STATE OF MAINE

EMERGENCY RULES FOR THE CERTIFICATION OF MARIJUANA TESTING FACILITIES

CODE OF MAINE RULES

CHAPTER 5

Department of Administrative and Financial Services

11 State House Station

Augusta, Maine 04333-0011

Effective date: September 2019

SUMMARY STATEMENT

This rule is promulgated by the Maine Department of Administrative and Financial Services (DAFS) after consultation with the Department of Health and Human Services (DHHS), Center for Disease Control and Prevention (CDC), and the Department of Agriculture, Conservation and Forestry to establish the certification process for testing facilities analyzing marijuana and marijuana products. This rule is intended to protect public health by establishing standards for testing marijuana and providing assurance that results of testing for contaminants do not exceed the maximum level standards where testing is required.

Table of Contents

General

This rule is promulgated on an emergency basis to establish the requirements for certification by the Maine Center for Disease Control and Prevention of marijuana testing facilities licensed under Maine's Adult Use Marijuana Program administered by the Office of Marijuana Policy, Department of Administrative and Financial Services, in order to mitigate potential threat to public health and safety following emergency legislative action. The marijuana testing facility certification program was established pursuant to P.L. 2019, Ch. 354, which was enacted as emergency legislation on June 18, 2019.

The activities described in this rule may be considered a violation of federal law. Persons cultivating, manufacturing, testing, selling, purchasing or otherwise receiving adult use marijuana or marijuana for medical use, or marijuana products derived from the same, may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with this rule does not exempt licensees, their employees or customers from possible federal prosecution. Neither the Department of Administrative and Financial Services nor the Department of Health and Human Services is responsible for the actions of licensed and/or certified marijuana testing facilities under this rule.

Section 1 – Marijuana Testing Facility Certification Program Established

Section 1.1 – Statutory Authority

The Department of Administrative and Financial Services (referred to heretofore as DAFS), acting through its Office of Marijuana Policy (referred to heretofore as OMP), has promulgated the following rule on an emergency basis in accordance with the statutory authority provided in 28-B MRS §104, in order to mitigate potential threat to public health and safety following emergency legislative action, for the purpose of implementing, administering and enforcing the provisions of 28-B MRS, chapter 1. The Department of Health and Human Services (referred to heretofore as DHHS), acting through its Center for Disease Control and Prevention (referred to heretofore as the CDC) shall implement the certification program described herein in accordance with the statutory authority provided in 22 MRS § 569.

Section 1.2 - Department Authority

DAFS and DHHS, through the CDC, may enforce this Rule and any relevant provisions of Titles 4, 5, 22 and 28-B, and any other general statutes, laws, executive orders or subsequently passed legislation. DAFS shall set licensing fees in accordance with 28-B MRS § 207, and CDC shall set certification and technology fees in accordance with 22 MRS § 569. DAFS, DHHS or an agent thereof shall have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, any marijuana testing facility and its business records. DAFS shall further have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, vehicles used to transport marijuana or marijuana products to a marijuana testing facility.

Section 1.3 - Communication with DAFS and/or DHHS

1.3.1 Written Communications. If an applicant or licensee is required to or elects to submit anything in writing to DAFS or DHHS, unless otherwise prescribed by DAFS or DHHS, the applicant or licensee may submit the writing to DAFS or DHHS via:

A. Mail;
B. In-person delivery;
C. Facsimile; or
D. E-mail.

1.3.2 Submission Deadline. If a written notification must be submitted by a deadline it must be received by DAFS or DHHS, regardless of method used to submit the writing, by 5 p.m. Eastern Time.

Section 1.4 – Definitions

1. **Acceptance criteria** means the specified limits placed on characteristics of an item, process or service defined in requirement documents.

2. **Accredited** means to be recognized as conforming to a standard by an accrediting organization, such as ISO/IEC 17025.

3. **Accredited college or university** is a college or university accredited by a regional or national accrediting agency recognized by the United States Department of Education.

4. **Accuracy** means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are a result of sampling and analytical operations; a data quality indicator.

5. **Action level** is the threshold value for determining whether a sample passes or fails an analytical test.

6. **Adult use marijuana** means marijuana cultivated, manufactured, distributed or sold by a marijuana establishment.

7. **Adult use marijuana product** means a marijuana product that is manufactured, distributed or sold by a marijuana establishment.

8. **Aliquot** is a portion of a sample that is used in an analysis performed by a testing facility.

9. **Analyst** means the designated individual who tests the samples by performing the "hands-on" analytical methods and associated techniques. The analyst is responsible for applying required testing facility practices and other pertinent quality controls to meet the required level of quality.

10. **Analyte** is a chemical, compound, element, bacteria, yeast, fungus or toxin that is identified or measured.

11. **Analytical batch** means a group of samples that is prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.

12. **Analytical method** is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

13. **Apparent activity** means any sight, sound, smell or other indication that persons are present at a marijuana establishment.

14. **Applicant** means a person who submits to certification by the Maine CDC as part of an application for a license to operate a marijuana testing facility issued by OMP.

15. **Approved proficiency testing provider** means a provider of proficiency testing samples whom the certification officer has deemed to meet the requirements of this Rule.

16. **Assessment** means the evaluation process used to measure or establish the performance effectiveness and conformance of a testing facility and/or its systems to defined criteria and standards and requirements of testing facility certification.

17. **Audit** means a systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and reporting aspects of a system to determine whether quality assurance, quality control and technical activities are being conducted as planned. An audit is conducted to determine whether these activities will effectively achieve quality objectives.

18. **Batch** means:
    a. A specific quantity of adult use marijuana harvested during a specified period of time from a specified cultivation area within a cultivation facility; or
    b. A specific quantity of adult use marijuana or adult use marijuana products produced during a specified period of time in a specified manufacturing area within a products manufacturing facility.

19. **Batch number** means a distinct group of number, letters or symbols or any combination thereof, assigned to a specific batch of adult use marijuana by a cultivation facility or to a specific batch of adult use marijuana or adult use marijuana products by a products manufacturing facility.

20. **Bias** means the systematic or persistent distortion of a measurement process, which causes errors in one direction, resulting in the expected sample measurement being different from the sample's true value.

21. **Cannabinoid** is a chemical compound that is unique to, and derived from, marijuana.

22. **Calibration** means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by standards.
    a. In calibration of support equipment, the values realized by standards are established using reference standards that are traceable to the International System of Units (SI).
    b. In calibration, per methods, the values realized by standards are typically established using reference materials that are either purchased by the testing facility with a certificate of analysis or purity or prepared by the testing facility using support equipment that has been calibrated or verified to meet specifications.

23. **Calibration curve** means the mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

24. **Calibration standard** means a substance or reference material used for calibration.

25. **CAS number** is the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service (CAS).

26. **CBD** is cannabidiol, CAS number 13956-29-1.

27. **CBDA** is cannabidiolic acid, CAS number 1244-58-2.

28. **Certificate of analysis** means the report prepared for the requester and OMP about the analytical testing performed and results obtained by the testing facility.

29. **Certification** means the process by which an agency or organization evaluates and recognizes a testing facility as meeting certain predetermined qualifications or standards, thereby certifying the testing facility. The Department of Health and Human Services is responsible for certification of all testing facilities.

30. **Certification officer** means the person designated by the Department of Health and Human Services to manage certification of testing facilities.

31. **Certified reference material** means reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute.

32. **Chain of custody form** means a record, either paper-based or electronic, that documents the possession of the samples from the time of collection to receipt by the testing facility, in accordance with chain of custody protocol prescribed by the testing facility. This record, at a minimum, must include the sample location, the number and types of containers, the mode of collection, the collector, the date and time of collection, preservation and requested analyses.

33. **Chain of custody protocols** mean the procedures developed and employed by the testing facility to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a chain of custody form that documents the collection, transport and receipt of compliance samples by the testing facility. In addition, these protocols document all handling of the samples within the testing facility.

34. **Colony forming unit (CFU)** means a unit of measurement of estimated number of bacteria or fungal cells in a sample.

35. **Contaminant** means an unacceptable level of an unwanted or objectionable substance, toxin, pollution or foreign material that causes impurity in a product. Contaminants include, but are not limited to, pesticides, microbiology, filth, heavy metals and residual chemical solvents.

36. **Corrective action** means an action taken by the marijuana testing facility to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance.

37. **Corrective action plan** means a report, including specific corrective actions and a specific date of completion, generated in response to deficiencies or findings of non-compliance.

38. **Cultivation facility** means a facility licensed under OMP Rule to purchase marijuana plants and seeds from other cultivation facilities, to sell adult use marijuana to products manufacturing facilities, to marijuana stores and to other cultivation facilities; and to sell marijuana plants and seeds to other cultivation facilities and immature marijuana plants and seedlings to marijuana stores. A cultivation facility includes a nursery cultivation facility, which may sell seeds, immature plants, and seedlings to consumers.

39. **Cultivator** means a cultivation facility licensed under 28-B MRS, Chapter 1, subchapters 2 and 3 or a person, qualifying patient, exempt caregiver, registered caregiver or registered dispensary that is authorized under 22 MRS, chapter 558-C to cultivate marijuana.

40. **Deficiency** means a failure of the testing facility to meet any one of the requirements in this rule.

41. **Demonstration of capability** means a procedure to establish the ability of the analyst to generate acceptably accurate and precise analytical results.

42. **Department of Administrative and Financial Services (DAFS)** means the Maine Department of Administrative and Financial Services. DAFS includes the Office of Marijuana Policy (OMP), which licenses adult use marijuana establishments, including marijuana testing facilities, and registers medical marijuana program participants including patients, registered caregivers, registered dispensaries, registered manufacturing facilities and registered inherently hazardous extraction facilities.

43. **Department of Health and Human Services (DHHS)** means the Maine Department of Health and Human Services. DHHS includes the Maine Center for Disease Control and Prevention (CDC), which certifies, through its Maine Marijuana Certification Program, the technology and testing methods used by marijuana testing facilities under this Rule.

44. **Disciplinary action** means any action taken by the CDC to limit, suspend, revoke, or deny the certification of an MTF as a result of the MTF's violation or other nonconformance with this rule, 28-B MRS, chapter 1, or other rules promulgated by DHHS or DAFS.

45. **Edible marijuana product** means a marijuana product intended to be consumed orally, including, but not limited to, any type of food, drink or pill containing marijuana.

46. **Exempt caregiver** means a medical marijuana caregiver who is exempt from the registration requirements of 22 MRS § 2425-A.

47. **Facility director** means the individual who is legally authorized to direct the activities of a testing facility and who commits the appropriate resources to comply with this rule.

48. **Field of testing** means those programs, matrices, methods or analyte combinations, for which certification is offered.

49. **Finished plant material** means marijuana that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds and any dead leaves or stems.

50. **Foreign material** means any physical contaminant or filth, including without limitation hair, insects, feces, packaging contaminants and manufacturing waste and by-products.

51. **Full active license** means a license issued by the Department of Administrative and Financial Services, Office of Marijuana Policy to a marijuana testing facility that has received CDC full certification and ISO/IEC 17025:2017 accreditation for at least one technology and analyte that authorizes testing of marijuana or marijuana products in accordance with 28-B MRS, Chapter 1, subchapters 2 and 6 and this rule.

52. **Full certification** means certification granted by the CDC to an MTF that has received ISO/IEC 17025:2017 accreditation and meets all other requirements of this Rule and authorizing it to seek an active license from DAFS.

53. **Homogeneity** means the amount of marijuana or marijuana concentrate and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or each portion of the product or concentrate, or a representative sample.

54. **Increment or sample increment** means a smaller sample that, together with other increments, makes up the primary sample.

55. **ISO/IEC 17025:2017** means the general requirements for the competence of testing and calibration laboratories issued in 2017 joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission.

56. **Licensee** means a natural person or business entity licensed pursuant to 28-B MRS, Chapter 1, subchapters 2 and 5 to operate an adult use marijuana establishment.

57. **Limit of detection (LOD)** means an estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect.

58. **Limit of quantitation** means the minimum level, concentration or quantity of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

59. **Manufacturer** means a manufacturing facility licensed under 28-B MRS, Chapter 1, subchapter 2 or a person, qualifying patient, registered caregiver or registered dispensary that is legally allowed to manufacture under 22 MRS, chapter 558-C.

60. **Marijuana** means the leaves, stems, flowers and seeds of a marijuana plant, whether growing or not. "Marijuana" includes marijuana concentrate but does not include hemp as defined in 7 MRS §2231 or a marijuana product.

61. **Marijuana concentrate** means the resin extracted from any part of a marijuana plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin, including, but not limited to hashish. In determining the weight of a marijuana concentrate in a marijuana product, the weight of any other ingredient combined with marijuana or marijuana concentrate to prepare the marijuana product may not be included.

62. **Marijuana flower** means the pistillate reproductive organs of a mature marijuana plant, whether processed or unprocessed, including the flowers and buds of the plant. Marijuana flower does not include marijuana trim or whole mature marijuana plants.

63. **Marijuana plant** means all species of the plant genus cannabis. Including but not limited to a mother plant, a mature marijuana plant, an immature marijuana plant or a seedling, but it does not include a marijuana product or "hemp" as defined in 7 MRS § 2231.

64. **Marijuana product** means a product composed of marijuana or marijuana concentrate and other ingredients that is intended for use or consumption. "Marijuana product" includes without limitation an edible marijuana product, a marijuana ointment and a marijuana tincture. Marijuana product does not include marijuana concentrate.

65. **Marijuana store** means a facility licensed under Title 28-B to purchase adult use marijuana, immature marijuana plants and seedlings from a cultivation facility; to purchase adult use marijuana and adult use marijuana products from a products manufacturing facility; and to sell adult use marijuana, adult use marijuana products, immature marijuana plants and seedlings to consumers.

66. **Marijuana testing facility (MTF)** means an entity licensed according to 28-B MRS §503, including those also registered as marijuana testing facilities in accordance with 22 MRS §2423-A, to test marijuana, marijuana products and other substances for research and development and to analyze contaminants in and the potency and cannabinoid profile of samples in an approved location.

67. **Marijuana trim** means any part of a marijuana plant, whether processed or unprocessed, that is not marijuana flower or a marijuana seed.

68. **Marijuana waste** means marijuana, marijuana plants or marijuana products that are unfit for retail sale for reasons including without limitation failed mandatory testing, expired products or crop failure.

69. **Matrix** means the component or substrate that contains the analyte of interest.

70. **Matrix spike** means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.

71. **Method** means a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis or quantification), systematically presented in the order in which they are to be executed.

72. **Method blank** means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation.

73. **Method detection limit** means the minimum measured concentration of a substance that can be reported with 99-percent confidence that the measured analyte is distinguishable from method blank results.

74. **Moisture content** means the percentage of water in a dry sample, by weight.

75. **Mycotoxin** means any toxic substance produced by a fungus and especially a mold.

76. **National Institute of Standards and Technology (NIST)** means a federal agency of the United States Department of Commerce's Technology Administration.

77. **Nonconformance or noncompliance** means a failure of a testing facility to meet any requirement in this rule.

78. **Non-target organism** means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

79. **Percent recovery** means the percentage of a measured concentration relative to the added (i.e. spiked) concentration in a reference material, matrix spike sample or matrix spike duplicate.

80. **Plant regulator** means any substance or mixture of substances intended through physiological action for accelerating or retarding the rate of growth or rate of maturation or for otherwise altering the behavior of plants or the produce thereof. "Plant regulator" does not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants or soil amendments.

81. **Practical experience** means hands-on post-secondary-education testing facility experience, using equipment, instruments, kits and materials routinely found in a testing facility.

82. **Primary sample** means a portion of marijuana or marijuana products collected from a production batch for testing.

83. **Production batch** means a prepared marijuana product that is finished plant material, marijuana concentrate or marijuana products made at the same time, using the same methods, equipment and ingredients.

84. **Products manufacturing facility** means a facility licensed under Title 28-B to purchase to adult use marijuana from a cultivation facility or another products manufacturing facility; to manufacture, label and package adult use marijuana and adult use marijuana products; and to sell adult use marijuana and adult use marijuana products to marijuana stores and to other products manufacturing facilities.

85. **Proficiency test** means an evaluation of a testing facility's performance against pre-established criteria, by means of inter-testing facility comparisons of test measurements.

86. **Proficiency test sample** means a sample prepared by a party independent of the testing facility tasked with evaluating the sample, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing facility evaluating the sample and its personnel.

87. **Provisional certification** means the process by which CDC evaluates and recognizes an MTF as meeting the requirements of this Rule with the exception ISO/IEC 17025 accreditation, for which an application must be pending.

88. **Provisional active license** means a license issued by DAFS to a marijuana testing facility that has received CDC provisional certification and has applied for, but not yet received, ISO/IEC 17025:2017 accreditation for at least one technology and analyte that authorizes testing of marijuana or marijuana products in accordance with 28-B MRS, Chapter 1, subchapter 2 and 6 and this rule.

89. **Precision** means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision serves as a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

90. **Preservation** means any conditions under which a sample must be kept to maintain chemical and/or biological integrity prior to analysis.

91. **Proficiency testing** means a way to evaluate a testing facility's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.

92. **Proficiency testing program** means the aggregate of providing rigorously controlled and standardized samples to a testing facility for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating testing facilities.

93. **Proficiency test sample** means a sample, the composition of which is unknown to the testing facility, provided to test whether the testing facility can produce analytical results within the specified acceptance criteria.

94. **Protocol** means the detailed written procedure for field and/or testing facility operation (e.g., sampling, analysis) that must be strictly followed.

95. **Qualifying patient** means a person who possesses a valid certification for the medical use of marijuana pursuant to 22 MRS § 2423-B.

96. **Quality assurance (QA)** means a set of operating principles that enable testing facilities to produce defensible data of known accuracy and precision. Quality assurance includes without limitation employee training, equipment preventative maintenance procedures, calibration procedures and quality control testing.

97. **Quality control (QC)** means the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet the stated requirements established by the client; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

98. **Quality control sample** means a sample used to assess the performance of all, or a portion of, the measurement system. One of any number of samples, such as certified reference materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

99. **Quality assurance manual** means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability and implementation of an agency, organization or marijuana testing facility, to ensure the quality of its product and the utility of its product to its users.

100. **Quality system** means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability and implementation plan of an organization for ensuring quality in its work processes, products (items) and services. The quality system provides the framework for planning, implementing and assessing work performed by the organization and for carrying out required QA and QC activities.

101. **Quantitate** means to undertake the arithmetic process of determining the amount of analyte in a sample.

102. **Raw data** means the documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, un-tabulated sample results, QC sample results, chromatograms, instrument outputs and handwritten records.

103. **Reagent** means a compound or mixture added to a system to cause a chemical reaction, or test if a reaction occurs. A reagent may be used to determine whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

104. **Reference material** means a material or substance, one or more of which the property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

105. **Reference method** means a method by which the performance of an alternate method is measured or evaluated.

106. **Registered caregiver** means a caregiver who is registered by OMP pursuant to 22 MRS § 2425-A.

107. **Registered dispensary** or **dispensary** means an entity registered under 22 MRS § 2425-A that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, sells, supplies or dispenses marijuana or related supplies and educational materials to qualifying patients and the caregivers of those patients.

108. **Relative standard deviation** means the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100 and is calculated using the following equation: **RSD = (s / x) × 100%**, where s = standard deviation and x = mean recovery. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used.

109. **Replicate** means two or more substantially equal aliquots analyzed independently for the same parameter.

110. **Reporting limit** means the lowest level of an analyte that can be accurately recovered from the matrix of interest (e.g., the level of quantitation).

111. **Requester** means a person who submits a request to a certified testing facility for state-mandated testing of marijuana or marijuana products.

112. **Sample** means, as applicable, an amount of:
    a. Marijuana or marijuana product provided to a testing facility by a marijuana establishment or other person for testing or research and development purposes in accordance with 28-B MRS, chapter 1, subchapter 6; or
    b. Adult use marijuana or adult use marijuana product collected from a licensee by DAFS for the purposes of testing the marijuana or marijuana product for quality control purposes pursuant to 28-B MRS §512(2).

113. **Sampler** means a person authorized to collect samples of marijuana, marijuana products and marijuana concentrates.

114. **Sampling date** means the date that a sample was collected in the field, in order to be reported as such, when reporting the sample results to testing facility clients or regulatory programs.

115. **Sanitize** means to sterilize, disinfect or make hygienic.

116. **Solid** means a matrix that includes soils; sediments; solid waste; and sludges.

117. **Standard** means the certified reference materials produced by NIST or other equivalent organization and characterized for absolute content, independent of analytical method or the dilutions made from these certified reference materials for the purposes of calibration or determining accuracy of a test method.

118. **Standard operating procedure (SOP)** means a written document that details the method for an operation, analysis or action, with thoroughly prescribed techniques and steps. SOPs are officially approved by the testing facility's senior management as the methods for performing certain routine or repetitive tasks.

119. **Synthetic cannabinoid** means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce psychoactive effects like those of marijuana.

120. **Target organism** is an organism that is being tested for in an analytical procedure or test method.

121. **Target or target analyte** means an analyte or list of analytes within a test method that may be analyzed and for which the testing facility has obtained certification from the certification officer to test as part of a field of testing.

122. **Technology** means a specific arrangement of analytical instruments, detection systems and/or preparation techniques.

123. **Technology Analyte Table (TAT)** means the table used to identify methods, analytes, programs and matrices available for certification.

124. **Testing or test** means the research and analysis of marijuana, marijuana products or other substances for contaminants, safety or potency. "Testing or test" does not include cultivation or manufacturing.

125. **THC** is tetrahydrocannabinol (THC, delta- 8 THC and delta-9 THC), CAS number 1972-08-3.

126. **THCA** is tetrahydrocannabinolic acid, CAS number 23978-85-0.

127. **Total CBD** is the combined amount of CBD and CBDA.

128. **Total THC** is the combined amount of THC and THCA.

129. **Tincture** means a liquid edible marijuana product with a concentration of greater than 1 mg of THC per ounce of liquid.

130. **Traceability** means the ability to trace the history, application or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

131. **Unusable** means that the marijuana can no longer be smoked, eaten, ingested, topically applied or otherwise ingested. Nor can the marijuana be further manipulated in a manner to extract more than a trace amount of cannabinoid.

132. **Validation** means the confirmation by examination and objective evidence that the requirements for a specific intended use are fulfilled.

133. **Verification** means the confirmation by examination of, and provision of, objective evidence that specified requirements have been fulfilled. Verification refers to the process of examining a result of a given activity to determine conformance with this rule.

134. **Water activity** means a measure of the quantity of water in a product that is available, and therefore capable of, supporting bacteria, yeasts and fungi. Water activity is reported in the unit A^w.

Section 2 – General CDC Certification and ISO/IEC 17025: 2017 Accreditation Requirements Prior to Issuance of a Marijuana Testing Facility License

Section 2.1 – Certification of Marijuana Testing Facility Required Prior to Issuance of a Full Active or Provisional Active License

An MTF must obtain certification by DHHS, CDC, as described in this Rule, before DAFS, OMP will issue to that MTF a full active or provisional active license.

2.1.1. MTF General Requirements. The MTF must:

A. Be an entity that can be held legally responsible;
B. Carry out its testing activities in such a way as to meet the requirements of this rule and to meet the needs of clients in accordance with the MTF's quality assurance manual;
C. Employ technical management and personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties and identify departures from the management system and initiate actions to prevent or minimize such departures;
D. Use personnel employed by, or under contract to, the MTF, and where contracted and additional technical and key support personnel are used, ensure that such personnel are supervised and competent and that they work in accordance with the MTF's quality system;
E. Have a written policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work or diminish confidence in its competence, impartiality, judgement or operational integrity;
F. Have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
G. Authorize specific personnel to perform particular types of sampling and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
H. Authorize specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.

2.1.2. Certification may be full or provisional. An MTF must receive from the CDC full or provisional certification for at least one analyte and technology to be used for the testing of adult use marijuana and adult use marijuana products before that MTF can seek a full active or provisional active license from OMP.

A. Full certification will be granted by the CDC to an MTF that can demonstrate that it has applied for and received ISO/IEC 17025:2017 accreditation and that it meets all other requirements of this Rule.
B. Provisional certification will be granted by the CDC to an MTF that can demonstrate that it has had an application accepted for, but has not yet received nor been denied, ISO/IEC 17025:2017 accreditation and that meets all other requirements of this rule.
C. Certification may be denied when an applicant has deficiencies and the certification officer determines that the applicant cannot consistently produce valid data.

Section 2.2 - ISO/IEC 17025:2017 Accreditation Requirements for CDC MTF Certification

2.2.1. The MTF must demonstrate ISO/IEC 17025: 2017 accreditation before the CDC will issue a full testing facility certification. The MTF may apply for full certification for only those fields of testing accredited by ISO/IEC 17025:2017. The MTF may apply for an OMP-issued full active license for only those fields of testing for which it has received ISO/IEC 17025:2017 accreditation and CDC certification. An on-site inspection by CDC will be required.

2.2.2. The MTF must apply for ISO/IEC 17025:2017 accreditation before the CDC will issue a provisional testing facility certification. An MTF applicant meeting all general requirements for certification, except for ISO/IEC 17025:2017 accreditation, may apply to the CDC for provisional certification by submitting a complete application and required fees. Following an on-site inspection of an applicant that has not received ISO/IEC

17025:2017 accreditation, the CDC will perform a review of data validation studies and a review of all other proof that the MTF has met certification requirements, and if the CDC determines the MTF meets all requirements, the CDC may grant the applicant a provisional certification. The provisional certification, if granted, expires 12 months from the date of issuance.

A. The MTF may apply for an OMP-issued provisional active license for only those fields of testing included in the application for ISO/IEC 17025:2017 accreditation.
B. Upon receipt of ISO/IEC 17025:2017 accreditation, the MTF must demonstrate proof of accreditation to OMP and the CDC within 5 business days. Upon receipt of such notice and following confirmation of accreditation, the CDC will issue to the MTF full certification for the accredited technologies and analytes which will expire on the same date as the originally issued provisional certification. An MTF can request a change in licensure status from provisional active to full active licensure for the remainder of the term of the originally issued provisional active license. Nothing in this section shall be construed to extend the term of certification or licensure beyond the term of the originally issued provisional certification or provisional active licensure.
C. Before the expiration of its provisional certification, the MTF must obtain ISO/IEC 17025:2017 accreditation for at least one field of testing included in its accreditation application; otherwise it must cease all operations until such accreditation is obtained for at least one field of testing.
D. If ISO/IEC 17025:2017 accreditation is denied to the MTF holding provisional certification, the facility must notify the CDC of the denial within one business day of receipt of the denial. The CDC shall revoke the provisional certification, upon the MTF's notification of denial of ISO/IEC 17025:2017 accreditation. Upon revocation of a provisional certification by the CDC, OMP shall revoke immediately the MTF's provisional active license.

Section 3 – Certification of Testing Facilities

Section 3.1 - Certification Required

An MTF may test marijuana or marijuana products only if it holds a current certification from DHHS, CDC. Initial certification will be for a period of 1 year, and annual recertification is required.

3.1.1. Applications must meet all CDC requirements.

A. At a minimum, the application for certification must include:
   (1) The name of the facility director in charge of the MTF and each employee's qualifications or job descriptions;
   (2) Resumes that document appropriate experience and education, including college transcripts and evidence of a completed degree, for personnel specified in section 4;
   (3) A quality assurance manual, meeting the specifications of subsection 3.2;
   (4) Standard operating procedures, meeting the specifications of subsection 3.3; and
   (5) The fields of testing for which the applicant seeks provisional certification or certification using the technology analyte table (TAT) maintained by the program and proof of ISO/IEC 17025:2017 accreditation for such fields of testing or, if applying for a provisional certification, proof that the applicant has submitted an approved application for ISO/IEC 17025:2017 accreditation for such fields of testing.

B. Applications for certification will not be considered complete until payment of the non-refundable application fee.

C. The MTF must submit the following additional documentation to obtain provisional or full certification from the CDC:
   (1) A description of the organization and management structure of the MTF, its place in any parent organization and the relationships between quality management, technical operations and support services;
   (2) A management plan defining the responsibilities of key personnel in the organization who have any involvement or influence on the testing, and if the MTF is part of an organization performing activities other than testing, identifying potential conflicts of interest;
   (3) Written policies and procedures that ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; and
   (4) A written policy defining legal chain of custody protocols and including procedures to control access to certificate of analysis data and other testing data to prevent it from being falsified or manipulated.

3.1.2. Certification is granted for specified matrices, technology and analytes.

A. The CDC will only certify applicants for the matrices, technologies and analytes required for testing under this rule.

B. The CDC may, at its discretion, allow applicants to submit an application to expand the scope of its certification for one or more of the fields of testing on an individual basis rather than requiring the applicant to meet all fields of testing for all available testing types.

C. The CDC must conduct a comprehensive on-site inspection of each MTF prior to granting certification. Following its inspection, the CDC must issue a written initial on-site assessment report which identifies any deficiencies noted during the CDC inspection. In order to receive certification, the MTF must correct any deficiencies identified and provide documentation of the correction to CDC within 30 days of receipt of the initial on-site inspection report.

3.1.3. An MTF must maintain its CDC certification at all times to remain licensed by DAFS.

A. The CDC may, upon reasonable cause, complaint, or to assess continued compliance with this rule, conduct an onsite inspection or review written or electronic records to determine the MTF's compliance with the certification requirements described in this section.

B. Upon the finding of significant or intentional deviation from certification requirements or if the MTF refuses to permit access to the site or records, the CDC may suspend or revoke the MTF's certification.
   (1) An MTF may not conduct testing of marijuana or marijuana products while its certification is suspended or revoked.
   (2) The CDC shall communicate any suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.
   (3) Simultaneously, the CDC shall inform OMP of its actions.

C. Annual recertification is required.
   (1) The recertification application shall include at minimum, the following:
      (a) Any changes to assertions made during initial certification or most recent recertification;
      (b) Any fines, enforcement or letters of warning by OMP;
      (c) Copies of updated SOPs;
      (d) Updated copies, at the CDC's discretion, of any materials required for initial certification.
   (2) The CDC may consider an MTF's compliance with certification requirements, proficiency testing, accuracy of testing and reporting implicated in this rule when determining whether to renew the MTF's certification.

Section 3.2 - Quality Assurance Program and Manual

3.2.1. The MTF must develop and implement a quality assurance program. The program must be sufficient to ensure the reliability and validity of the analytical data produced by the MTF. The MTF operations must also meet the requirements of the ISO 17025:2017 accreditation.

3.2.2. The MTF must develop and maintain a written quality assurance program manual.

A. The manual must contain the following elements:
   (1) Document title;
   (2) Identification on each page to ensure that the page is recognized as part of the manual and clear identification of the end of the manual;
   (3) The MTF's name and address;
   (4) Identification of the MTF's approved signatories;
   (5) A revision number;
   (6) A date indicating when the revision became effective;
   (7) A table of contents, applicable lists of references, glossaries and appendices;
   (8) Listing of all certified testing methods;
   (9) Relevant organizational charts showing the organization and management structure of the MTF and, if applicable, its place within a larger business entity; and
   (10) Job descriptions of key staff and reference to the job descriptions of other MTF staff;

B. The manual must address all aspects of the MTF's quality assurance program, including without limitation the following:
   (1) Quality control;
   (2) Quality assurance objectives for measurement data;
   (3) Traceability of all data, analytical results and certificates of analysis;
   (4) Equipment preventative maintenance;
   (5) Equipment calibration procedures and frequency;
   (6) Performance and system audits;
   (7) Corrective action;
   (8) Record retention, including retention of quality assurance records;
   (9) Document control;

(10) Standardization of testing procedures;
(11) Method validation;
(12) Maintenance, calibration and verification procedures;
(13) Major equipment, support equipment and reference measurement standards (e.g., NIST traceable thermometers and weights);
(14) Verification practices, which may include proficiency testing programs, use of reference materials, internal quality control processes and inter-MTF comparisons;
(15) Reporting analytical results and generating the certificate of analysis;
(16) Traceability of measurements;
(17) Adoption of new testing methods;
(18) Handling of samples, including subcontract testing;
(19) Collection and transportation of samples;
(20) Feedback and corrective action related to testing discrepancies or departures from documented policies and procedures;
(21) Policy for permitting departures from documented policies and procedures or from standard specifications;
(22) Handling of complaints;
(23) Protection of confidentiality and proprietary rights;
(24) Data review;
(25) Chain of custody forms;
(26) Annual internal audits;
(27) Evaluation of employee credentials;
(28) Employee training, including initial data integrity training for new personnel and annual data integrity training for all current employees with written documentation of attendance;
(29) Electronic signatures, where applicable;
(30) How data accuracy and precision are determined for each accredited method and analyte within each test category;
(31) Disposal of marijuana waste; and
(32) Review of all new work to ensure that the MTF has appropriate facilities and resources before commencing such work; and
(33) Meeting all applicable ISO 17025:2017 accreditation requirements.

C. The manual may include separate procedures or incorporate documents by reference.

3.2.3. The quality assurance program and manual must be reviewed and updated regularly to remain current.

A. The facility director and quality assurance officer must review, amend if necessary and approve the quality assurance program and manual.
(1) Routine review is required at least annually.
(2) The facility director must also review and amend the quality assurance program and manual whenever there is a change in methods, MTF equipment or facility director.
(3) Documentation of the review process must include the scope of the review, identification and signature of the reviewer and the date the review was completed.

B. Method detection limits and reporting limits may be determined by methods used by the U.S. Environmental Protection Agency.
(1) The MTF may use the procedure for determining the method detection limit described in 40 C.F.R. Part 136, Appendix B, revised as of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017; or
(2) Other methods published by the federal U.S. Food and Drug Administration for the determination of limit of detection (LOD) and limit of quantitation including Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, April 2015.

Section 3.3 - Standard Operating Procedures (SOPs).

3.3.1. Written SOPs are required. The MTF must possess written SOPs used by MTF personnel for the analysis of samples and must prepare written procedures for all MTF activities, including, but not limited to, sample collection, sample acceptance, sample analysis, operation of instrumentation, generation of data and performance of corrective action.

A. Only the facility director, quality assurance officer or designee may make changes to SOPs.
B. Such changes are effective only when documented in writing and approved by the facility director or quality assurance officer.
C. The SOPs must be formatted to include:
    (1) A table of contents;
    (2) A unique identification of the SOP, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the manual and a clear identification of the end of the manual;
    (3) Page numbers;
    (4) The MTF's name;
    (5) A revision number; and
    (6) A date indicating when the revision became effective.
D. Each analytical method SOP must include or reference the following topics, where applicable:
    (1) Identification of the method;
    (2) Applicable matrix or matrices;
    (3) Limits of detection and quantitation;
    (4) Scope and application, including parameters to be analyzed;
    (5) Summary of the method;
    (6) Definitions;
    (7) Interferences;
    (8) Safety;
    (9) Equipment and supplies;
    (10) Reagents and standards;
    (11) Sample collection, preservation, shipment and storage;
    (12) Quality control (QC);
    (13) Calibration and standardization;
    (14) Procedure;
    (15) Data analysis and calculations;
    (16) Method performance;
    (17) Pollution prevention;
    (18) Data assessment and acceptance criteria for QC measures;
    (19) Corrective actions for out-of-control data;
    (20) Contingencies for handling out-of-control or unacceptable data;
    (21) Waste management;
    (22) References; and
    (23) Any tables, diagrams, flowcharts and validation data.
E. For pesticide analysis, the SOP must include established and documented detection limits for each matrix type.

3.3.2. Written SOPs are requirements of certification and licensing and must be followed.

A. Actual practice must conform to the written procedures.
    (1) The MTF must maintain copies of the methods from which the procedures are developed and must ensure that the applicable requirements are incorporated into each procedure.
    (2) A copy of each procedure must be available to all personnel that engage in that activity.
    (3) An analyst must use the MTF’s SOP beginning on its effective date.

B. Standard operating procedure requirements may be considered confidential material, and OMP and the CDC may not disclose the information except in conjunction with agency actions.
C. The MTF must maintain a record of effective dates for all procedures and must review SOPs at least annually. A copy of the procedure and the record of effective dates must be maintained for the same period that records of the data generated by those procedures are required to be maintained.
D. The MTF must keep all standard operating procedures on the MTF premises and in the field, as necessary, and must ensure that each standard operating procedure is accessible to MTF personnel during operating hours. The MTF must make the standard operating procedures available to the CDC upon request.
E. All changes to the SOPs must be documented.
    (1) Changes to the SOPs must be incorporated at least annually.
    (2) The MTF's facility director must review, approve, sign and date each SOP and each revision to a SOP.
    (3) The SOPs must include the dates of issue and dates of revision, if any.

Section 3.4 - Proficiency Testing

The MTF must participate in a proficiency-testing program provided by an ISO-17043-accredited proficiency test provider, at least annually by October 31 each year. The CDC may waive proficiency testing requirements if no proficiency tests are available.

3.4.1. Proficiency tests are required.

A. Any MTF seeking to obtain certification must successfully complete at least one proficiency test sample (unless a proficiency test is not available) for each requested field of testing.
    (1) The proficiency test must occur within six months of the date that the MTF submits its application.
    (2) When any MTF is granted certification, it must continue to complete proficiency testing studies for each field of testing and maintain a history of at least one acceptable evaluation for each field of testing out of the most recent two proficiency test sample results submitted to the proficiency test provider.
    (3) To maintain certification, the MTF must complete the annual study, and any corrective action study required, by October 31 each year.
    (4) Failure to participate in a proficiency test may result in disciplinary action against the MTF, including suspension or revocation of certification.
B. Proficiency testing must be conducted according to the following guidelines:
    (1) The MTF must rotate the proficiency tests among MTF staff, so that all methods and all staff performing the methods have participated in proficiency tests over a reasonable planned period, as defined in the MTF quality assurance manual.
    (2) The MTF must analyze the proficiency test samples following the approved MTF standard operating procedures and using the same equipment that are used for testing.
    (3) MTF employees who participate in a proficiency test must sign corresponding analytical reports or attestation statements to certify that the proficiency test was conducted in the same manner as the MTF ordinarily conducts testing.
    (4) The facility director must review and approve all proficiency test samples analyzed and results reported.
    (5) The MTF must authorize the proficiency test provider to release the results of the proficiency test to OMP and CDC at the same time that the results are submitted to the MTF.
    (6) Prior to the closing date of a study, MTF personnel, including corporate personnel, may not:
        (a) Communicate with any individual at another MTF, concerning the analysis of the proficiency test sample prior to the closing date of the study;
        (b) Subcontract the analysis of any proficiency test sample or a portion of a proficiency test sample to another MTF for any analysis;

(c) Knowingly receive and analyze any proficiency test sample or portion of a proficiency test sample from another MTF, for which the results of the proficiency test sample are intended for use for initial or continued certification; or

(d) Attempt to obtain the assigned value of any proficiency test sample.

(7) The MTF must analyze proficiency test samples in the same manner used for routine samples, using the same staff, sample tracking, sample preparation and analysis methods, SOPs, calibration techniques, QC procedures and acceptance criteria.

(8) The MTF must follow sample preparation steps for the proficiency test sample, as instructed by the approved proficiency test provider for which the proficiency test sample was obtained.

(9) Testing facilities under the same ownership may not participate in the same study by the same approved proficiency test provider for the same fields of testing, except when a study is not again available for that field of testing by any approved proficiency test provider within the calendar year.

C. Errors in reporting the proper matrix, the method used or the tested analytes in the proficiency test study by the MTF must be graded as "not acceptable."

3.4.2. MTFs must provide proficiency test results.

A. The MTF must evaluate and report the analytical result for certification as follows:

(1) For instrument technology that employs a multi-point calibration, the working range of the calibration under which the proficiency test sample is analyzed must be the same range as used for routine samples.

(a) A result for any proficiency test at a concentration above or equal to the lowest calibration standard must be reported as the resultant value.

(b) A result for any proficiency test at a concentration less than the lowest calibration standard must be reported as less than the value of the lowest calibration standard.

(c) A result for any proficiency test greater than the highest calibration standard must be diluted to fall within the range of the calibration curve.

(2) For instrument technology (e.g., ICP-AES or ICP-MS) that employs standardization with a zero point and a single point calibration standard, the MTF must evaluate the analytical result in the same range as used for routine samples.

(a) A result for any proficiency test at a concentration above or equal to the reporting limit must be reported as the resultant value.

(b) A result for any proficiency test at a concentration less than the reporting limit must be reported as less than the value of the reporting limit.

(c) A result for any proficiency test greater than the high calibration standard must be diluted to be within the working range.

B. The MTF must ensure that the proficiency test results include the correct physical address of the MTF.

C. The MTF must report the analytical results to the proficiency test provider on or before the closing date of the study using the reporting format specified by the proficiency test provider.

D. On or before the closing date of the study, the MTF must authorize the proficiency test provider to release the MTF's final evaluation report directly to the CDC.

E. The MTF must supply results by authorizing the approved proficiency test provider to release all PT results and corrective action results to the certification officer by an electronic format specified by the certification officer. The CDC must evaluate only results received directly from the proficiency test provider.

F. The MTF may not request a revised report from the proficiency test provider, when the revisions to the report are due to any error on the part of the MTF.

3.4.3. Successful performance is required.

A. The MTF must successfully participate in a proficiency test for each matrix, technology and analyte.

(1) Test results are considered "satisfactory" for an analyte tested in a specific technology, or if the results demonstrate a positive identification of an analyte tested in a specific technology, including quantitative results, when applicable.

(2) An MTF must analyze only the analytes for which proficiency test results were considered "satisfactory."
(3) The reporting of a false-positive result is an "unsatisfactory" score for the proficiency test.

B. The MTF must take corrective action and document corrective action, when the MTF fails to score 100% on a proficiency test.
(1) Within 30 days of receiving an "unacceptable," "questionable," or "unsatisfactory" proficiency test result, an MTF must submit the proficiency-test results and detailed corrective action responses to the CDC.
(a) This information must include root-cause analysis and remedial action plans.
(b) The MTF must not accept samples or analyze the analytes for which proficiency test results were considered "unacceptable," or "unsatisfactory," until completing the corrective action and resolving the problem.
(c) The MTF must enroll in the next available round of proficiency tests.
(d) Such enrollment should be documented in the corrective action plan initiated in response to a proficiency test failure.
(2) The MTF may not continue to report results for analytes that were deemed "unacceptable," "questionable" or "unsatisfactory" if the MTF has two successive failed proficiency test studies for any analyte and technologies.
(3) Within 180 days of an unacceptable or unsatisfactory proficiency test result, the MTF must submit a written report showing whether the MTF successfully implemented the corrective action to the CDC.

C. If the facility fails two successive proficiency test studies for any analyte and technology, certification for that analyte and technology is suspended immediately. Certification may be reinstated pending successful completion of two successive proficiency test studies.

3.4.4. Proficiency test sample study records must be maintained.

A. The MTF must maintain copies of all written, printed and electronic records pertaining to proficiency test sample analyses for 5 years.
B. Proficiency test records must include, without limitation:
(1) Bench sheets;
(2) Instrument strip charts or printouts;
(3) Data calculations;
(4) Data reports; and
(5) Proficiency test study report forms used by the MTF to record proficiency test results.
C. The MTF must make all retained records available to marijuana certification officers during on-site assessments of the MTF.

Section 3.5 - Conducting Annual Internal Audit

A. The MTF must conduct an internal audit at least once per year, or per the ISO/IEC 17025:2017 accrediting body's requirement, whichever is more frequent.
B. The internal audit must cover everything required to be covered by this Rule and ISO/IEC 17025:2017 internal-audit standards.
C. The internal audit will be reviewed during the on-site assessment by the CDC, during an inspection by the CDC, or at the request of the CDC.
D. Failure to conduct an internal audit or failure to submit the results of an internal audit to the CDC may subject the MTF to suspension or revocation of certification.

Section 4 – Required MTF Personnel, Training and Supervision

Section 4.1 - Required Personnel

Certification requires an MTF to employ a qualified facility director and sufficient MTF analysts and staff to handle the anticipated volume of testing. The MTF must either employ a qualified quality assurance officer (QAO) or designate the facility director to fulfill that role. The MTF must ensure that a testing facility director or QAO meeting the requirements of this rule is onsite and available during the hours of operation indicated on the facility's operating plan.

4.1.1. General requirements.

A. All management of the MTF and performance of required testing and related activities must be performed by personnel who meet the required educational and experience requirements.

B. Only degrees issued by, or courses completed at, an accredited college or university may fulfill the educational requirements of this section.

C. To meet practical laboratory experience requirements, prior work experience must:

(1) Have involved full-time work of 30 or more hours per week;

(2) Not have been completed as part of any educational requirement, even if it did not lead to the conferring of a degree; and

(3) Have taken place in a laboratory or MTF performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body

4.1.2. Facility director.

A. To be a facility director of a certified MTF under this rule, a person must meet one of the following:

(1) A doctoral degree in a chemical or biological science and 1 year of practical laboratory experience;

(2) A master's degree in a chemical or biological science and 2 years of practical laboratory experience; or

(3) A bachelor of science degree in a chemical or biological science and 4 years of practical laboratory experience.

B. The facility director must be capable of fulfilling all the following core responsibilities:

(1) Oversee and direct the scientific methods of the MTF;

(2) Ensure that the MTF achieves and maintains quality standards of practice;

(3) Supervise all MTF personnel; and

(4) Be present in the MTF an average of 60% of hours of operation.

C. The facility director may not have been convicted of an offense punishable by 1 year or more in prison and related to conduct involving dishonesty, fraud, deceit or gross negligence with the intent to substantially benefit himself, herself or another or to substantially injure another.

D. The testing facility must appoint a deputy when the testing facility director is absent from the testing facility for more than 15 consecutive calendar days.

(1) The deputy facility director must meet the qualifications for testing facility director or QAO.

(2) Testing facility management must notify OMP and CDC in writing when the absence of the testing facility director is expected to, or in fact exceeds, 60 consecutive calendar days.

E. Any requests for a waiver of any provision under this paragraph must be submitted in writing to the CDC, which reserves the right to deny such a request.

4.1.3. Quality assurance officer (QAO).

A. To be a QAO of a certified MTF under this rule, a person must satisfy one of the following:

(1) Meet the qualification criteria required for a facility director; or

(2) Hold a bachelor's degree in one of the chemical or biological sciences; or

(3) Have completed at least 2 years of college coursework and at least 1 year of practical laboratory experience.

B. The QAO must be capable of fulfilling all the following core responsibilities:
   (1) Ensure that the MTF achieves and maintains quality standards of practice;
   (2) Review MTF quality control data, conduct annual internal audits, notify management of deficiencies found in the quality system, ensure the accuracy and integrity of certificates of analysis and be free from internal and external influences, when evaluating data and conducting audits;
   (3) Provide documented training and/or experience in QA and QC procedures and demonstrate knowledge of the approved analytical methods and quality system requirements, as well as maintain the QA documents up to date;
   (4) Have direct access to MTF management; and
   (5) Whenever possible, conduct functions that are independent from the MTF operations for which they have quality assurance oversight.

C. The QAO, regardless of other duties and responsibilities, must have defined responsibility and authority for ensuring that the management system related to quality and integrity of testing results is implemented and complied with at all times.

D. The QAO duties and responsibilities may alternatively be carried out by the MTF technical director.

4.1.4. MTF analyst. To be an analyst of a certified MTF under this rule, a person must meet one of the following standards:

A. Fulfill the qualification criteria required for the facility director; or

B. Hold a bachelor's degree in one of the chemical, agricultural, environmental or biological sciences; or

C. Demonstrate completion of at least 2 years of college coursework and at least 1 year of practical laboratory experience.

D. Any person who performs analytical tasks must meet the experience and educational requirements of an analyst and must be able to demonstrate proper performance of analytical tasks.

4.1.5 MTF sampler. Any person who performs sample collection for an MTF must meet the experience and educational requirements of a sampler contained in Section 5.1.3 of this Rule and be able to demonstrate appropriate sampling methods.

Section 4.2 - Verification and Maintenance of Personnel Documentation

The MTF must verify and maintain documentation of qualifications of all employees and contracted workers. Required documentation includes the following:

A. Documentation of the employee's education:
   (1) The colleges and universities attended by the employee and the names and addresses of the colleges and universities, the major course of study, dates of attendance, degrees conferred and completion date;
   (2) Official transcripts from the registrar of the colleges and universities attended by the employee showing all courses, course credits, degrees conferred, and dates degrees were conferred; and
   (3) Records from credential evaluation services, including translations of transcripts from non-English-language colleges and universities. For an employee who attended a college or university not located in the United States (U.S.) or its territories, the requirement that the college or university be accredited is satisfied if the educational credentials of the employee are found, by the credential evaluation service, to be equivalent to those of a person who attended an accredited U.S. college or university.

B. Documentation of each employee's experience:
   (1) Name and address of the laboratory or MTF where the employee received non-course related experience, dates of employment, number of hours per week employed and a description of the testing and analytic methods performed by the person; and

(2) Signed documentation of such experience from the director or equivalent of the laboratory or MTF.

C. Records of all individual identification cards including the identification number and the date of issuance and expiration for every principal office, board member and employee of the MTF.

D. Personnel plans reflecting sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. MTF management must:
   (1) Specify and document the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests;
   (2) Establish job descriptions to include the minimum level of qualifications, experience and basic MTF skills necessary for all positions in the MTF;
   (3) Document authority of specific personnel to perform particular types of sampling and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
   (4) Document authority of specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.

E. Records of the relevant authorization(s), demonstration(s) of capability, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information must be readily available and include the date on which authorization and/or competence is confirmed.

F. Documentation of the initials and signatures of anyone analyzing or reviewing data so that the records can be traced back to the individual approving the data.

Section 4.3 - Personnel Training and Supervision

The MTF management must:

A. Provide adequate supervision of staff by persons familiar with methods and procedures;

B. Formulate goals with respect to the education and training skills of the MTF personnel, including:
   (1) Policies and procedures for identifying training needs and providing training of personnel;
   (2) Ensuring relevance of the training program to the present and anticipated tasks of the MTF; and
   (3) Making documentation available upon request from the CDC;

C. Ensure all technical MTF staff has demonstrated capability in the activities for which they are responsible; and

D. Ensure that the training of the MTF personnel is kept up to date (on-going) by providing the following:
   (1) Documentation that each employee has read, understands and uses the latest version of the MTF's quality documents and security plan;
   (2) Training documentation on equipment, techniques and/or procedures;
   (3) Training in ethical and legal responsibilities; and
   (4) Documentation of each analyst's continued performance at least once per year.

Section 5 – Samples for Testing and Research

An MTF must offer a service to collect samples from a cultivator or manufacturer location, maintain a sampling plan for receiving samples, or both.

Section 5.1 - Sampling Protocols for Collecting Samples at Cultivator or Manufacturer Locations

5.1.1. SOPs. If the MTF offers a service to collect samples from a cultivator or manufacturer location (as required for mandatory testing), the MTF must develop and maintain standard operating procedures (SOPs) for this service.

A. SOPs must cover each sampling method, including appropriate equipment and devices and cleaning practices to prevent contamination.
B. The MTF must have details in its SOPs or sampling plan, from appropriate industry reference where possible, on how they will achieve random sampling in unusual production units or circumstances.
C. Each SOP must clearly indicate the effective date of the document, the revision number and the signature of the approving authority.
D. All required SOPs must be readily accessible to all pertinent personnel.

5.1.2. Sampling plans. For each site, the MTF must develop and maintain a sampling plan.

A. Prior to initiating a sampling event, a written sampling plan will be generated detailing the requirements of the project for each site.
B. The sampling plan must specify:
    (1) An adequate sample size for the analyses required, including all required quality control samples and any potential confirmation analysis; and
    (2) Enough representative sample increments to meet the client-specified confidence intervals and the minimum regulation
C. A sampling plan must detail the following:
    (1) Sampling devices;
    (2) Sample size by weight or volume for each production batch, including adequate sample amounts for required quality control samples and confirmation analyses;
    (3) Number of sample increments;
    (4) Storage, including temperature and other environmental factors;
    (5) Random sample selection;
    (6) Proper labeling of samples “For Testing Purposes Only”;
    (7) Transportation, including temperature and other environmental factors;
    (8) Chain of custody for sampling, transportation and testing; and
    (9) Representativeness of the samples collected, including random selection of sampling locations, ensuring the samples collected reflect the total composition of the product
D. Sampling plans must be designed to meet specified sample quality criteria. This requires a sampling plan that includes enough representative sample increments to meet the client-specified confidence intervals
E. The sampling plan will stay consistent for repeated sampling.
F. The sampling plan should be as complete as possible before arriving on the sample site.
G. Any deviation from or addition to the sampling plan must be documented in detail and must be included in the final report.

5.1.3. Sampler Qualifications. Employees or contractors (samplers) who collect samples from cultivators or manufacturers must have a current individual identification card issued by OMP and must meet the following qualifications:

A. Sampler must be physically able to perform the duties.
B. Sampler must pass initial and ongoing demonstrations of capability.
C. Sampler must be authorized to transport the required quantity of marijuana items.
D. When available samplers must complete 8 hours of initial training on various sampling techniques.
E. When available samplers must complete 8 hours of periodic refresher training annually.

5.1.4. Transportation of Samples. A sampler may transport a sample from a cultivator or manufacturer to the MTF for testing and analysis.

A. The sampler shall ensure the samples are not visible to the public. Samples shall be locked in a fully enclosed box, container or cage that is secured to the inside of the vehicle or trailer. For the purposes of this section, the inside of the vehicle includes the trunk.
B. The sampler shall ensure that packages or containers holding marijuana goods samples are neither tampered with nor opened during transport.
C. The sampler shall only travel between cultivators or manufacturers for whom the MTF is conducting regulatory compliance testing and the MTF's premises when engaged in the transportation of samples. A sampler shall not deviate from the travel requirements described in this section, except for necessary rest, fuel or vehicle repair stops.
D. The sampler may transport multiple samples obtained from multiple cultivators or manufacturers at once.
E. No person under the age of 21 years old or non-employee of the MTF shall be in a vehicle or trailer transporting samples.
F. All samples being transported must have a label with the following statement: "For Testing Purposes Only."

Section 5.2 - Sampling Protocols for Accepting Samples Collected by Cultivators or Manufacturers

If the MTF does not offer a service to collect samples from a cultivator or manufacturer location, it must develop and maintain a sampling plan for receiving samples.

5.2.1. SOPs. If the MTF accepts samples for additional analysis from a cultivator or manufacturer, it must develop and maintain SOPs for receiving samples.

A. The SOPs must have detailed chain of custody protocols for receiving the sample, including taking possession of a chain of custody form from the cultivator or manufacturer.
B. The SOPs must require cultivators and manufacturers to address factors such as storage, environmental conditions, transportation of the batch or sample and labeling samples for transport "For Testing Purposes Only."
C. The SOPs must address representativeness of the samples received from the cultivator or manufacturer; the sampling locations must be selected at random by the cultivator or manufacturer, designed so that the samples collected reflect the total composition of the product.
D. The SOPs must be designed to meet specified sample quality criteria. This requires a sampling plan that includes enough representative sample increments to meet the client-specified confidence intervals and the minimum regulation.
E. The SOPs must address volume of sample to be collected by the cultivator or manufacturer from each production batch. This specification will ensure that adequate sample volume is collected for the analyses required, including all required quality control samples and any potential confirmation analysis.

5.2.2. Acceptance of samples.

A. An MTF may accept a sample provided by a cultivator, manufacturer, dispensary, qualifying patient or a registered or exempt caregiver only if the cultivator, manufacturer, qualifying patient or registered or exempt caregiver attests to conducting sampling in accordance with best practice that meets the MTF's requirements.
B. The sample must meet all specifications as set forth in the sampling plan consistent with requirements of this rule and other OMP or CDC guidance.

Section 5.3 – Chain of Custody and Document Control Requirements

Testing facilities must develop and implement a chain of custody protocol to ensure accurate documentation of the handling, storage and destruction of marijuana samples.

5.3.1. Chain of custody forms. The chain of custody protocol must require the use of a chain of custody form that contains, at a minimum, the following:

A. MTF name, physical address and certification number of the MTF analyzing the sample;
B. Cultivator or manufacturer name, physical address and license or registration number; or if a registered caregiver, the registration card identification number; or if an exempt caregiver, the caregiver's name and address; or if a qualifying patient, the patient's name and address;
C. Information regarding each sample increment, as follows:
    (1) Unique sample-increment identifier, as indicated on the sample container;
    (2) Date and time of the sample-increment collection;
    (3) The printed names and signatures of the sampler(s);
    (4) For marijuana products that need to be stored at specific temperatures: All conditions, including sample temperature at time of collection and temperature of the cooler used for transport;
    (5) The printed name and signature of the person at the MTF receiving the samples; and
    (6) The location of the sample within the MTF storage area.

5.3.2. Document control.

A. Each time the sample changes custody, is transported, is removed from storage at the MTF, or is destroyed, the date, time and the names and signatures of persons involved in these activities must be recorded on the chain of custody form.
B. All documents must be controlled and retained in accordance with this rule.
    (1) A sampling plan, the sampling record and chain of custody are required for each batch.
    (2) If there is a quality assurance project plan for the client, the sampling plan can be abbreviated to include the client and MTF information and any variation or modification that occurred in the sampling event.

Section 5.4 - Sample Rejection

A. When samples are received by the MTF, the MTF must check the integrity of the samples. The MTF must deem a sample compromised if one or more of the following has occurred:
    (1) Broken shipping container;
    (2) Evidence that the sample has been tampered with, manipulated, adulterated or contaminated;
    (3) Evidence that the sample was not collected in the manner required by this rule or the MTF's sampling standard operating procedures;
    (4) Missing or incomplete chain of custody form or sampling field log;
    (5) The temperature of the sample is out of the required range; or
    (6) Any other factor that may have negatively impacted the integrity of the sample since its collection.
B. If the sample is rejected, the MTF must document the sampling or handling errors, contact the client, request a re-sample and document the conversation with the client.

Section 5.5 - Sample Collection

A. At minimum, the MTF must develop and implement SOPs for collecting samples that support accurate analyses of cannabinoids, residual solvents and processing chemicals, contaminants, pesticides, microbiological impurities, mycotoxins, water activity, filth and foreign material and heavy metals.
B. The MTF must collect or receive adequate samples of the product in its final form (finished plant material; marijuana concentrate; or a marijuana product).

C. The sampler shall collect at least five increments (by weight) from each un-packaged production batch. The MTF will combine these increments to make one complete sample for testing. A production batch must not exceed 20 pounds of harvested finished plant material.
D. The sampler will collect the required number of increments of prepackaged samples, based on batch size, as stated in Table 5.5-A. Each increment consists of one prepackaged unit.

Table 5.5-A: Prepackaged Samples

Marijuana Product Batch (units)	**Number of Sample Increments**
2-150	2
151-500	3
501-1000	4
1001-2000	5

Section 5.6 - Sample Preparation and Testing

A. The MTF must designate an area for preparation of marijuana product samples for analysis.
B. The preparation area must include:
    (1) Disposable gloves to be worn, to avoid sample contamination;
    (2) Decontaminated tool(s), including stainless steel spatulas, knives and/or disposable pipettes and plastic;
    (3) Decontaminated stainless-steel bowls and implements for homogenizing samples appropriately;
    (4) Clean, decontaminated surfaces for sample processing;
    (5) Decontaminated sample containers appropriate for processing;
    (6) Labels and pens with indelible ink; and
    (7) Necessary supplies for thoroughly cleaning, decontaminating and drying sample preparation tools and equipment between sample.

Section 6 – Testing of Marijuana and Marijuana Products

Section 6.1 - Mandatory Testing Required

An adult use marijuana licensee may not sell or distribute adult use marijuana or an adult use marijuana product to a consumer or to another licensee unless the marijuana or marijuana product has been tested pursuant to this Rule and that mandatory testing has demonstrated that the marijuana or marijuana product does not exceed the maximum level of allowable contamination for any contaminant that is injurious to health and for which testing is required, except that OMP may temporarily waive mandatory testing requirements under this section for any contaminant or factor for which OMP has determined that there exists no licensed MTF in the state capable of and certified to perform such testing.

Section 6.2 - Mandatory Testing and Additional Analysis

Marijuana products must be tested in accordance with this Rule. OMP or a client may request additional analyses which will be specified by the MTF in the written sampling plan.

A. The following tests are mandatory for all marijuana or marijuana products in their final form for consumer use prior to being sold or transferred to a qualifying patient or person 21 years of age or older:
   (1) **Filth and foreign material.** Any visible contaminant, including without limitation hair, insects, feces, mold, sand, soil, cinders, dirt, packaging contaminants and manufacturing waste and by-products.
   (2) **Residual solvents, poisons and toxins.** Acetone, acetonitrile, butanes, ethanol, ethyl acetate, ethyl ether, heptanes, hexane, isopropyl alcohol, methanol, pentane, propane, toluene, total xylenes (m, p, o-xylenes), 1,2-dichloroethane, benzene, chloroform, ethylene oxide, methylene chloride, trichloroethylene and any others used.
   (3) **Pesticides, fungicides, insecticides and growth regulators.** Bifenthrin, cyfluthrin, daminozide, etoxazole, imazalil, myclobutanil, spiromesifen trifloxystrobin, and any others used. MTFs must also report any pesticides that appear on testing and which are the list of 195 pesticides federally prohibited on organic produce.
   (4) **Other harmful chemicals.** Cadmium (Cd), lead (Pb), arsenic (As) and mercury (Hg)
   (5) **Dangerous molds and mildew.** Total yeast and mold, and for any marijuana or marijuana product that is further manufactured after failure of such test, mycotoxins including aflatoxins (B1, B2, G1 and G2) and ochratoxin A.
   (6) **Harmful microbes.** Total viable aerobic bacteria, total coliforms, bile tolerant gram (-) bacteria, enterobacter, *E. coli* (pathogenic strains) and Salmonella (spp.).
   (7) **THC potency, homogeneity and cannabinoid profiles.** THC and any other cannabinoid to be referenced in labeling or marketing materials.

B. Testing for water activity is mandatory for marijuana plant material that is dried and prepared as a product in its final form of intended use and that is to be sold or transferred by a cultivation facility, products manufacturing facility, marijuana store, registered caregiver or registered dispensary.

C. A cultivation facility, products manufacturing facility or registered or exempt caregiver may submit for additional analysis samples of marijuana that is not in its final form for intended use, but such testing shall not be considered mandatory, and marijuana that is further manufactured must then undergo mandatory testing.

D. OMP or its designee will publish a Best Practice Guide that includes a sampling plan and preservation instructions appropriate to each matrix type.

E. An MTF must perform and do a certificate of analysis for any test(s) requested by the CDC or OMP on any sample.

Section 6.3 - Testing Methodology

A. Testing facilities must develop and implement scientifically valid testing methodologies for the chemical, physical and microbial analysis of marijuana and marijuana products. A method validated in accordance with this section is deemed a scientifically valid testing methodology. The MTF must not perform testing using a method that has not been validated.

B. To the extent practicable, the MTF's testing methodologies must comport with the following guidelines:
   (1) U.S. Food and Drug Administration's Bacterial Analytical Manual, 2016;
   (2) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Edition, 2016;
   (3) Methods of analysis for contaminant testing published in the 2016 United States Pharmacopeia and the National Formulary (USP-NF); or
   (4) If the MTF wants to use an alternative scientifically valid testing methodology, the MTF must validate the methodology and submit the standard operating procedure for the new methodology to the CDC.

Section 6.4 - Validation of Non-Standard Test Methods and Modified Standard Test Methods

A. The MTF may use a nonstandard method, an MTF-designed or -developed method, a standard method used outside its intended scope or an amplification or a modified standard method for the analysis of samples, so long as the MTF receives CDC certification for the use of such a nonstandard method.

B. The MTF must validate a desired method to use for the analysis of samples for each matrix. The MTF must use one of the following guidelines for validating a method, depending on the type of method:
   (1) U.S. Food and Drug Administration's Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, 2015; or
   (2) U.S. Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, 2015.

C. At a minimum, the MTF must conduct a level-one (emergency-use) single-MTF validation study for all methods for testing for microbiological impurities or chemicals.

D. An MTF must include and address the criteria listed in Table 6.4-A in the MTF's level-one validation study.

Table 6.4-A. Microbiological-analysis method validation studies.

Criteria	Requirement
Number of target organisms; inclusivity	5
Number of non-target organisms; exclusivity	5
Number of analyte levels per matrix: Qualitative methods	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: Quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level
Reference method comparison	No

E. For purposes of validating standards for microbiological analysis, the following definitions apply:
   (1) "Exclusivity" is the specificity of the test method. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.
   (2) "Inclusivity" is the sensitivity of the test method, meaning its capability to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.

F. For chemical analysis method validation studies:
   (1) When high-concentration reference standards are available, testing facilities must employ direct spiking of the sample matrix.
   (2) When high-concentration standards for matrix spiking are unavailable, matrix spikes may be made through post-processing and dilution spiking of samples before analysis, rather than direct sample-matrix spike.

G. Testing facilities must use reference materials validation studies when marijuana reference materials become available.

Section 6.5 - Certificate of Analysis

A. For each primary sample of a batch tested, the MTF must generate and provide a certificate of analysis to the requester and the CDC within two business days of the completion of the final data review.

B. The certificate of analysis must, at a minimum, contain the following information:
   (1) MTF's name, mailing address and physical address;
   (2) Sample-identifying information, including matrix type and unique sample identifiers;
   (3) Sample history, including date collected, date received by MTF, whether the sample was collected by the MTF or received from a cultivator or manufacturer and date or dates of sample preparations and analyses;

(4) The identity of the test methods used to analyze cannabinoids, residual solvents, pesticides, microbiological contaminants, mycotoxins, heavy metals and, if applicable, terpenes;
(5) Test results for sample homogeneity, if applicable; cannabinoids; residual solvents; pesticides; microbiological contamination; and, if applicable, terpenes;
(6) Test results for water activity and visual inspection for filth and foreign material;
(7) The reporting limit for each analyte tested;
(8) The total primary sample weight in grams, reported to three significant figures;
(9) Whether the primary sample and batch "passed" or "failed" MTF testing;
(10) The licensee for whom the testing was performed, including license number, name and production batch number; and
(11) A disclaimer that not all potential/existing hazards were tested.

C. The MTF must validate the accuracy of the information contained in the certificate of analysis, and the facility director or QAO must sign and date the certificate of analysis.

Section 6.6 - Cannabinoids

A. When testing cannabinoid profile, the minimum representative sample size of 0.5 grams dry weight is required for all marijuana and marijuana products.
B. When testing cannabinoid profile, the MTF must minimally test for and report measurements for the following cannabinoids using instrumentation stated in Table 6.6-A:

Table 6.6-A. Cannabinoid Potency

Cannabinoid Potency as % of weight	**Instrumentation**
Δ^9-THC	LC-DAD, LC-MS, LC-MS/MS or GC-FID
THCA	LC-DAD, LC-MS, LC-MS/MS or GC-FID
CBD	LC-DAD, LC-MS, LC-MS/MS or GC-FID
CBDA	LC-DAD, LC-MS, LC-MS/MS or GC-FID
Total THC (as sum of THCA, delta-8 THC and delta-9 THC)	LC-DAD, LC-MS, LC-MS/MS or GC-FID
Total CBD (as sum of CBDA and CBD)	LC-DAD, LC-MS, LC-MS/MS or GC-FID

Note: Testing Facility calculation for Total THC = delta-8 THC + delta-9 THC + (THCA*0.877)
LC = Liquid Chromatography; DAD = Diode Array Detector; MS = Mass spectrometry; GC = Gas chromatography; FID = Flame ionization detector

C. For samples from production batches, the MTF must report, to three significant figures, the concentration in milligrams per gram (mg/g) or mg/L of the cannabinoids listed in Table 6.6-A. The MTF must report this information in the certificate of analysis.
D. The MTF may test for, and provide test results for, additional cannabinoids, if requested to do so by the client of the MTF; however, these additional tests will not be certified by the CDC.

E. If synthetic cannabinoids are detected during analysis, the COA must report that the batch failed analysis.
F. When testing for homogeneity of cannabinoids in marijuana products:
    (1) The MTF must perform a homogeneity test for Total THC or Total CBD, whichever is purported by the manufacturer to be the largest ingredient content, for each production batch. If the amounts of Total THC and Total CBD are very similar (near 1:1), the MTF must test for homogeneity of Total THC.
    (2) A homogeneity test requires at least two increments, collected separately from those collected for the field primary sample, from different regions of the production batch, following procedures in the CDC's best management practices for sampling marijuana for testing purposes and the MTF's standard operating procedure for sampling.
    (3) The MTF must determine the relative standard deviation of Total THC or Total CBD content between the increments. If the relative standard deviation is greater than 15%, then the batch "fails" the homogeneity test.
    (4) If a homogeneity test is not performed or if a batch fails homogeneity testing, the batch fails and must be destroyed or, at the discretion of OMP, remediated and retested.
    (5) If the product batch passes homogeneity testing, the MTF may perform all other analyses required under this rule.
G. When testing for homogeneity of edible marijuana products, a minimum size sample of 0.5 grams is required.
    (1) The number of samples required for analysis is specified in Table 5.5-A. Each increment constitutes one packaged unit.
    (2) Total THC and, if applicable, Total CBD values between samples must not vary by more than 15% or the product fails testing.

Section 6.7 - Residual Solvents and Processing Chemicals

A. The minimum sample size of 0.5 grams of representative sample is required for residual solvent analysis.
B. The MTF must analyze samples in each production batch for residual solvents and processing chemicals, including but not limited to inherently hazardous substances, in accordance with Table 6.7-A.
    (1) The MTF is not required to analyze for residual solvents and processing chemicals in dried flower, kief and hashish or marijuana products manufactured without chemical solvents.
    (2) The MTF is not required to analyze an orally-consumed tincture marijuana product containing alcohol for residual ethanol.
C. For the purposes of residual solvent testing, the MTF must report that the sample "passed" residual-solvent testing, if the concentrations of residual solvents are reported at or below the residual solvents and processing chemicals action levels in Table 6.7-A below. However, the MTF must report a sample failed if the MTF detects any level of a potentially or inherently hazardous substance which the licensee does not have listed on their operating plan.
D. The MTF must report the solvents and processing chemicals listed in this section, in parts per million (ppm) to three significant figures. The MTF must report this information in the certificate of analysis.
E. The MTF must test both the concentrations of solvents and processing chemicals in the sample within the certificate of analysis, as well as document clearly whether the sample "passed" or "failed" residual solvent and processing-chemicals testing.
F. If the sample fails residual solvent testing, the batch may be remediated in accordance with all applicable rules from OMP.
G. A remediated batch that previously failed a test due to exceeding the action levels for residual solvents must be retested for solvents.
H. The batch must be destroyed when it is either not remediated, or a sample from the remediated batch fails testing.

Table 6.7-A. Concentration Limits for Residual Solvents, mg/kg.

Chemical Name	**CAS No.**	**Cannabis Product**
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Butanes[a]	106-97-8	5000
Ethanol[b]	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Heptanes	142-82-5	5000
Hexane**	110-54-3	290
Isopropyl alcohol[b]	67-63-0	5000
Methanol	67-56-1	3000
Pentane	109-66-0	5000
Propane[a]	74-98-6	5000
Toluene**	108-88-3	890
Total Xylenes (m, p, o-xylenes) **	1330-20-7	2170
1,2-Dichloroethane	107-06-2	1
Benzene**	71-43-2	1
Chloroform	67-66-3	1
Ethylene oxide	75-21-8	1
Methylene chloride	75-09-2	1
Trichloroethylene	79-01-6	1
Any other solvent detected not permitted for use		None Detected

** Due to the possible presence in the solvents approved for use, limits have been listed accordingly

Note**:**

A. USP does not provide residual solvent limits for this solvent, the default USP Class 3 limits for acceptable use solvents was assigned as a limit.
B. Products that are orally consumed and/or topically applied are exempt from ethanol limits.

Section 6.8 - Residual Pesticides and Growth Regulators

A. The minimum sample size is 0.5 grams of representative samples for all marijuana and marijuana products.

B. The MTF must test all finished plant material samples for residual pesticides, including plant regulators, to ensure pesticide use and use of plant regulators are in compliance with applicable rules related to pesticides. Once a batch has passed this testing, the marijuana product resulting from this batch does not need to be tested again for pesticides and growth regulators.

C. The results of pesticide analyses must be less than the MTF's established detection limit for each matrix. The MTF may not adjust the established detection limit for any matrix without approval from OMP and the CDC. The MTF will need to provide documentation of detection limit studies prior to approval of newly adjusted testing limits.

D. The MTF must report the levels detected in milligrams per kilograms (mg/kg) to three significant figures in the certificate of analysis. If a sample is found to contain pesticides above the MTF's detection limit, the sample "fails" pesticide testing.

E. The MTF must analyze pesticides, in addition to those in listed in Table 6.8-A, based on the approach used by USDA in its *2010-2011 Pilot Study: Pesticide Residue Testing of Organic Produce*, November 2012, to analyze 195 prohibited pesticides the USDA has prohibited in organic food. The MTF must utilize analytic procedures in accordance with 7 CFR, Part 205 and the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodologies for determining the presence of contaminants in agricultural products.

   (1) Although no single analytical method currently exists to analyze all 195 prohibited pesticides, testing facilities must analyze as many compounds on the USDA target analyte list for organic food as required by OMP. A marijuana establishment licensee may not use any of the prohibited substances listed in Table 6.8-A, nor may it use any of the 195 prohibited pesticides on the USDA's prohibited pesticides list. A complete list of the USDA National Organic Program prohibited pesticides is included in Appendix A of this rule.

   (2) If result(s) of pesticide analysis indicates the presence of any of the prohibited pesticides, or, if, as an approved pesticide, test result is in excess of the tolerances or maximum residue limits (MRLs) determined unsafe or potentially harmful by the US Environmental Protection Agency (US EPA) for that pesticide, the batch fails.

F. The list of pesticides and growth regulators in Table 6.8-A and Appendix A is not comprehensive, however, the vast majority of available pesticide products are prohibited from use on marijuana. Using a pesticide or growth regulator on a site for which it is not labeled, or applying a pesticide or growth regulator in a manner inconsistent with label instructions is a violation of State and Federal law.

Table 6.8-A. Instrumentation Requirements for Pesticides and Growth Regulators

Pesticide	CAS #	Chemical Class	Instrumentation
Bifenthrin	82657-04-3	Insecticide	GC-ECD; GC-MS/MS OR LC-MS/MS
Cyfluthrin	6859-37-5	Acaricide	LC/UV; LC-MS/MS
Daminozide	1596-84-5	Growth Regulator	LC/UV; LC-MS/MS
Etoxazole	153233-91-1	Insecticide	GC-MS (/MS); LC-MS/MS
Imazalil	35554-44-0	Fungicide	GC-ECD; LC-MS/MS
Myclobutanil	88671-89-0	Fungicide	GC-ECD; GC-NPD; GC-MS/MS; LC-MS/MS
Spiromesifen	283594-90-1	Insecticide	GC-MS; LC-MS/MS
Trifloxystrobin	141517-21-7	Fungicide	GC-NPD; GC-MS/MS

GC = Gas Chromatography; FLD = Fluorescence; LC = Liquid Chromatography; Detector; MS = Mass spectrometry; ECD = Electron Capture Detector; UV = Ultra Violet Detector; NPD = Nitrogen-Phosphorus Detector

Section 6.9 - Heavy Metals

A. The minimum representative sample size is 0.5 grams of all marijuana and marijuana products.
B. When testing for heavy metals, the MTF must analyze all samples for concentrations of the heavy metals listed in Table 6.9-A below.
C. The MTF must report the concentration of each heavy metal in micrograms per gram (µg/kg) in the certificate of analysis.
D. The MTF must report that the sample "passed" heavy-metal testing, if the concentrations of heavy metals listed in the table below are below the following heavy metal action levels.
E. The MTF may test for and report test results for additional metals, if the instrumentation detects additional metals in the samples, or if requested by the State or the client of the MTF testing.

Table 6.9-A. Concentration Limits for Metals, (µg/kg)

Heavy Metal	Inhalation	Ingestion or Suppository	Topical Application	Instrumentation
Cadmium (Cd)	200	500	5000	AA, ICP-OES or ICP-MS
Lead (Pb)	500	500	10,000	AA, ICP-OES or ICP-MS
Arsenic (As)	200	1500	1000	AA, ICP-OES or ICP-MS
Mercury (Hg)	100	3000	1000	CVAA or ICP-MS

AA – Atomic Adsorption; ICP = Inductively Coupled Plasma; OES – Optical Emission Spectrometry;

MS = Mass Spectrometry; CVAA = Cold Vapor Atomic Absorption Review USP 2232

*These limits apply to marijuana and marijuana concentrate intended for ingestion, inhalation or dermal application. These limits are based on inhalation limits described in USP<232> Elemental Impurities-Limits.

Section 6.10 - Microbiological Impurities

A. The minimum, representative sample size of 1.2 grams of finished plant material. The minimum representative sample size of 1.0 g of edible products is required for analysis.
B. The MTF must also test all marijuana concentrates for microbiological impurities. For the purposes of microbiological testing, the MTF must report that the sample "passed" microbiological-impurity testing if the contaminants listed in Table 6.10-A below do not exceed the limits. If the marijuana product is found to have a contaminant in levels exceeding those established as permissible under this rule, then it failed contaminant testing.
C. If a processing method can effectively sterilize the batch, then the batch may be:
    (1) Used to make a concentrate or extract (if unprocessed); or
    (2) Further processed (if processed); or
    (3) Destroyed.
D. If the Marijuana cultivator or manufacturer chooses the option to remediate following a failed fungus or mold test, the batch will need to be retested by the same MTF and will need to include mycotoxin analysis. This will include Aflatoxins (B1, B2, G1 and G2) and Ochratoxin A. The mycotoxin results must be less than 20 ug/kg to be considered a passing result.

Table 6.10-A. Limits for Microbiological Contaminants.

Marijuana Material	**Total Viable Aerobic Bacteria (CFU/g)**	**Total Yeast and Mold (CFU/g)**	**Total Coliforms (CFU/g)**	**Bile Tolerant Gram (-) Bacteria (CFU/g)** **Enterobacter**	**E. coli (pathogenic strains) and Salmonella (spp.)**
Unprocessed and Processed Plant Material	10^5	10^4	10^3	10^3	None detected in 1g sample
CO_2 and Solvent-Based Extracts	10^4	10^3	10^2	10^2	None detected in 1g sample

Based on analytical limits based on American Herbal Pharmacopoeia, Revision 2014.

E. The MTF must report whether the strains listed in Table 6.10-A are detected, or are not detected, in one gram. The MTF must report this information in the certificate of analysis. If any strains are detected, the batch fails testing and may not be released for sale.
F. The MTF may test for and provide test results for additional microorganisms if requested.

Section 6.11 - Water Activity

A. The minimum representative sample size of 0.5 grams of dried flower and 1.0 g of edible products is required for analysis.
B. If the water activity in a dried flower production batch sample is at or below, 0.65 A_w, the sample "passes" water-activity testing.
C. If the water activity in solid and semi-solid edible marijuana products is at, or below, 0.85 A_w, the sample "passes" water-activity testing.
D. The MTF must report the water-activity level of the sample in A_w to two significant figures.
E. The MTF must report this information in the certificate of analysis.
F. The MTF may provide additional information on moisture content and water activity results, if the MTF determines that it is important, or if it is requested.

Section 6.12 - Visual Inspection for Filth and Foreign Material

A. The minimum sample size is 0.5 grams of representative samples.
B. The MTF must visually inspect all samples for signs of filth and foreign material present in the sample. "Filth and foreign material" includes, but is not limited to, hair, insects, feces, packaging contaminants and manufacturing waste and by-products.
    (1) The samples shall not pass if any living or dead insect, at any life cycle stage; one hair; or one count of mammalian excreta is found per three grams of sample.
    (2) The sample shall not pass if more than one fourth of the total area is covered by mold, sand, soil, cinders, dirt or imbedded foreign material.
C. The MTF must report in the certificate of analysis whether the sample "passed" or "failed" visual inspection for filth and foreign material.
    (1) If it fails visual inspection for filth and foreign-material, the batch fails testing.

(2) A production batch that fails must be destroyed unless it can be remediated pursuant to any rules of OMP.
(3) Failed batches not successfully remediated must be destroyed.

Section 6.13 - Terpenes

A. The MTF may also report individual terpene results, as requested.

B. If the product labeling reports that the sample contains discrete terpenes, the MTF must test for those terpenes. The MTF must report to one-hundredth of a percent the concentration in percentage in the certificate of analysis.

Section 6.14 - Quality Control

A. The MTF must use quality control samples, when available, in the performance of each assay for chemical and microbiological analyses. If the MTF cannot get a marijuana standard in matrix, the MTF shall use a second source standard obtained from a second vendor to validate the original calibration stock.
   (1) The MTF must analyze the quality control samples in the exact same manner as the test samples, to validate the testing results.

B. The MTF must run quality control samples with every analytical batch of samples. For chemical analyses, the MTF must prepare and analyze samples in batches of up to 20 samples, to include a method blank, a laboratory control sample, a sample duplicate, a matrix spike sample, and a reference material when available.
   (1) A method blank means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation.
      (a) Method blanks are analyzed under the same conditions, including sample preparation steps, as the other samples in the analytical batch to demonstrate the analytical process does not introduce contamination.
      (b) If the method blank contains analytes of interest greater than half of the reporting limit or limit of quantitation, the data needs to be flagged in the certificate of analysis. If the method blank is above half the reporting limit, the MTF must flag the data.
      (c) If the method blank contains analytes of interest above the limit of quantitation, it should be reanalyzed once. If the method blank is still above the limit of quantification, the MTF should seek to locate and reduce the source of the contamination, and then the entire batch should be re-prepared and reanalyzed. If the method blank results still do not meet the acceptance criteria, and reanalysis is not practical, then the MTF must halt performing the analysis until resolution of this issue. Resolution of the issue requires the reduction of method blank measurements below the limit of quantification.
   (2) A laboratory control sample means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes, (or a material containing known and verified amounts of analytes), and taken through all sample preparation and analytical steps of the procedure, unless otherwise noted in a reference method.
      (a) When reference standards are commercially available in usable concentrations, and are applicable to the method being run, the MTF must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples.
      (b) The MTF must calculate the percent recovery for quantitative chemical analysis, for the laboratory control sample spiked with a known amount of reference standard. The acceptable percent recovery is ±20%.

(c) If the percent recovery is outside of the acceptable range, the MTF must investigate the cause, correct the problem and re-run the batch of samples. If the problem persists, the MTF must re-prepare the samples and run the analysis again, if possible. If a laboratory control sample is performed and fails, it must be noted in the certificate of analysis.

(3) A sample duplicate means a separate aliquot of the sample carried through the complete preparation and analytical procedure.

(a) The acceptance criteria between the primary sample and the duplicate sample must be less than 20% relative percent difference. Relative percent difference is calculated using the following equation: RPD = | (primary sample measurement – duplicate sample measurement) | / ([primary sample measurement + duplicate sample measurement] / 2) × 100%.

(b) Limits must be set at <20% until enough data points are established to create lab defined limits. At no point can lab calculated limits be greater than the 20% listed in this rule.

(4) A matrix spike means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.

(a) When reference standards are commercially available in usable concentrations and are applicable to the method being run, the MTF must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples.

(b) The MTF must calculate the percent recovery for quantitative chemical analysis by analyzing an aliquot of sample spiked with a known amount of reference standard. An aliquot of the sample is analyzed without the spike, and the result is subtracted from the spiked value. The sample result, after subtraction, is divided by the expected result and multiplied by 100. If interferences are present in the sample, results may be significantly higher or lower than the actual concentration contained in the sample. The acceptable percent recovery is 70% to 130%.

(c) If the percent recovery is outside of the range, the MTF must investigate the cause, correct the problem and re-run the batch of samples. If the problem persists, the MTF must re-prepare the samples and run the analysis again, if possible. If a matrix spike is performed and fails, it must be noted in the report.

(5) A reference material means a material or substance one or more of which the property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

(a) When available, reference material must be certified and obtained from an outside source.

(b) If a reference material is not available from an outside source, the MTF must make its own in-house reference material. Reference material made in-house must be made from a different source of standards than what the calibration standards are made from.

(c) The reference material must fall within the quality control acceptance criteria. If it does not, the MTF must document and correct the problem, and if necessary, run the batch again.

C. For microbiological analysis, quality control samples must be run as needed.

D. The MTF must prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of the instrument and quantitation of analyses in samples.

E. All quality control measures must be assessed and evaluated on an ongoing basis. QC acceptance criteria in the MTF's QA manual must be used to determine the validity of data.

F. Upon request by the CDC, the MTF must in a timely manner generate and submit to CDC a quality control sample report that includes QC parameters and measurements, analysis date and matrix.

G. CDC may require in writing reasonable additional quality control measures for any testing methodology as found in previously established Federal or State guidelines such as:
   (1) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Ed., 2016;
   (2) U.S. Food and Drug Administration's NCIMS 2400 Forms, Rev. 04/2019; or
   (3) State of Maine Comprehensive and Limited Environmental Laboratory Accreditation Rule, 10-144 CMR ch. 263 (2018).

Section 7 – Recordkeeping Requirements

Section 7.1 - Recordkeeping Requirements

A. The MTF must maintain analytical records to demonstrate to the CDC the following: the analyst's name; date of analysis; approver of the certificate of analysis and relevant data package; the test method; and the materials used.
   (1) MTF recordkeeping may be on paper or on electronic, magnetic or optical media and must be stored in such a way that the data are readily retrieved when requested by the OMP or the CDC.
   (2) If the MTF recordkeeping is not on paper, the MTF must be able to produce them in hard copy for OMP or the CDC, upon request.
   (3) All MTF records must be kept for a minimum of five years.
   (4) OMP and the CDC must be allowed access to all electronic data, including standards records, calibration records, extraction logs, MTF notebooks and all other MTF-related documents listed below.

B. The MTF must maintain all documents, forms, records and standard operating procedures associated with the MTF's methods, including without limitation the following:
   (1) Current personnel qualification, training and competency documentation, including, but not limited to, resumes, training records, continuing education records, analytical proficiency testing records and demonstration of capability records or attestations for MTF work;
   (2) Method verification and validation records, including records relating to method modification; method detection limit and reporting limit determination; ongoing verification, such as proficiency testing; and reference material analysis;
   (3) Quality control and quality assurance records, including the MTF's quality assurance manual and control charts with control limits;
   (4) Chain of custody records, including chain of custody forms, applicable field sample logs, and record relating to sample receipt, sample descriptions, sample rejections, laboratory information management system (LIMS), sample storage, sample retention and disposal;
   (5) Records relating to purchasing and supply, purchase requisitions, packing slips, and supplier records;
   (6) Certificates of analysis;
   (7) Records of equipment installation, maintenance and calibration, including date; name of person performing the installation, calibration or maintenance; and description of the work performed; internal maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records and daily verification-of-calibration records;
   (8) Customer service records, including include contracts with customers, customer request records, transaction records and customer feedback;
   (9) Records related to the handling of complaints, nonconformities, and corrective action, including records of internal investigations, customer notifications and implementation of corrective action plans;

(10) Internal and external audit records, including audit checklists, standard operating procedures and audit observation and findings reports, including the date and name of the person or persons performing the audit;
(11) Management review records, including technical data review reports and final management review reports, with review date and the identity of the reviewer;
(12) MTF data reports, data review and data approval records, which must include the analysis date and the name of the analysts, including instrument and equipment identification records, records with unique sample identifiers, analysts' MTF notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data and test-method raw data;
(13) Proficiency testing records, including the proficiency test schedule, proficiency test reports, and records of data review, data reporting, nonconforming work, corrective action, quality control and quality assurance;
(14) Electronic data, backed-up data, records regarding the protection of data and MTF-security records, including raw unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, authorized personnel records and MTF-access records and surveillance- and security-equipment records;
(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' MTF notebooks and logbooks, supplier records and all other data-related records; and
(16) MTF contamination and cleaning records, including autoclave records, acid wash logs and records and general MTF safety and chemical-hygiene protocols.

C. If the records are missing or incomplete, or if the MTF does not produce the records for OMP or the CDC upon request, OMP or the CDC may take disciplinary action against the MTF. The MTF shall have 7 calendar days from issuance of request to respond.

Section 7.2 - Data Package Requests

A. The MTF must retain the entire data package for each sample the MTF analyzes for a minimum of five years and make available to OMP or the CDC upon request. The data package must contain, at a minimum, the following information:
(1) The name and address of the MTF that performed the analytical procedures;
(2) The names, functions and signatures of the MTF personnel that performed sample preparation and analyses and reviewed and approved the data;
(3) All sample and batch quality control sample results;
(4) Raw data for each sample;
(5) Instrument raw data, if any;
(6) Instrument test method with parameters;
(7) Instrument tune report;
(8) All instrument calibration data;
(9) Test method worksheets or forms used for sample identification, characterization and calculations, including chromatograms, sample preparation worksheets and final datasheets;
(10) Quality control report with worksheets, forms or copies of MTF notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials and standards used for analysis;
(11) Analytical batch sample sequences;
(12) The field sample log and the chain of custody form; and
(13) The certificate of analysis created, as required under this rule.

B. The MTF must make the data package for a sample available.

C. After the data package has been compiled, the facility director or QAO must:
(1) Review the analytical results for technical correctness and completeness;
(2) Verify that the results of each analysis carried out by the MTF are reported accurately, clearly, unambiguously and objectively and that the measurements are traceable; and

(3) Approve the measurement results by signing and dating the data package prior to release of the data by the MTF.

D. The testing facility must submit requested sample results to the CDC in an electronic format acceptable to the Maine Marijuana Certification Program (MMCP). This includes the reporting of all required laboratory quality control information and associated acceptance limits.

Section 7.3 - Electronic Data

A. Testing facilities must store all raw unprocessed instrument output data files and processed quantitation output files on some form of electronic, magnetic or optical media. The MTF must allow access to these records for inspection and audit.

B. Testing facilities must install, manage and maintain password-protection for electronically stored data, including any certificate of analysis.

Section 8 – Waste Disposal Plan

Section 8.1 – Waste Disposal SOP required

In addition to the SOPs required in Section 3 of this rule, an MTF must possess and follow written SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products. All waste must be managed according to the following requirements:

A. Solid waste, as defined in the *Maine Hazardous Waste, Septage and Solid Waste Management Act*, 38 MRS § 1303-C(29), must be managed in accordance with the *Solid Waste Management Rules*, 06-096 CMR, Ch. 400-425.

B. The MTF must destroy nonhazardous used or unused marijuana test samples in accordance with the facility's standard operating procedure and this rule.

C. To render marijuana goods into marijuana waste, the MTF must grind up the marijuana and mix it with other ground material not suitable for human consumption. The resulting mixture must be at least 50% non-marijuana material. Licensees must render goods into marijuana waste one batch at a time and track that batch through its disposal in the statewide inventory tracking system.

D. It is unlawful for any MTF to dispose of marijuana goods or waste in a trashcan, dumpster or other similar receptacle, unless the nonhazardous goods or waste is composted and made unusable as described in this section. Testing facilities are required to quarantine marijuana goods on the premises for at least 3 business days to permit OMP time to investigate or witness the destruction process.

E. The MTF must document the quarantine, rendering into marijuana waste, and disposal or deposition of the marijuana waste. An MTF may retain and utilize marijuana and marijuana products for use as standards or for method development.

F. Hazardous wastes, as defined by 38 MRS § 1303-C(15), with the exception of infectious and pathogenic wastes, and in 06-096 CMR, Ch. 850, must be managed in accordance with Maine's Standards for Hazardous Waste Facilities Rules, Interim Licenses for Waste Facilities for Hazardous Wastes Rules, Licensing of Hazardous Waste Facilities Rules and Hazardous Waste Manifest Requirements (See 06-096 CMR, Chs. 850-857).

G. If there is a conflict between another applicable rule or regulation and this rule, the more restrictive requirement applies.

Section 9 – Changes to MTF Operations

Section 9.1 - Post-Certification Change Notification

A. The MTF must provide OMP and the CDC with a written notice of any change described below at least thirty calendar days prior to the proposed effective date of the change:
   (1) Change in ownership of the MTF as defined in Section 2 of this rule;
   (2) Change in the MTF's facility director or QAO;
   (3) Changes in the approved location for an analysis;
   (4) Major changes in analytical equipment;
   (5) Change to approved premises floor plan submitted to OMP in the MTF's license application, including without limitation proposed premises expansion;
   (6) Discontinuation of, or failure to launch, MTF activities.

B. When there is a change in location or change in technology of analysis, the MTF must provide results of proficiency testing samples or a demonstration of capability, analyzed in the new MTF location or analyzed under a change in instrumentation.

Section 9.2 - Post-Certification Change Notification

Unless the MTF provides timely notification of the above changes and receives prior approval or waiver of the requirement of prior notice and approval by OMP and the CDC, the certification of the field of testing is void and must be returned to the CDC.

Section 10 – Denial, Suspension, Limitation or Revocation of Certification by the CDC

Section 10.1 - Denial, Suspension or Revocation of Provisional Certification

A. The CDC may suspend a provisional certification if the provisional licensee fails to obtain ISO/IEC 17025:2017 accreditation within the period of the original provisional certification.
B. The CDC shall revoke a provisional certification if the provisional licensee is denied ISO/IEC 17025:2017 accreditation.

Section 10.2 - Denial, Suspension or Revocation of Certification

A. The CDC may deny, revoke, suspend, or not renew the certification of any MTF for engaging in conduct that includes, but is not limited to, the following:
   (1) Failure to observe any term of certification;
   (2) Failure to observe any order, request or other directive made under the statutory authority vested in OMP or the CDC;
   (3) Engaging in, aiding, abetting, causing or permitting any action prohibited under 22 MRS, chapter 558-C or 28-B MRS, chapter 1;
   (4) Failure to comply with any regulatory requirement of these rules and any other applicable state regulation or statute;
   (5) Making false or deceptive representation on any application for certification or renewal thereof;
   (6) Failure to maintain professional, competent and ethical standards of practice;
   (7) Making false or deceptive representation of any testing results and reports thereof;
   (8) Failure to provide timely and accurate data reporting;
   (9) Engaging in false or deceptive advertising; or
   (10) Providing services associated with product labeling for a licensed establishment, registered dispensary, or an exempt or registered caregiver; a principal officer, board member of a registered dispensary; or an employee or assistant of a registered dispensary or an exempt or registered caregiver who has a financial or other interest in the MTF.
B. The CDC may deny, revoke or suspend the certification of any MTF if the municipality wherein the MTF is located has informed OMP that it has revoked, suspended or not renewed local authorization of the MTF.
C. The CDC shall communicate any denial, suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.

Section 11 – Certification Fees for Testing Facilities

Section 11.1 - CDC Certification Fees

The following fees are required for MTF certification. However, these fees are subject to an annual maximum of $2,500 per MTF.

A. Provisional Certification: An MTF that has applied for but has not yet obtained ISO/IEC 17025:2017 accreditation is required to pay a base fee of $1,250 plus appropriate technology fees to apply for a provisional certification.
B. Full Certification: The CDC shall issue full certification to an MTF holding provisional certification in good standing once the MTF provides proof of ISO/IEC 17025:2017 accreditation and pays an application fee of $500.
C. Full Certification without Provisional Certification: An applicant that has received ISO/IEC 17025:2017 accreditation but does not have provisional certification may apply for full certification directly. The MTF is required to pay an application fee of $1,000 for initial certification, plus applicable technology fees.
D. Renewal: The MTF is required to pay an annual application fee of $1,000 plus appropriate technology fees to apply for annual recertification.
E. Technology fees: An applicant must pay the fees listed in Table 11.1-A for each technology certified.

Table 11.1-A. Technology Fees

Technology	**Technology Fee**
Bacteriology Molecular Biology Visual Inspection Homogeneity Water Activity	$50 per technology
Metals	$125 per technology
Organic Compounds	$150 per technology

Section 11.2 - Payment of Certification Fees Required Prior to Full Active or Provisional Active Licensure

A. OMP may not issue a provisional active license or active license until the applicant meets all requirements and pays all applicable fees.
B. All applications or requests to change the scope of activities to be conducted under an MTF license must be accompanied by the applicable fees specified in this section.
C. Application fees apply to the addition of technologies for reinstatement after revocation or denial of licenses.
D. Payment of fees must be in the form of a check or money order, made payable to the ‘‘Treasurer, State of Maine.’’

Appendix A

List of 195 pesticides prohibited from use on organic produce by the USDA National Organic Program (NOP), adapted from NOP and USDA Science and Technology Programs' *2010-2011 Pilot Study: Pesticide Residue Testing of Organic Produce*, November 2012.

Pesticide	**Type of Pesticide**
1-Naphthol	Insecticide
2,4 Dimethylphenyl formamide (DMPF)	Insecticide
3-Hydroxycarbofuran	Insecticide
4,4-Dibromobenzophenone	Acaricide
5-Hydroxythiabendazole	Fungicide
Acephate	Insecticide
Acetamiprid	Insecticide
Acetochlor	Herbicide
Aldicarb	Insecticide
Aldicarb sulfone	Insecticide
Aldicarb sulfoxide	Insecticide
Aldrin	Insecticide
Allethrin	Insecticide
Atrazine	Herbicide
Azinphos methyl	Insecticide
Azoxystrobin	Fungicide
Bendiocarb	Insecticide
BHC alpha	Insecticide
Bifenazate	Acaricide
Bifenthrin	Insecticide
Biteranol	Fungicide
Boscalid	Fungicide
Bromacil	Herbicide
Buprofezin	Insecticide
Captan	Fungicide
Carbaryl	Insecticide
Carbendazim (MBC)	Fungicide
Carbofuran	Insecticide
Carfentrazone ethyl	Herbicide
Chlorantraniprole	Insecticide

Chlordane cis	Insecticide
Chlordane trans	Insecticide
Chlorfenapyr	Insecticide
Chlorothalonil	Fungicide
Chlorpropham (CIPC)	Herbicide / Growth Regulator
Chlorpyrifos	Insecticide
Chlorpyrifos methyl	Insecticide
Chlorthal (DCPA)	Herbicide
Clofentezine	Acaricide
Clothianidin	Insecticide
Coumaphos	Insecticide
Cyazofamid	Fungicide
Cycloate	Herbicide
Cyfluthrin	Insecticide
Cyhalothrin lambda	Insecticide
Cypermethrin	Insecticide
Cyprodinil	Fungicide
Cyromazine	Insect Growth Regulator
DDD o,p'	Insecticide
DDD p,p'	Insecticide
DDE o,p'	Insecticide
DDE p,p'	Insecticide
DDT p,p'	Insecticide
Deltamethrin	Insecticide
Diazinon	Insecticide
Diazinon oxygen analog	Insecticide
Dichlorvos (DDVP)	Insecticide
Dicloran	Fungicide
Dicofol o,p'	Insecticide
Dicofol p,p'	Insecticide
Dieldrin	Insecticide
Difenoconazole	Fungicide
Diflubenzuron	Insecticide
Dimethoate	Insecticide
Dimethomorph	Fungicide
Dinotefuran	Insecticide

Diphenamid	Herbicide
Diphenylamine	Fungicide
Disulfoton sulfone	Insecticide
Diuron	Herbicide
Endosulfan I	Insecticide
Endosulfan II	Insecticide
Endosulfan sulfate	Insecticide
Endrin	Insecticide
Epoxiconazole	Fungicide
Esfenvalerate	Insecticide
Ethion	Insecticide
Ethoprop	Insecticide
Ethoxyquin	Fungicide / Growth Regulator
Etoxazole	Acaricide
Etridiazole	Fungicide
Famoxadone	Fungicide
Fenamidone	Fungicide
Fenamiphos	Insecticide
Fenamiphos sulfone	Insecticide
Fenamiphos sulfoxide	Insecticide
Fenarimol	Fungicide
Fenbuconazole	Fungicide
Fenhexamid	Fungicide
Fenoxaprop ethyl	Herbicide
Fenpropathrin	Insecticide
Fenpyroximate	Acaricide
Fenthion	Insecticide
Fipronil	Insecticide
Flonicamid	Insecticide
Fludioxonil	Fungicide
Fluoxastrobin	Fungicide
Fluridone	Herbicide
Flutolanil	Fungicide
Fluvalinate total	Insecticide
Folpet	Fungicide
Fonofos	Insecticide

Heptachlor	Insecticide
Heptachlor epoxide	Insecticide
Hexachlorobenzene	Fungicide
Hexaconazole	Fungicide
Hexythiazox	Insecticide
Hydroprene	Insect Growth Regulator / Acaricide
Imazalil	Fungicide
Imidacloprid	Insecticide
Indoxacarb	Insecticide
Iprodione	Fungicide
Lindane	Insecticide
Linuron	Herbicide
Malathion	Insecticide
Malathion oxygen analog	Insecticide
Metalaxyl	Fungicide
Methamidophos	Insecticide
Methidathion	Insecticide
Methiocarb	Insecticide
Methomyl	Insecticide
Methoxychlor	Insecticide
Methoxyfenozide	Insecticide
Metolachlor	Herbicide
Metribuzin	Herbicide
Mevinphos total	Insecticide
MGK-264	Insecticide
Myclobutanil	Fungicide
Naled	Insecticide
Napropamide	Herbicide
Nonachlor cis	Insecticide
Nonachlor trans	Insecticide
Norflurazon	Herbicide
Norflurazon desmethyl	Herbicide
Omethoate	Insecticide
o-Phenylphenol	Fungicide
Oxadixyl	Fungicide
Oxamyl	Insecticide

Oxamyl oxime	Insecticide
Oxydemeton methyl sulfone	Insecticide
Oxyfluorfen	Herbicide
Parathion methyl	Insecticide
Pendimethalin	Herbicide
Pentachlorobenzene	Fungicide
Permethrin total	Insecticide
Phenmedipham	Herbicide
Phorate sulfone	Insecticide
Phorate sulfoxide	Insecticide
Phosalone	Insecticide
Phosmet	Insecticide
Piperonyl butoxide	Insecticide
Pirimicarb	Insecticide
Prallethrin	Insecticide
Prochloraz	Fungicide
Procymidone	Fungicide
Profenofos	Insecticide
Prometryn	Herbicide
Pronamide	Herbicide
Propanil	Herbicide
Propargite	Insecticide
Propetamphos	Insecticide
Propham	Herbicide
Propiconazole	Fungicide
Pymetrozine	Insecticide
Pyraclostrobin	Fungicide
Pyridaben	Insecticide / Acaricide
Pyrimethanil	Fungicide
Pyriproxyfen	Insecticide / Growth Regulator
Quinoxyfen	Fungicide
Quintozene	Fungicide
Resmethrin total	Insecticide
Simazine	Herbicide
Spinetoram	Insecticide
Spirodiclofen	Acaricide

Spiromesifen	Insecticide
Sulfentrazone	Herbicide
Tebuconazole	Fungicide
Tebufenozide	Insecticide
Tefluthrin	Insecticide
Tetrachlorvinphos	Insecticide
Tetraconazole	Fungicide
Tetradifon	Insecticide
Tetrahydrophthalimide (THPI)	Fungicide
Tetramethrin	Insecticide
Thiabendazole	Fungicide
Thiacloprid	Insecticide
Thiamethoxam	Insecticide
Thiodicarb	Insecticide
Triadimefon	Fungicide
Triadimenol	Fungicide
Tribufos	Herbicide
Trifloxystrobin	Fungicide
Triflumizole	Fungicide
Trifluralin	Herbicide
Vinclozolin	Fungicide

STATUTORY AUTHORITY:
28-B MRS ch. 1; 22 MRS §569

EMERGENCY ADOPTION:
September 4, 2019 – filing 2019-161