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.

"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.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of medical cannabidiol.

"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 review by authorized personnel 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 specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

"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.

"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.

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

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

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

"Certified" means that 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.

"Combusted" means the addition of a flame to medical cannabidiol or raw flower cannabis for the purposes of burning for inhalation, or smoking cannabis.

"Consumable hemp product" means a hemp product that includes a substance that is metabolized or is otherwise subject to a biotransformative process when introduced into the human body.

1. A consumable hemp product may be introduced into the human body by ingestion or absorption by any device including but not limited to an electronic device.
2. A consumable hemp product may exist in a solid or liquid state.
3. A hemp product is deemed to be a consumable hemp product if it is any of the following:

- Designed by the processor, including the manufacturer, to be introduced into the human body.
- Advertised as an item to be introduced into the human body.
- Distributed, exported, or imported for sale or distribution to be introduced into the human body.

"Consumable hemp product" includes but is not limited to any of the following:

1. A noncombustible form of hemp that may be digested, such as food; internally absorbed, such as chew or snuff; or absorbed through the skin, such as a topical application.

2. Hemp processed or otherwise manufactured, marketed, sold, or distributed as food, a food additive, a dietary supplement, or a drug.

"Consumable hemp product" does not include a hemp product if the intended use of the hemp product is introduced into the human body by any method of inhalation, as prohibited under Iowa Code section 204.14A.

"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.

"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.

"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. Chronic pain.
10. Severe, intractable autism with self-injurious or aggressive behaviors.
11. Post-traumatic stress disorder.
12. Corticobasal degeneration.
13. Ulcerative colitis.
14. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

"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 the same as defined in Iowa Code section 124E.2.

"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.

"Health care practitioner" means the same as defined in Iowa Code section 124E.2.

"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.

"Investor" means a person making a cash investment of at least 5 percent interest in an applicant or licensed manufacturer or dispensary with the expectation of receiving financial returns.

"Laboratory" means the same as defined in Iowa Code section 124E.2.

"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.

"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 hawki, as administered by the Iowa Medicaid enterprise of the department.

"Medical cannabidiol" means the same as defined in Iowa Code section 124E.2.

"Medical cannabidiol waste" means medical cannabidiol that is unused, unwanted, damaged, defective, expired, or contaminated and that is returned to a dispensary or manufacturer for disposal.

"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.

"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.

"Owner" means a person with a 5 percent or greater ownership interest in an applicant or licensed manufacturer or dispensary.

"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.

"Patient registration number" means the unique identification number issued to a patient by the department upon approval of a patient's application by the department as described in 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.

"Plant material" means any plant of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

"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 the same as defined in Iowa Code section 124E.2.

"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 shall 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.

"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 ensuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"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.

"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.

"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.

"Security alarm system" means the same as defined in rule 661—277.2(100C).

"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 study" or *"studies"* means the process of determining the shelf-life or expiration date of a medical cannabidiol product. After storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in 641—Chapter 154.

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

"Synthetic or semisynthetic cannabinoid" means a cannabinoid extracted from a cannabis plant, a cannabis flower, a hemp plant, or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. "Synthetic or semisynthetic cannabinoid" includes but is not limited to any tetrahydrocannabinol created from cannabidiol.

"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.

"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.

"Total tetrahydrocannabinol" means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

"Tracking number" means the sales identification number assigned by a dispensary to a transaction at the time of the sale of a medical cannabidiol product.

"Trade name" means the name that manufacturers give to a product or range of products.

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

"Valid photo identification" means any of the following for a patient or primary caregiver: (1) a valid Iowa driver's license, (2) a valid Iowa nonoperator's identification card, or (3) an alternative form of valid photo identification. An individual who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. An individual who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. An individual who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

"Vaporization" means the heating of a medical cannabidiol concentrate or extract to a specific temperature using a device. For the purposes of these rules, vaporization does not include raw or dried cannabis flower.

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

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