

R 1300 Series – Discipline

Basis and Purpose – R 1302

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(2)(c), 12-43.4-202(3)(a)(I), 12-43.4-202(3)(a)(XVI) 12-43.4-202(3)(b)(IX) and 24-4-104(4)(a), C.R.S., and sections 12-43.3-601 and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). 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 order. Summary suspensions 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, and welfare imperatively require 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.

R 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:
 - 4i. 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.
 - 5ii. 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 ~~other~~ disciplinary sanction should the charges contained in the Order to Show Cause notice be sustained upon final hearing.
 - iii. 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 R 1304 – Administrative Hearings.~~

Basis and Purpose – R 1304

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(2)(c), 12-43.4-202(2)(d), 12-43.4-202(3)(a)(I), and sections 12-43.4-601 and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). 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.

R 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) 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 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 Subsections 12-43.3-202(1)(d) and 12-43.4-202(2)(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 Subsections 12-43.3-202(1)(d) or 12-43.4-202(2)(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 Subsections 12-43.3-202(1)(d) or 12-43.4-202(2)(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.

R 700 Series – Retail Marijuana Testing Facilities

Basis and Purpose – R 703

The statutory authority for this rule is found at subsection 12-43.4-202(3)(a)(IV) and section 12-43.4-405, C.R.S. The purpose of this rule is to establish a frame work for certification for Retail Marijuana Testing Facilities.

R 703 –Retail Marijuana Testing Facilities: Certification Requirements

- A. Certification Types. A Retail Marijuana Testing Facility may only perform tests on Samples that the Retail Marijuana Testing Facility is certified by the Division to perform.
1. Residual solvents;
 2. ~~Poisons or Toxins; Repealed.~~
 3. ~~Harmful Chemicals; Repealed.~~
 4. ~~Dangerous Molds, Mildew or Filth; Repealed.~~
 5. ~~Harmful Microbials, such as E. Coli or Salmonella;~~
 6. ~~Pesticides; and Repealed~~
 7. THC and other Cannabinoid potency.
 8. Chemical Contaminants; and
 9. Biological Contaminants.
- B. Certification Procedures. The Retail Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the applicable requirements in this rule.
1. Certification Inspection. A Retail Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.
 2. Standards for Certification. A Retail Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, proficiency testing, quality control, quality assurance, security, chain of custody, specimen retention, space, records, and results reporting.
 3. Personnel Qualifications
 - a. Laboratory Director. A Retail Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule R 704 – Retail Marijuana Testing Facilities: Personnel.

- b. Employee Competency. A Retail Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).
4. Standard Operating Procedure Manual. A Retail Marijuana Testing Facility must have a written procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.
 - a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.
 - b. A Retail Marijuana Testing Facility must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. See Rule R 901 – Business Records Required.
5. Analytical Processes. A Retail Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Retail Marijuana Testing Facility must provide this listing to the Division upon request.
6. Proficiency Testing. A Retail Marijuana Testing Facility must successfully participate in a Division approved proficiency testing program in order to obtain and maintain certification.
7. Quality Assurance and Quality Control. A Retail Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
8. Security. A Retail Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
9. Chain of Custody. A Retail Marijuana Testing Facility must establish a system to document the complete chain of custody for samples from receipt through disposal.
10. Space. A Retail Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.
11. Records. A Retail Marijuana Testing Facility must establish a system to retain and maintain records for a period not less than three years.
12. Results Reporting. A Retail Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner.

Basis and Purpose – R 704

The statutory authority for this rule is found at subsection 12-43.4-202(3)(a)(IV) and section 12-43.4-405, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Retail Marijuana Testing Facility.

R 704 –Retail Marijuana Testing Facilities: Personnel

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Retail 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 Retail Marijuana Testing Facility.
 2. The laboratory director for a Retail 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 R 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 Retail 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 Retail Marijuana Testing Facility, the Retail 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 Retail Marijuana Testing Facility must hire a permanent laboratory director within 45 days from the date of the previous laboratory director's departure, unless the Retail 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 Retail Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

Basis and Purpose – R 712

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VI), 12-43.4-202(3)(c)(VII), and 12-43.4-405, 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 Retail Marijuana Testing Facilities. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of House Bill 15-1283, which modified 12-43.4-202(3)(a)(IV)(E), C.R.S. The bill established that the acceptable potency variance, which the Division must determine, must be at least plus or minus 15 percent.

R 712 – Retail Marijuana Testing Facilities: Sampling and Testing Program

- A. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Retail Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
- B. Test Batches
 - 1. Retail Marijuana and Retail Marijuana Concentrate. A Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
 - 2. Retail Marijuana Product. A Retail Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Retail Marijuana Product for every type of test that it conducts.
- C. Rejection of Test Batches and Samples
 - 1. A Retail Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
 - 2. A Retail 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 Retail Marijuana Establishment. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product failed a contaminant test, then the Retail Marijuana Testing Facility must immediately notify the Retail Marijuana Establishment that submitted the sample for testing and report the failure in accordance with all Inventory Tracking System procedures.
- E. Permissible Levels of Contaminants. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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 (Bacteria, Fungus)

<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; Retail Marijuana Products; Water- and Food-Based Concentrates
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
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

<u>Substance</u>	<u>Acceptable Limits Per Gram</u>	<u>Product to be Tested</u>
Butanes	< 800 5,000 Parts Per Million	Solvent-Based Concentrates

	(PPM)	
Heptanes	< 500-5,000 Parts Per Million (PPM)	
Benzene**	< 42 Parts Per Million (PPM)	
Toluene**	< 4890 Parts Per Million (PPM)	
Hexane**	< 40290 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 R 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: < 401.0 ppm Arsenic – Max Limit: < 40-0.4 ppm Cadmium – Max Limit: < 4.4-0.4 ppm Mercury – Max Limit: < 2-0-0.2 ppm	Flower; Water-, Food-, and Solvent-Based Concentrates; and Retail Marijuana Products

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 Retail 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 Retail Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division’s Retail Marijuana Testing Facility Certification Policy Statement.

2. Reporting of Results

- a. For potency tests on Retail Marijuana and Retail 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 Retail Marijuana Product, whether conducted on each individual production batch or via Process Validation per rule R 1503, results must be reported by listing the total number of milligrams contained within a single Retail Marijuana Product unit for sale for each cannabinoid and affirming the THC content is homogenous.

3. Dried Flower. All potency tests conducted on Retail Marijuana must occur on dried and cured Retail Marijuana that is ready for sale.
4. Failed Potency Tests for Retail Marijuana Products
 - a. If an individually packaged Edible Retail Marijuana Product contained within a Test Batch is determined to have more than 100 mgs of THC within it, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (F)(5) of this rule R 712 shall apply to potency testing.
 - b. If the THC content of a Marijuana Product is determined through testing to not be homogenous, then it shall be considered to have failed potency testing. A Retail Marijuana Product shall be considered to not be homogenous if 10% of the infused portion of the Retail Marijuana Product contains more than 20% of the total THC contained within entire Retail Marijuana Product.
5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

R 1500 Series – Retail Marijuana Testing Program

Basis and Purpose – R 1501

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), 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 protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Retail Marijuana sampling and testing program.

R 1501 – Retail Marijuana Testing Program – Contaminant Testing

- A. Contaminant Testing Required. Until a Retail Marijuana Cultivation Facility's or a Retail Marijuana Product Manufacturing Facility's cultivation or production process has been validated under this rule, it shall not wholesale, transfer, or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product unless Samples from the Harvest Batch or Production Batch from which that Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product was derived was tested by a Retail Marijuana Testing Facility for contaminants and passed all contaminant tests required by paragraph C of this rule.
- B. Validation of Process – Contaminant Testing
1. Retail Marijuana. A Retail Marijuana Cultivation Facility'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. Retail Marijuana Concentrate or Retail Marijuana Product. A Retail Marijuana Cultivation Facility's or a Retail Marijuana Products Manufacturing Facility'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 a Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana and Production Batch of Water- or Food-Based Retail Marijuana Concentrate and Retail Marijuana Product must be tested for microbial contamination by a Retail 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 Retail Marijuana and Production Batch of Retail Marijuana Concentrate and Retail Marijuana Product must be visually inspected, in addition to other required mold testing, by a Retail Marijuana Testing Facility for toxic amounts of mold and mildew contamination.
 - b. Filth Contaminant Testing. Each Harvest Batch of Retail Marijuana must be visually inspected by a Retail Marijuana Testing Facility for toxic amounts of filth.
 3. ~~Filth Contaminant Testing. Each Harvest Batch of Retail Marijuana must be visually inspected by a Retail Marijuana Testing Facility for toxic amounts of filth.~~ Repealed.
 4. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Retail Marijuana Concentrate produced by a Retail Marijuana Products Manufacturing Facility must be tested by a Retail Marijuana Testing Facility for residual solvent contamination. 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 R 605.
- D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility wholesaling, transferring, or processing into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants, biological contaminants, harmful chemicals, adulterants or other types of microbials, molds, metals, filth or residual solvents.
- E. Exemptions
1. Retail Marijuana Concentrate. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from this rule if the Retail Marijuana Products Manufacturing Facility that produced it does not wholesale or transfer any of portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing.
- F. Required Re-Validation - Contaminants.
1. Material Change Re-validation. If a Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility 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 Retail Marijuana Establishment's process must be re-validated.

- a. Pesticide. It shall be considered a Material Change if a Retail Marijuana Cultivation Facility 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 Retail Marijuana Products Manufacturing Facility begins using a new or different solvent or combination of solvents.
 - c. Notification. A Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility that makes a Material Change must notify the Retail 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 Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility that produced it may not wholesale, transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any of the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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 Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility shall follow the procedures in paragraph B of rule R 1507 for any package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility shall also submit three additional Test Batches of the Retail Marijuana or Retail Marijuana Product for contaminant testing by a Retail Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility shall re-validate its process for contaminants.
 3. Expiration of Process Validation. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility shall be required to re-validate its process once the one year of process validation expires, or the Retail Marijuana Establishment shall comply with the requirements of paragraph A of this rule R 1501.
- G. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Basis and Purpose – R 1502

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), 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 protect the public health and safety by establishing the mandatory testing portion of the Division's Retail Marijuana sampling and testing program.

R 1502 – Retail Marijuana Testing Program – Mandatory Testing

- A. Required Sample Submission. A Retail Marijuana Establishment may be required by the Division to submit a Sample(s) of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product it possesses to a Retail 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. ~~harmful chemicals and adulterants.~~
 2. When a Sample(s) is required to be submitted for testing, the Retail Marijuana Establishment may not sell, wholesale, transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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 Retail Marijuana Establishment's process has been validated.
 2. Inspection or Enforcement Tests. The Division may require a Retail Marijuana Establishment to submit a Sample for testing if the Division has reasonable grounds to believe that:
 - a. Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product is contaminated or mislabeled;
 - b. A Retail Marijuana Establishment 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 Retail Marijuana Establishment 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 R 1500 series are the minimum required testing standards. Retail Marijuana Establishments are responsible for receiving enough testing on any Retail Marijuana, Retail Marijuana Concentrate, and/or Retail Marijuana Product they produce to ensure the marijuana consumables are safe for human consumption.
- D. Additional Sample Types. The Division may also require a Retail Marijuana Establishment to submit Samples comprised of items other than Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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. ~~harmful chemicals and adulterants.~~ 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 Retail Marijuana Concentrate,
 4. Any ingredient or substance used in the manufacturing of a Retail Marijuana 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 – R 1504

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VI), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), 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 protect the public health and safety by establishing sampling procedures and rules for the Division's Retail Marijuana sampling and testing program.

R 1504 – Retail Marijuana Testing Program – Sampling Procedures

- 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 Retail Marijuana Establishment, 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 Retail Marijuana or Retail Marijuana Product, or any Samples of the Retail Marijuana or Retail Marijuana Product, for the purpose of circumventing contaminant testing detection limits or potency testing requirements. A violation of this sub-paragraph (A)(3) shall be considered a license violation affecting public safety.
- B. Samples for Test Batches of Retail Marijuana and Retail Marijuana Concentrate. Each Test Batch of Retail Marijuana or Retail Marijuana Concentrate must be comprised of a representative selection of Samples.
1. Minimum Number of Samples. At a minimum, each Test Batch of Retail Marijuana or Retail 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 Retail Marijuana Product
1. Finished Product. Test Batches of Retail Marijuana Product must be comprised of finished product that is packaged for sale.
 2. Multiple Production Batches. If more than one Production Batch of Retail Marijuana 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. Retail Marijuana Testing Facility Selection. The Division will generally permit a Retail Marijuana Establishment to select which Retail Marijuana Testing Facility will test a Sample collected pursuant to this rule. However, the Division may elect, at its sole discretion, to assign a Retail 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.

R 1000 Series – Labeling, Packaging, and Product Safety**Basis and Purpose – R 1004**

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), and 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(V), 12-43.4-404(4)(a), 12-43.4-404(b)(I-II), 12-43.4-404(6), 12-43.4-404(8), 12-43.4-901(2)(a), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that every Retail Marijuana Products Manufacturing Facility labels each Shipping Container and Container holding a Retail Marijuana Product with all of the necessary and relevant information for the receiving Retail Marijuana Establishment. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Retail Marijuana Product as this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of House Bill 15-1283, which modified 12-43.4-202(3)(a)(IV)(E), C.R.S. The bill established that the acceptable potency variance, which the Division must determine for correct labeling, must be at least plus or minus 15 percent.

R 1004 – Packaging and Labeling Requirements of a Retail Marijuana Product by a Retail Marijuana Products Manufacturing Facility

Rule R 1004 is effective beginning October 1, 2016.

- A. Packaging of Retail Marijuana Product by a Retail Marijuana Products Manufacturing Facility
1. General Standard. Every Retail Marijuana Products Manufacturing Facility must ensure that each Container holding a Retail Marijuana Product is placed in a Shipping Container prior to transport or transfer to another Retail Marijuana Establishment.
 2. Single-Serving Edible Retail Marijuana Product. Every Retail Marijuana Products Manufacturing Facility must ensure that each Single-Serving Edible Retail Marijuana Product is packaged within a Child-Resistant Container prior to transport or transfer to another Retail Marijuana Establishment.
 3. Bundled Single-Serving Edible Retail Marijuana Product. A Retail Marijuana Products Manufacturing Facility may bundle Single-Serving Edible Retail Marijuana Products that are packaged in Child-Resistant packaging and labeled pursuant to Rule R 1004.5(B) into a larger package that does not need to be Child-Resistant so long as:
 - a. The total amount of active THC contained within the larger package does not exceed 100 milligrams;
 - b. The larger package complies with the Universal Symbol labeling requirement of subparagraph (B)(1)(i) of this rule R 1004; and
 - c. The larger package complies with the Serving Size and Total Active THC Statement requirement of subparagraph (B)(2)(c) of this rule R 1004.
 4. Multiple-Serving Edible Retail Marijuana Product. Every Retail Marijuana Products Manufacturing Facility must ensure that each Multiple-Serving Edible Marijuana Product is packaged within a Child-Resistant Container that maintains

its Child-Resistant effectiveness for multiple openings prior to transport or transfer to another Retail Marijuana Establishment.

4.5 Liquid Edible Retail Marijuana Product.

- a. Each Liquid Edible Retail Marijuana Product that is a Single-Serving Edible Retail Marijuana Product shall be packaged pursuant to subparagraph (A)(2) of this rule R 1004.
- b. Each Liquid Edible Retail Marijuana Product that is a Multiple-Serving Edible Retail Marijuana Product shall be:
 - i. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving in increments equal to or less than 10mg of active THC per serving, with no more than 100mg of active THC total per Child-Resistant package; and
 - ii. The measurement component must be within the Child-Resistant cap or closure of the bottle and not a separate component.

5. Retail Marijuana Product that is not Edible Retail Marijuana Product. Every Retail Marijuana Products Manufacturing Facility must ensure that each Retail Marijuana Product that is not an Edible Retail Marijuana Product is individually packaged within a Container prior to transport or transfer to another Retail Marijuana Establishment.

- B. Labeling of Retail Marijuana Product Containers by a Retail Marijuana Products Manufacturing Facility. A Retail Marijuana Products Manufacturing Facility must ensure that a label(s) is affixed to every Container holding a Retail Marijuana Product that includes all of the information required by this rule prior to transport or transfer to another Retail Marijuana Establishment.

1. Required Information (General). Every Retail Marijuana Products Manufacturing Facility must ensure the following information is affixed to every Container holding a Retail Marijuana Product:
 - a. The license number of the Retail Marijuana Cultivation Facility(-ies) where the Retail Marijuana used to produce the Retail Marijuana Product was grown;
 - b. The Production Batch Number(s) of Retail Marijuana Concentrate(s) used in the production of the Retail Marijuana Product.
 - c. The license number of the Retail Marijuana Products Manufacturing Facility that produced the Retail Marijuana Product.
 - d. A net weight statement.
 - e. The Production Batch Number(s) assigned to the Retail Marijuana Product.
 - f. A statement about whether the Container is Child-Resistant.
 - g. A clear set of usage instructions for non-Edible Retail Marijuana Product.

- h. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Products Manufacturing Facility that manufactured the Retail Marijuana Product. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
- i. The Universal Symbol, which must be located on the front of the packaging and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: “Contains Marijuana. Keep out of the reach of children.”;
- j. The following warning statements:
 - i. **“There may be health risks associated with the consumption of this product.”**
 - ii. **“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.4-202(3)(a)(IV)(E), C.R.S.”**
 - iii. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
 - iv. **“The intoxicating effects of this product may be delayed by two or more hours.”**
 - v. **“There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”**
 - vi. **“Do not drive a motor vehicle or operate heavy machinery while using marijuana.”**
- k. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana used to produce the Retail Marijuana Product.
- l. A complete list of solvents and chemicals used in the creation of any Retail Marijuana concentrate that was used to produce the Retail Marijuana Product.
- m. **Required Potency Statement. For each Production Batch of Retail Marijuana Product packaged within a Container, the Retail Marijuana Products Manufacturing Facility shall ensure the potency of at least the Retail Marijuana Product’s THC and CBD is included on a highlighted label that is affixed to the Container. The potency shall be expressed in milligrams for each cannabinoid.**

- 2. Required Information (Edible Retail Marijuana Product). Every Retail Marijuana Products Manufacturing Facility must ensure that the following information or statement is affixed to every Container holding an Edible Retail Marijuana Product:

- a. Ingredient List. A list of all ingredients used to manufacture the Edible Retail Marijuana Product; which shall include a list of any potential allergens contained within.
 - b. Statement Regarding Refrigeration. If the Retail Marijuana Product is perishable, a statement that the Retail Marijuana Product must be refrigerated.
 - c. Serving Size and Total Active THC Statement. Information regarding: the size of Standardized Serving Of Marijuana for the product by milligrams, the total number of Standardized Servings of Marijuana in the product, and the total amount of active THC in the product by milligrams. For example: **“The serving size of active THC in this product is X mg, this product contains X servings of marijuana, and the total amount of active THC in this product is X mg.”** This information must appear as a highlighted label.
 - d. Statement of Production Date. The date on which the Edible Retail Marijuana Product was produced.
 - e. Statement of Expiration Date. A product expiration date, for perishable Retail Marijuana Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container holding a Retail Marijuana Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.
 - f. A nutritional fact panel that must be based on the number of THC servings within the Container.
3. Permissive Information (Edible Retail Marijuana Product). Every Retail Marijuana Products Manufacturing Facility may affix a label(s) with the following information to every Container holding an Edible Retail Marijuana Product:
 - a. The Retail Marijuana Product’s compatibility with dietary restrictions.
 4. Required Potency Statement.
 - a. Every Retail Marijuana Products Manufacturing Facility must ensure that a label is affixed to the Container that includes the number of THC servings within the Container, and at least the Retail Marijuana Product’s THC and CBD content.
 - b. Nothing in this rule permits a Retail Marijuana Establishment to transfer, wholesale, or sell Retail Marijuana Product that has failed potency testing and has not subsequently passed the additional potency testing required by rule R 1507(C).
 5. Required Contaminant Testing Statement.
 - a. When All Required Contaminant Tests Are Not Performed. If a Retail Marijuana Testing Facility did not test a Production Batch of Retail Marijuana Product for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **“The Retail Marijuana**

Product contained within this package has not been tested for contaminants.” Except that when a Retail Marijuana Products Manufacturing Facility has successfully validated its process regarding contaminants for the particular Retail Marijuana Product pursuant to rule R 1501, then the Container instead shall be labeled with the following statement: **“The Retail Marijuana Product contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**

- b. When All Contaminant Tests Are Performed and Passed. If a Retail Marijuana Testing Facility tested a Production Batch of Retail Marijuana Product for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **“The Retail Marijuana Product contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - c. Nothing in this rule permits a Retail Marijuana Establishment to transfer, wholesale, or sell Retail Marijuana Product that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule R 1507(B).
- D. Labeling of Retail Marijuana Product Shipping Containers by Retail Marijuana Products Manufacturing Facility. Prior to transporting or transferring any Retail Marijuana Product to another Retail Marijuana Establishment, a Retail Marijuana Manufacturing Products Facility must ensure that a label is affixed to a Shipping Container holding Retail Marijuana Product that includes all of the information required by this rule. A Retail Marijuana Products Manufacturing Facility must include the following information on every Shipping Container:
1. The number of Containers holding a Retail Marijuana Product within the Shipping Container; and
 2. The license number of the Retail Marijuana Products Manufacturing Facility(-ies) that produced the Retail Marijuana Product within the Shipping Container.

Basis and Purpose – R 1005.5

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-402(4), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that the labeling on each Container of Retail Marijuana includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. Further, the State Licensing Authority believes based on written and oral comments it has received through the rulemaking process that prohibiting labels that are intended to target individuals under the age of 21 and requiring child-resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to all Retail Marijuana as this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of House Bill 15-1283, which modified 12-43.4-202(3)(a)(IV)(E), C.R.S. The bill established that the acceptable potency variance, which the Division must determine for correct labeling, must be at least plus or minus 15 percent.

R 1005.5 – Packaging and Labeling of Retail Marijuana by a Retail Marijuana Store

Rule 1005.5 is effective beginning October 1, 2016.

- A. Packaging of Retail Marijuana by a Retail Marijuana Store. A Retail Marijuana Store must ensure that all Retail Marijuana is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Retail Marijuana Store must place the Container within an Exit Package that is Child-Resistant.
- B. Labeling of Retail Marijuana by a Retail Marijuana Store. A Retail Marijuana Store must affix all of the information required by this rule to every Container in which Retail Marijuana is placed no later than at the time of sale to a consumer:
1. A Retail Marijuana Store must include the following information on every Container:
 - a. The license number of the Retail Marijuana Cultivation Facility(-ies) where the Retail Marijuana was grown;
 - b. The license number of the Retail Marijuana Store that sold the Retail Marijuana to the consumer;
 - c. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Store that sold the Retail Marijuana to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
 - d. The Harvest Batch Number(s) assigned to the Retail Marijuana within the Container;
 - e. The date of sale to the consumer;
 - f. The net weight, in grams to at least the tenth of a gram, of the Retail Marijuana prior to its placement in the Container;
 - g. The Universal Symbol, which must be located on the front of the Container and no smaller than $\frac{1}{2}$ of an inch by $\frac{1}{2}$ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. Keep out of the reach of children.";
 - h. The following warning statements:
 - i. **"There may be health risks associated with the consumption of this product."**
 - ii. **"This marijuana's potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.4-202(3)(a)(IV)(E), C.R.S."**
 - iii. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

- iv. **“Do not drive or operate heavy machinery while using marijuana.”**
 - i. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana.
2. Required Potency Statement. For each Harvest Batch of Retail Marijuana packaged within a Container, the Retail Marijuana Store shall ensure the potency of at least the Retail Marijuana’s THC and CBD is included on a **highlighted** label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Retail Marijuana cultivated by the same Retail Marijuana Cultivation Facility within the last six months.
3. Required Contaminant Testing Statement.
- a. **When All Required Contaminant Tests Are Not Performed.** If a Retail Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then a Retail Marijuana Store must ensure that a label is affixed to a Container holding any Retail Marijuana from that Harvest Batch with the following statement: **“The marijuana contained within this package has not been tested for contaminants.”** Except that when a Retail Marijuana Cultivation Facility has successfully validated its process regarding contaminants pursuant to rule R 1501, then the Container instead shall be labeled with the following statement: **“The marijuana contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - b. **When All Required Contaminant Tests Are Performed and Passed.** If a Retail Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and all the required test(s) passed, then the Container shall be labeled with the following statement: **“The marijuana contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - c. Nothing in this rule permits a Retail Marijuana Establishment to transfer, wholesale, or sell Retail Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule R 1507(B).

Basis and Purpose – R 1006

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(c)(III), 12-43.4-202(3)(c)(V), 12-43.4-402(2), 12-43.4-402(4), 12-43.4-402(5), 12-43.4-901(2)(a), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that the labeling on each Container holding a Retail Marijuana Product includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. Further, the State Licensing Authority believes based on written and oral comments it has received through the rulemaking process that prohibiting labels that are intended to target individuals under the age of 21 and requiring child-resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Retail Marijuana Product as this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the

mandate of House Bill 15-1283, which modified 12-43.4-202(3)(a)(IV)(E), C.R.S. The bill established that the acceptable potency variance, which the Division must determine for correct labeling, must be at least plus or minus 15 percent.

R 1006 – Packaging and Labeling of Retail Marijuana Product by a Retail Marijuana Store

Rule R 1006 is effective October 1, 2016.

- A. Packaging Requirements for a Retail Marijuana Store.
1. Beginning December 1, 2016, a Retail Marijuana Store shall not purchase, take possession of, or sell Retail Marijuana Product that does not comply with rules R 604 and R 1004.
 2. A Retail Marijuana Store must ensure that each Edible Retail Marijuana Product placed within a Container for sale to a consumer pursuant to this rule must also be placed in an Opaque Exit Package at the point of sale to the consumer.
 3. A Retail Marijuana Store must ensure that each Retail Marijuana Product that is not an Edible Retail Marijuana Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Retail Marijuana Store must place the Container within an Exit Package that is Child-Resistant.
- B. Labeling of Retail Marijuana Product by a Retail Marijuana Store. Every Retail Marijuana Store must ensure that a label(s) is affixed to every Exit Package at the time of sale to a consumer that includes all of the information required by this rule. If an Exit Package is not required pursuant to paragraph (A)(3) of this rule, and the Retail Marijuana Store elects not to provide one, then the Retail Marijuana Store must ensure the labels required by this rule are affixed to each Container.
1. Required Information.
 - a. The license number of the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer;
 - b. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
 - c. The date of sale to the consumer;
 - d. The following warning statements:
 - i. **“There may be health risks associated with the consumption of this product.”**
 - ii. **“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.4-202(3)(a)(IV)(E), C.R.S.”**

- iii. “This product was produced without regulatory oversight for health, safety, or efficacy.”
 - iv. “The intoxicating effects of this product may be delayed by two or more hours.”
 - v. “There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”
 - vi. “Do not drive a motor vehicle or operate heavy machinery while using marijuana.”
- e. The Universal Symbol, which must be located on the front of the Container or Exit Package as appropriate and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: “Contains Marijuana. Keep out of the reach of children.”.
- f. Required Potency Statement. For each Production Batch of Retail Marijuana Product, the Retail Marijuana Store shall ensure the potency of at least the Retail Marijuana Product’s THC and CBD is included on a highlighted label that is affixed to the Container. The potency shall be expressed in milligrams for each cannabinoid.

Basis and Purpose – R 1007.5

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-402(4), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that the labeling on each Container holding a Retail Marijuana Concentrate includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. Further, the State Licensing Authority believes based on written and oral comments it has received through the rulemaking process that prohibiting labels that are intended to target individuals under the age of 21 and requiring Child-Resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Retail Marijuana Concentrate because this is a public health and safety concern. The allowable plus or minus 15% potency variance has been included in the rule pursuant to the mandate of House Bill 15-1283, which modified 12-43.4-202(3)(a)(IV)(E), C.R.S. The bill established that the acceptable potency variance, which the Division must determine for correct labeling, must be at least plus or minus 15 percent.

R 1007.5 – Packaging and Labeling of Retail Marijuana Concentrate by a Retail Marijuana Store

Rule 1007.5 is effective beginning October 1, 2016.

- A. Packaging of Retail Marijuana Concentrate by a Retail Marijuana Cultivation Facility. A Retail Marijuana Store must ensure that all Retail Marijuana Concentrate is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Retail Marijuana Store must place the Container within an Exit Package that is Child-Resistant.

- B. Labeling of Retail Marijuana Concentrate by Retail Marijuana Stores. Every Retail Marijuana Store must ensure that a label(s) is affixed to every Container holding Retail Marijuana Concentrate that includes all of the information required by this rule no later than at the time of sale to a consumer:
1. Every Retail Marijuana Store must ensure the following information is affixed to every Container holding a Retail Marijuana Concentrate:
 - a. The license number of the Retail Marijuana Cultivation Facility(-ies) where the Retail Marijuana used to produce the Retail Marijuana Concentrate within the Container was grown;
 - b. The license number of the Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility that produced the Retail Marijuana Concentrate;
 - c. The Production Batch Number assigned to the Retail Marijuana Concentrate;
 - d. The license number of the Retail Marijuana Store that sold the Retail Marijuana Concentrate to the consumer;
 - e. The net weight, in grams to at least the tenth of a gram, of the Retail Marijuana Concentrate prior to its placement in the Container;
 - f. The date of sale to the consumer;
 - g. The following warning statements:
 - i. **“There may be health risks associated with the consumption of this product.”**
 - ii. **“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.4-202(3)(a)(IV)(E), C.R.S.”**
 - iii. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
 - iv. **“There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”**
 - v. **“Do not drive a motor vehicle or operate heavy machinery while using marijuana.”**
 - h. The Universal Symbol, which must be located on the front of the Container and no smaller than $\frac{1}{2}$ of an inch by $\frac{1}{2}$ of an inch, and the following statement which must be labeled directly below the Universal Symbol: “Contains Marijuana. Keep out of the reach of children.”;
 - i. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana used to produce the Retail Marijuana concentrate; and

- j. A complete list of solvents and chemicals used to produce the Retail Marijuana Concentrate.
2. Required Potency Statement. For each Production Batch of Retail Marijuana Concentrate packaged within a Container, the Retail Marijuana Store shall ensure the potency of at least the Retail Marijuana Concentrate's THC and CBD is included on a highlighted label that is affixed to the Container. The potency shall be expressed in milligrams for each cannabinoid.
3. Required Contaminant Testing Statement.
- a. When All Required Contaminant Tests Are Not Performed.
 - i. Solvent-Based Retail Marijuana Concentrate. If a Retail Marijuana Testing Facility did not test a Production Batch of Solvent-Based Retail Marijuana Concentrate for residual solvents, mold, and mildew, then the Container shall be labeled with the following statement: **“The Retail Marijuana Concentrate contained within this package has not been tested for contaminants.”** Except that when a Retail Marijuana Products Manufacturing Facility has successfully validated its process regarding contaminants pursuant to rule R 1501, the Container instead shall be labeled with the following statement: **“The Retail Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - ii. Food- and Water-Based Retail Marijuana Concentrate. If a Retail Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Retail Marijuana Concentrate for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **“The Retail Marijuana Concentrate contained within this package has not been tested for contaminants.”** Except that when a Retail Marijuana Cultivation Facility or a Retail Marijuana Products Manufacturing Facility has successfully validated its process regarding contaminants pursuant to rule R 1501, then the Container instead shall be labeled with the following statement: **“The Retail Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - b. When All Required Contaminant Tests Are Performed and Passed.
 - i. Solvent-Based Retail Marijuana Concentrate. If a Retail Marijuana Testing Facility tested a Production Batch of Solvent-Based Retail Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: **“The Retail Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule R 1501.”**
 - ii. Food- and Water-Based Retail Marijuana Concentrate. If a Retail Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed,

then the Container shall be labeled with the following statement:
“The Retail Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule R 1501.”

- c. Nothing in this rule permits a Retail Marijuana Establishment to transfer, wholesale, or sell Retail Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule R 1507(B).