33-44-01-01. Definitions.

7. "Container ~~unique~~ identification number" means the ~~unique~~ identification number that was generated by the manufacturing facility at the time the usable marijuana was packaged and labeled for sale to the dispensary.

11. "Harvest lot" means a specifically identified quantity of the same strain of marijuana that is cultivated utilizing the same growing practices, harvested within a seventy-two-hour period at the same location, and cured under uniform conditions.

14. "Medical marijuana waste" means the same as defined in North Dakota Century Code chapter 19-24.1 ~~and also includes any wastewater generated during production and processing~~.

19. "Process lot" means any amount of:
    a. Cannabinoid concentrate of the same type and processed within a forty-eight-hour period using the same extraction methods, standard operating procedures, and batches, not to exceed three, of the same strain from the same or a different harvest lot; or
    b. Medical cannabinoid product of the same type and processed within a forty-eight-hour period using the same ingredients, standard operating procedures, and ~~batches from the same or a different harvest lot or~~ a process lot or process lots of the same strain, not to exceed three, of cannabinoid concentrate as defined in subsection a.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-01
Law Implemented: NDCC 19-24.1-01

33-44-01-08. Compassion center inventory limits.

1. ~~Except as otherwise provided by this section, a manufacturing facility may not possess more than one thousand plants, regardless of the stage of growth.~~A manufacturing facility shall grow an amount of marijuana sufficient to meet the qualifying patient population demands. A manufacturing facility may possess ~~an additional~~ up to fifty plants for the ~~exclusive~~ purpose of department-authorized research and development related to production and processing. Plants for research and development shall:

    a. Be included in inventory;

    b. Be located in a restricted area separate from the restricted area containing plants used for producing and processing of usable marijuana; and

c. Not be used in the production and processing of usable marijuana that is sold to a dispensary for patient consumption unless authorized by the department in writing.

2. A manufacturing facility with a registration certificate may use additional structures located within five hundred feet [152.40 meters] of the location described in the original application. Prior to using additional structures, the manufacturing facility must submit a written request to the department. The written request must include the reason the structures are necessary, verification the additional structures do not jeopardize public health or safety, and evidence from the appropriate local government official that the additional structures are at least one thousand feet [304.80 meters] from a property line of a pre-existing public or private school. The department shall approve or deny a request within 30 calendar days. The department shall deny a request if the department makes an affirmative finding the use of additional structures would jeopardize public health or safety or the additional structures are within one thousand feet [304.80 meters] of a property line of a pre-existing public or private school.

~~2.~~3. A dispensary may not possess more than three thousand five hundred ounces (99.22 kilograms) of usable marijuana at any time, regardless of formulation.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-24
Law Implemented: NDCC 19-24.1-24

33-44-01-09. Use of pesticides prohibited.

The use of pesticides is prohibited. A compassion center may not use pesticides, as defined by the environmental protection agency, in the production, processing, or storage of marijuana. ~~Pesticides include:~~

~~Organochlorines.~~

~~Organophosphates.~~

~~Carbamates.~~

~~Insecticidal, fungicidal, or growth regulatory compounds.~~

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-22
Law Implemented: NDCC 19-24.1-22

33-44-01-12. Restricted access areas.

1. Except as provided in 33-44-01-13, compassion center restricted access areas include:

    a. All areas containing marijuana, usable marijuana, and medical marijuana waste.

    b. All areas used for production and processing.

2. A compassion center shall use an electronic controlled access system to limit entrance to all restricted access areas of its facility.

    a. An electronic controlled access system must:

        (1) Limit access to authorized individuals.

        (2) Track specific personnel entry and exit times.

        (3) Lock down the facility in the event of a security threat.

        (4) Store data for retrieval.

        (5) Remain operable in the event of power failure.

        (6) Enable remote administration.

    b. A compassion center shall immediately submit stored controlled-access-system data to the department upon request.

    c. Restricted access areas must be identified with a sign that states: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only.”

3. Individuals authorized to enter restricted access areas include:

    a. Compassion center agents;

    b. Laboratory agents;

    c. Authorized department personnel; ~~and~~

    ~~c.~~d. Individuals accompanied by a compassion center agent when the compassion center agent has received written authorization from authorized department personnel; and

~~d.~~e. Individuals accompanied by authorized department personnel.

4. A compassion center shall maintain documentation of access to restricted areas for individuals included in paragraphs b, c, ~~and~~ d, and e of subsection 3. The documentation must include date of entry, time of entry, time of exit, name of individual, reason for access, and any other information required by the department. The documentation must be retained for at least three years.

5. Law enforcement, fire personnel, or emergency medical service professionals may enter restricted access areas in the event of an emergency requiring immediate action.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-13. Dispensary display areas.

1. A dispensary may have a display area where usable marijuana is displayed in enclosed locked cases accessible only by compassion center agents. The purpose of the display area is to provide registered qualifying patients and registered designated caregivers the opportunity to view usable marijuana and receive education regarding its use. Usable marijuana may not be visible from the street or other public areas.

2. Individuals authorized to enter dispensary display areas include:

   a. Registered qualifying patients;

   b. Registered designated caregivers;

   c. Compassion center agents;

   d. Authorized department personnel; ~~and~~

   ~~d.~~e. Individuals accompanied by a compassion center agent when the compassion center agent has received written authorization from authorized department personnel; and

   ~~e.~~f. Individuals accompanied by authorized department personnel.

3. Before allowing an individual to enter a dispensary display area, the dispensary shall verify the validity of a cardholder's registry identification card.

History: Effective April 1, 2018

General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-17. Surveillance requirements.

1. To prevent unauthorized access to marijuana and usable marijuana, the compassion center shall have video surveillance equipment to deter the unauthorized entrance into restricted access areas.

    a. The compassion center must operate, monitor, and maintain in good working order a closed-circuit television surveillance system on all of its premises, which must operate at all times and visually record:

        (1) All phases of production and processing.

        (2) All compassion center points of entry and exit, sales and display areas, ~~storage facilities,~~ and garages.

        (3) The entrance to the video surveillance room.

        (4) Any parking lot, which must have appropriate lighting for the normal conditions of the area under surveillance.

    b. Video surveillance systems must:

        (1) Capture clear and certain identification of any person entering or exiting a compassion center.

        (2) Have the ability to produce a clear, color, still photo either live or from a recording.

        (3) Have an embedded date-and-time stamp on all recordings which must be synchronized and not obscure the picture.

        (4) Continue to operate during a power outage.

    c. Video recording specifications include:

        (1) A video recording must export still images in an industry standard image format, including .jpg, .bmp, and .gif.

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

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

(4) Upon completion of the required retention period, all recordings must be erased or destroyed before disposal.

2. The compassion center shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

3. The compassion center must ensure that twenty-four hour recordings from all video cameras are:

   a. Available for viewing by the department through a secure internet connection.

   b. Retained for a period of at least ninety calendar days during the first year of operation, and upon department approval, for at least sixty calendar days thereafter.

   c. Maintained free of alteration or corruption.

   d. Retained longer if the compassion center is given notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-18. Alarm system requirements.

1. A compassion center shall install and maintain a professionally monitored security alarm system that provides intrusion ~~and fire~~ detection of all:

   a. Facility entrances and exits.

   b. Rooms with exterior windows.

   c. Rooms with exterior walls.

   d. Roof hatches.

   e. Skylights.

~~f. Storage rooms.~~

2. 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:

   a. Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal.

   b. Motion detectors.

   c. Pressure switches.

   d. A duress alarm.

   e. A panic alarm.

   f. A holdup alarm.

   g. An automatic voice dialer.

   h. A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

3. At a minimum, a compassion center shall have fire detection devices in all restricted access areas.

~~3.~~4. A compassion center's security alarm system and all devices must continue to operate during a power outage.

~~4.~~5. The compassion center shall test the security alarm system and all devices on a monthly basis and maintain a record of all tests.

~~5.~~6. The compassion center's security alarm system must be inspected and all devices tested annually by a qualified alarm vendor.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-22. Compassion center and laboratory incidents.

1. Compassion centers and the laboratory shall contact 911 in the event of an emergency and contact law enforcement or 911 to report criminal activities.

2. Compassion centers and the laboratory shall provide the department with written notice, within twenty-four hours, of any of the following:

    a. A breach of security;

    b. Failures of, or tampering with, security and surveillance equipment, cameras, or recordings;

    c. Power failures lasting longer than two hours;

    d. Embezzlement or fraud;

    e. Contacting 911 or contact with law enforcement;

    f. Incidents that occur while transporting marijuana, usable marijuana, and medical marijuana waste; and

    g. Attempts to obtain marijuana or usable marijuana in a manner not prescribed by North Dakota Century Code chapter 19-24.1 and these rules.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-24. Strain or brand names.

A manufacturing facility may not use strain or brand names containing any words that refer to products commonly associated with minors, marketed ~~by~~ to minors, or any names that are false or misleading.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-25. Usable marijuana packaging.

Alll usable marijuana packaging used by a manufacturing facility shall be approved by the department. A manufacturing facility shall package all usable marijuana intended for distribution according to the following standards:

1. Usable marijuana containers must be:

a. Plain.

b. Tamper-evident.

c. Child-resistant.

2. Usable marijuana must be packaged to minimize its appeal to children.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-26. Manufacturing facility labeling.

1. A manufacturing facility shall label all usable marijuana in accordance with the following before their sale or transfer to a dispensary:

   a. A container holding dried leaves and flowers must include the following information:

      (1) Manufacturers' business or trade name and registry certification number;

      (2) Container ~~unique~~ identification number;

      (3) Harvest lot number;

      (4) Date of harvest;

      (5) Name of strain;

      (6) Net weight in U.S. customary and metric units;

      (7) Concentration of total tetrahydrocannabinol~~, tetrahydrocannabinolic acid,~~ and total cannabidiol;

      (8) Activation time expressed in words or through a pictogram;

      (9) Expiration date;

      (10) Universal symbol; and

      (11) Consumer warnings that state:

(a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

(b) “For use by North Dakota registered qualifying patients only.”

(c) "Keep out of reach of children."

(d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

b. A container holding a cannabinoid concentrate must include the following information:

(1) Manufacturing facility’s business or trade name and registry certification number;

(2) Container ~~unique~~ identification number;

(3) Process lot number;

(4) Product identity;

(5) Date the concentrate was made;

(6) Net weight or volume in United States customary and metric units;

(7) If applicable, serving size and number of servings per container or amount suggested for use by the consumer or patient at any one time;

(8) Concentration or amount of tetrahydrocannabinol, and the concentration or amount of cannabidiol, by weight or volume in each amount suggested for use and in the container;

(9) Activation time, expressed in words or through a pictogram;

(10) Expiration date;

(11) Universal symbol,

(12) Pediatric symbol, if applicable; and

(13) Consumer warnings that state:

(a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

(b) “For use by North Dakota registered qualifying patients only.”

(c) "Keep out of reach of children."

(d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

c. A container holding a medical cannabinoid product must include the following information:

(1) Manufacturers’ business or trade name and registry certification number;

(2) Container ~~unique~~ identification number;

(3) Process lot number;

(4) Product identity;

(5) Date the product was made;

(6) Net weight or volume in United States customary and metric units;

(7) Serving size and number of servings per container;

(8) Concentration or amount of tetrahydrocannabinol, and the concentration or amount of cannabidiol, by weight or volume in each serving and in each container;

(9) List of ingredients in descending order or predominance by weight or volume used to process the medical cannabinoid product;

(10) Activation time, expressed in words or through a pictogram;

(11) Expiration date;

(12) Universal symbol;

(13) Pediatric symbol, if applicable; and

(14) Consumer warnings that state:

(a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

(b) “For use by North Dakota registered qualifying patients only.”

(c) "Keep out of reach of children."

(d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

2. Usable marijuana labels required in accordance with this section must be no smaller than eight point, arial or calibri, font. If, due to the size of the container, sufficient space does not exist for a label containing all of the required information, the manufacturing facility may:

   a. Use a peel-back or accordion label if, the peel-back or accordion label is easily identified as containing the required information; or

   b. Reduce the size of the required information to six point font.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-36. Laboratory procurement process.

The department may ~~enter a~~ contract with a laboratory or laboratories to conduct random quality sampling testing of a compassion center's marijuana and usable marijuana. The department shall procure the laboratory testing services in accordance with North Dakota Century Code chapter 54-44.4. An awarded laboratory must be properly accredited as determined by the department.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-42. Compliance testing requirements for dried leaves and flowers.

~~1. A manufacturing facility shall have every batch from a harvest lot of dried leaves and flowers tested for pesticides and degradation compounds in accordance with section 33-44-01-47.~~

~~In addition to testing required in subsection 1, a~~ A manufacturing facility shall have every batch from a harvest lot of dried leaves and flowers, to be packaged in a container for transfer to a dispensary, tested for the following:

a. Pesticides and degradation compounds in accordance with section 33-44-01-47.

b. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.

~~a.~~c. Heavy metals in accordance with section 33-44-01-48.1.

~~b.~~d. Water activity and moisture content in accordance with section 33-44-01-50.

~~c.~~e. Concentration in accordance with section 33-44-01-51.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-43. Compliance testing requirements for cannabinoid concentrates.

1. A manufacturing facility shall have every process lot of cannabinoid concentrate, to be packaged in a container for transfer to a dispensary, tested for the following:

   a. Pesticides and degradation compounds in accordance with section 33-44-01-47.

   b. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.

   ~~b.~~c. Heavy metals in accordance with section 33-44-01-48.1.

   ~~c.~~d. Solvents in accordance with section 33-44-01-49.

   ~~d.~~e. Concentration in accordance with section 33-44-01-51.

~~2. A manufacturing facility shall have every process lot of cannabinoid concentrate intended for use in processing a medical cannabinoid product tested for:~~

   ~~a. Pesticides and degradation compounds in accordance with section 33-44-01-47.~~

   ~~b. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.~~

   ~~c. Solvents in accordance with section 33-44-01-49.~~

~~3.~~2. ~~A cannabinoid concentrate may not be used in processing a medical cannabinoid product unless the requirements of testing in subsection 2 have been met.~~

~~4.~~3. A manufacturing facility is exempt from testing for solvents under this section if the manufacturing facility did not use any solvent or the department provides the manufacturing facility with a written exemption if the manufacturing facility uses a closed loop carbon dioxide extraction method.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-44. Compliance testing requirements for medical cannabinoid products.

A manufacturing facility shall have every process lot of a medical cannabinoid product, to be packaged in a container for transfer to a dispensary, tested for the following:

1. Pesticides and degradation compounds in accordance with section 33-44-01-47.

2. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.

~~1.~~3. Heavy metals in accordance with section 33-44-01-48.1.

4. Solvents in accordance with section 33-44-01-49.

~~2.~~5. Concentration in accordance with section 33-44-01-51.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-46. Manufacturing facility requirements for labeling, storing, and securing usable marijuana batches.

When samples are taken from a harvest or process lot batch, a manufacturing facility shall:

1. Ensure the batch is labeled with the following information:

    a. The manufacturing facility's name;

b. The harvest lot or process lot unique identification number;

c. The name of the laboratory that took samples;

d. The unique identification sample numbers ~~provided by the laboratory agents~~; and

e. The date the samples were taken.

2. Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to required tests being completed.

3. Be able to easily locate a batch stored and secured under subsection 2 and provide that location to the department or a laboratory upon request.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-48.1. Standards for heavy metals compliance testing.

A batch fails heavy metals testing if the presence of one of the following metals, at a minimum, is above the following listed limit:

	Parts Per Million (ppm)
Inorganic arsenic	0.4
Cadmium	0.3
Lead	1.0
Mercury	0.2

History:
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-51. Standards for concentration compliance testing.

1. Usable marijuana concentration testing must include:

a. Tetrahydrocannabinol (THC).

b. Tetrahydrocannabinolic acid (THCA).

c. Cannabidiol (CBD).

d. Cannabidiolic acid (CBDA).

2. The total tetrahydrocannabinol and total cannabidiol must be calculated as follows:

   a. Total tetrahydrocannabinol, where M is the mass or mass fraction of delta-9 tetrahydrocannabinol or delta-9 tetrahydrocannabinolic acid:

      M total delta-9 THC = delta-9 THC + (0.877 x M delta-9 THCA)

   b. Total cannabidiol, where M is the mass or mass fraction of cannabidiol and cannabidiolic acid:

      M total CBD = M CBD + (0.877 x M CBDA)

3. Test results must report ~~total~~ tetrahydrocannabinol, tetrahydrocannabinolic acid, ~~and total~~ cannabidiol, and cannabidiolic acid content by dry weight calculated as follows:

   a. P ~~total~~ THC(dry) = P ~~total~~ THC(wet) / [1-(P moisture/100)].

   ~~a.~~b. P THCA(dry) = P THCA(wet) / [1-(P moisture/100)].

   c. P ~~total~~ CBD(dry) = P ~~total~~ CBD(wet) / [1-(P moisture/100)].

   ~~b.~~d. P CBDA(dry) = P CBDA(wet) / [1-P moisture/100)].

4. The concentration test fails if the total amount of tetrahydrocannabinol and tetrahydrocannabinolic acid, as calculated pursuant to this section, exceeds the maximum concentration or amounts permitted in North Dakota Century Code chapter 19-24.1.

5. The concentration test fails if the concentration amount identified by the laboratory varies from the concentration amount identified by the manufacturing facility, if known, by more than plus or minus fifteen percent.

6. The concentration test fails if the tetrahydrocannabinol or cannabidiol content of a medical cannabinoid product is determined through testing not to be homogenous. A medical cannabinoid product is considered not to be homogenous if ten percent of the infused portion of the medical cannabinoid product contains more than twenty percent of the total tetrahydrocannabinol or cannabidiol contained within the entire medical cannabinoid product.

7. If the samples do not pass testing standards for concentration, the manufacturing facility must comply with section 33-44-01-52.

History: Effective April 1, 2018
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-52. Failed test samples.

1. If a sample fails any test, the manufacturing facility may submit a written request to the department for a reanalysis. The request must be received by the department within seven calendar days from the date the laboratory sent notice of the failed test to the manufacturing facility. The department, in consultation with the laboratory, shall determine whether a reanalysis will be performed on the samples held by the laboratory or a new sample will be selected from the batch. The reanalysis must be completed by the laboratory within thirty days from the date the reanalysis request was received.

2. If a sample fails a test or a reanalysis under subsection 1:

   a. The batch may be remediated or sterilized in accordance with this section; or

   b. If the batch is not or cannot be remediated or sterilized under this section, the batch must be disposed of in accordance with section 33-44-01-15.

3. If a sample from a batch of dried leaves and flowers, cannabinoid concentrate, or cannabinoid product fails pesticide or degradation compound testing, the batch may not be remediated and must be disposed of as ordered by the department or the department of agriculture. An affected or contaminated batch may not be destroyed without obtaining written permission from the department or the department of agriculture. ~~A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for pesticides and degradation compounds testing:~~

   ~~a. If a sample from a batch of dried leaves and flowers fails pesticide or degradation compound testing, the batch may not be remediated and must be disposed of as ordered by the department or the department of agriculture. An affected or contaminated batch may not be destroyed without obtaining written permission from the department or the department of agriculture.~~

   ~~b. If a batch from a processing lot using dried leaves and flowers that originally passed pesticide and degradation compound testing under section 33-44-01-47 has a sample failing pesticide and degradation compound testing, the batch may be remediated if written approval from the department is obtained prior to remediation.~~

   ~~c. A batch that is remediated in accordance with subdivision b of subsection 6 must be sampled and tested in accordance with these rules.~~

~~d. A batch that fails pesticide and degradation compound testing after undergoing remediation in accordance with subdivision b of subsection 6 is considered contaminated and must be disposed of as ordered by the department or the department of agriculture. A contaminated batch may not be destroyed without obtaining written permission from the department or the department of agriculture.~~

4. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for microbiological contaminant or mycotoxin testing:

   a. If a sample from a batch of dried leaves and flowers fails microbiological contaminant or mycotoxin testing, the batch may be used to make a cannabinoid concentrate if:

      (1) The processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a carbon dioxide closed loop system; or

      (2) The processing method selectively removes the mycotoxins from the batch.

   b. If a sample from a batch of a cannabinoid concentrate fails microbiological contaminant or mycotoxin testing, the batch may be further processed if:

      (1) The processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a carbon dioxide closed loop system; or

      (2) The processing method selectively removes the mycotoxins from the batch.

   c. If a sample from a batch of a medical cannabinoid product fails microbiological contaminant or mycotoxin testing, the batch may be remediated if written approval from the department is obtained prior to remediation.

   d. A batch that is remediated in accordance with subdivisions a, b, or c of subsection ~~3~~ 4 must be sampled and tested in accordance with these rules.

   e. A batch that fails microbiological contaminant or mycotoxin testing after undergoing remediation in accordance with subdivisions a, b, or c of subsection ~~3~~ 4 must be disposed of in accordance with section 33-44-01-15.

5. If a sample from a batch of dried leaves and flowers, cannabinoid concentrate, or cannabinoid product fails heavy metals testing, the batch may be remediated if

written approval from the department is obtained prior to remediation. A batch that is remediated must be sampled and tested in accordance with these rules. A batch that fails heavy metals testing after undergoing remediation must be disposed of in accordance with section 33-44-01-15.

~~5.~~6. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for solvent testing:

a. If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level established in these rules.

b. A batch that is remediated in accordance with subdivision a of subsection ~~4~~ 6 must be sampled and tested in accordance with these rules.

c. A batch that fails solvent testing after undergoing remediation in accordance with subdivision a must be disposed of in accordance with section 33-44-01-15.

~~6.~~7. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for water activity and moisture testing:

a. If a sample from a batch of dried leaves and flowers fails for water activity or moisture testing, the batch from which the sample was taken may:

(1) Be used to make a cannabinoid concentrate or a medical cannabinoid product and must comply with testing requirements established in these rules; or

(2) Continue to dry or cure.

b. A batch that undergoes additional drying or curing as described in paragraph 2 of subdivision a of subsection 7 must be sampled and tested for water activity and moisture content and concentration testing in accordance with these rules.

~~7.~~8. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for concentration testing:

a. A batch that has a sample failing concentration testing under subsection 4 of section 33-44-01-51 may be remediated to meet the concentration limits permitted in North Dakota Century Code chapter 19-24.1.

b. If a sample from a batch of pediatric medical marijuana fails concentration testing, the manufacturing facility may use the batch for nonpediatric usable marijuana rather than remediating the pediatric medical marijuana in accordance with subdivision a of subsection 8. No additional testing is required

if the manufacturing facility does not label the usable marijuana for pediatric use and does no further processing with a batch of pediatric medical marijuana failing concentration testing. Any usable marijuana processed with a batch from a failed pediatric medical marijuana concentration test must be sampled and tested in accordance with these rules.

c. A batch that has a sample failing concentration testing under subsection 5 of section 33-44-01-51 may be remediated or the manufacturing facility may use the concentration test results of the laboratory for labeling purposes.

d. A batch that has a sample failing concentration testing under subsection 6 of section 33-44-01-51 may be remediated.

e. A batch that is remediated in accordance with subdivisions a, c, or d of subsection 8 must be sampled and tested in accordance with these rules.

~~8.~~9. A manufacturing facility shall, as applicable:

a. Have detailed written procedures for remediation processes to be used pursuant to this section.

b. Document all remediation processes used pursuant to this section.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-55. Manufacturing facility quality control and quality assurance program.

1. A manufacturing facility shall develop and follow a written quality control and quality assurance program. The program must be established to protect qualifying patient health and implemented in a manner to assist in complying with testing required in sections 33-44-01-42, 33-44-01-43, and 33-44-01-44. A manufacturing facility is not prohibited by these rules to test marijuana and usable marijuana as part of a quality control and quality assurance program.

2. A quality control and quality assurance program must include an assessment of the profile of the active ingredients, including expiration date, and the presence of inactive ingredients and contaminants. Testing results must be used to determine appropriate conditions and expiration dates.

3. A manufacturing facility shall develop and follow written procedures for sampling marijuana and usable marijuana. Procedures must be developed related to

sampling methods, sample collection, and documentation of sampling. Test results from random samples must be retained for at least three years.

4. The manufacturing facility shall develop and follow written procedures for performing stability testing of usable marijuana to determine product expiration date. Once an expiration date has been determined through testing described in subsection 5, a manufacturing facility must perform periodic stability testing to verify expiration dates. ~~If stability testing has not been completed within one year of production, a manufacturing facility may assign a tentative expiration date based on available stability information. After the manufacturing facility verifies the tentative expiration date, or determines the appropriate expiration date, the manufacturing facility shall include the expiration date on each batch of marijuana or usable marijuana.~~

~~4.~~5. If stability testing has not been completed within one year of production, a manufacturing facility may assign a tentative expiration date based on available stability information. Stability testing is to include, at a minimum, an assessment of pesticides and degradation compounds, microbiological contaminants and mycotoxins, heavy metals, solvents, and concentration. When applicable, the stability testing must include water activity and moisture content. If an expiration date is one year or less, at a minimum, a stability test must be performed once before fifty percent of the period has expired and at the end of the expiration date. If an expiration date is more than one year, at a minimum, a stability test must be performed at no less than six-month intervals and at the end of the expiration date. After the manufacturing facility verifies the tentative expiration date, or determines the appropriate expiration date, the manufacturing facility shall include the expiration date on each batch of marijuana or usable marijuana.

~~5.~~6. A manufacturing facility shall retain a uniquely labeled reserve sample representing each harvest lot, process lot of cannabinoid concentrate to be packaged in a container for transfer to a dispensary, and process lot of medical cannabinoid product ~~batch of usable marijuana~~ for at least one year following the ~~batch's~~ expiration date. The reserve sample must be stored in the same immediate container-closure system the usable marijuana is packaged in for dispensaries, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all required tests.

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