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-60-05-6

RULE TITLE: Licensing Analytical Laboratories for Sampling and Testing Cannabis

REASON FOR RULEMAKING: The Rhode Island Department of Health (RIDOH) is proposing to revise Licensing for Sampling and Testing Cannabis [216-RICR-60-05-6] to add several references, definitions, and sections regarding the testing of cannabis among other amendments.

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

TESTIMONY AND COMMENTS:

RIDOH received a comment expressing support for the removal of the requirement that laboratory directors be of “good moral character.” RIDOH thanks you for your comment.

RIDOH received a comment inquiring if the proposed amendments impact the rules concerning cannabis microbial testing. RIDOH notes that rules regarding microbial testing have not been amended at this time.

RIDOH received a comment stating “Our scientists recommend microbial testing specifications that will ensure that adult-use and medical cannabis plant material and manufactured products are safe for consumers and patients.” RIDOH notes that the proposed rule requires cannabis testing laboratories to measure the overall amount of yeast and mold in cannabis products using culture methods as an indication that the products do not contain gross mold or yeast contamination which is an indication the environment for producing cannabis products for human consumption is sanitary. The consumer and patient safety are protected by certifying the cannabis produced is not grossly contaminated by a variety of yeast and mold that can grow in a poorly controlled production environment. There have been no changes made to the proposed rule regarding microbial testing.

RIDOH received a comment expressing concern regarding the allowed methods for cannabis testing. The commenter indicated that they do not recommend plating methods for required cannabis microbial testing. RIDOH responds that not only does the proposed rule measure the total yeast and mold as an indication of cannabis

product quality they also require confirmatory testing for the presence of pathogenic bacteria in cannabis products when the culture based presumptive test method results is positive for the presence of pathogenic bacteria.

RIDOH received a comment expressing concern that “the procedures listed underneath Table 1 above in “3. Procedure”, there are no FDA, USP, or WHO approved methods using any microbiological procedures that have been validated using cannabis as the sample type.” RIDOH responds that the AOAC has published plating methods for the analyzing of microbial contamination. The proposed rule requires licensed cannabis testing laboratories to follow microbial testing methodology designed to culture and confirm living microbial contamination from the cannabis products to be certified for human consumption. There have been no changes made to the proposed rule regarding microbial testing.

RIDOH received a comment recommending molecular methods for microbial testing, such as qPCR. RIDOH responds that the potential for underestimating the total yeast and mold when using qPCR is significant. There have been no changes made to the proposed rule regarding microbial testing.

RIDOH received a comment expressing concern regarding the testing required for additional pesticides. This comment also indicated that the requirements being added would necessitate the purchase of costly equipment which only one such laboratory would have the capability to purchase. RIDOH responds that two of the three Analytical Laboratories licensed by RIDOH to sample and test cannabis already own and use the instrumentation necessary to analyze the pesticides at the concentrations written in the proposed rule. The proposed rule does not require additional instrumentation to analyze the additional pesticides in order to measure the specified concentrations.

RIDOH received a comment requesting that the upper limits for yeast and mold should be increased from 10,000 (CFU/g) to 100,000 (CFC/g). RIDOH responds that the upper limits for yeast and mold are set at 10,000 CFU/g to protect public safety and to ensure the cannabis products are produced in a clean environment. Rhode Island requires all cannabis (marijuana) to be produced indoors and therefore the limit of 10,000 CFU/g is considered reasonable compared to yeast and mold allowed in outdoor cannabis production. Allowing higher concentrations of yeast and mold in cannabis products will lower standards for consumer protection.

RIDOH received a comment stating the batch size for testing cannabis flower should be 15 pounds rather than 10 pounds. RIDOH notes that batch size is not regulated by RIDOH. This rule is established by the Dept of Business Regulation and therefore cannot be amended at this time.

RIDOH received a comment indicating that testing of batch products “requires that the laboratory grind the product prior to testing for both flower and pre-roll material, therefore testing ground and flower separately is redundant. This doubles the testing cost for the same product. Allowing one test to be used for both flower and pre-rolls

would eliminate the double testing and reduce the operational costs for cultivators and consumers." RIDOH responds that the proposed rule does not change the requirement that final cannabis products (as sold) must be tested. Any post-testing processing of intermediate cannabis products may introduce changes in the test results including contamination or altered cannabinoid concentration.

RIDOH received a comment stating "cannabis products that are tested, determined to be out of compliance and which undergo subsequent remediation should only be required to undergo the tests for which the products were out of compliance and not the full panel of tests. Requiring a full panel of testing for post-remedial products is redundant, and expensive and does not add any value to consumers." RIDOH notes that this requirement is established by the Department of Business Regulation to ensure that all final products undergo required testing for parameters and therefore cannot be amended at this time.

RIDOH received a comment suggesting that "in the event retesting of potency is required, the testing regulations should allow the lab that performed the initial potency test to conduct the potency re-test." RIDOH responds that this requirement is established by the Department of Business Regulation. However, if the licensed laboratory determined its potency analysis was originally not in control it is required to correct the problem and test the potency with the system in control for the analysis.

RIDOH received a comment recommending the inclusion of equations for Total THC, Total CBD, and Total Cannabinoids and discouraging the use of Total Active Cannabinoids as a requirement. RIDOH responds that RIDOH-licensed cannabis testing laboratories are required to measure and report the concentration of the percentages of Δ9-tetrahydrocannnabinol (Δ9-THC), delta 8 tetrahydrocannabinol (Δ8-THC), (cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) in the total amount of THC in the cannabis products as sold. Percentage of other cannabinoids may be reported but are not required. The proposed rule is not intended to measure and report the overall cannabinoid potency for the consumer.

RIDOH received a comment stating "Some of the additional pesticides added to the previous list have practical analytical implications that will require significant capital investment for labs, hindering the rapid implementation of the proposed changes." The commenter also stated that they would "strongly recommend an incremental expansion of the list that would make economic and practical sense." Lastly, the commenter stated "We discourage the inclusion of a waiver of potency testing on infused cannabis products if [sic] the manufacturing of remains consistent from batch to batch in this amendment." RIDOH responds that the proposed rule includes added clarification for pesticide testing requirements to ease the burden on RIDOH licensed cannabis testing laboratories. The number and required criteria pesticides regulated in cannabis products is clarified. The proposed rule sets the concentration criteria at levels analytical laboratories can achieve using LC tandem MS instrumentation currently being used by two of the three licensed laboratories.

CHANGES TO THE TEXT OF THE RULE: No changes to the text of the rule were made.

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.