Office of Medical Cannabidiol
Iowa Department of Public Health
Lucas State Office Building, 6th Floor
321 East 12th Street
Des Moines, IA 50319

Medical Cannabidiol Manufacturing Facility Inspection Checklist

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1.0 General Inspection Data

Inspection: (Circle)	Scheduled	Unscheduled	Annual
Licensee:		Inspection Date:	
Doing Business As:		Start:	
Primary Contact:		End:	
Facility Address:		Inspector:	

641-154.28 (124E) Inspection by Department or Independent Consultant

A manufacturing facility is subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and the associated administrative rules, and local laws and regulations.

Types of Inspections - 641-154.28(1):
Aspects of business operations
The manufacturing facility
Vehicles used for transport or delivery of medical cannabidiol or plant material
Financial information and inventory documentation
Physical and electronic security system
Other inspections as determined by the department

This inspection checklist is intended to assist the medical cannabidiol manufacturer in becoming operational by December 1, 2018. It also contains information that Office of Medical Cannabidiol will monitor for regulatory compliance as the manufacturer becomes operational.

Grading Criteria:
C = Compliant
NC = Not Compliant
NE = Not Evaluated
NA = Not Applicable

For additional information or questions concerning this checklist or the medical cannabidiol program, please contact Owen Parker, Medical Cannabidiol Program Manager, Owen.Parker@idph.iowa.gov.

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2.0 Manufacturer Operations - 641-154.17(1) - The operating documents of a manufacturer shall include all of the following, and be available during inspection:					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
2.1 Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:					
2.1.1 The forms and quantities of medical cannabidiol produced in the facility					
2.1.2 The methods of planting, harvesting, drying, and storing cannabis					
2.1.3 The estimated types and amounts of crop inputs used in production					
2.1.4 The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated					
2.1.5 The disposal methods for all waste					
2.1.6 Employee training methods for the specific phase of production					
2.1.7 Biosecurity measures used in the production and manufacturing of medical cannabidiol					
2.1.8 Strategies for identification and reconciling discrepancies in inventory of plant material or medical cannabidiol					
2.1.9 Sampling strategy and quality testing for labeling purposes					
2.1.10 Medical cannabidiol packaging and labeling procedures					
2.1.11 Procedures for recall and market withdrawal of medical cannabidiol					
2.1.12 Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary					
2.1.13 A business continuity plan					
2.1.14 Records relating to all transport activities; and other information requested by the department:					
2.2 Procedures to ensure accurate record keeping					
2.3 Procedures for the implementation of the appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance Into areas containing medical cannabidiol					
A manufacturer shall maintain records that reflect all financial transactions for at least five years					

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3.0 Security Requirements - 641-154.18 – The department may request assistance from the Iowa Department of Public Safety in ensuring manufacturers meet the security requirements in this rule.					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
3.1 154.18(1) – *Visitor Logs* – Visitors to the manufacturing facility shall sign visitor manifests with name, date, times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors					
3.2 154.18(2) – *Restricted Access* – A manufacturer shall use a controlled access system and written manifest to limit entrance to all restricted access areas of its manufacturing facility and shall retain a record of all persons who entered the restricted access areas, a) and shall do all of the following:					
3.2.1 Limit access to unauthorized individuals					
3.2.2 Maintain a log of individuals with approved access, including dates of approvals and revocations					
3.2.3 Track times of personnel entry to and exit from facility					
3.2.4 Store data for retrieval for a minimum of one year					
3.2.5 Limit access to only authorized individuals in the event of a power failure					
3.2.6 Restricted access areas shall be identified with signs that state: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only”					
3.3 154.18(3) – *Perimeter Intrusion Detection System* – *a) Computer-Controlled Video Surveillance System* – A manufacturer shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours a day, 7 days a week, and visually records:					
3.3.1 All phases of medical cannabidiol production					
3.3.2 All areas that might contain plant materials and cannabidiol, including safes and vaults					
3.3.3 All points of entry and exit					
3.3.4 The entrance to the video surveillance control room					

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Rule	C	NC	NE	N/A	Comments
3.3.5 Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance					
b) *Camera Specifications* - Cameras shall:					
3.3.6 Capture clear and certain identification of any person entering or exiting a manufacturing facility					
3.3.7 Have the ability to produce a clear, color still photograph live or from a recording					
3.3.8 Have on all recordings an embedded date-and-time stamp that is synchronized to the recordings and does not obscure the picture					
3.3.9 Continue to work during a power outage					
c) *Video recording specifications* – Cameras shall:					
3.3.10 A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif					
3.3.11 Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered					
3.3.12 Exported video shall be saved in an industry standard format that can be played on standard computer operating system					
3.2.13 Recordings are destroyed or erased prior to disposal at the end of the retention period					
d) *Retention* – A manufacturer shall ensure that recordings from all video cameras are:					
3.3.14 Available to the department upon request					
3.3.15 Retained for at least 60 days					
3.3.16 Retained free of alteration or corruption					
e) *Required Signage – 3.3.17* A manufacturer shall post a sign at every entrance to the manufacturing facility that reads “THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE”					
3.4 154.18(4) – *Security Alarm System Requirements – a)* A manufacturer shall install and maintain a professionally monitored security system that provides intrusion and fire detection of all:					
3.4.1 Facility entrance and exits					
3.4.2 Rooms with exterior windows					
3.4.3 Rooms with exterior walls					
3.4.4 Roof hatches					

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Rule	C	NC	NE	N/A	Comments
3.4.5 Skylights					
3.4.6 Storage Rooms					
b) For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:					
3.4.7 Motion detectors, pressure switches, duress alarm, panic alarm, holdup alarm, automatic voice dialer, failure notification system					
c) A manufacturer's alarm system shall continue to function during a power outage					
d) A manufacturer's alarm system shall be inspected and all devices tested annually by a qualified alarm vendor, and shall provide documentation of inspection upon request					
3.5 154.18(5) – *Personnel Identification System – a)* Employee identification card requirements:					
3.5.1 Employee Name					
3.5.2 Date of issuance and expiration					
3.5.3 Alphanumeric identification number that is unique to the employer					
3.5.4 Photographic image of employee					
b) A manufacturer's employees keep the identification visible at all times					

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4.0 Advertising and Marketing - 641-154.20(1) – *Permitted marketing and advertising activities*. – a) manufacturer may:					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
4.1 Display the manufacturer's business name and logo on medicinal cannabidiol labels, signs, and informational material provided to patients, the name or logo shall not include:					
4.1.1 Images of cannabis or paraphernalia					
4.1.2 Colloquial references to cannabis					
4.1.3 Names of cannabis plant strains or varieties					
4.1.4 Unsubstantiated medical claims					
4.1.5 Medical symbols that bear a resemblance to medical associations					
4.2 154.20(3) –*Inconspicuous display* – A manufacturer shall arrange displays of medical cannabidiol, interior signs, and other exhibits to prevent public viewing from outside the dispensary					

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5.0 Packaging and Labeling - 641-154.21(1) – *Medical cannabidiol packaging* – A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
5.1 A manufacturer shall label packaged medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for elderly patients					
Manufacturer shall use medical containers that are:					
5.1.1 Of sufficient size to accommodate separate dispensary label containing information in 154.46					
5.1.2 Designed to maximize shelf life					
5.1.3 Tamper-evident					
5.1.4 Child-resistant					
5.1.5 Not bearing resemblance to commonly available non-medical products					
5.1.6 The packaging minimizes its appeal to children					
5.1.7 The packaging depicts nothing other than the manufacturer's business logo					
5.2 154.21(2) *Trade names* – A manufacturer's trade names shall comply with the following:					
5.2.1 Names shall be limited to those that clearly reflect the form's medical cannabidiol nature					
5.2.2 Names shall not be identical to, or similar to the name of an existing nonmedical cannabidiol product					
5.2.3 Names shall not be identical to, or similar to, the name of an unlawful product or substance					
5.2.4 Names shall no contain language that suggest using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition					
5.3 154.21(3) – *Packaging label* – a) A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:					
5.3.1 The name of the manufacturer					
5.3.2 The medical cannabidiol's primary active ingredients, including THC, THCa, CBD, CBDa					

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Rule	C	NC	NE	N/A	Comments
5.3.4 All ingredients of the product shown with common or usual names, including any colors, and artificial preservatives, listed in descending order by predominance of weight					
5.3.5 Instructions for storage, including light and temperature requirements					
5.3.6 Product expiration date					
5.3.7 The date of manufacture and lot number					
5.3.8 A notice with the statement, including capitalization: “This product has not been analyzed or approved by the US-FDA. 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.”					
5.3.9 The universal warning symbol provided by the department					
5.3.10 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.”					
5.3.11 Labeling text shall not include any false or misleading statements					
5.3.12 Labeling text font shall be no smaller than 6 point					

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6.0 Vehicle Requirements for Transport - 641-154.22(4) – a) A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
6.1 Packaged in tamper-evident, bulk containers					
6.2 Transported so it is not visible or recognizable from outside the vehicle					
6.3 Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer					

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7.0 Disposal of Medical Cannabidiol and Plant Material - 641-154.23					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
7.1 154.23(1) – *Return of Medical Cannabidiol from Dispensaries and Laboratory*					
a) The manufacturer shall maintain a written record of disposal that includes:					
7.1.1 The date the medical cannabidiol was returned					
7.1.2 The quantity of medical cannabidiol returned					
7.1.3 The type and lot number of medical cannabidiol returned					
7.2 154.23(2) – *Medical cannabidiol and plant material waste* – A manufacturer shall store, secure, and manage medical cannabidiol waste and plant material waste in accordance with all federal, state, and local regulations					
a) Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of non-consumable , solid wastes					
7.3 154.23(3) – *Liquid and chemical waste disposal* – A manufacturer shall dispose of all liquid and chemical waste generated by cultivating and manufacturing medical cannabidiol in accordance with federal, state, and local regulations					
7.4 154.23(4) – *Waste-tracking requirements* – A manufacturer shall use forms approved by the department to maintain accurate and comprehensive records regarding waste material. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste					

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8.0 Production Requirements - 641-154.25					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
8.1 154.25(1) – *Cultivation and Processing*					
8.1.1 All phases of production take place in designated, restricted access areas that are monitored by a surveillance camera system					
8.1.2 The production process shall be designed to limit contamination including mold, fungus, bacterial disease, rot, pests, non-organic pesticides, and mildew					
8.1.3 Each production area shall allow for access, observation, and inventory of each plant group					
8.1.4 Biosecurity measures described in operating documents are in place					
8.2 154.25(2) – *Record Keeping and Tracking Requirements* – a) manufacturer uses the departments seed-to-sale tracking software to maintain records of all crop inputs for five years, including the following:					
8.2.1 Date of input application					
8.2.2 Name of employee applying input					
8.2.3 The crop input that was applied					
8.2.4 The plants having received the application					
8.2.5 A copy or electronic link to the safety data sheet for the crop application					
8.3 154.25(4) - *General Sanitation Requirements* – A manufacturer shall take reasonable measures and precautions to ensure that:					
8.3.1 Employees who are ill are relieved of duties involving contact with plant material or extraction/production of cannabidiol.					
8.3.2 Handwashing facilities are:					
1.) Convenient and furnished with running water					
2.) Located in all production areas					
3.) Equipped with effective hand-cleaning and hand-sanitizing preparations and sanitary towel service or drying devices					

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Rule	C	NC	NE	N/A	Comments
8.3.3 Employees maintain personal cleanliness, including washing hands thoroughly before and after duty					
8.3.4 Litter and waste are routinely removed and the operating systems for waste disposal are inspected routinely					
8.3.5 Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair					
8.3.6 Lighting is adequate where all *Cannabis* is processed and stored					
8.3.7 Pests are not present, waste is disposed of promptly, and odors are not present					
8.3.8 Buildings, fixtures, and facilities are sanitary					
8.3.9 Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant materials and medical cannabidiol					
8.3.10 All contact surfaces, utensils, and equipment used in production are clean and sanitary					
8.3.11 The manufacturing facility has a water supply sufficient for operations					
8.3.12 Employees have accessible toilet facilities that are sanitary and in repair					
8.4 154.25(5) – *Storage* – a) A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring that:					
1.) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day					
8.4.1 A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:					
1.) In areas that are maintained in a clean, orderly, and well-ventilated condition					
2.) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind					

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Rule	C	NC	NE	N/A	Comments
8.4.2 To prevent degradation, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable medical cannabidiol under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container					
8.4.3 A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate, secure storage area includes a container, closet, or room that can be secured					

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9.0 Quality Assurance Program - 641-154.25 (1) – 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.					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
9.1 154.26(2) – *Sampling protocols* – A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:					
9.1.1 Conduct sample collection in a manner that provides analytically sound and representative samples					
9.1.2 Document every sampling event and provide this documentation to the department upon request					
9.1.3 Describe all sampling and testing plans in written procedures that include the sampling method and number of units per lot to be tested					
9.1.4 Ensure that samples from each lot are:					
9.1.4.1 Taken in an amount necessary to conduct the applicable test					
9.1.4.2 Labeled with the lot number					
9.1.5 Test results are retained (for 5 years).					
9.2 154.26(3) – *Sampling and testing* – A manufacturer shall:					
9.2.1 Describe all sampling and testing plans in written protocols that include the sampling method and the number of units per lot to be tested					
9.3 154.26(4) – *Stability Testing* – a) the quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration date, the procedures shall describe:					
9.3.1 Sample size and test intervals based on statistical criteria for each attribute examined to ensure valid stability estimates					
9.3.2 Storage conditions for samples retained for testing					
9.3.3 Reliable and specific test methods					

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Rule	C	NC	NE	N/A	Comments
b) Stability studies shall include:					
9.3.4 Medical cannabidiol testing at appropriate interval levels					
9.3.5 Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed					
c) If product-expiration-date studies have not been completed, a product expiration date not to exceed one year is printed on the product.					
9.4 154.26(5) – *Reserve Samples* – a) A manufacturer shall retain a uniquely labeled reserve sample that contain at least twice the quantity necessary to perform the tests, and represents each lot of medical cannabidiol and store it under conditions consistent with product labeling					
9.5 154.26(8) – *Recall and market withdrawal procedures* – Each manufacturer shall establish a procedure for recalling or withdrawing product from the market, which includes:					
9.5.1 Factors that make a recall or market withdrawal necessary					
9.5.2 Manufacturer's personnel who are responsible for overseeing the recall					
9.5.3 How to notify affected parties of a recall or market withdrawal.					

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10.0 Supply and Inventory – 641-154.27					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
10.1 154.27(2) – *Inventory controls and procedures* – A manufacturer shall establish inventory controls and procedures for conducting reviews to prevent and detect and diversion, theft, or loss					
10.2 154.27(3) – *Real-time inventory required* – The manufacturer shall use a seed-to-sale tracking system to maintain real-time inventory of plant material and medical cannabidiol to include:					
10.2.1 Quantity and form of medical cannabidiol maintained by the manufacturer at the facility on a daily basis					
10.2.2 The number of plants being grown at the manufacturing facility on a daily basis					
10.2.3 The names of employees or employee conducting the inventory					
10.3 154.27(4) – *Waste Inventory* – a manufacturer shall maintain a record of its inventory of all medical cannabidiol waste and plant material waste for disposal					
10.4 154.27(5) – *Reconciliation procedures* – a manufacturer shall reconcile its physical inventory no less often than every 2 weeks. Reconciliation shall include plant material at the manufacturing facility and in transit; and medical cannabidiol products at the manufacturing facility, at distribution or storage facilities, and in transit. Procedures should include protocol for notifying law enforcement within 72 hours of discovering a discrepancy					
10.5 154.27(6) – *Scales* – All scales used to weigh usable plant material for purposes of these rules shall be ISO-certified					

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11.0 Local Safety Inspections – 641-154.28					
Rule	**C**	**NC**	**NE**	**N/A**	**Comments**
A manufacturer shall provide proof of and local licensing or permits, including:					
1. Local Fire Department					
2. Building inspector					
3. Code enforcement					
4. Other					

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12.0 Inspections and Briefing Acknowledgement		
Item	**Acknowledgement**	**Comments**
An exit interview was conducted		
Deficiencies and plans for correction were discussed with the facility representative		

I have received information on the above subjects, and am aware I must abide by the laws and regulations covering the licensing and operation of my business pursuant to Iowa Code chapter 124E and the associated administrative rules. I am aware that the department reserves the right to assess penalties for violations of noncompliance.

_____ _____

Licensee Authorized Representative Date

_____ _____

Inspector Date