216- 40-20 in the Rhode Island Code of Regulations which are not being amended at this time. The radiation control program also administers Regulation of Tanning Facilities [216-RICR-40-10-24]. In addition, the radiation control program has a contract with the US FDA to perform annual inspections of all FDA-certified mammography facilities in Rhode Island (approximately forty facilities).

These amendments are being proposed as the 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 has provisions to address future technological advances in therapeutic radiation machines. These proposed amendments will allow the program to properly achieve its goals of properly protecting patients, the general public and occupationally exposed workers from unnecessary exposure to the harmful effects of ionizing radiation.

Radiation therapy has made a significant number of advances in the past thirty years and this technology will continue to advance for the foreseeable future. The equipment used to administer radiation therapy has also undergone significant changes over this period and has evolved into a system which has become highly dependent on computers to accurately deliver the appropriate

radiation therapy dose to the patient. These proposed amendments will allow for a more effective regulation of therapeutic radiation machines.

These proposed amendments pertain to the licensing of individual facilities that utilize therapeutic radiation machines. There are currently seven facilities in Rhode Island that utilize therapeutic radiation machines and would be subject to these proposed amendments.

These current radiation control regulations require that the person in charge of a therapeutic radiation machine facility be licensed as a physician in Rhode Island [216-RICR-40-05-1] and have Board Certification in a discipline related to radiation oncology. The current regulations also require that the technologists operating the equipment have a current Rhode Island license as a radiation therapist pursuant to 216-RICR-40-05-34. These proposed amendments constitute no change in these areas because these requirements already exist under the current regulations.

Virtually all states have some type of regulation for therapeutic radiation machines that are based, in whole or part, on SSRCR Part X. Given that the latest revision to SSRCR Part X was only published in January 2023, it is unlikely that any other states have completed adoption of the new Part X. A number of states are in the process of doing so, however, a specific implementation timetable is not available at this time.

Proposed Amendments

The proposed amendments are extensive. Please refer to the *Concise Statement of Proposed Non-Technical Amendments* document for a more detailed description of the changes.

Status Quo

If the status quo were to be maintained the radiation control program would continue to make its best effort to regulate the use of therapeutic radiation machines with regulations that were originally adopted about thirty years ago and do not directly address some of the newer technology in common use in the field.

Rhode Island is very fortunate to have therapeutic radiation facilities that are run by highly qualified physicians and medical physicists. These individuals would likely follow appropriate guidance from cognizant professional groups regardless of the current state of the regulations. However, the same cannot be said with any certainty about any new radiation oncology facilities that may open in Rhode Island.

A failure to amend the proposed regulations would not result in RIDOH being out of n compliance with the law. The radiation control program's enabling statute [R.I. Gen. Laws § 23-1.3-2(c)(4)] only requires that the radiation control program *formulate and promulgate, amend, and repeal codes and rules and regulations, including licensing and registration of radiation sources, persons, and services as may be necessary to prohibit and prevent unnecessary radiation.* It does not establish any timeline for implementing the changes. While new/amended regulations that are necessary to maintain compatibility with comparable regulations of the NRC must typically be adopted within three years of the NRC's final adoption date, there is no such *timeliness* requirement to adopt SSRCR revisions.

Benefits

Patients receiving radiation therapy, workers occupationally exposed to ionizing radiation during the delivery of treatment doses and the general public will all benefit from the proposed amendments because compliance with these regulations will maximize the dose delivery to patients and minimize unnecessary exposure to ionizing radiation to occupationally exposed workers and the general public. Licensees will also benefit by having regulations that not only reflect the current state of the art with regards to technology used to administer radiation therapy but also include provisions that will make it easier to regulate future advances that are not specifically addressed in the regulations. However, it is not possible to assign any specific monetary value to this benefit.

The intent of the regulations is to ensure that facilities using therapeutic radiation machines will maximize the dose delivery to patients and minimize unnecessary exposure to ionizing radiation to occupationally exposed workers and the general public. The proposed amendments address this intent.

The proposed amendments will make it easier for the radiation control program to effectively regulate the current and future generations of therapeutic radiation machines. Much of the technology in common use with current generation therapeutic radiation machines wasn't even envisioned when the current regulations were originally adopted. These proposed amendments contain specific provisions as to how therapeutic radiation machine facilities may receive approval to use new technology that has received FDA approval but is not specifically addressed in the regulations. This approval process would be much more complex if the radiation control program had to handle these situations under the current regulations.

The radiation control program does not believe that these proposed amendments will have any significant impact on costs to the public as a whole or to the taxpayers.

As stated above, the primary benefit of adopting these proposed amendments will be to maximize the dose delivery to patients and minimize unnecessary exposure to ionizing radiation to occupationally exposed workers and the general public. Unfortunately, the nature of these benefits can't easily be assigned a specific monetary value.

The anticipated benefits will be both immediate and long-term, as the proposed amendments will allow the radiation control program to effectively regulate the current generation of therapeutic radiation machines and provide a roadmap on approval/regulation of newer technology that has received FDA approval but is not specifically address in the regulations.

Costs

Based on the intent of these proposed amendments and the potential benefits previously described, the radiation control program does not believe there are any notable drawbacks or concerns associated with these proposed amendments.

Except as outlined below with regard to staff retraining, the radiation control program does not believe that promulgation of these proposed amendments will result in a significant fiscal impact for either the State or RIDOH. The proposed amendments include a new provision that requires

licensees to either obtain (and maintain) certification from an appropriate professional group or establish an external audit program to review its quality control activities. Although there is a cost associated with either of these options, it would not constitute any new costs because all of the current licensees have already obtained certification. Furthermore, third-party certification of healthcare facilities (e.g., JCAHO) is the industry standard. Given the intent of these proposed amendments, It is not believed there will be a significant fiscal impact on the general public.

The radiation control staff will need to be oriented in the new regulatory requirements and the changes in inspection protocols necessitated by these proposed amendments. However, no *de novo* processes will need to be developed. Consequently, it is anticipated that all required staff training can be completed within approximately one month and, after that point, all activities associated with the proposed regulations can be easily accommodated with existing staff resources.

Given that there are currently only seven radiation therapy facilities in Rhode Island that would be impacted by these amendments, no additional radiation control program staff will be needed to implement these proposed amendments. Once the initial staff training on these amendments has been completed, all future licensing and inspection activity will be absorbed into the existing workload.

There may be some minor costs associated with orienting the licensee's professional staff to the requirements in the proposed amendments. However, the constantly evolving nature of radiation therapy necessitates that the professional staff always be in a training mode and these proposed changes could easily be accommodated in the licensee's existing training protocols without any significant fiscal impact on the licensee.

The radiation control program has recently (within the past twelve months) completed inspections of all seven therapeutic radiation facilities, based on observations made during these inspections it does not appear that any of the facilities will need to make significant revisions to their day-to-day operations to accommodate the changes in the proposed amendments.

Based on the intent of these proposed amendments, there should be no impact on the accessibility of healthcare for patients or the public associated with the promulgation of these proposed amendments. Furthermore, the potential costs to medical providers, patients and the general public appear to be minimal.

Regulatory Alternatives and Determination

In developing the proposed amendments, the Department considered the following three alternatives:

1) **Continue with the existing regulations (i.e., *status quo*)**
   For reasons previously identified in this analysis, this was a non-viable option.

2) **Develop appropriate amendments using in-house staff**
   This option was determined to be non-viable because of the significant staff time that would be required to research and develop appropriate amendments.

3) **Adopt amendments which are compatible with Part X of the SSRCR**
This option was selected because the January 2023 amendments to Part X had been developed by a CRCPD working group which included both state radiation control program staff with considerable experience in the licensing and inspection of therapeutic radiation machine facilities and practicing medical physicists with extensive experience in the day-to-day operation of therapeutic radiation machines. The development of the revised Part X included vetting with appropriate professional societies and a public comment period. Input received during the vetting process was reviewed by the working group and, where appropriate, incorporated into the final January 2023 version of Part X.

Based on the information presented above, RIDOH has determined that the proposed amendments are the most effective option available and therefore, they will be presented as proposed.