

M 1300 Series – Discipline

Basis and Purpose – M 1302

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), 12-43.3-202(2)(a)(XX), and 24-4-104(4)(a), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to set forth the process for summary suspensions when the State Licensing Authority has cause to immediately suspend a license prior to and pending a hearing and final agency action. Summary suspension will be imposed when the State Licensing Authority has reason to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or that the public health, safety, or welfare imperatively requires emergency action. The rule ensures proper due process for Licensees when their licenses are temporarily or summarily suspended by requiring prompt initiation of disciplinary proceedings after such suspensions. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause.

M 1302 – ~~Disciplinary Process:~~ Summary Suspensions

A. How a Summary Suspension Action is Initiated

1. When the State Licensing Authority has reasonable grounds to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or that the public health, safety, or welfare imperatively requires emergency action it shall serve upon the Licensee a Summary Suspension Order that temporarily or summarily suspends the license.
2. The Summary Suspension Order shall identify the nature of the State Licensing Authority's basis for the summary suspension. The Summary Suspension Order shall also provide an advisement that the Licensee may be subject to further discipline or revocation following a hearing on an Order to Show Cause~~should the charges contained in the notice be sustained following a hearing.~~
3. Proceedings for suspension or revocation shall be promptly instituted and determined after the Summary Suspension Order is issued in accordance with the following procedure:-
 - a. ~~4.~~ 4.—After the Summary Suspension Order is issued, the State Licensing Authority shall promptly issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why the Licensee's license should not be suspended, revoked, restricted, fined or subject to other disciplinary sanction.
 - b. ~~5.~~ The Order to Show Cause shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The Order to Show Cause shall also provide an advisement that the license could be suspended, revoked, restricted, fined or subject to ~~the~~ disciplinary sanction should the charges contained in the Order to Show Cause notice be sustained upon final hearing.
 - c. The Order to Show Cause shall be filed with the Department's Hearings Division. The hearing on the allegations set forth in the Order to Show Cause shall be expedited to the extent practicable and will be conducted in accordance with Rule M 1304 – Administrative Hearings.

~~6. Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order.~~

- B. ~~Duration of Summary Suspension Hearings. Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order. Summary suspension hearings will be expedited to the extent practicable and will be conducted in accordance with Rule M 1304 – Administrative Hearings.~~

Basis and Purpose – M 1304

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to establish what entity conducts the administrative hearings, the procedures governing administrative hearings, and other general hearings issues. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause, and to clarify that an answer is required only for two types of administrative notices: an Order to Show Cause and a Notice of Grounds for Denial.

M 1304 – Administrative Hearings

A. General Procedures

1. Hearing Location. Hearings will generally be conducted by the Department ~~'s~~ of Revenue, Hearings Division. Unless the hearing officer orders a change of location based on good cause, as described in this rule, hearings generally will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer. Under unusual circumstances where justice, judicial economy and convenience of the parties would be served, hearings may be held in other locations in the state of Colorado.
2. Scope of Hearing Rules. This rule shall be construed to promote the just and efficient determination of all matters presented.
3. Right to Legal Counsel. Any Denied Applicant or Respondent has a right to legal counsel throughout all processes described in rules associated with the denial of an application and disciplinary action. Such counsel shall be provided solely at the Denied Applicant's or Respondent's expense.

B. Requesting a Hearing

1. A Denied Applicant that has been served with a Notice of Denial may request a hearing within 60 days of the service of the Notice of Denial by making a written request for a hearing to the Division. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to:

Marijuana Enforcement Division
Attn: Hearing Request
455 Sherman Street, Suite 390
Denver, CO 80203

The written request for a hearing must be received by the Division within the time stated in the Notice of Denial. An untimely request for hearing will not be considered.

2. A Denied Applicant that timely requests a hearing following issuance of a Notice of Denial shall be served with a Notice of Grounds for Denial, and shall be entitled to a hearing regarding the matters addressed therein.
3. A Respondent that has been served with an Order to Show Cause shall be entitled to a hearing regarding the matters addressed therein.

C. When a Responsive Pleading is Required

1. A Respondent shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any ~~administrative notice or~~ Order to Show Cause. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Respondent fails to file a required answer, the hearing officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.
2. A Denied Applicant shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any ~~administrative notice or~~ Notice of Grounds for Denial. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Denied Applicant fails to file a required answer, the hearing officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

D. Hearing Notices

1. Notice to Set. The Division shall send a notice to set a hearing to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record.
2. Notice of Hearing. The Hearings Division shall notify the Division and Denied Applicant or Respondent of the date, place, time and nature of the hearing regarding denial of the license application or whether discipline should be imposed against the Respondent's license at least 30 days prior to the date of such hearing, unless otherwise agreed to by both parties. This notice shall be sent to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record. Hearings shall be scheduled and held as soon as is practicable.
 - a. ~~If an Order of Summary Suspension has issued, the hearing on the Order to Show Cause~~ Summary suspension hearings will be scheduled and held promptly.
 - b. Continuances may be granted for good cause, as described in this rule, shown. A motion for a continuance must be timely.
 - c. For purposes of this rule, good cause may include but is not limited to: death or incapacitation of a party or an attorney for a party; a court order staying proceedings or otherwise necessitating a continuance; entry or substitution of an attorney for a party a reasonable time prior to the hearing, if the entry or substitution reasonably requires a postponement of the hearing; a change in the parties or pleadings sufficiently significant

to require a postponement; a showing that more time is clearly necessary to complete authorized discovery or other mandatory preparation for the hearing; or agreement of the parties to a settlement of the case which has been or will likely be approved by the final decision maker. Good cause normally will not include the following: unavailability of counsel because of engagement in another judicial or administrative proceeding, unless the other proceeding was involuntarily set subsequent to the setting in the present case; unavailability of a necessary witness, if the witness' testimony can be taken by telephone or by deposition; or failure of an attorney or a party timely to prepare for the hearing.

E. Prehearing Matters Generally

1. Prehearing Conferences Once a Hearing is Set. Prehearing conferences may be held at the discretion of the hearing officer upon request of any party, or upon the hearing officer's own motion. If a prehearing conference is held and a prehearing order is issued by the hearing officer, the prehearing order will control the course of the proceedings. Such prehearing conferences may occur by telephone.
2. Depositions. Depositions are generally not allowed; however, a hearing officer has discretion to allow a deposition if a party files a written motion and can show why such deposition is necessary to prove its case. When a hearing officer grants a motion for a deposition, C.R.C.P. 30 controls. Hearings will not be continued because a deposition is allowed unless (a) both parties stipulate to a continuance and the hearing officer grants the continuance, or (b) unless the hearing officer grants a continuance over the objection of any party in accordance with subsections (D)(2)(b) and (c) of this rule.
3. Prehearing Statements Once a Hearing is Set. Prehearing Statements are required and unless otherwise ordered by the hearing officer, each party shall file with the hearing officer and serve on each party a prehearing statement no later than seven calendar days prior to the hearing. Parties shall also exchange exhibits at that time. Parties shall not file exhibits with the hearing officer. Parties shall exchange exhibits by the date on which prehearing statements are to be filed. Prehearing statements shall include the following information:
 - a. Witnesses. The name, mailing address, and telephone number of any witness whom the party may call at hearing, together with a detailed statement of the expected testimony.
 - b. Experts. The name, mailing address, and brief summary of the qualifications of any expert witness a party may call at hearing, together with a statement that details the opinions to which each expert is expected to testify. These requirements may be satisfied by the incorporation of an expert's resume or report containing the required information.
 - c. Exhibits. A description of any physical or documentary evidence to be offered into evidence at the hearing. Exhibits should be identified as follows: Division using numbers and Denied Applicant or Respondent using letters.
 - d. Stipulations. A list of all stipulations of fact or law reached, as well as a list of any additional stipulations requested or offered to facilitate disposition of the case.

4. Prehearing Statements Binding. The information provided in a party's prehearing statement shall be binding on that party throughout the course of the hearing unless modified to prevent manifest injustice. New witnesses or exhibits may be added only if: (1) the need to do so was not reasonably foreseeable at the time of filing of the prehearing statement; (2) it would not unduly prejudice other parties; and (3) it would not necessitate a delay of the hearing.
5. Consequence of Not Filing a Prehearing Statement Once a Hearing is Set. If a party does not timely file a prehearing statement, the hearing officer may impose appropriate sanctions including, but not limited to, striking proposed witnesses and exhibits.

F. Conduct of Hearings

1. The hearing officer shall cause all hearings to be electronically recorded.
2. The hearing officer may allow a hearing, or any portion of the hearing, to be conducted in real time by telephone or other electronic means. If a party is appearing by telephone, the party must provide actual copies of the exhibits to be offered into evidence at the hearing to the hearing officer when the prehearing statement is filed.
3. The hearing officer shall administer oaths to all witnesses at hearing. The hearing officer may question any witness.
4. The hearing, including testimony and exhibits, shall be open to the public unless otherwise ordered by the hearing officer in accordance with a specific provision of law.
 - a. Reports and other information that would otherwise be confidential pursuant to Subsection 12-43.3-202(1)(d), C.R.S., may be introduced as exhibits at hearing. Such exhibits shall not be sealed from public inspection unless confidential pursuant to a provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.
 - b. Any party may move the hearing officer to seal an exhibit or order other appropriate relief if necessary to safeguard the confidentiality of evidence, if such evidence is confidential pursuant to a specific provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.
5. Court Rules.
 - a. To the extent practicable, the Colorado Rules of Evidence apply. Unless the context requires otherwise, whenever the word "court," "judge," or "jury" appears in the Colorado Rules of Evidence, such word shall be construed to mean a hearing officer. A Hearing officer has discretion to consider evidence not admissible under such rules, including but not limited to hearsay evidence, pursuant to section 24-4-105(7), C.R.S.
 - b. To the extent practicable, the Colorado Rules of Civil Procedure apply. However, Colorado Rules of Civil Procedure 16 and 26-37 do not apply, although parties are encouraged to voluntarily work together to resolve the case, simplify issues, and exchange information relevant to the case prior to a hearing. Unless the context otherwise requires, whenever the

word “court” appears in a rule of civil procedure, that word shall be construed to mean a hearing officer.

6. Exhibits.
 - a. All documentary exhibits must be paginated by the party offering the exhibit into evidence.
 - b. The Division shall use numbers to mark its exhibits.
 - c. The Denied Applicant or Respondent shall use letters to mark its exhibits.
7. The hearing officer may proceed with the hearing or enter default judgment if any party fails to appear at hearing after proper notice.
- G. Post Hearing. After considering all the evidence, the hearing officer shall determine whether the proponent of the order has proven its case by a preponderance of the evidence, and shall make written findings of evidentiary fact, ultimate conclusions of fact, conclusions of law, and a recommendation. These written findings shall constitute an Initial Decision subject to review by the State Licensing Authority pursuant to the Colorado Administrative Procedure Act and as set forth in Rule M 1306 – Administrative Hearing Appeals/Exceptions to Initial Decision.
- H. No Ex Parte Communication. Ex parte communication shall not be allowed at any point following the formal initiation of the hearing process. A party or counsel for a party shall not initiate any communication with a hearing officer or the State Licensing Authority, or with conflicts counsel representing the hearing officer or State Licensing Authority, pertaining to any pending matter unless all other parties participate in the communication or unless prior consent of all other parties (and any pro se parties) has been obtained. Parties shall provide all other parties with copies of any pleading or other paper submitted to the hearing officer or the State Licensing Authority in connection with a hearing or with the exceptions process.
- I. Marijuana Enforcement Division Representation. The Division shall be represented by the Colorado Department of Law.

M 500 Series – Medical Marijuana Optional Premises Cultivation Operation: License Privileges**Basis and Purpose – M 501**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12-43.3-310(4), 12-43.3-406(1)(c), and 12-43.3-406(4)(b), C.R.S. The purpose of this rule is to establish that it is unlawful for an Optional Premises Cultivation Operation to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 501 – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

- A. Privileges Granted. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.
- B. Licensed Premises. To the extent authorized by Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation, a Medical Marijuana Optional Premises Cultivation Facility may share a location with a commonly-owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location.
- C. Cultivation of Medical Marijuana Authorized. A Medical Marijuana Optional Premises Cultivation Operation may Propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.
- D. Authorized Sales. A Medical Marijuana Optional Premises Cultivation Operation may only transfer Medical Marijuana to the Medical Marijuana Center or Medical Marijuana Infused Products Manufacturer it is designated to pursuant to section 12-43.3-403, C.R.S.
- E. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to Rule M 1002 - Labeling Requirements: General Requirements and securely sealed in a tamper-evident manner.
 - 1. The packages must be transported to the receiving Medical Marijuana Business within 48 hours of receiving notification that the Harvest Batch from the processed Medical Marijuana passed required testing, and recorded as inventory at the receiving Medical Marijuana Business.
 - 2. In the event that the Harvest Batch from the processed Medical Marijuana does not pass required testing, the Licensee shall follow the procedures in rule M 1507 for the Harvest Batch. If the Harvest Batch ultimately passes required testing, then the packages of Medical Marijuana associated with the Harvest Batch must be transported to the Medical Marijuana Business within 48 hours of receiving notification that the Harvest Batch passed the additional round of testing, and recorded as inventory at the receiving Medical Marijuana Business.
- F. Authorized Marijuana Transport. A Medical Marijuana Optional Premises Cultivation is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this rule prevents a Medical Marijuana Optional Premises Cultivation from transporting its own Medical Marijuana.

M 700 Series –Medical Marijuana Testing Facilities**Basis and Purpose – M 704**

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility.

M 704 – Medical Marijuana Testing Facilities: Personnel

This rule shall be effective on July 1, 2016.

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this rule.
1. The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Medical Marijuana Testing Facility.
 2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:
 - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
 - b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
 - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule M 901 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- C. Responsibilities of the Laboratory Director. The laboratory director must:
1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;

2. Establish and adhere to a written standard operating procedure used to perform the tests reported;
3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;
8. Ensure that the laboratory is enrolled in a Division approved proficiency testing program;
9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
12. Ensure that reports of test results include pertinent information required for interpretation;
13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
15. Ensure that prior to testing any samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to

assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

17. Ensure that an approved standard operating procedure manual is available to all personnel responsible for any aspect of the testing process; and
18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

C.5 Change in Laboratory Director. In the event that the laboratory director leaves employment at the Medical Marijuana Testing Facility, the Medical Marijuana Testing Facility shall:

1. Provide written notice to the Colorado Department of Public Health and Environment and the Marijuana Enforcement Division within seven days of the laboratory director's departure; and
2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 45 days from the date of the previous laboratory director's departure, unless the Medical Marijuana Testing Facility receives a written waiver from the Division Director.

D. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the three years of full-time laboratory experience.

E. Laboratory Testing Analyst

1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing.
2. Responsibilities. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

Basis and Purpose – M 712

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.4-203(2.5)(a), 12-43.3-202(2)(a)(XIV), 12-43.4-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XX), and 12-43.3-405, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII,

Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division’s mandatory testing and random sampling program that is applicable to Medical Marijuana Testing Facilities. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of Senate Bill 15-260. Section 1 of the bill required the State Licensing Authority to establish an acceptable potency variance. The acceptable potency variance has been set at plus or minus 15% to comport with the potency variance mandated by the Retail Code.

M 712 – Medical Marijuana Testing Facilities: Sampling and Testing Program

This rule shall be effective on July 1, 2016.

- A. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
- B. Test Batches
 - 1. Medical Marijuana and Medical Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
 - 2. Medical Marijuana Infused-Product. A Medical Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Medical Marijuana Infused-Product for every type of test that it conducts.
- C. Rejection of Test Batches and Samples
 - 1. A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
 - 2. A Medical Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance with these rules or any additional Division sampling procedures or was not collected by Division personnel.
- D. Notification of Medical Marijuana Business. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product failed a contaminant test, then the Medical Marijuana Testing Facility must immediately notify the Medical Marijuana Business that submitted the sample for testing and report the failure in accordance with all Inventory Tracking System procedures.
- E. Permissible Levels of Contaminants. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product is found to have a contaminant in levels exceeding those established as permissible under this rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.
 - 1. Microbials

| <u>Substance</u> | <u>Acceptable Limits Per Gram</u> | <u>Product to be Tested</u> |
|-----------------------------------------------------------|-----------------------------------|------------------------------------|
| –Shiga-toxin producing Escherichia coli (STEC)*- Bacteria | < 1 Colony Forming Unit (CFU) | Flower; Medical Marijuana Infused- |

| | | |
|--------------------------------|---------------------------------------------|---------------------------------------------------------------|
| Salmonella species* – Bacteria | < 1 Colony Forming Unit (CFU) | Product; Water- and Food-Based Medical Marijuana Concentrates |
| Total Yeast and Mold | < 10 ⁴ Colony Forming Unit (CFU) | |

*Testing facilities should contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

2. Residual Solvents

| Substance | Acceptable Limits Per Gram | Product to be Tested |
|-----------------------------------------------------------|-------------------------------------------------------|---------------------------------------------|
| Butanes | < 800 <u>5,000</u> Parts Per Million (PPM) | Solvent-Based Medical Marijuana Concentrate |
| Heptanes | < 500 <u>5,000</u> Parts Per Million (PPM) | |
| Benzene** | < 42 Parts Per Million (PPM) | |
| Toluene** | < 1890 Parts Per Million (PPM) | |
| Hexane** | < 10290 Parts Per Million (PPM) | |
| Total Xylenes (m,p, o-xylenes)** | < 42,170 Parts Per Million (PPM) | |
| Any solvent not permitted for use pursuant to Rule R 605. | None Detected | |

** Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule M 605, limits have been listed here accordingly.

3. Metals

| Substance | Acceptable Limits Per Gram | Product to be Tested |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Metals (Arsenic, Cadmium, Lead and Mercury) | Lead – Max Limit: < 10 <u>1.0</u> ppm Arsenic – Max Limit: < 10 <u>0.4</u> ppm Cadmium – Max Limit: < 4.4 <u>0.4</u> ppm Mercury – Max Limit: < 2.0 <u>0.2</u> ppm | Flower; Water-, Food-, and Solvent-Based Medical Marijuana Concentrates; and Medical Marijuana-Infused Product |

4. Other Contaminants

| | |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pesticide | If testing identifies the use of a banned Pesticide or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing. |
| Chemicals | If Test Batch is found to contain levels of any chemical that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing. |
| Microbials | If Test Batch is found to contain levels of any microbial that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing. |
| Molds, Mildew, and Filth | If a Test Batch is found to contain levels of any mold, mildew, or filth that could be toxic if consumed, then that Test Batch shall be considered to have failed contaminant testing. |

5. Division Notification. A Medical Marijuana Testing Facility must notify the Division if a Test Batch is found to contain levels of a contaminant not listed within this rule that could be injurious to human health if consumed.

F. Potency Testing

1. Cannabinoids Potency Profiles. A Medical Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division's Medical Marijuana Testing Facility Certification Policy Statement.
2. Reporting of Results
 - a. For potency tests on Medical Marijuana and Medical Marijuana Concentrate, results must be reported by listing a single percentage concentration for each cannabinoid that represents an average of all samples within the Test Batch.
 - b. For potency tests conducted on Medical Marijuana Infused-Product, results must be reported by listing the total number of milligrams contained within a single Medical Marijuana-Infused Product unit for sale for each cannabinoid and affirming the THC content is homogenous.
3. Dried Flower. All potency tests conducted on Medical Marijuana must occur on dried and cured Medical Marijuana that is ready for sale.
4. Failed Potency Tests for Medical Marijuana Infused-Product
 - a. If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.
5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

M 1500 Series – Medical Marijuana Testing Program

Basis and Purpose – M 1501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

M 1501 – Medical Marijuana Testing Program – Contaminant Testing

~~Rule M 1501 shall be effective beginning July 1, 2016.~~

- A. Contaminant Testing Required. Until an Optional Premises Cultivation Operation's and Medical Marijuana-Infused Products Manufacturer's cultivation or production process has been validated under this rule, it shall not wholesale, transfer, or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product unless Samples from the Harvest Batch or Production Batch from which that Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product was derived was tested by a Medical Marijuana Testing Facility for contaminants and passed all contaminant tests required by paragraph C of this rule.
- B. Validation of Process – Contaminant Testing
1. Medical Marijuana. An Optional Premises Cultivation Operation's cultivation process shall be deemed valid regarding Contaminants if every Harvest Batch that it produced during at least a six week period but no longer than a 12 week period passed all contaminant tests required by paragraph C of this rule. This must include at least 6 Test Batches that contain Samples from entirely different Harvest Batches.
 2. Medical Marijuana Concentrate or Medical Marijuana Infused-Product. An Optional Premises Cultivation Operation's or a Medical Marijuana-Infused Products Manufacturer's production process shall be deemed valid regarding contaminants if every Production Batch that it produced during at least a four week period but no longer than an eight week period passed all contaminant tests required by paragraph C of this rule. This must include at least four Test Batches that contain Samples from entirely different Production Batches.
 3. Process Validation is Effective for One Year. Once an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer has successfully obtained process validation for contaminants, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.
- C. Required Contaminant Tests.
1. Microbial Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Water- or Food-Based Medical Marijuana Concentrate and Medical Marijuana-Infused Product must be tested for microbial contamination by a Medical Marijuana Testing Facility. The microbial contamination test must

include, but need not be limited to, testing to determine the presence of ~~and amounts present of~~ Salmonella sp., ~~and shiga-toxin producing~~ Escherichia coli., and ~~the amount of~~ total yeast and mold.

2. Biological Contaminant Testing.

a. Mold and Mildew Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Medical Marijuana Concentrate and Medical Marijuana Infused-Product must be visually inspected, in addition to other required mold testing, by a Medical Marijuana Testing Facility for toxic amounts of mold and mildew contamination.

b. Filth Contaminant Testing. Each Harvest Batch of Medical Marijuana must be visually inspected by a Medical Marijuana Testing Facility for toxic amounts of filth.

3. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer must be tested for residual solvent contamination by a Medical Marijuana Testing Facility. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, butane, heptanes, benzene*, toluene*, hexane*, and xylenes*. * Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per rule M 605.

D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer wholesaling, transferring, or processing into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants or other types of biological contaminants, microbials, molds, metals, filth or residual solvents.

E. Exemptions

1. Medical Marijuana Concentrate. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this rule if the Medical Marijuana-Infused Products Manufacturer that produced it does not wholesale or transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana-Infused Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing.

F. Required Re-Validation - Contaminants.

1. Material Change Re-validation. If an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer makes a Material Change to its cultivation or production process, then it must have the first five Harvest Batches or Production Batches produced using the new standard operating procedures tested for all of the contaminants required by paragraph C of this rule regardless of whether its process has been previously validated regarding contaminants. If any of those tests fail, then the Medical Marijuana Business's process must be re-validated.

- a. Pesticide. It shall be considered a Material Change if an Optional Premises Cultivation begins using a new or different Pesticide during its cultivation process and the first five Harvest Batches produced using the new or different Pesticide must also be tested for Pesticide.
 - b. Solvents. It shall be considered a Material Change if a Medical Marijuana-Infused Products Manufacturer begins using a new or different solvent or combination of solvents.
 - c. Notification. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that makes a Material Change must notify the Medical Marijuana Testing Facility that conducts contaminant testing on the first five Harvest Batches or Production Batches produced using the new standard operating procedures.
 - d. Testing Required Prior to Wholesale, Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this rule, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced it may not wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any of the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch.
2. Failed Contaminant Testing Re-Validation. If a Sample the Division requires to be tested fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedures in paragraph B of rule M 1507 for any package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana or Medical Marijuana-Infused Product for contaminant testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall re-validate its process for contaminants.
 3. Expiration of Process Validation. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall be required to re-validate its process once the one year of process validation expires, or the Medical Marijuana Business shall comply with the requirements of paragraph A of this rule M 1501.
- G. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1502

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Medical Marijuana sampling and testing program.

M 1502 – Medical Marijuana Testing Program – Mandatory Testing

Rule M 1502 shall be effective beginning July 1, 2016.

- A. Required Sample Submission. A Medical Marijuana Business may be required by the Division to submit a Sample(s) of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product it possesses to a Medical Marijuana Testing Facility at any time regardless of whether its process has been validated and without notice.
1. Samples collected pursuant to this rule may be tested for potency or contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, residual solvents, biological contaminants, and chemical contaminants.
 2. When a Sample(s) is required to be submitted for testing, the Medical Marijuana Business may not sell, wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from the package, Harvest Batch or Production Batch from which the Sample was taken, unless or until it passes all required testing.
- B. Methods for Determining Required Testing.
1. Random Testing. The Division may require Samples to be submitted for testing through any one or more of the following processes: random process, risk-based process or other internally developed process, regardless of whether a Medical Marijuana Business's process has been validated.
 2. Inspection or Enforcement Tests. The Division may require a Medical Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:
 - a. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or mislabeled;
 - b. A Medical Marijuana Business is in violation of any product safety, health or sanitary law, rule or regulation; or
 - c. The results of a test would further an investigation by the Division into a violation of any law, rule or regulation.
 3. Beta Testing. The Division may require a Medical Marijuana Business to submit Samples from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.
- C. Minimum Testing Standards. The testing requirements contained in the M 1500 series are the minimum required testing standards. Medical Marijuana Businesses are responsible for receiving enough testing on any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana Infused-Product they produce to ensure the marijuana consumables are safe for human consumption.
- D. Additional Sample Types. The Division may also require a Medical Marijuana Business to submit Samples comprised of items other than Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, residual

solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Samples that may be required to be submitted for contaminant testing:

1. Specific plant(s) or any portion of a plant(s),
 2. Any growing medium, water or other substance used in the cultivation process,
 3. Any water, solvent or other substance used in the processing of a Medical Marijuana Concentrate,
 4. Any ingredient or substance used in the manufacturing of a Medical Marijuana-Infused Product; or
 5. Swab of any equipment or surface.
- E. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – M 1504

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Medical Marijuana sampling and testing program.

M 1504 – Medical Marijuana Testing Program – Sampling Procedures

~~Rule M 1504 shall be effective beginning July 1, 2016.~~

- A. Collection of Samples
1. Sample Collection. All Samples submitted for testing pursuant to this rule must be collected by Division personnel or in accordance with the Division's sampling policy.
 2. Sample Selection. The Division may elect, at its sole direction, to assign Division personnel to collect Samples. A Medical Marijuana Business, its Owners and employees shall not attempt to influence the Samples selected by Division personnel.
 3. ~~Adulteration or Alteration Prohibited. A Licensee or its agent shall not adulterate or alter, or attempt to adulterate or alter, any Medical Marijuana or Medical Marijuana-Infused Product, or any Samples of the Medical Marijuana or Medical Marijuana-Infused Product, for the purpose of circumventing contaminant testing detection limits or potency testing requirements. A violation of this subparagraph (A)(3) shall be considered a license violation affecting public safety.~~
- B. Samples for Test Batches of Medical Marijuana and Medical Marijuana Concentrate. Each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of a representative selection of Samples.

1. Minimum Number of Samples. At a minimum, each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of at least the following number of separately taken Samples:
 - a. For Test Batches comprised of Harvest Batches or Production Batches weighing up to 10 pounds, eight separate Samples must be taken.
 - b. For Test Batches comprised of Harvest Batches or Production Batches weighing more than 10 pounds but less than 20 pounds, 12 separate Samples must be taken.
 - c. For Test Batches comprised of Harvest Batches or Production Batches weighing 20 pounds or more but less than 30 pounds, 15 separate Samples must be taken.
 - d. For Test Batches comprised of Harvest Batches or Production Batches weighing 30 pound or more but less than 40 pounds, 18 separate Samples must be taken.
 - e. For Test Batches comprised of Harvest Batches or Production Batches weighing 40 pounds or more but less than 100 pounds, 23 separate Samples must be taken.
 - f. For Test Batches comprised of Harvest Batches or Production Batches weighing 100 pounds or more, 29 separate Samples must be taken.
 2. Multiple Harvest Batches or Production Batches. If more than one Harvest Batch or Production Batch is combined into a single Test Batch, then that Test Batch must include at least one Sample from each Harvest Batch or Production Batch.
- C. Samples for Test Batches of Medical Marijuana-Infused Product.
1. Finished Product. Test Batches of Medical Marijuana-Infused Product must be comprised of finished product that is packaged for sale.
 2. Multiple Production Batches. If more than one Production Batch of Medical Marijuana-Infused Product is combined into a single Test Batch, then that Test Batch must include at least one finished product that is packaged for sale from each Production Batch combined into that Test Batch.
- D. Medical Marijuana Testing Facility Selection. The Division will generally permit a Medical Marijuana Business to select which Medical Marijuana Testing Facility will test a Sample collected pursuant to this rule. However, the Division may elect, at its sole discretion, to assign a Medical Marijuana Testing Facility to test the Sample.
- E. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.