COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Heather Krug, State Cannabis Sciences Program Manager, Colorado State Public Health Laboratory

Through: Scott Bookman, Interim Director, Division of Disease Control and Public Health Response (DCPHR) *SB*
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Date: December 16, 2020

Subject: Request for Rulemaking Hearing concerning New rule 5 CCR 1005-5, *Hemp Testing Laboratory Certification*.

Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Engagement, and Proposed New Rule, 5 CCR 1005-5, Hemp Testing Laboratory Certification.

The Department is requesting a rulemaking hearing to establish new rules for certification of hemp testing laboratories. The need for these rules is described below.

The Colorado Department of Agriculture (CDA) regulates the cultivation of industrial hemp as authorized through Title 35, Article 61 C.R.S. Hemp cultivators are subject to sampling by the CDA to test for Tetrahydrocannabinol (THC) content before harvest, as established by Rules Pertaining To The Administration And Enforcement Of The Industrial Hemp Regulatory Program Act (8 CCR 1203-23). Industrial hemp with a THC level exceeding 0.3% is not legally considered hemp and is instead considered marijuana, a controlled substance. To date, this testing has been performed exclusively by the CDA laboratory, with the CDA capable of testing approximately 30% of all registered hemp producing areas in Colorado annually.

On October 31, 2019 the United States Department of Agriculture (USDA) released interim final rules on industrial hemp production. A key element of the interim final rule is the requirement to test 100% of registered hemp producers in the state. Thus, with the CDA laboratory limited in the amount of industrial hemp they can test, cultivators will look to private laboratories to complete this testing. Furthermore, Colorado Senate Bill 20-197 requires that hemp samples be submitted to a state certified industrial hemp testing laboratory.

The Department is well positioned to be the agency that certifies laboratories to perform hemp testing because it already has expertise in lab inspection, as it currently inspects and recommends marijuana testing labs for certification and certifies clinical, environmental, and forensic laboratories. The Department also houses the state's cannabis reference lab. As such, the Department possesses unique expertise of both lab certification and the technical aspects of cannabis testing.

In addition to the testing of hemp biomass for THC content, the Department regulates hemp-derived products under the provisions of section 25-5-426, C.R.S. and has a need for testing of these cannabidiol (CBD) oils and foods for THC content and other contaminants of concern in food products, such as

pathogenic bacteria and toxins. Hemp-derived products include foods, tinctures, and oils in various forms such as capsules made by extracting CBD and other components from hemp biomass.

While all hemp and hemp-derived product testing can be performed by state certified marijuana testing facilities, there is a need to establish state-certified hemp testing laboratories that can operate outside of the close-looped marijuana seed-to-sale system. Marijuana testing facilities must track all samples they receive through this system as part of the diversion prevention measures applicable to legal marijuana products in Colorado. While hemp companies can elect to use this system and submit samples to marijuana testing facilities, doing so increases the cost of testing for these companies. Many also want to remain separate from any association with the marijuana industry.

Finally, the Colorado Hemp Advancement and Management Plan (CHAMP) stakeholders have recommended the development of a Hemp Testing Laboratory Certification Program to comply with state and USDA rules to guarantee THC testing of all hemp lots grown in Colorado, and to protect public safety by ensuring human-consumable products meet standards for safety and purity. Further, it is important to establish a state-level testing framework in the absence of federal guidelines from the Food and Drug Administration.

Testing information from certified labs is crucial for:

- Maintaining compliance with the USDA;
- Implementing an important part of the hemp electronic traceability system;
- Assuring potency and purity to consumers and businesses purchasing hemp products; and
- Protecting businesses and the public against inaccurate or misleading product claims and against product impurities and food-borne illnesses.

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. A summary of the feedback received and, if the Department incorporated this feedback, is detailed in the Stakeholder Engagement section.

Thus, in response to the regulatory need and stakeholder recommendations, the Department is requesting a rulemaking hearing to establish rules for hemp testing laboratory certification. In total, laboratory certification will promote accuracy and reproducibility of test results. Accurate testing of hemp and hemp-derived products will allow for the identification of non-compliant hemp, aid in the consistency of products available to consumers, help ensure label claims are accurate, and protect public health and safety by ensuring products are free of contaminants.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for New rule
5 CCR 1005-5, *Hemp Testing Laboratory Certification*

Basis and Purpose.

Colorado became a national leader in industrial hemp cultivation and production when it launched one of the first successful pilot hemp programs in the United States in 2015. The recent passage of the 2018 Agricultural Improvement Act, commonly called the Farm Bill, requires each state department of agriculture to submit a state management plan to the United States Department of Agriculture (USDA), outlining how various aspects of hemp cultivation and processing will be managed within their jurisdiction.

Hemp is an emerging specialty crop that has received considerable attention from agricultural producers, consumers, manufacturing businesses, and policymakers both internationally and in the State of Colorado. Hemp cultivation may provide an alternative enterprise to improve grower profitability and a potential engine of economic development and business creation, while also contributing to the sustainability of Colorado's natural resources as a substitute crop. Hemp can be manufactured and processed into numerous industrial and commercial goods for which there is a national and international demand. On the industrial front, applications range from building materials and textiles to food ingredients and wellness products. As the supply chain grows and matures, Colorado is poised to benefit. For this growth in demand to occur, however, the industry must be proactive about early-stage issues like standardization, unproven use cases and efficacy, and the accuracy of dosing for consumable products.

Colorado citizens voted to pass Amendment 64 to the Colorado Constitution in 2012, which, in part, directed the General Assembly to enact legislation governing the cultivation, processing, and sale of industrial hemp.[1] The legislation enacted in 2013 delegated responsibility for most hemp-related registration and inspection oversight to the Colorado Department of Agriculture (CDA). Statutory authority for Colorado's Industrial Hemp Program appears in Title 35 Article 61 of the Colorado Revised Statutes. In the following years, CDA promulgated a comprehensive set of rules to administer and enforce the Colorado Industrial Hemp Regulatory Program Act ("hemp program"), which is enabled by regulations set forth at 8 CCR 1203-23. Under the Colorado hemp program, CDA regulates the cultivation of industrial hemp. In order to grow industrial hemp in Colorado, cultivators must register annually with the CDA. Colorado has the largest industrial hemp registered land area in the nation with 88,743 acres. Notably, the CDA does not have jurisdiction over the processing, sale, or distribution of industrial hemp products. Any amount of hemp being grown requires a registration with CDA. Even though the 2018 Farm Bill removed hemp from the Controlled Substance Act, it did not de-regulate it. Prior to the 2018 Farm Bill, there was a grey area of hemp being legal at the State level under the 2014 Farm Bill Pilot Program, but yet still considered a "Controlled Substance" and illegal according to Federal laws. The 2018 Farm Bill eliminates the grey area, but still mandates States to maintain information on any land (regardless of size) where hemp is grown (regardless of quantity). The CDA's authority is limited to cultivation; the oversight for processing, sales and distribution is provided by CDPHE, pursuant to section 35-61-108, C.R.S. Hemp product manufacturers must register with the CDPHE to process hemp and produce hemp-derived products.

[1]. As defined in the Colorado Revised Statutes, and in the 2018 Farm Bill, the term "industrial hemp" means the plant species *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Δ-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

The 2018 Farm Bill changed hemp production in several ways, by 1) clarifying that both hemp and hemp products are legal in the U.S., 2) amending the Controlled Substances Act to remove hemp from the definition of marijuana, and 3) revising language in the 2014 Farm Bill Pilot Program to expressly include products derived from hemp in the legal definition of industrial hemp. Finally, the 2018 Farm Bill also allowed commercial cultivation and manufacturing of hemp outside of the 2014 Farm Bill pilot projects. Under the 2018 Farm Bill, each state must submit a management plan to the USDA for approval that includes a framework outlining how the state will regulate and monitor the various aspects of hemp production. The 2018 Farm Bill also instructs the USDA to promulgate federal rules for commercial hemp production. Importantly, the 2018 Farm Bill does not address regulations for processing and manufacturing of hemp products into food, drugs, and cosmetics, such regulations are still forthcoming from the FDA.

The USDA issued its first set of hemp regulations in October 2019, the Interim Final Rule (IFR), which formally addressed hemp cultivation, harvest, and testing. The IFR established a regulatory framework for USDA oversight of domestic hemp production under the 2018 Farm Bill. The IFR established requirements for approval of state or tribal plans regulating the production of hemp in their territories. Rules addressed the production, sampling, testing, and disposal of hemp plants, and set thresholds for acceptable amounts of Tetrahydrocannabinol (THC).

To respond to the needs and emerging issues of the hemp industry, the state organized a collaborative initiative with a broad group of stakeholders and state agencies known as the Colorado Hemp Advancement and Management Plan (CHAMP) in 2019. The CHAMP initiative represented a broad stakeholder effort that included representatives from:

- CDA
- Governor's Office
- Colorado Department of Public Health and Environment (CDPHE)
- Department of Revenue (DOR)
- Department of Regulatory Agencies (DORA)
- Office of Economic Development and International Trade (OEDIT)
- Department of Public Safety (DPS)
- Department of Education (CDE)
- Ute Mountain Ute Tribe
- Southern Ute Indian Tribe
- Local governments
- State institutions of higher learning
- Industry experts

Through the CHAMP process, stakeholders crafted economic advancement principles for the entire hemp supply chain, including research and development, seed, cultivation, testing, transportation, processing, manufacturing, marketing, and finance and insurance. The CHAMP initiative ensured that a wide range of stakeholders, including members of the public, had the opportunity to comment on and participate in shaping a variety of hemp-related policies the State of Colorado should strive to implement through a series of in-person meetings of eight different stakeholder groups as well as a travelling series of public engagement meetings held across the state. The goals of this collaborative process were to develop a robust and functional hemp supply chain, as well as inform the state’s hemp management plan for submission to the USDA.

A key area of focus of both the CHAMP initiative and the USDA IFR is testing. The new federal rules include regulations on reporting and testing requirements, including the requirement to establish a procedure for accurate and effective sampling and testing of *all* hemp production areas.

Currently, hemp cultivators are subject to sampling by the CDA to test for THC content before harvest, to ensure it does not exceed the allowable threshold of 0.3% THC. In 2019, crops from approximately 30% of the 2,634 registered hemp producing areas were sampled. The CDA currently tests these samples in its laboratory facilities in Broomfield, CO. In addition, hemp product manufacturers must also be able to document that the final product does not contain more than 0.3% THC, but there is not yet an established testing program or approved laboratories to perform this testing. The CDA lab only has capacity to test hemp samples from approximately 30% of registrants at its laboratory. The CDA lab also only tests plant material for THC content; it does not test hemp-derived products for THC or for contaminants. Therefore, hemp products are currently only tested on a voluntary basis.

Certified marijuana testing facilities are allowed to test hemp products, but are required to track all samples received through the marijuana seed-to-sale tracking system. Use of this system is not mandatory for hemp registrants and, if utilized, increases costs, so many elect not to use marijuana testing facilities. As a result new labs have begun offering hemp testing, but these labs currently have no state oversight and are not subject to any accreditation/certification requirements.

Due to the unique testing needs of the nascent and evolving hemp industry, the CHAMP initiative stakeholders established a recommendation that the state develop a certification program that provides guidance and oversight to private analytical laboratories on quality assurance requirements, appropriate analytical methods, and general testing procedures. Establishing a Hemp Testing Laboratory Certification Program would create the foundation for reliable laboratory testing to comply with the USDA rules to ensure THC testing of all hemp lots grown in Colorado, and to protect public safety by ensuring human-consumable products meet standards for safety and purity.

Testing information from certified labs is crucial for:

- Maintaining compliance with the USDA;
- Implementing an important part of the eventual hemp electronic traceability system;
- Assuring potency and purity to consumers and businesses purchasing hemp products; and
- Protecting businesses and the public against inaccurate or misleading product claims and against product impurities and food-borne illnesses.

The recommendation further specified that CDPHE will serve as the certifying agency for labs that test hemp and consumable hemp products. CDPHE is well positioned to certify these laboratories to perform hemp testing because it already has expertise in lab certification, as it currently inspects and recommends marijuana testing labs for certification and certifies clinical, environmental, and forensic laboratories. The Department can adapt its process for certifying these other labs for hemp testing labs; the processes, procedures, and equipment are very similar. The Department also houses the state's cannabis reference lab. As such, the Department possesses unique expertise of both lab certification and the technical aspects of cannabis testing.

Thus, the proposed rule establishes a Hemp Testing Laboratory Certification Program, and specifically includes criteria for:

- Laboratory certification authorizations
- General limitations or prohibited acts
- Certification requirements
- Laboratory personnel qualifications
- Standard operating procedure requirements
- Analytical processes
- Proficiency Testing
- Quality assurance and quality control

- Certificates of Analysis (reporting)
- Chain of custody
- Records retention
- Business records required
- Waste Disposal

Below is an explanation of each set of criteria. It is important to note that this proposed rule is largely consistent with the Department of Revenue certification rules found in Colorado Marijuana Rules (1 CCR 212-3) for marijuana testing facilities. Consistency in state certification requirements for all cannabis testing laboratories is necessary to ensure hemp is tested under equivalent laboratory standards.

Laboratory Certification Authorizations:

This section requires a certified Hemp Testing laboratory to verify the entity submitting samples for testing is a registered hemp cultivator or product manufacturer (i.e., is legally producing industrial hemp). This section also specifies that for any required test, the laboratory must be certified in that testing category in order to perform testing for compliance purposes. The rule allows labs to transfer samples to other certified laboratories which may be necessary in the event a laboratory instrument becomes inoperable.

General Limitations or Prohibited Acts:

This section specifies that Hemp Testing Laboratories are not allowed to transfer hemp to anyone except another certified laboratory and shall destroy any remaining sample after testing is completed as laboratories are not permitted to distribute hemp products. The section prohibits testing of unregistered hemp and requires laboratories to reject any sample that may have been tampered with or otherwise contaminated to help ensure test results are accurate. Conflicts of interest are also prohibited and the laboratory must establish policies to prevent these conflicts; this is also a requirement of International Organization for Standardization (ISO) accreditation to the standard for *General requirements for the competence of testing and calibration laboratories* (ISO/IEC 17025:2017).

Certification Requirements:

The CHAMP stakeholder recommendations included that hemp testing requirements align with marijuana testing requirements. Thus, this section includes the same certification categories: residual solvents, microbials, mycotoxins, pesticides, THC and other cannabinoid potency, and metals and aligns with Colorado Marijuana Rules - Retail Marijuana Testing Facilities: Certification Requirements (1 CCR 212-3 Rule 6-415(A)). This alignment also includes requiring ISO 17025 accreditation for the applicable methods for which the laboratory is seeking certification. The section specifies the allowances for provisional certification while a Hemp Testing Laboratory is seeking accreditation and DEA registration. This section further outlines the components of certification expectations.

Laboratory Personnel Qualifications:

Qualified staff with the appropriate scientific experience are critical to ensuring testing and associated quality assurance practices are performed and documented accurately and consistently. This section outlines the qualification requirements for each level of testing personnel and is consistent with personnel qualification requirements for marijuana testing facilities. This rule also outlines all of the responsibilities of the laboratory director who holds ultimate responsibility for these duties and certification standards are met.

Standard Operating Procedure Requirements:

Standard operating procedures (SOPs) are an essential tool for ensuring that laboratory staff are trained on and consistently perform testing procedures in accordance with the validated methodology. These SOPs also describe pre-analytic and post-analytic lab processes such as sample receipt and retention. The procedural requirements outlined in this section provide clarity to laboratories, including which details must be included in written SOPs to meet certification standards.

Analytical Processes:

In order to have confidence in any testing method, certain performance criteria must be established, met, and shown to be consistent. The application of parameters applied during method validation allow for the general acceptance of data generated during subsequent analyses. This section specifies the performance criteria that must be evaluated and proven satisfactory through method validation, such as accuracy and precision, for a laboratory to be certified to perform that test method. The USDA IFR specified that laboratory methods must meet the standard method performance requirements established by AOAC International (AOAC). AOAC is an organization that develops consensus standards for performing analytical testing. These are agreed upon, reproducible protocols for analytical methods. The AOAC requirements have not yet been established for all possible methodologies, so the rule specifies flexibility in that validation of methods should follow AOAC, United States pharmacopoeia (USP), FDA or other established guidelines as appropriate.

This section also details requirements for the use of specific types of instrumentation used to test cannabis. These requirements create a baseline for consistency across laboratories, as methods may vary slightly from lab to lab.

Proficiency Testing:

Proficiency testing is an assessment of the performance of a Hemp Testing Laboratory's methodology and processes. It is also known as inter-laboratory comparison. The goal of proficiency testing is to ensure results are accurate, reproducible, and consistent. Laboratory standardization is achieved when test results with the same high levels of accuracy and precision can be reproduced across analytical systems, laboratories, and over time. Proficiency testing ensures the production of credible and comparable data across laboratories, and is therefore a critical component of obtaining and maintaining laboratory certification.

Quality Assurance and Quality Control (QA/QC):

Quality assurance programs encompass a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods, the volume of specimens tested, or staff turnover. Test results produced by Hemp Testing Laboratories will have a significant influence on public health and industry product acceptability, making QA/QC critical to daily operations. A good QA/QC program does the following:

- Establishes SOPs for each step of the laboratory testing process, ranging from specimen handling to instrument performance validation.
- Defines administrative requirements, such as mandatory recordkeeping, data evaluation, and internal audits to monitor adherence to SOPs.
- Specifies corrective actions, documentation, and the persons responsible for carrying out corrective actions when problems are identified; and
- Sustains high-quality employee performance.

Certificate of Analysis (reporting):

This section specifies the necessary information that must be included on the test result report (certificate of analysis) to ensure the result is traceable to the submitter and sample. It also includes requirements necessary for interpretation of the result such as units of measurement and the methodology's limit of detection. Certificates of Analysis are provided to the submitting cultivator or manufacturer and regulatory agency as required. The section requires total THC concentration to be reported as the measured amount plus the method's uncertainty as required by the USDA IFR, as well as other contaminants required for testing by Colorado Wholesale Food And Shellfish Regulations (6 CCR 1010-21).

Chain of Custody:

Chain of custody is essential to ensure that the end results report by the laboratory correspond to the appropriate sample. Elements of these chain of custody requirements also help ensure that samples are received and stored under appropriate conditions so as to not impact the final result. This section also includes a requirement for the lab to separate and store a retain sample which is necessary for situations where additional testing is required after initial testing and is required by the USDA IFR.

Records Retention:

This section requires Hemp Testing Laboratories to establish processes for preserving records that are essential for verifying the accuracy and traceability of test results. This is necessary for state certification, ISO 17025 accreditation, and at any time a test result is in question.

Business Records Required:

The rule specifies that required records must be maintained for the current year plus three preceding years.

Waste Disposal:

Laboratory waste generated by Hemp Testing Laboratories may include controlled substances (i.e., marijuana), biohazardous waste, and chemical hazardous waste. This section requires compliance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements when disposing of lab generated waste.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: CRS 35-61-105.5(2)(d) and CRS 25-1.5-101(1)(f)

Is this rulemaking due to a change in state statute?
_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
_X____ No
Does this rulemaking include proposed rule language that incorporate materials by reference?
_____ Yes ___ URL
_X____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?
_____ Yes
__X____ No

Does the proposed rule language create (or increase) a state mandate on local government?
___X_ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed.

REGULATORY ANALYSIS
for New rule
5 CCR 1005-5, *Hemp Testing Laboratory Certification*

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule
Hemp Testing Laboratories	~10	C/B
Marijuana Testing Facilities	11	C/B
Hemp Product Manufacturers	~500	S/B
Hemp Cultivators	1279	S/B
Hemp Consumers	~1,400,000	B
State Hemp Registration Programs	2	S

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.

S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.

B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

The Department already has expertise in lab inspection and certification as it currently performs this work for other types of laboratories. As such, it is believed that this work can be the most cost effective and efficient when performed by the Departement. The Department has received $216,277 appropriated from the Industrial Hemp Registration Program Cash Fund to perform hemp laboratory certification activities. Because this certification program is new and the number of labs who will seek this certification is uncertain, the Department will charge a fee equivalent to those paid to marijuana testing facilities. The Department will evaluate whether these fees are sufficient to sustain the program over time and rely on the cash funds to initiate the program and to provide support until the adequacy of fees is fully assessed.

Economic outcomes

Please describe any anticipated financial costs or benefits to these individuals/entities.

C: The Department expects to charge Hemp Testing Laboratories the same fees as marijuana testing facilities:

Annual Certification Fee (includes one testing method), per category	$500.00
On-site inspection base charge	$250.00
Additional On-Site Charges, per method	$150.00
Desk audits (remedial proficiency testing review, personnel review, new testing method review, etc.)	$150.00
Applicable Travel Costs	Actual Costs

S: There may be an increase in test prices for hemp cultivators and manufacturers submitting samples to Hemp Testing Laboratories due the lab's new costs for certification.

B: Consumers may see an increase in hemp prices due to increased testing costs.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

Favorable non-economic outcomes:

C: The quality management requirements of lab certification will require hemp testing laboratories to establish documentation of their processes and testing creating defensible data in the event their test results are questioned.

S: Reproducible, accurate testing of hemp and hemp products will increase regulatory compliance and product safety, resulting in fewer enforcement actions against non-compliant hemp registrants and fewer product recalls as contaminated products will be less likely to be in the marketplace.

B: Consumers will have increased confidence in hemp product label claims and fewer adverse health events from contaminated products.

Unfavorable non-economic outcomes: N/A

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

Type of Expenditure	**Year 1**	**Year 2**
Total Personnel	*$197,177*	*$199,177*
• PHY SCI RES/SCIENTIST IV (anticipated hiring by calendar 2021)	$62,787	$115,914
• PHY SCI RES/SCIENTIST I (anticipated hiring by calendar 2021)	$45,101	$83,263
• One-time, Year 1 vacancy savings due to COVID-affected hiring delays	$89,289	$0
Total Operating	*$19,100*	*$17,100*
• Computer and Furniture, FTE one-time costs and any average annual maintenance and license costs	$15,833	$3,000
• Training and new program planning costs	$2,500	$4,000
• Contractual costs	$0	$3,500
• Travel, professional fees, miscellaneous employee operating costs	$767	$6,600
Total	*$216,277*	*$216,277*

Anticipated CDPHE Revenues: Unknown. Hemp is a nascent industry in Colorado and, thus, the need for testing hemp biomass and hemp products is just emerging. At this time, CDPHE cannot reliably estimate how many labs it will certify in the near term, or if the proposed fee structure will be sufficient to generate revenue for the Department.

B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

___ Comply with a statutory mandate to promulgate rules.
_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
___ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.
_X_ Advance the following CDPHE Strategic Plan priorities:
Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:

___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
___ Data collection and dissemination (Goal 1, 2, 3, 4, 5)
___ Implement quality improvement/a quality improvement project (Goal 1, 2, 3, 5)
___ Employee Engagement (Goal 1, 2, 3)
___ Decisions incorporate health equity and environmental justice (Goal 1, 3, 4)
_X_ Detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, 5)
___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include: N/A

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunctions with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

The only alternative considered was to not require state certification and require only accreditation to the ISO 17025 standard. This idea was not supported by stakeholders who wanted to ensure hemp labs were held to high standards to allow Colorado to continue be a leader in the hemp industry, as well as to ensure that the state could hold labs accountable to any requirements unique to the Colorado Hemp Management Plan and CDA and CDPHE regulations.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

Like other models of laboratory accreditation, state certification of hemp testing laboratories is a means of determining the technical competence of laboratories to perform specific types of testing and measurement. It also provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing services to meet their needs.

The following resources informed the Department's proposed rulemaking:

- Colorado Hemp Advancement and Management Plan
- USDA Interim Final Rule 84 FR 58522
- Industrial Hemp Regulatory Program (Title 35, Article 61 C.R.S.)
- Rules Pertaining To The Administration And Enforcement Of The Industrial Hemp Regulatory Program Act (8 CCR 1203-23)
- Colorado Wholesale Food And Shellfish Regulations (6 CCR 1010-21)
- Colorado Marijuana Rules (1 CCR 212-3)
- International Organization for Standardization. (2017). *General Requirements For The Competence Of Testing And Calibration Laboratories* (ISO Stand No. 17025:2017)

STAKEHOLDER ENGAGEMENT
for 5 CCR 1005-5, Hemp Testing Laboratory Certification

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The Department developed the proposed rules and has sought feedback through an early stakeholder engagement process. These early efforts included sending an email notification of upcoming new rules, summarization of draft proposed changes, draft rule text, and a dedicated online survey where staff could collect feedback from stakeholders. An email announcing upcoming rulemaking was sent to 662 individuals who were asked to sign up if they wished to participate in the stakeholder engagement process. Feedback was then solicited from approximately 70 individuals representing: members of the public, hemp testing laboratories, marijuana testing facilities, hemp cultivators, hemp product manufacturers, Colorado Hemp Industries Association, Grow Hemp Colorado, Colorado Department of Agriculture, Colorado Marijuana Enforcement Division, CDPHE Manufactured Food Safety Program.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

_XX_ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

__ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. Stakeholders were sent an email notification about the rulemaking and proposed changes on November 3, 2020. The November email notification contained a draft version of the proposed rule language and a link to an online form where interested individuals could submit informal feedback. From that initial email, the Department received informal feedback from 12 stakeholders out of approximately 70 stakeholders contacted.

The Department received a few questions through the stakeholder feedback process. To the extent possible, the Department responded to stakeholders who asked clarifying questions or referred them to publicly available information on our website.

Below is a summary of feedback received from stakeholders and how the Department is responding to the suggestions.

- There was significant feedback received suggesting changes to several definitions in the proposed rule. However, these definitions are included in other existing and proposed regulations across several agencies (Colorado Department of Public Health and Environment [CDPHE], Colorado Department of Agriculture [CDA], and Marijuana Enforcement Division [MED]). The Department will need to continue discussions with stakeholders to ensure that any changes made are appropriately consistent with these other regulations.

- Stakeholders expressed a lack of clarity regarding the application of certification requirements to compliance testing versus voluntary testing. The Department agrees with this feedback and has modified the proposed rule to include a definition of "Sample" to provide clarity throughout the rule that any sample referred to is a compliance sample.

- The proposed rule includes a requirement for labs to report cannabinoid results to the CDA via email. Several stakeholders expressed concern that reporting via email would be inefficient for both labs and CDA. The Department conferred with CDA to determine if the rule could be modified to exclude this specific manner of reporting. CDA agreed that the rule could reflect mandatory reporting to the agency in a non-specific manner as the agency is currently considering alternative systems for collecting test results. The Department will defer to CDA regarding the specific mechanism for reporting.

- Stakeholders expressed that Drug Enforcement Agency (DEA) registration should be removed from the rule as a certification requirement. However, DEA registration is required by the United States Department of Agriculture (USDA) Interim Final Rule (IFR), thus, DEA registration needs to remain in rule language for now. Stakeholders may note that the USDA has delayed enforcement of this requirement until October 31, 2021. Additionally, the USDA has not yet issued a final rule and the Department will evaluate any necessary change to this proposed rule, including the requirement for DEA registration, at the time USDA implements a final rule.

- The terms "THC" and Total THC" are often used interchangeably, but are not in fact interchangeable. Stakeholders pointed out specific sections of rule where there was opportunity to clarify which term was technically correct. The Department has made these changes throughout the rule.

- Some feedback was not directly applicable to this rule as a result of the overlap between this rule and other hemp regulations. The Department will share this feedback with the appropriate state agency for their consideration.

- Stakeholders suggested that hemp testing laboratories should not report test results as pass or fail, but instead report only the test result, either quantitatively or qualitatively as appropriate. The Department agrees that the responsibility of determining whether a test result is acceptable or unacceptable falls upon the hemp registrant and applicable regulatory body and has therefore incorporated this suggestion.

- Some feedback suggested the rule be modified to more specifically define certain requirements. For example, it was suggested that rather than stating the lab ensure appropriate environmental conditions, the rule should specify the lab must ensure it has appropriate heat and humidity controls, ventilation, etc. However, these specifications can vary depending on the type of testing performed and the requirements specified by instrumentation manufacturers. These details are thoroughly reviewed during laboratory audits. The Department will leave the general requirements in rule and evaluate specific requirements on a case-by-case basis during audits.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking. N/A

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Colorado State Public Health Lab, Disease Control and Public Health Response Division

Hemp Testing Laboratory Certification

5 CCR 1005-5

Rule 1: Authority and Definitions

1.1 Authority

This regulation is established under the authority contained in sections 35-61-105.5(2)(d) and 25-1.5-101(1)(f) et seq., C.R.S.

1.2 Scope and Purpose

The purpose of this rule is to establish criteria for the certification of laboratories to test Industrial Hemp and hemp-derived products.

1.3 Definitions

The following terms, whenever used in or referred to in these regulations, shall have the following respective meanings:

1.3.1 “Acceptability Criteria” means the specified limits placed on the characteristics of an item or method that are used to determine data quality.

1.3.2 “Accreditation” means approval by an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

1.3.3 “Action Level” means the threshold value that provides the criterion for determining whether a Sample passes or fails an analytical test.

1.3.4 “Analyte” means the substance of interest in the analysis.

1.3.5 “Cannabinoid” means a class of lipophilic molecules that are naturally occurring in cannabis, including Industrial Hemp and marijuana.

1.3.6 “CBD” means cannabidiol.

1.3.7 “CBDA” means cannabidiolic acid.

1.3.8 “Chain of Custody” or “COC” means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a Sample.

1.3.9 “Corrective Action” means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.

1.3.10 “Certificate of Analysis” means an official document issued by a certified Hemp Testing Laboratory that shows results of scientific tests performed on a product.

1.3.11 “Delta-9 tetrahydrocannabinol” or “delta-9 THC” has the same meaning as "tetrahydrocannabinols" as set forth in section 27-80-203 (24). C.R.S. Delta-9 THC is the primary psychoactive component of cannabis. For the purposes of these regulations, the terms "Delta-9 THC" and "THC" are interchangeable.

1.3.12 “Department” means the Colorado Department of Public Health and Environment.

1.3.13 “Exclusivity” means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the Target Organisms from similar but genetically distinct non-target organisms.

1.3.14 “Hemp Testing Laboratory” means a public or private laboratory certified, or approved by the Department, to perform compliance testing or research on Industrial Hemp and Industrial Hemp Products.

1.3.15 “Inclusivity” means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of Target Organisms by a defined relatedness.

1.3.16 “Industrial Hemp” or “hemp” means the plant Cannabis sativa L. and any part of the plant, including the seeds, all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Total THC concentration of no more than 0.3% on a dry-weight basis.

1.3.17 “Industrial Hemp Cultivator” means a producer that grows Industrial Hemp under a current registration issued by the Colorado Department of Agriculture.

1.3.18 “Industrial Hemp Extract” means an unfinished industrial hemp product or industrial hemp product produced through a solvent or non-solvent based industrial hemp manufacturing process, including but not limited to oils, distillates, resins, and isolates.

1.3.19 “Industrial Hemp Manufacturer” means a facility that manufactures, produces, packs, processes (extracts), treats, packages, or holds/warehouses Industrial Hemp Products and unfinished Industrial Hemp Products.

1.3.20 “Industrial Hemp Product” means a finished product containing Industrial Hemp that is for human use or consumption and:

a. Is a cosmetic as defined in 25-5-402(6) C.R.S.; or

b. Is a dietary supplement as defined in 25-5-426(2)(d) C.R.S.; or

c. Is a food as defined in 25-5-402(11) C.R.S.;

d. Is a food additive as defined in 25-5-402(12) C.R.S.;

e. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives; and

f. Contains a Delta-9 THC concentration of no more than 0.3% and

g. Is not a drug as defined in 25-5-402(9) C.R.S.

1.3.21 “Limit of Detection” or “LOD” means the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%).

1.3.22 “Limit of Quantitation” or “LOQ” means the lowest concentration at which the Analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

1.3.23 “Matrix” means the components of a Sample other than the Analyte(s) of interest (i.e., Sample type).

1.3.24 “Measurement Uncertainty” is defined as a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. The following equation is recommended:

Equation: □ = □ × □□

Where, $u_c u_c = \sqrt{u_r^2 + u_R^2 + u_{bias}^2}\sqrt{u_r^2 + u_R^2 + u_{bias}^2}$

And:

u = standard uncertainty (standard deviation)

u_r = uncertainty due to repeatability

u_R = uncertainty due to reproducibility

u_{bias} = uncertainty due to accuracy (bias)

u_c = combined standard uncertainty

U = Expanded uncertainty = $\frac{u}{Mean} * k_{95\%\ confidence\ level}\frac{u}{Mean} * k_{95\%\ confidence\ level}$, k = 2

k = coverage factor, use 2 for a 95% confidence level

1.3.25 “Moisture Content” means the percentage of water in a Sample, by weight.

1.3.26 “Nonconformance” means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system, as defined by the laboratory’s written Corrective Action and Preventive Action procedures.

1.3.27 “Person” means a natural person, an estate, a trust, an entity, or a state or other jurisdiction.

1.3.28 “Preventive Action” means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.

1.3.29 “Proficiency Testing” means an assessment of the performance of a Hemp Testing Laboratory’s methodology and processes. Proficiency Testing is also known as inter-laboratory

comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.

1.3.30 "Quality Control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.

1.3.31 "Reference Material" means material containing a known concentration of an Analyte of interest that is in solution or in a homogeneous Matrix.

1.3.32 "Reference Method" means the method by which the performance of an alternate method is measured or evaluated.

1.3.33 "Sample" means the Industrial Hemp, Industrial Hemp Product submitted to a Hemp Testing Laboratory for compliance testing.

1.3.34 "Scope of Accreditation" means the tests or types of tests performed, materials or products tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted.

1.3.35 "Standard Operating Procedure" (SOP) means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

1.3.36 "Target Organism" means an organism that is being tested for in an analytical procedure or test method.

1.3.37 "THC" means tetrahydrocannabinol.

1.3.38 "THCA" means tetrahydrocannabinolic acid.

1.3.39 "Total CBD" means the sum of the percentage by weight of CBDA multiplied by 0.877 plus the percentage by weight of CBD i.e., Total CBD= (%CBDA x 0.877) + % CBD.

1.3.40 "Total THC" means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + % THC.

1.3.41 "Unfinished Industrial Hemp Product" means an oil, concentrate or other substance that has a total THC concentration above 0.3% and less than or equal to 5.0%, is not for consumer use or distribution, must be sold or transferred between registered industrial hemp manufacturers, and will undergo further refinement or processing into an industrial hemp product.

Rule 2: Hemp Testing Laboratory Certification Authorizations

2.1 Testing of Industrial Hemp Authorized. A Hemp Testing Laboratory may accept Samples of Industrial Hemp, Industrial Hemp Products, and Unfinished Industrial Hemp Products from Persons registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S. or registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S. for testing and research purposes only.

2.1.1 Before a Hemp Testing Laboratory accepts a Sample of Industrial Hemp, Industrial Hemp Product or Unfinished Industrial Hemp Product, the laboratory shall verify that the Person submitting the Sample is registered with the Colorado Department of Agriculture or registered with the Colorado Department of Public Health and Environment.

2.2 A Hemp Testing Laboratory shall be permitted to test Industrial Hemp, Industrial Hemp Product, and Unfinished Industrial Hemp Product for required tests pursuant to Colorado Wholesale Food And Shellfish Regulations (6 CCR 1010-21) and section 35-61-105.5(d), C.R.S. only in the category(ies) that the Hemp Testing Laboratory is certified to perform testing in pursuant to Rule 4.1 – Hemp Testing Laboratory: Certification Requirements.

2.3 Transferring Samples to another Certified Hemp Testing Laboratory. A Hemp Testing Laboratory may transfer Samples to another certified Hemp Testing Laboratory for testing. All laboratory reports provided to a Hemp Registrant must identify the Hemp Testing Laboratory that actually conducted the test.

2.4 A Hemp Testing Laboratory shall provide the results of any required compliance testing performed on Industrial Hemp, Industrial Hemp Product and Unfinished Industrial Hemp Product to the Person submitting the Sample. Results for Total THC compliance testing of Industrial Hemp must also be provided to the Colorado Department of Agriculture.

Rule 3: Hemp Testing Laboratories: General Limitations or Prohibited Acts

3.1. Conflicts of Interest. The Hemp Testing Laboratory, including those that are internal departments of hemp registrants, shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Hemp Testing Laboratory's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Hemp Testing Laboratory's testing processes or results. At a minimum, employees, owners or agents of a Hemp Testing Laboratory who participate in any aspect of the analysis, resulting, and/or reporting of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Industrial Hemp Registrant or Industrial Hemp Manufacturer that provided the Sample. The Hemp Testing Laboratory shall provide documentation showing a clear delineation between production and lab testing activities reflected in their quality management system documentation. Any conflicts of interest must be documented and disclosed.

3.2. Transfer of Industrial Hemp and Industrial Hemp Product Prohibited. A Hemp Testing Laboratory shall not transfer Industrial Hemp or Industrial Hemp Product to an Industrial Hemp Registrant or Industrial Hemp Manufacturer or a consumer, except that a Hemp Testing Laboratory may transfer a Sample to another Hemp Testing Laboratory.

3.3. Destruction of Received Samples. A Hemp Testing Laboratory shall properly dispose of all Samples it receives, that are not transferred to another Hemp Testing Laboratory, after all necessary tests have been conducted and any required period of storage. *See* Rule 14 – Waste Disposal.

3.4 Sample Rejection. A Hemp Testing Laboratory shall reject any Sample where the condition of the Sample at receipt indicates that the Sample may have been tampered with or could have become contaminated as a result of damaged or improper packaging.

3.5 Testing of Unregistered Industrial Hemp or Industrial Hemp Products Prohibited.

3.5.1 A Hemp Testing Laboratory is authorized to accept or test Industrial Hemp only if (1) the entity providing the Samples of Industrial Hemp is regulated by Article 61 of Title 35, C.R.S., and (2) the Industrial Hemp is submitted by a registered cultivator.

3.5.2 A Hemp Testing Laboratory is authorized to accept or test Industrial Hemp Product only if the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Title 25, C.R.S.

Rule 4: Hemp Testing Laboratories: Certification Requirements

4.1. Certification Types. For required tests, the Hemp Testing Laboratory must be certified by the Department in the category in order to perform that type of testing.

4.1.1 Residual solvents;

4.1.2 Microbials;

4.1.3 Mycotoxins;

4.1.4 Pesticides;

4.1.5 THC and other Cannabinoid potency; and

4.1.6 Metals.

4.2 Certification Procedures and Principles. The Hemp Testing Laboratory certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the requirements in this Rule.

4.2.1 Certification Inspection. A Hemp Testing Laboratory must be inspected prior to initial certification and annually thereafter by the Department.

4.2.2 Standards for Certification. A Hemp Testing Laboratory 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 Procedures, analytical processes, Proficiency Testing, Quality Control, quality assurance, security, Chain of Custody, Sample retention, Sample disposal, space, records, and results reporting.

4.2.2.1 A Hemp Testing Laboratory must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2017 Standard (ISO/IEC 17025), or any subsequent superseding ISO/IEC 17025 standard, by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). In order to obtain and maintain certification in a testing category from the Department, the Hemp Testing Laboratory's Scope of Accreditation must specify that particular testing category, including the applicable methods and Analytes. In addition, Hemp Testing Laboratories must be registered with the United State Drug Enforcement Administration.

4.2.2.2 Certification will be granted when laboratories have met all certification requirements, including ISO/IEC 17025 accreditation and DEA registration.

4.2.2.3 The Department may grant provisional certification for a testing category if the laboratory has not yet obtained ISO/IEC 17025 accreditation, but meets all other certification requirements. Such provisional certification shall be for a period not to exceed twelve months.

4.2.2.4 The Department may grant conditional certification to laboratories who have obtained ISO/IEC 17025 accreditation and, and have met all other certification requirements, but are not registered with the DEA.

4.2.3 Personnel Qualifications.

4.2.3.1 Laboratory Director. A Hemp Testing Laboratory 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 5 – Hemp Testing Laboratories: Personnel.

4.3.2 Employee Competency. A Hemp Testing Laboratory 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). Analysts must, at a minimum, annually (or upon method modification) demonstrate continued acceptable competency.

4.2.4 Standard Operating Procedures. A Hemp Testing Laboratory must have written Standard Operating Procedures 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.

4.2.4.1 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.

4.2.4.2 A Hemp Testing Laboratory must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. *See* Rule 11 – Hemp Testing Laboratories: Records Retention and Rule 13 – Hemp Testing Laboratories: Business Records Required.

4.2.4.3 A Hemp Testing Laboratory must inform the Department of any major changes to Standard Operating Procedures pertaining to analytical methods subsequent to initial certification. Major method changes include, but are not limited to: modifications to Sample preparation, changes in column type, changes in enrichment media, changes in solvent(s) used, etc.

4.2.5 Analytical Processes. A Hemp Testing Laboratory must maintain a listing of all analytical methods used and all Analytes tested and reported. The Hemp Testing Laboratory must provide this listing to the Department upon request.

4.2.6 Proficiency Testing. A Hemp Testing Laboratory must successfully participate in a Department approved Proficiency Testing program in order to obtain and maintain certification.

4.2.7 Quality Assurance and Quality Control. A Hemp Testing Laboratory must establish and follow a quality assurance and Quality Control program to ensure sufficient monitoring of laboratory processes and quality of results reported.

4.2.8 Security. A Hemp Testing Laboratory must be located in a secure setting to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.

4.2.9 Chain of Custody. A Hemp Testing Laboratory must establish a system to document the complete Chain of Custody for Samples from receipt through disposal.

4.2.10 Space. A Hemp Testing Laboratory 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.

4.2.11 Records. A Hemp Testing Laboratory must establish a system to retain and maintain records for a period not less than three years. *See* Rules 11 – Hemp Testing Laboratory: Records Retention and Rule 13 – Hemp Testing Laboratories: Business Records Required.

4.2.12 Results Reporting. A Hemp Testing Laboratory must establish processes to ensure results are reported in a timely and accurate manner. A Hemp Testing Laboratory's process may require that the Industrial Hemp Registrant or Industrial Hemp Product Manufacturer remit payment for any test conducted by the laboratory prior to reporting results. A Hemp Testing Laboratory's process established under this subparagraph (12) must be maintained on the premises of the Hemp Testing Laboratory.

4.2.13 Conduct While Seeking Certification. A Hemp Testing Laboratory, and its agents and employees, shall provide all documents and information required or requested by the Department and its employees in a full, faithful, truthful, and fair manner.

Rule 5: Hemp Testing Laboratories: Personnel

5.1 Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Hemp Testing Laboratory, 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.

5.1.1 The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Hemp Testing Laboratory.

5.1.2 The laboratory director for a Hemp Testing Laboratory must meet one of the following qualification requirements:

5.2.2.1 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

5.2.2.2 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

5.2.2.3 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; OR

5.2.2.4 Hold a bachelor's degree in one of the natural sciences and have at least seven 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.

5.2 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 13 - Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.

5.3 Responsibilities of the Laboratory Director. The laboratory director must:

5.3.1 Ensure that the Hemp Testing Laboratory has adequate space, equipment, materials, and controls available to perform the tests reported;

5.3.2 Establish and ensure adherence to written Standard Operating Procedures used to perform the tests reported;

5.3.3 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;

5.3.4 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;

5.3.5 Ensure that the test methodologies selected are fit-for-purpose and appropriate to ensure the quality of results required for the level of testing the laboratory is certified to perform;

5.3.6 Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

5.3.7 Ensure that testing analysts perform the test methods as required for accurate and reliable results;

5.3.8 Ensure that the laboratory is enrolled in and successfully participates in a Department approved Proficiency Testing program;

5.3.9 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;

5.3.10 Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

5.3.11 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;

5.3.12 Ensure that reports of test results include pertinent information required for interpretation;

5.3.13 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;

5.3.14 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;

5.3.15 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;

5.3.16 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 Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interests, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

5.3.17 Ensure that an approved Standard Operating Procedure manual is available to all personnel responsible for any aspect of the testing process; and

5.3.18 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 Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

5.4 Change in Laboratory Director. In the event that the laboratory director leaves employment at the Hemp Testing Laboratory, the Hemp Testing Laboratory shall:

5.4.1 Provide written notice to the Department within seven days of the laboratory director's departure; and

5.4.2 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.

5.4.3 The Hemp Testing Laboratory must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.

5.4.4 Notwithstanding the requirement of subparagraph 5.4.3, the Hemp Testing Laboratory may submit a waiver request to the Department to receive an additional 60 days to hire a permanent laboratory director provided that the Hemp Testing Laboratory submits a detailed oversight plan along with the waiver request.

5.5. 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.

5.6. Laboratory Testing Analyst.

5.6.1 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.

5.6.2 Responsibilities. In order to independently perform any test for a Hemp Testing Laboratory, an individual must at least meet the educational requirements for a testing analyst.

Rule 6: Hemp Testing Laboratories: Standard Operating Procedures

6.1 Standard Operating Procedures must include, but need not be limited to, procedures for:

6.1.1 Sample receiving;

6.1.2 Sample accessioning;

6.1.3 Sample storage;

6.1.4 Identifying and rejecting unacceptable Samples;

6.1.5 Recording and reporting discrepancies;

6.1.6 Security and stability of Samples, aliquots and extracts and records;

6.1.7 Sample retention to assure stability, as follows:

6.1.7.1 For Samples submitted for testing other than pesticide contaminant testing, Sample retention for 14 days;

6.1.7.2 For Samples submitted for pesticide contaminant testing, Sample retention for 90 days.

6.1.8 Validating a new or revised method prior to testing Samples to include the performance criteria as stated in Rule 7.1.5;

6.1.9 Aliquoting Samples to avoid contamination and carry-over;

6.1.10 Preparation of Samples;

6.1.11 Disposal of Samples;

6.1.11 The theory and principles behind each assay;

6.1.12 Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to a certified vendor that meets the accreditation requirements of the laboratory, such as National Institute of Standards of Technology (NIST), ISO 17034, other other similar entities;

6.1.13 Special requirements and safety precautions involved in performing assays;

6.1.14 Frequency and number of control and calibration materials;

6.1.15 Recording and reporting assay results;

6.1.16 Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

6.1.17 Pertinent literature references for each method;

6.1.18 Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;

6.1.19 Acceptability Criteria for the results of calibration standards and controls as well as between two aliquots, Sample duplicates, new standard lots, or columns;

6.1.20 A documented system for reviewing the results of testing calibrators, controls, standards, and Sample test results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results; and

6.1.21 A documented system for issuing, implementing, and monitoring Corrective Actions, including instructions for the laboratory to contact the requesting entity, when required;

6.1.22 Policies and procedures to follow when Samples are requested for referral and testing by another certified Hemp Testing Laboratory or an approved local or state agency's laboratory;

6.1.23 Protocol and criteria for calculating and applying Measurement Uncertainty;

6.1.24 Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials; and

6.1.25 Procedures and/or protocols for general laboratory upkeep and cleaning, including specific procedures to eliminate or avoid cross-contamination.

Rule 7: Hemp Testing Laboratories: Analytical Processes

7.1 Method Validation and Verification. Analytical method selection, validation, and verification must ensure that the test method used is fit-for-purpose and that the laboratory can successfully perform the testing.

7.1.1 The demonstration of testing validity must ensure consistent, accurate and reproducible analytical performance in the matrices tested by the laboratory.

7.1.2 Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of Rules Pertaining to the Administration and Enforcement of the Industrial hemp Regulatory Program Act, 8 CCR 1203-23 Part 6.1 and Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations, 6 CCR 1010-21.

7.1.3 To the extent practicable, laboratory test methods must meet AOAC International (AOAC) standard method performance requirements.

7.1.4 The laboratory must implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices in accordance with AOAC, United States Pharmacopeia (USP), United States Food and Drug Administration (FDA), and other reputable validation guidelines and methodology prior to reporting results. Validation, verification, or Matrix extension of methodology must include when applicable, but is not limited to:

7.1.4.1 Verification of Accuracy

7.1.4.2 Verification of Precision

7.1.4.3 Verification of Analytical Sensitivity

7.1.4.4 Verification of Analytical Specificity

7.1.4.5 Verification of the LOD

7.1.4.6 Verification of the LOQ

7.1.4.7 Verification of the Reportable Range

7.1.4.8 Identification of Interfering Substances

7.1.4.9 Verification of Recovery

7.1.4.10 Inclusivity

7.1.4.11 Exclusivity

7.1.4.12 Measurement Uncertainty

7.1.4.12.1 Subsequent to initial validation, Measurement Uncertainty must be re-evaluated at least annually or whenever method modifications are made.

7.1.4.13 For GC cannabinoid methods, experimental determination of actual conversion rate of THCA to THC.

7.1.5 Validation or verification of methodology must be documented in a validation report. The validation report shall include, but is not limited to, the following:

7.1.5.1 Validation plan;

7.1.5.2 Introduction and summary;

7.1.5.3 Materials, to include identification of certified Reference Materials, and preparation methods;

7.1.5.4 Method parameters;

7.1.5.5 Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;

7.1.5.6 Instrument calibration data, if any;

7.1.5.7 Data, calculations, and results;

7.1.5.8 Method Acceptability Criteria performance data;

7.1.5.9 Conclusion and discussion;

7.1.5.10 And References.

7.1.6 Software must be validated prior to testing Samples, including but not limited to: analytical software, application programming interface(s) (APIs), laboratory information management systems (LIMS), etc.

7.1.7 Prior to use, methodology must have a Standard Operating Procedure approved and signed by the laboratory director.

7.1.8 Testing analysts must have documentation of competency assessment prior to testing Samples.

7.1.9 Any changes to the approved methodology must be revalidated and documented prior to testing Samples. The documentation of changes and revalidation must be provided to the Department prior to implementation.

7.2 Gas Chromatography (GC). A Hemp Testing Laboratory using GC must:

7.2.1 Document the conditions of the gas chromatograph, including the detector response;

7.2.2 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.2.3 Ensure that records are maintained and readily available to the staff operating the equipment;

7.2.4 Document the performance of new columns before use;

7.2.5 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

7.2.6 Establish Acceptability Criteria for variances between different aliquots and different columns;

7.2.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7.2.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and

7.2.9 Monitor and document the performance of the instrument each day of testing.

7.3 Gas Chromatography Mass Spectrometry (GC/MS). A Hemp Testing Laboratory using GC/MS must:

7.3.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.3.2 Document and maintain records when cleaning or changes in source, source conditions, column, or other routine maintenance are made to the instrument;

7.3.3 Ensure that records are maintained and readily available to the staff operating the equipment;

7.3.4 Maintain records of mass spectrometric tuning;

7.3.5 Establish written criteria for an acceptable mass-spectrometric tune;

7.3.6 Document corrective actions if a mass-spectrometric tune is unacceptable;

7.3.7 Monitor analytic analyses to check for contamination and carry-over;

7.3.8 Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and Samples for identification of an Analyte;

7.3.9 Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.3.10. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;

7.3.11 Define the criteria for designating qualitative results as positive;

7.3.12 When a library is used to qualitatively identify an Analyte, the identity of the Analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system;

7.3.13 Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject Samples; and

7.3.14 Monitor and document the performance of the instrument each day of testing.

7.4 Immunoassays. A Hemp Testing Laboratory using Immunoassays must:

7.4.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.4.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.4.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and

7.4.4 Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

7.5 High Performance Liquid Chromatography (HPLC). A Hemp Testing Laboratory using HPLC must:

7.5.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.5.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.5.3 Monitor and document the performance of the HPLC instrument each day of testing;

7.5.4 Evaluate the performance of new columns before use;

7.5.5 Create written standards for acceptability when eluting solvents are recycled;

7.5.6 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay;

7.5.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7.5.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and

7.5.9 Monitor and document the performance of the instrument each day of testing.

7.6 Liquid Chromatography Mass Spectrometry (LC/MS). A Hemp Testing Laboratory using LC/MS must:

7.6.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.6.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.6.3 Establish written criteria for an acceptable mass-spectrometric tune;

7.6.4 Maintain records of mass spectrometric tuning;

7.6.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;

7.6.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.6.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7.6.8 Compare two transitions and retention times between calibrators, controls and Samples within each run;

7.6.9 Document and maintain records when changes or cleaning in source, source conditions, eluent, or column are made to the instrument;

7.6.10 Evaluate and document the performance of the instrument after routine and preventative maintenance and when changes in: source, source conditions, eluent, or column are made prior to reporting test results; and

7.6.11 Monitor and document the performance of the instrument each day of testing.

7.7 Inductively Coupled Plasma Mass Spectrometry (ICP/MS). A Hemp Testing Laboratory using ICP must:

7.7.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.7.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.7.3 Establish written criteria for an acceptable mass-spectrometric tune;

7.7.4 Maintain records of mass spectrometric tuning;

7.7.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;

7.7.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.7.7 Document the monitoring of the response (counts per second) of the internal standard to ensure consistency overtime of the analytical system;

7.7.8 Compare mass-to-charge ratios between calibrators, controls and Samples within each run;

7.7.9 Monitor analyses to check for contamination and carry-over;

7.7.10 Evaluate and document the performance of the instrument after routine and preventative maintenance and when changes in: source, conditions, or detector are made prior to reporting test results; and

7.7.11 Monitor and document the performance of the instrument each day of testing.

7.8 Microbial Assays. A Hemp Testing Facility using microbial assays must:

7.8.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.8.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.8.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer;

7.8.4 Verify the method at the Action Levels for each Analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study;

7.8.5 The laboratory shall include controls for each set of Samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7.8.6 For molecular methods, the laboratory shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7.8.7 PCR-based methods must include validated internal amplification controls; and

7.8.8 Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Where applicable, confirmation of viability must be performed.

7.9 Other Analytical Methodology. A Hemp Testing Laboratory using any other analytical methodology must:

7.9.1 Perform and document preventive maintenance as required by the manufacturer or SOP;

7.9.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.9.3 Ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology; and

7.9.4 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples.

7.10 Cannabinoid Methodology. At a minimum, analytical testing of Samples for delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD) must use post-decarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) and cannabidiolic acid (CBDA) into THC and CBD. The results reported must reflect the Total THC and Total CBD content.

7.10.1 The Cannabinoid concentrations of Industrial Hemp shall be determined and reported on a dry weight basis. Dry weight basis means the Moisture Content does not exceed 15%; and

7.10.2 The Cannabinoid concentrations of Industrial Hemp Products shall be determined and reported on an "as-is" basis (i.e., in the form submitted to the laboratory).

Rule 8: Hemp Testing Laboratories: Proficiency Testing

8.1 Proficiency Testing Required. A Hemp Testing Laboratory must participate in a Proficiency Testing program for each approved category in which it seeks certification under Rule 4 – Hemp Testing Laboratories: Certification Requirements.

8.2. Participation in Designated Proficiency Testing Event. If required by the Department as part of certification, the Hemp Testing Laboratory must have successfully participated in Proficiency Testing in the category for which it seeks certification, within the preceding 12 months.

8.2.1 The laboratory shall request the proficiency testing provider to send results concurrently to the Department, if available, or the laboratory shall provide the proficiency testing results to the Department within 3 business days after the laboratory receives notification of their results.

8.3 Continued Certification. To maintain continued certification, a Hemp Testing Laboratory must participate twice per calendar year in a designated Proficiency Testing program with continued satisfactory performance as determined by the Department as part of certification. The Department may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.

8.4 Analyzing Proficiency Testing Samples. A Hemp Testing Laboratory must analyze Proficiency Test Samples using the same procedures with the same number of replicate analyses, standards, testing analysts, equipment, and data review processes as used in its Standard Operating Procedures.

8.5 Proficiency Testing Attestation. The laboratory director and all testing analysts who participated in Proficiency Testing must sign corresponding attestation statements.

8.6 Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results after receiving them from the proficiency testing provider.

8.7 Remedial Action. A Hemp Testing Laboratory must take and document remedial action when a score of less than 100% is achieved on any test during Proficiency Testing. Remedial action documentation must include a review of Samples tested and results reported since the last successful Proficiency Testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.

8.8 Unsatisfactory Participation in a Proficiency Testing Event. Unless the Hemp Testing Laboratory positively identifies at least 80% of the target Analytes tested, participation in the Proficiency Testing event will be considered unsatisfactory. A positive identification must include accurate

quantitative and qualitative results as applicable. Any false positive result reported will be considered unsatisfactory participation in the Proficiency Testing event.

8.9 Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsatisfactory participation in a Proficiency Testing event may result in limitation, suspension or revocation of certification. A Hemp Testing Laboratory's certification will be suspended for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event. Failure to achieve a satisfactory score in the next test event will result in the revocation of the certification and will require two successful consecutive Proficiency Testing events before the laboratory may be eligible to reapply for certification.

Rule 9: Hemp Testing Laboratories: Quality Assurance and Quality Control

9.1 Quality Assurance Program Required. A Hemp Testing Laboratory must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:

9.1.1 Review of instrument preventive maintenance, repair, and troubleshooting;

9.1.2 Documentation of Nonconformances and implementation of Corrective Actions and Preventative Actions when necessary;

9.1.3 Review of quality assurance documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

9.1.3 Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and

9.1.4. Review of the performance of validated methods used by the Hemp Testing Laboratory to include calibration standards, controls and the Standard Operating Procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

9.2 Quality Control Measures Required. A Hemp Testing Laboratory must establish, monitor and document on an ongoing basis the Quality Control measures taken by the laboratory to ensure the proper functioning of equipment, validity of Standard Operating Procedures and accuracy of results reported. The laboratory must ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology. Such Quality Control measures must include, but shall not be limited to:

9.2.1 Documentation of instrument preventive maintenance, repair, troubleshooting and Corrective Actions taken when performance does not meet established levels of quality;

9.2.2 Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;

9.2.3 Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;

9.2.4 Annually verifying working thermometers against a certified reference thermometer. Certified reference thermometers shall be calibrated traceable to the SI (International System of Units) through NIST, or equivalent by an ISO/IEC 17025 accredited calibration laboratory with a listed certification date;

9.2.5 Recording temperatures on all equipment when in use where temperature control is specified in the Standard Operating Procedures, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;

9.2.6 Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;

9.2.7 Avoiding mixing different lots of reagents in the same analytical run;

9.2.8 Performing and documenting a calibration curve with each analysis using at minimum five calibrators throughout the reporting range;

9.2.9 For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of Samples analyzed;

9.2.10 For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;

9.2.11 Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;

9.2.12 For multi-Analyte assays, performing and documenting calibration curves and controls specific to each Analyte, or at minimum, one with similar chemical properties as reported in the analytical run;

9.2.13 Analyzing an appropriate Matrix blank and control with each analytical run, when available;

9.2.14 Analyzing calibrators and controls in the same manner as unknowns;

9.2.15 Documenting the performance of calibration standards and controls for each analytical run to ensure the Acceptability Criteria as defined in the Standard Operating Procedure is met;

9.2.16 Documenting all Corrective Actions taken when unacceptable calibration, control, and standard or instrument performance does not meet Acceptability Criteria as defined in the Standard Operating Procedure;

9.2.17 Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and

9.2.18 Performing testing analysts that follow the current Standard Operating Procedures for the test or tests to be performed.

Rule 10: Hemp Testing Laboratories: Certificate of Analysis

10.1 The laboratory shall generate a Certificate of Analysis (COA) for each Sample that the laboratory analyzes.

10.2 The laboratory shall ensure that the COA contains the results of all requested analyses performed for the Sample.

10.3 The laboratory shall, within 1 business day of completing Total THC analysis of a Sample, provide a copy of the COA to the submitting Industrial Hemp Cultivator or Industrial Hemp Manufacturer and the Colorado Department of Agriculture Hemp Regulatory Program.

10.4 The COA shall contain, at minimum, the following information:

10.4.1 Laboratory's name, address, and contact information;

10.4.2 Industrial Hemp Cultivator's or Industrial Hemp Manufacturer's name and address;

10.4.3 Sample identifying information, including Matrix type and unique Sample identifiers;

10.4.4 Sample received date, and the date(s) of Sample analyses and corresponding testing results;

10.4.5 Units of measure;

10.4.6 The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);

10.4.7 For Samples of Industrial Hemp, reported cannabinoid results must include the range of estimated uncertainty shall be reported as a ± value in the same units of measure as the test result, following best practices for significant figures and rounding; and

10.4.7.1 For Samples of Industrial Hemp, reported cannabinoid results must provide a calculated Total THC value + uncertainty on a dry weight basis.

10.4.8 A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any Identified and documented discrepancies.

10.5 The laboratory shall report test results for each representative Sample on the COA as follows:

10.5.1 When reporting qualitative results for each Analyte, the laboratory shall indicate presence or absence;

10.5.2 When reporting quantitative results for each Analyte, the laboratory shall use the appropriate units of measurement;

10.5.3 When reporting results for any Analytes that were detected below the analytical method LOQ, indicate "<LOQ";

10.5.4 When reporting results for any Analytes that were not detected or detected below the LOD, indicate "ND" or "<LOD"; and

10.6 The laboratory director or supervisory analyst shall validate the accuracy of the information contained on the COA.

Rule 11: Hemp Testing Laboratories: Chain of Custody

11.1 General Requirements. A Hemp Testing Laboratory must establish an adequate Chain of Custody and Sample requirement instructions that must include, but not limited to:

11.1.1 Issue instructions for the minimum Sample requirements and storage requirements;

11.1.1.1 Separate Sample into a test and a retain Sample;

11.1.1.1.1 The Sample shall be fully homogenized prior to dividing into test and retain Samples. The test and retain Samples shall each be sufficient to conduct the required analyses on the Sample;

11.1.1.1.2 The test Sample shall be carried through analysis; and

11.1.1.1.3 Retain Sample shall be packaged and stored in accordance with rule 6.1.7.

11.1.2 Document identifying information of the submitting Industrial Hemp Cultivator or Industrial Hemp Manufacturer, including harvest or production batch identification;

11.1.3 Assign and document a unique Sample identifier;

11.1.4 Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;

11.1.5 Document the condition, temperature, Matrix, and amount of Sample provided at the time of receipt;

11.1.6 Document all persons handling the original Samples, aliquots, and extracts;

11.1.7 Document all Transfers of Samples, aliquots, and extracts referred to another certified Hemp Testing Laboratory for additional testing or whenever requested by a client;

11.1.8 Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;

11.1.9 Secure the Laboratory during non-working hours;

11.1.10 Secure short and long-term storage areas when not in use;

11.1.11 Ensure Samples are stored appropriately as defined in the written SOP; and

11.1.12 Document the disposal of Samples, aliquots, and extracts.

Rule 12: Hemp Testing Laboratories: Records Retention

12.1 General Requirements. A Hemp Testing Laboratory must maintain all required business records. *See* Rule 13 - Business Records Required.

12.2 Specific Business Records Required Record Retention. A Hemp Testing Laboratory must establish processes to preserve records in accordance with Rule 13 that includes, but is not limited to;

12.2.1 Test Results, including final and amended reports, and identification of analyst and date of analysis;

12.2.2 Quality Control and quality assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;

1.2.3 Standard Operating Procedures;

12.2.4 Personnel Records;

12.2.5 Chain of Custody Records;

12.2.6 Proficiency Testing Records; and

12.2.7 Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.

Rule 13: Hemp Testing Laboratories: Business Records Required

13.1 General Requirements.

13.1.1 A Hemp Testing Laboratory shall retain all records required by this rule for the current year and three preceding calendar years.

13.1.1.1 On premises records: The Hemp Testing Laboratory records for the preceding six months (or complete copies of such records) must be maintained onsite at all times; and

13.1.1.2 On- or off-premises records: Records associated with older periods may be archived onsite or offsite.

13.1.2 The records must include, but shall not be limited to:

13.1.2.1 Current Employee List – This list must provide the full name and job title of each employee who works at the laboratory;

13.1.2.3 Visitor Log – List of all visitors entering any limited or restricted access areas as defined by the laboratory;

13.1.2.4 Waste Log – Comprehensive records regarding all waste that accounts for, reconciles, and evidences all waste activity related to the disposal of any Sample that tests above 0.3% THC with at least 95% confidence and the disposal of any chemically hazardous or biohazardous waste;

13.1.2.5 Testing Records – The laboratory must maintain all testing records, to include calibration records, analytical data, calculations, test reports, and worksheets;

13.1.2.6 Standard Operating Procedures – All Standard Operating Procedures as required by these Rules;

13.1.2.7 Corrective Action and Preventive Action records;

13.1.2.8 Chain of Custody records; and

13.1.2.9 All other records required by these Rules.

13.1.3 Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Laboratories are required to exercise due diligence in preserving and maintaining all required records.

13.1.4 Provision of Any Requested Record to the Department. A Hemp Testing Laboratory must provide on-demand access to on-premises records following a request from the Department during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Department.

Rule 14: Waste Disposal

14.1 All Applicable Laws Apply. All waste must be stored, secured, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements, including but not limited to the “Regulations Pertaining to Solid Waste Sites and Facilities” (6 CCR

1007-2, Part 1) and "Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements" (5 CCR 1003-2) established by the Colorado Department of Public Health and Environment pursuant to the Title 25, Article 9, Part 1, C.R.S.

14.2 Liquid Waste. Liquid waste from Hemp Testing Laboratories shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules, and other requirements.

14.3 Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state and local laws, statutes, regulations, rules, and other requirements.