

Public Comment Responsiveness Summary
Radioactive Materials Rule

A public hearing was held on July 20, 2018 in Burlington, Vermont, regarding the proposed Radioactive Materials Rule (formerly the Radiological Health Rule). During the public comment period and the hearing, the Vermont Department of Health (“Department”) received and reviewed public comments. The following is summary of comments received from the public and the Department’s response to each comment. Comments of a similar or consistent nature have been consolidated and responded to accordingly.

- 1. Comment:** The Department received several different comments raising concerns over the incorporation by reference of the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs). Specific concerns included that the CRCPD is not a regulatory body and the SSRs were drafted to serve as guidance only, the SSRs are not updated in a consistent manner and would lack the opportunity for public participation, some sections of the SSRs do not reflect the most recent science in their respective areas, and the incorporation by reference of the SSRs was confusing and difficult to navigate.

Response: The Department’s primary goal in this regulatory update was to incorporate the federal regulations required by the Nuclear Regulatory Commission to become an Agreement State with authority to license and inspect byproduct, source, and special nuclear materials. The Department’s secondary goal was to update the existing Radiological Health Rule concurrently with the Agreement State provisions. After reviewing the public comments, the Department has removed all sections and provisions of the Rule that referenced and incorporated the CRCPD SSRs. For the purposes of this rulemaking, the proposed Rule will now only address the regulations necessary to become an Agreement State, and the existing Radiological Health Rule will remain in effect without any changes or incorporation of the SSRs.

- 2. Comment:** One commenter noted a concern that what has been proposed in section 20, “Medical Diagnostic & Interventional X-ray & Imaging Systems”, was not designed with Vermont in mind nor included input from VT physicists or hospitals.

Response: As discussed in the response above, the Department has removed all sections and provisions of the Rule that referenced and incorporated the CRCPD SSRs. For the purposes of this rulemaking, the proposed Rule will now only address the regulations necessary to become an Agreement State, and the existing Radiological Health Rule will remain in effect without any changes or incorporation of the SSRs.

- 3. Comment:** One commenter noted that the FDA’s approach is to require “annual” testing on the one modality it deemed most critical, mammography, and further stated that the FDA realizes the practical difficulty of doing this test every year on the anniversary of the last test and therefore allows 14 months between tests, while the Joint Commission allows similar flexibility for CT. The commenter was concerned that the state is proposing a more stringent criteria by requiring that the interval between tests may “not... exceed 12 months” for all X-ray equipment, not just mammography and CT. It was further noted that it is sometimes challenging for the commenter to meet deadlines for the more flexible FDA/JC rules for just 12 units, and it will be much more challenging to do so for the nearly 100 units covered under the proposed regulations, particularly in light of the fact that there are only two individuals in the state that do this work.

Response: As discussed in the response above, the Department has removed all sections and provisions of the Rule that referenced and incorporated the CRCPD SSRs. For the purposes of this rulemaking, the proposed Rule will now only address the regulations necessary to become an Agreement State, and the existing Radiological Health Rule will remain in effect without any changes or incorporation of the SSRs.

- 4. Comment:** A commenter expressed a concern with section of the Rule that states, “Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary X-ray installation.” Specifically, the concern was that this would include “C-arms”, which the commenter stated are commonly used in ways that would be in violation of this rule, and that compliance would cost millions of dollars with little to no benefit to the patient.

Response: As discussed in the response above, the Department has removed all sections and provisions of the Rule that referenced and incorporated the CRCPD SSRs. For the purposes of this rulemaking, the proposed Rule will now only address the regulations necessary to become an Agreement State, and the existing Radiological Health Rule will remain in effect without any changes or incorporation of the SSRs.