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-40-20-9

RULE TITLE: Medical Use of Radioactive Material

REASON FOR RULEMAKING: Revise incorporation by reference date to 2021 to

capture updates to 10 C.F.R. Part 35.

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

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TESTIMONY AND COMMENTS:

The Agency received one comment suggesting a revision to the technical language in §.9.4.5(A). The Agency has determined that the language in that section is equivalent to that used by the NRC in comparable sections of 10 C.F.R. Part 35 and that no changes were needed.

The Agency received one comment suggesting that all references to "misadministrations" be changed to "medical events" for consistency with language used by the Nuclear Regulatory Commission (NRC) and many other Agreement States. The Agency concurs with this recommendation and will change all references to "misadministrations" to "medical events." However, the technical language as to what constitutes a "medical event" will remain unchanged.

CHANGES TO THE TEXT OF THE RULE: All references to "misadministrations" in Part 9 were changed to "medical events".

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.