ARC 3707C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to medical cannabidiol and providing an opportunity for public comment

The Department of Public Health hereby proposes to amend Chapter 154, "Medical Cannabidiol Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 17A.3(1)"b," 124E.11(2)"c," 124E.11(2)"g" and 136.3(9).

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 124E.

Purpose and Summary

The proposed amendments add definitions for the proposed new rules for laboratory testing; make minor technical corrections to Iowa Code references; and update the rules on form and quantity of medical cannabidiol, package labeling, quality control program, sampling and testing, and stability testing. New rules are also proposed for laboratory testing.

The Department's Medical Cannabidiol Board made and the Board of Medicine reviewed and approved the form and quantity recommendations included in the proposed amendments. The proposed rules for laboratory testing were developed by the Department with review from the state hygienic laboratory, an independent laboratory in Iowa, and a number of state agencies with current laboratory functions.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's variance and waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on April 17, 2018. Comments should be directed to:

Randy Mayer
Department of Public Health
321 East 12th Street
Des Moines, Iowa 50319
Email: randall.mayer@idph.iowa.gov

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

April 17, 2018	Room 518
1 to 1:30 p.m.	Lucas State Office Building
	Des Moines, Iowa

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend a public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Department and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule 641—154.1(124E) as follows:

641—154.1(124E) Definitions. For the purposes of these rules, the following definitions shall apply:

"Acceptance criteria" means the specified limits placed on characteristics of an item or method that are used to determine data quality.

"Accreditation" means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

"Accredited nonpublic school" means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

"Action level" means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

"Aliquot" means a portion of a sample that is used in an analysis.

"Analyte" means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

"Analytical batch" means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

"Analytical method" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

"Audit" means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

"Background investigation" means a thorough review of an entity, an owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

"Batch" means a set of cannabis plants that are grown, harvested, and processed together, such that they are exposed to substantially similar conditions throughout cultivation and processing.

"Batch number" means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is first planted. The batch number shall contain the manufacturer's number and a sequence to allow for inventory and traceability.

"Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

"Bordering state" means the same as defined in Iowa Code section 331.910.

"Cannabinoid" means a chemical compound that is unique to and derived from cannabis.

"Cannabis" means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

"CAS number" means a unique numerical identifier assigned to every chemical substance described in the open literature by Chemical Abstracts Service.

"CBD" means cannabidiol, Chemical Abstracts Service number 13956-29-1.

"CBDA" means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

"CBG" means cannabigerol, Chemical Abstracts Service number 25654-31-3.

"CBN" means cannabinol, Chemical Abstracts Service number 521-35-7.

"Certificate of analysis" means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

"Certification" means a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.

"Certified" means a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department's requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

"Certified reference material" means a reference material prepared by a certifying body.

"Crop input" means any substance applied to or used in the cultivation and growth of a cannabis plant. "Crop input" includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

"Data-quality assessment" means a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the intended use of the data.

"Date of expiration" means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

"Date of issuance" means the date of issuance of the medical cannabidiol registration card by the department of transportation.

"Debilitating medical condition" means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
   - Severe or chronic pain.
   - Nausea or severe vomiting.
   - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.

7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:

- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

8. Parkinson's disease.
9. Untreatable pain.

"Department" means the Iowa department of public health.

"Department of transportation" means the Iowa department of transportation.

"Director" means the director of the Iowa department of public health.

"Dispensary" means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. "Dispensary" includes the employees and agents of the dispensary.

"Dispensary facility" means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

"Dispense" or *"dispensing"* means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

"Disqualifying felony offense" means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

"Edible medical cannabidiol products" means food items containing medical cannabidiol. "Edible medical cannabidiol products" does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

"Field duplicate sample" means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

"Form and quantity" means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

"Frequency" means the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

"Health care practitioner" means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient's primary care provider. "Health care practitioner" shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.

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

"Inspection" means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

"International Electrotechnical Commission" or *"IEC"* means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

"International Organization for Standardization" or *"ISO"* means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

"Laboratory" means the state hygienic laboratory at the University of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved

accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

"Limit of detection" or *"LOD"* means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

"Limit of quantitation" or *"LOQ"* means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

"Lot" means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"Lot number" means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

"Manufacture" or *"manufacturing"* means the process of converting harvested cannabis plant material into medical cannabidiol.

"Manufacturer" means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. "Manufacturer" includes the employees and agents of the manufacturer.

"Manufacturing facility" means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

"Market withdrawal" means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

"Mass spectrometry" means an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio.

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

"Matrix spike duplicate" means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

"Matrix spike sample" means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

"Medical assistance program" means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

"Medical cannabidiol" means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter.

"Medical cannabidiol waste" means medical cannabidiol that is returned, damaged, defective, expired, or contaminated.

"Medical cannabis goods" means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

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

"Moisture content" means the percentage of water in a dry sample by weight.

"National criminal history background check" means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

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

"Patient" means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

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

"Permanent resident" means a natural person who physically resides in Iowa as the person's principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

"Pharmaceutical grade" means medical cannabidiol that meets standards for content, contamination, and consistency set by the department as determined by testing conducted at a laboratory pursuant to Iowa Code chapter 124E and these rules.

"Plant material" means any cannabis plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

"Plant material waste" means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

"Primary caregiver" means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of Iowa Code chapter 124E and these rules.

"Primary care provider" means any health care practitioner involved in the diagnosis and treatment of a patient's debilitating medical condition.

"Primary sample" means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

"Process lot" means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

"Product expiration date" means the date after which a medical cannabidiol product may not be sold by a manufacturer or a dispensary.

"Production" or *"produce"* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

"Proficiency test" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"Proficiency test sample" means a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

"Public or private school" means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

"Qualitative analysis" means identification of an analyte in a substance or mixture.

"Quality assurance" means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

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

"Quality control samples" means samples produced and used for the purpose of assuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"Quantitative analysis" means measurement of the quantities of chemical components present in a substance or mixture. Quantitative analysis typically uses a certified reference material, if available, to create a calibration curve.

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

"Recall" means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

"Reference material" means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

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

"Relative percent difference" or *"RPD"* means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value (primary sample measurement - duplicate sample measurement) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

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

"Requester" means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

"Residual solvents and processing chemicals" means volatile organic chemicals that are used or produced in the manufacture or production of medical cannabidiol.

"Restricted access area" means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

"Sample" means a representative part of or a single item from a larger whole or group.

"Sanitize" means to sterilize, disinfect, or make hygienic.

"Semiquantitative analysis" means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

"Significant figures" means the number of digits used to express a measurement.

"Stability" or *"stable"* means that after storage of an unopened package of medical cannabidiol, the contents shall not vary in concentrations of THC and CBD by more or less than 15 percent by

weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids from the concentration indicated on the package label. Thus, after storage, a solid product labeled as containing a concentration of CBD of 10 milligrams per gram shall have a detected concentration of CBD that is no more than 11.50 milligrams per gram and no less than 8.50 milligrams per gram.

"Standard operating procedure" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

"State" means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

"Synthetic cannabinoid" means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce biological effects similar to those of natural cannabinoids.

"Tamper-evident" means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

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

"Testing laboratory record" means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

"THC" or *"delta-9 THC"* means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

"THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

"Untreatable pain" means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

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

"Written certification" means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

ITEM 2. Amend rule 641—154.14(124E) as follows:

641—154.14(124E) Form and quantity of medical cannabidiol.

~~**154.14(1)** *Patient.* A patient in possession of a valid medical cannabidiol registration card issued pursuant to this chapter shall not possess a quantity of medical cannabidiol in excess of 32 ounces.~~

~~**154.14(2)** *Primary caregiver.* A primary caregiver in possession of a valid medical cannabidiol registration card issued pursuant to this chapter shall not possess a quantity of medical cannabidiol in excess of 32 ounces for each patient for whom the person is registered as a primary caregiver.~~

~~**154.14(3)** *Form and quantity.*~~ The form and quantity of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board ~~established pursuant to Iowa Code chapter 124E and~~, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

154.14(1) *Quantity.* A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.

154.14(2) *Form.*

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Nebulizable inhaled forms.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule 641—154.1(124E).

ITEM 3. Amend paragraph **154.17(2)"h"** as follows:

h. Sell medical cannabidiol that is not packaged and labeled in accordance with rule ~~645—154.21(124E)~~ 641—154.21(124E);

ITEM 4. Amend subparagraph **154.21(1)"c"(1)** as follows:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule ~~645—154.46(124E)~~ 641—154.46(124E);

ITEM 5. Amend subrule 154.21(3) as follows:

154.21(3) *Package labeling.*

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name and address of the manufacturer where the medical cannabidiol was manufactured;

(2) The medical cannabidiol's primary active ingredients, including ~~levels~~ concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid;

(3) Directions for use of the product, including recommended and maximum amount by age and weight, if applicable;

(4) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

(5) Instructions for storage, including light and temperature requirements, if any;

(6) ~~Date of expiration~~ Product expiration date;

(7) The date of manufacture and lot number;

(8) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

(9) The universal warning symbol provided by the department; and

(10) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

b. Labeling text shall not include any false or misleading statements.

c. A package may contain multiple labels if the information required by this rule is not obstructed.

d. Labeling text font size shall be no smaller than 6 point.

ITEM 6. Amend subrules 154.26(1), 154.26(3) and 154.26(4) as follows:

154.26(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.26(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;

b. Conduct sampling and testing of all medical cannabidiol lots using acceptance criteria that are protective of patient health. At a minimum, testing of lots shall occur after packaging but before transport or sale to a dispensary. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants;

c. Refrain from ~~packing~~ packaging or selling ~~a~~ medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. ~~Lots~~ Medical cannabidiol from a process lot that ~~fail~~ fails quality assurance testing ~~for potency or for residual solvents and chemicals~~ may be remixed and retested;

d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria except for potency of CBD and THC. Medical cannabidiol from a lot that fails quality assurance testing based on potency of CBD or THC may be remixed and retested;

~~*d.*~~ *e.* Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:

(1) Criteria for when remixing and retesting are warranted;

(2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

~~*e.*~~ *f.* Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product ~~shelf life~~ expiration dates. The procedures shall describe:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to ensure valid stability estimates;

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

b. Stability studies shall include:

(1) Medical cannabidiol testing at appropriate intervals; and

(2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If ~~shelf-life~~ product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.

d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.

e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

ITEM 7. Reserve rules **641—154.66** to **641—154.69**.

ITEM 8. Adopt the following **new** heading to precede rule 641—154.70(124E):

LABORATORY TESTING

ITEM 9. Adopt the following **new** rules 641—154.70(124E) to 641—154.76(124E):

641—154.70(124E) Requirements of a laboratory.

154.70(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals.

154.70(2) *Additional tests upon request.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for other analyses as requested by the department.

154.70(3) *Level of quantitation.* A laboratory shall be able to demonstrate that its LOQ is below any action level established by the department.

154.70(4) *Inventory tracking.*

a. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the receipt of medical cannabis goods from a manufacturer for testing.

b. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the return of medical cannabis goods or waste to a manufacturer.

154.70(5) *Hazardous waste disposal.*

a. A laboratory shall discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. A laboratory shall document the waste disposal procedures followed for each sample.

641—154.71(124E) Requirements of a manufacturer.

154.71(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing requested by the department or laboratory for medical cannabis goods produced by the manufacturer.

154.71(2) *Sample waste retrieval.* A manufacturer shall retrieve analyzed samples and waste containing medical cannabis goods from the laboratory at a duration and frequency approved by the department.

641—154.72(124E) Content testing.

154.72(1) *Cannabinoids.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;
(2) THCA;
(3) CBD;
(4) CBDA;
(5) CBG; and
(6) CBN.

b. A laboratory shall report that the primary sample passed THC potency testing if the detected concentration of THC does not exceed 3 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids and if the detected concentration of THC does not vary from the manufacturer's labeled concentration by more or less than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing a concentration of THC of 10 mg/g shall have a detected concentration of THC that is no more than 11.50 mg/g and no less than 8.50 mg/g.

c. A laboratory shall report that the primary sample failed THC potency testing if the detected concentration of THC exceeds 3 percent by weight in mg/ml for liquids and mg/g for solids or if the detected concentration of THC varies from the labeled concentration of THC by more or less than 15 percent by weight in mg/ml for liquids and mg/g for solids.

d. A laboratory shall report that the primary sample passed CBD potency testing if the detected concentration of CBD does not vary from the manufacturer's labeled concentration by more or less than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing

a concentration of CBD of 10 mg/g shall have a detected concentration of CBD that is no more than 11.50 mg/g and no less than 8.50 mg/g.

e. A laboratory shall report that the primary sample failed potency testing if the detected concentration of CBD varies from the labeled concentration of CBD by more or less than 15 percent by weight in mg/ml for liquids and mg/g for solids.

f. For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(1)*"b"* and 154.72(1)*"c."*

g. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

154.72(2) *Contaminants—residual solvents and processing chemicals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall analyze primary samples for residual solvents and processing chemicals.

b. The department shall provide a list of residual solvents and processing chemicals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each residual solvent or processing chemical for which a primary sample is tested, a laboratory shall report that the primary sample passed the testing if the concentration of residual solvent or processing chemical is at or below the action level approved by the department.

d. For each residual solvent or processing chemical for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of residual solvent or processing chemical is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for residual solvents and processing chemicals and the laboratory determines that a primary sample contains residual solvent or processing chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the residual solvent or processing chemical analytes.

f. The laboratory may test for and provide test results for additional residual solvents or processing chemicals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each residual solvent or processing chemical for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any target residual solvent or processing chemical that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(2)*"c"* and 154.72(2)*"d."*

(3) The names and amounts of any additional residual solvents and processing chemicals identified by the laboratory.

h. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

i. When a laboratory identifies additional residual solvents and processing chemicals in a primary sample, the laboratory shall:

(1) Notify the department of the additional residual solvents and processing chemicals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(3) *Contaminants—pesticides.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for pesticides.

b. The department shall provide a list of pesticides for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of pesticide is at or below the action level approved by the department.

d. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of pesticide is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for pesticides and the laboratory determines that a primary sample contains pesticide analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the pesticide analytes.

f. The laboratory may test for and provide test results for additional pesticides if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each pesticide for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any pesticide that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(3)*"c"* and 154.72(3)*"d."*

(3) The names and amounts of any additional pesticides identified by the laboratory.

h. If the primary sample fails testing for pesticides, the lot fails laboratory testing.

i. When a laboratory identifies additional pesticides in a primary sample, the laboratory shall:

(1) Notify the department of the additional pesticides and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(4) *Contaminants—metals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for metals.

b. The department shall provide a list of metals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each metal for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of metal is at or below the action level approved by the department.

d. For each metal for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of metal is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for metals and the laboratory determines that a primary sample contains metal analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the metal analytes.

f. The laboratory may test for and provide test results for additional metals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each metal for which the primary sample was tested.

1. The concentrations shall be listed in micrograms per gram or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any metal that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(4)*"c"* and 154.72(4)*"d."*

(3) The names and amounts of any additional metals identified by the laboratory.

h. If the primary sample fails testing for metals, the lot fails laboratory testing.

i. When a laboratory identifies additional metals in a primary sample, the laboratory shall:

(1) Notify the department of the additional metals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(5) *Contaminants—microbiological impurities.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for microbiological impurities.

b. The department shall provide a list of microbiological impurities for which primary samples are to be tested on the department's website (www.idph.iowa.gov).

c. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the microbiological impurity is not detected in 1 gram of matrix or as approved by the department. A primary sample may be reported as passed if a screening procedure yields a negative result or if a presumptively positive result is not found to be positive on the confirmatory procedure.

d. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the microbiological impurity is detected in 1 gram of matrix or as approved by the department. Confirmatory procedures shall be conducted on all presumptively positive results.

e. If a laboratory is using methods to test primary samples for microbiological impurities and the laboratory determines that a primary sample contains microbiological impurities that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification of the biological impurity.

f. The laboratory may test for and provide test results for additional microbiological impurities if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name of each microbiological impurity for which the primary sample was tested.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(5)*"c"* and 154.72(5)*"d."*

(3) The names of any additional microbiological impurities identified by the laboratory.

h. If the primary sample fails testing for microbiological impurities, the lot fails laboratory testing.

i. When a laboratory identifies additional microbiological impurities in a primary sample, the laboratory shall:

(1) Notify the department of the additional microbiological impurities detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(6) *Additional tests.* The laboratory may perform additional tests if asked to do so by a requester.

641—154.73(124E) Reporting requirements.

154.73(1) *Reporting test results.* The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

154.73(2) *Tentatively identified analytes.* A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

a. Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.73(3) *Additional reporting requirements.*

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

(1) All requirements of Standard ISO/IEC 17025;

(2) Date of primary sample collection;

(3) Date the primary sample was received by the laboratory;

(4) Date of each analysis;

(5) The LOQ and action level for each analyte, as applicable;

(6) Whether the primary sample and lot passed or failed laboratory testing; and

(7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements ≥ LOD but < LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

641—154.74(124E) Record-keeping requirements.

154.74(1) *Data package.* A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

a. The name and address of the laboratory that performed the analytical procedures;

b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel that performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;

c. All primary sample and analytical batch quality control sample results;

d. Raw data for each primary sample analyzed;

e. Instrument raw data, if any was produced;

f. Instrument test method with parameters;

g. Instrument tune report, if one was created;

h. All instrument standard calibration data;

i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

k. The analytical batch sample sequence;

l. The field sample log; and

m. The chain-of-custody form.

154.74(2) *Review of data package.* After the laboratory has compiled a data package, another individual at the laboratory shall independently review the data package. The reviewer shall:

a. Assess the analytical results for technical correctness and completeness;

b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;

c. Verify that the measurements can be traced back; and

d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.74(3) *Data package record retention.* The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.74(4) *Other records.* A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabis goods.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabis goods:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

641—154.75(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.75(1) *Quality control samples required.*

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

154.75(2) *Types of quality control samples.* At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website (www.idph.iowa.gov).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample with every 10 to 20 samples for each analytical method. The acceptance criterion between the primary sample and the duplicate sample is less than 20 percent relative percentage difference.

154.75(3) *Certified reference material for chemical analysis.* The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

154.75(4) *Calibration standards.* The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

154.75(5) *Quality control-sample report.* A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

154.75(6) *Limit-of-detection and limit-of-quantitation calculations.* For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

641—154.76(124E) Security requirements. The department may request assistance from the department of public safety in ensuring a laboratory meets the security requirements in this rule.

154.76(1) *Security policy requirement.* A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabis goods and samples. The security policy shall apply to all staff and visitors at a laboratory facility.

154.76(2) *Visitor logs.* Visitors to a laboratory facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

154.76(3) *Restricted access.* A laboratory shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its laboratory facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry;

(4) Track times of personnel movement between restricted access areas;

(5) Store data for retrieval for a minimum of one year; and

(6) Remain operable in the event of a power failure.

b. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted areas.

c. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.76(4) *Personnel identification system.* A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility and that meets the requirements of this subrule and subrule 154.76(2).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

(1) Revoke the employee's access to the laboratory; and

(2) Obtain and destroy the employee's identification card, if possible.

154.76(5) *Video monitoring and surveillance.*

a. Video surveillance system. A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

b. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. Video recording specifications.

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A laboratory shall ensure that 24-hour recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for a minimum of 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

154.76(6) *Chain-of-custody policy and procedures.* A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

a. Chain of custody is maintained for samples which may have probable forensic evidentiary value; and

b. Annual training is available for individuals who will be involved with testing medical cannabis goods.

154.76(7) *Information technology systems security.* A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.