

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE PROPOSED RULE IS:

64-4.212 MMTC Regulatory Compliance Testing

(1) The capitalized terms used in this rule shall have the same meaning as provided in the CMTL Definitions rule.

(2) An MMTC must contact a Certified Marijuana Testing Laboratory (CMTL) and arrange for the CMTL to select and collect a random and representative sample of Final Product from every Retail Batch for regulatory compliance testing from an MMTC's department-approved processing facility or department-approved fulfillment and storage facility.

(3) All Final Products must pass regulatory compliance testing as provided in the CMTL Sample Testing rule prior to being transported by an MMTC to a dispensing facility and prior to being dispensed to a qualified patient or caregiver.

(4) Within 14 calendar days of receipt of a failed Certificate of Analysis from a CMTL due to Contaminants Unsafe for Human Consumption, an MMTC must:

(a) Provide the department with a completed Notification of Resampling and Retesting form as provided in paragraph (5)(a);

(b) Provide the department with a completed Notification of Remediation form as provided in the MMTC Remediation rule; or

(c) Provide notice to the department via email to OMMUlabs@flhealth.gov indicating that the MMTC will dispose of the Retail Batch in accordance with the MMTC Marijuana Waste Management and Disposal rule.

(5) An MMTC may arrange for a previously failed Retail Batch to be resampled and retested by a CMTL.

(a) Prior to the resampling and retesting of a previously failed Retail Batch, the MMTC must provide the failed Certificate of Analysis together with completed Form DH XXX-OMMU-XX/2021, Notification of Resampling and Retesting, which is incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX> to the department via email to OMMUlabs@flhealth.gov. An MMTC must arrange for resampling and retesting of the previously failed Retail Batch within 30 calendar days of submission of the Notification of Resampling and Retesting form to the department.

(b) Prior to the resampling and retesting of a previously failed Retail Batch, the MMTC must ensure the CMTL conducting resampling and retesting has a copy of the failed Certificate of Analysis.

29 (c) The previously failed Retail Batch must be quarantined, clearly marked “not for retail sale,” and shall not be
30 transported by the MMTC to any dispensing facility or dispensed to a qualified patient or caregiver except as provided
31 in subparagraph (5)(d)2.

32 (d) A previously failed Retail Batch must pass two complete regulatory compliance tests using two new samples
33 in order for the Retail Batch to be eligible for dispensation by an MMTC. The previously failed Retail Batch may only
34 be resampled and retested twice.

35 1. If the previously failed Retail Batch passes the first retest, an MMTC may arrange for the Retail Batch to be
36 retested again by a CMTL.

37 2. If the previously failed Retail Batch passes the second retest, the Retail Batch is eligible for dispensation by
38 the MMTC. An MMTC must provide two passing Certificates of Analysis for the previously failed Retail Batch to
39 the department via email to OMMUlabs@flhealth.gov prior to removing the Retail Batch from quarantine and
40 transferring it to a dispensing facility or dispensing it to a qualified patient or caregiver.

41 3. If the previously failed Retail Batch fails either retest, the MMTC shall dispose of the Retail Batch in
42 accordance with the MMTC Marijuana Waste Management and Disposal rule or remediate it if permitted by the
43 MMTC Remediation rule. The MMTC shall provide the department with the appropriate notice required by paragraph
44 (4)(b) or (4)(c).

45 (e) If a CMTL is unable to complete regulatory compliance testing after sampling as provided in the CMTL
46 Submission of Product for Testing rule, the MMTC from which the sample was collected may have the impacted
47 Retail Batch(es) resampled and tested as an initial Retail Batch sample.

48 (6) If a Retail Batch fails regulatory compliance testing due to the labeled potency of total active THC, total active
49 CBD, or any individual cannabinoid printed on the Final Product packaging, the MMTC shall correct the labeled
50 potency to display the accurate concentration measured by the CMTL prior to dispensing the Final Product to qualified
51 patients or caregivers.

52 (7) An MMTC may request testing of marijuana at any point during cultivation or processing. However, such
53 testing does not exempt an MMTC from regulatory compliance testing in accordance with CMTL rules prior to
54 dispensing the Final Product to qualified patients or caregivers.

55 (8) An MMTC shall bear the costs associated with resampling and retesting of a previously failed Retail Batch.

56 (9) Notwithstanding subsection (4), an MMTC that has a previously failed Retail Batch(es) in its possession on
57 the effective date of this rule shall have 14 calendar days from the effective date of this rule to provide the department
58 with the appropriate notice(s) required by paragraphs (4)(a) through (4)(c).

59 (10) Prior to December 31, 2026, the department shall review this rule and amend, modify or repeal the rule if it
60 is determined to create barriers to entry for private business competition, is duplicative, outdated, obsolete, overly
61 burdensome, or imposes excessive costs. In the event the department fails to complete this rule review, the department
62 shall begin the rule repeal process in accordance with chapter 120, F.S.

63 *Rulemaking Authority 381.986(8)(e)11., 381.986(8)(k), FS. Law Implemented 381.986(8)(e)11., FS. History-New.*

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