Rules Package 7

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General Requirements

OAC 1301:18-1-01: Definitions – to add

- **Anything of Value** means any gift that is valued over twenty-five dollars, and may not be a cash gift. Such gifts to one individual may not exceed $100 in a one calendar year period.
- **Batch** means cannabis plant material obtained from cannabis plants that were grown together and exposed to substantially the same conditions throughout cultivation and harvested over no more than a 72-hour period and adhere to the following:
    - For **final form flower or buds**:
        - The batch must be created using cannabis plants of the same exact strain
        - The net weight cannot exceed fifteen pounds which must be dried and manicured immediately prior to testing.
    - For **fresh frozen** cannabis plant material:
        - The batch must be created using cannabis plants of the same exact strain and may only be destined for extraction at a licensed processor.
        - The net weight cannot exceed one hundred and twenty-five pounds
    - For **shake and trim**, the batch may contain more than one cannabis strain and include shake, trim, and other resinous trichomes obtained incidental to the trimming and manicuring process.
        - For **final form** shake and trim destined solely for **direct customer sale:**
            - The net weight cannot exceed twenty-five (25) pounds
        - For shake and trim destined solely for **extraction:**

- The net weight cannot exceed fifty (50) pounds

- **Bulk cannabis extract** means a solvent-based cannabis extract that is destined for use as an ingredient in another cannabis product and does not exceed fifty (50) pounds.
- **Bulk cannabis plant material** means dried cannabis plant material obtained from cannabis plants that were grown together and exposed to substantially the same conditions throughout cultivation and harvested over no more than a 72-hour period and does not exceed fifty (50) pounds.
    - A batch of bulk dried plant material created pursuant to this subsection may only contain unmanicured flower or buds if the entire batch is destined **solely for further production, manufacture, or extraction.**
- **Bulk cannabis distillate** means cannabis distillate that is destined for use as an ingredient in another cannabis product, created within a 72-hour period using the same extraction method, same operating procedures, and same batch or batches of starting plant material. The 72-hour period begins when the cannabis extract is added to the distillation apparatus.
- **Cannabis Distillate** means a byproduct of cannabis extract that is highly refined to isolate a desired compound through a series of heating, vacuuming, or condensation step.
- **Cannabis Extract** means a form of cannabis obtained by separating cannabinoids or terpenes from any part of the cannabis plant by physical or chemical means, so as to provide a product that contains a higher concentration of the desired compounds than the cannabis plant material itself. Cannabis extract may be destined for further refinement for use as an ingredient in a cannabis product or as a standalone cannabis product destined for direct customer sale.
- **Cannabis Products Lot** means cannabis products of the same exact type produced at the same time in one homogeneous mixture using the exact same ingredients, standard operating procedures and batches of source plant material or cannabis concentrate.
    - A lot of cannabis products which is sold in uniform units shall not contain more than 35,000 units.
- **Infused single serving unit** is a combination inhalable product that consists of dried plant material and cannabis extract, wrapped in rolling paper. The cannabis extract may be included in the product by combining with the dried plant material, applying to the rolling paper, or both. A lot of infused single serving units may not exceed 35,000 units.
- **Non-solvent-based cannabis concentrate** means a final form cannabis extract destined solely for direct customer sale that does not involve an approved solvent, including bubble hash, rosin press, and other approved non-solvent-based methods.
- **Non-solvent-based cannabis concentrate lot:** Except as otherwise provided by this rule, up to ten pounds (4536g) of cannabis extract created using the same extraction method, same operating procedures, and same batch or batches of starting plant material.
- **Remediation** means the process of neutralization or removal of dangerous substances or other contaminants from cannabis following a failed test.
- **Representative sample** means a sample that is comprised of several sample increments of cannabis or cannabis products that are collected from a batch or lot for testing.
- **Solvent-based Cannabis Concentrate** means a final form cannabis extract destined for direct customer sale that is created through solvent-based extraction, including butanes, propane, heptane, carbon dioxide, ethanol, and other solvents as approved by the division of cannabis control. A solvent-based cannabis concentrate does not include any cannabis extract that is created through a water-based extraction method.

- **Solvent-based cannabis concentrate lot:** Except as otherwise provided by this rule, up to ten pounds (4536g) of cannabis extract created using the same extraction method, same operating procedures, and same batch or batches of starting plant material.
- **Topical cannabis product** means non-edible cannabis or cannabis products that are intended to be applied topically and absorbed transdermal, including without limitation salves, creams, lotions, transdermal patches or balms.
- **Total THC** means the sum of THC and THCA. Total THC is calculated by a cannabis testing facility using the following equation: Total THC = delta-9 THC + delta-8 THC + (THCA*0.877).
- **Vaporization Solution:**
    - A lot of **vaporization solution** is created only from a single lot of cannabis extracts and may be considered the final form for all state-required testing.
- **Water activity** means the measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi and which is reported in units Aw.

Consumer Protection and Product Safety

OAC 1301:18-4-11: Limitations on Remediation

- **(A)** Each cultivator and processor shall establish, maintain, and comply with written policies and procedures to ensure all cannabis complies with all standards for state-required testing.
    - **(1)** Notwithstanding any other provision, a cultivator or processor may conduct limited remediation **solely as permitted and outlined under this rule.**
    - **(2)** In accordance with rule 1301:18-4-13 of the Administrative Code, a licensee that conducts remediation in accordance with this rule shall:
        - **(b)** Conduct remediation, on a test sample only **one time** prior to submission to all state-required testing; and
    - **(3)** Unless otherwise authorized by this rule, the following applies:
        - **(b)** Test samples are not submitted more than once to a licensed testing laboratory to perform any testing analysis on any test panels or analytes prior to submitting the associated batch or lot to all state-required testing pursuant to rule 1301:18-4-13 of the Administrative Code.
- **(B) Processors Remediation for Cannabis Extracts**
    - **(1)** In the event a processor determines that the lot does not meet the standards established by the division for cannabinoid potency or terpene content, a processor may remediate the associated lot one time.
    - **(2)** If a processor utilizes this method, it may submit the test sample to the same laboratory to retest the remediated concentrate.
        - **(a)** For solvent-based concentrates and bulk distillate, the levels of excess approved residual solvents.
            - **(i)** In the event a processor determines that the lot does not meet the standards established by the division for residual solvents, a processor may remediate the associated lot by purging the excess allowable solvents one time.
            - **(ii)** If a processor utilizes this method, they may submit the test sample to the same laboratory to retest the remediated extract.
- **(C) Cultivators**
    - **(1)** In the event a cultivator determines that the plant material does not meet the standards established by the division for moisture content, the cultivator may:

        - **(a)** Remediate the batch of plant material by drying the plant material for an additional amount of time; and
        - **(b)** Have the same laboratory retest the remediated dried plant material one time.
    - **(2)** However, if the certificate of analysis demonstrates the presence of other microbial contaminants **other than** shiga toxin-producing E. Coli ("STEC") or salmonella, the cultivator may sell the coordinating batch of plant material to a licensed processor **solely** for extraction by hydrocarbon-based, food-grade ethanol-based, or carbon dioxide-based extract methods only.
        - **(a)** In accordance with these rules, the **cannabis extract** created pursuant to this paragraph must be tested for microbial contamination and meet all standards established by the division **prior to use** in any cannabis product.

OAC 1301:18-4-13: Minimum Standards for State-Required Testing

- **(A)** In accordance with all guidance, mandates, and directives provided by the division of cannabis control, **each cultivator and processor** shall establish, maintain, and comply with written policies and procedures to ensure all cannabis meets all standards for state-required testing and division 1301:18 of the Administrative Code.
    - **(1)** In addition to the requirements of this rule, upon determination by the division that any additional tests are necessary, each licensee is required to comply with such directive.
- **(B) Cannabis plant material destined for a technology solution.**
    - **(1)** Each batch of cannabis plant material is to adhere to all mandates outlined under rule 1301:18-1-01 of the Administrative Code.
    - **(2)** Prior to subjecting a batch of cannabis plant material to a technology solution, each **cultivator** shall test the batch of plant material for the following microbial contaminants:
        - **(a)** Salmonella;
        - **(b)** Shiga toxin-producing E. Coli ("STEC"); and
        - **(c)** Any other contaminant the division deems necessary.
    - **(3)** If the certificate of analysis demonstrates the presence of shiga toxin-producing E. Coli ("STEC") or Salmonella, the batch shall not be treated using technological solutions and shall be immediately destroyed in accordance with 1301:18-3-12 of the Administrative Code.
- **(C) Bulk cannabis plant material.**
    - **(1)** Unless otherwise provided by this rule, for **bulk cannabis plant material** destined solely for further production, manufacture, or extraction, each batch of bulk plant material must be **tested by the originating licensee** prior to transfer or distribution in accordance with the following:
        - **(a)** Each batch of plant material cannot exceed fifty (50) pounds.
        - **(b)** The minimum allowable sample size for each batch is fifteen (15) grams
        - **(c)** Each sample increment equals one (1) gram
        - **(d)** Each test sample shall be tested, at a minimum, for the following prior to transfer or sale:
            - **(i)** Microbial contaminants as follows:
                - **(A)** Salmonella;
                - **(B)** Shiga toxin-producing E. Coli ("STEC"); and
                - **(C)** Any other contaminant the division deems necessary; and
            - **(ii)** Pesticides, herbicides, and growth regulators.
- **(D) Fresh frozen cannabis plant material.**

- **(1)** Each batch of fresh frozen cannabis plant material destined solely for extraction at a processor:
  - **(a)** Each batch of fresh frozen plant material is to adhere to all mandates outlined under rule 1301:18-1-01 of the Administrative Code.
  - **(b)** The minimum allowable test sample size for each batch is 0.5% of the net weight of the fresh frozen cannabis plant material, or fifty-five (55) grams, whichever is larger.
    - **(i)** Each sample increment equals five (5) grams.
  - **(c)** Each test sample shall be tested, at a minimum, for the following prior to transfer or sale:
    - **(i)** Microbial contaminants as follows:
      - **(A)** Salmonella;
      - **(B)** Shiga toxin-producing E. Coli ("STEC"); and
      - **(C)** Any other contaminant the division deems necessary; and
    - **(ii)** Pesticides, herbicides, and growth regulators.

- **(E) Final Form Dried Cannabis Plant Material.**
  - **(1)** Dried cannabis plant material destined solely for **direct customer sale** at a dispensary:
    - **(a)** Each batch is to be in **final form** and adhere to all mandates under rule 1301:18-1-01 of the Administrative Code.
    - **(b)** The minimum allowable sample size for each batch is 0.5% of the net weight of the batch, or twenty-three (23) grams, whichever is larger.
      - **(i)** Each sample increment equals one (1) gram.
    - **(c)** Each test sample shall be tested, at a minimum, for the following:
      - **(a)** Microbial contaminants, including:
        - **(1)** Total yeast and mold;
        - **(2)** Total Enterobacteriaceae;
        - **(3)** Salmonella;
        - **(4)** Shiga toxin-producing E. Coli ("STEC"); and
        - **(5)** Any other contaminant the division deems necessary;
      - **(b)** Mycotoxins;
      - **(c)** Moisture content;
      - **(d)** Water activity;
      - **(e)** Foreign matter contamination;
      - **(f)** Heavy metals;
      - **(g)** Pesticides, herbicides, and growth regulators;
      - **(h)** Cannabinoid potency, including, at a minimum:
        - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
        - **(ii)** Delta-9-tetrahydrocannabinol;
        - **(iii)** Delta-8-tetrahydrocannabinol;
        - **(iv)** Cannabidiolic acid (CBDA);
        - **(v)** Cannabidiol (CBD);
        - **(vi)** Tetrahydrocannabivarin (THCV);
        - **(vii)** Cannabinold (CBN);
        - **(viii)** Cannabigerolic acid (CBGA);
        - **(ix)** Cannabigerol (CBG);
        - **(x)** Cannabichromenic acid (CBCA);
        - **(xi)** Cannabichromene (CBC);

- **(xii)** Cannabidivarinic acid (CBDVA);
- **(xiii)** Cannabidivarin (CBDV); and
- **(xiv)** Any other cannabinoid determined by the division.

- **(i)** Terpenes, including, at a minimum:
  - **(i)** Alpha-bisabolol;
  - **(ii)** Alpha-humulene;
  - **(iii)** Alpha-pinene;
  - **(iv)** Terpinolene;
  - **(v)** Beta-caryophyllene;
  - **(vi)** Beta-myrcene;
  - **(vii)** Beta-pinene;
  - **(viii)** Caryophyllene oxide;
  - **(ix)** Limonene; and
  - **(x)** Linalool.

- **(F) Raw Single Serving Units.**
  - **(1)** Prior to creating a lot of final form raw single serving units destined for direct customer sale, each processor is to ensure each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided by this rule.
  - **(2) Single Batch Raw Single Serving Units.**
    - **(a)** A processor **may** use a **single batch** of cannabis plant material to create a lot of final form raw single serving units in accordance with the following:
      - **(i)** Each batch of plant material must be tested for cannabinoid potency at the originating cultivator prior to creating the final form product, including, at a minimum, the following:
        - **(A)** Delta-9-tetrahydrocannabinolic acid (THCA);
        - **(B)** Delta-9-tetrahydrocannabinol;
        - **(C)** Delta-8-tetrahydrocannabinol;
        - **(D)** Cannabidiolic acid (CBDA);
        - **(E)** Cannabidiol (CBD);
        - **(F)** Tetrahydrocannabivarin (THCV);
        - **(G)** Cannabinold (CBN);
        - **(H)** Cannabigerolic acid (CBGA);
        - **(I)** Cannabigerol (CBG);
        - **(J)** Cannabichromenic acid (CBCA);
        - **(K)** Cannabichromene (CBC);
        - **(L)** Cannabidivarinic acid (CBDVA);
        - **(M)** Cannabidivarin (CBDV); and
        - **(N)** Any other cannabinoid determined by the division.
      - **(ii)** The minimum allowable sample size for each batch of plant material is five (5) grams.
      - **(iii)** Each sample increment equals one (1) gram.
    - **(b)** The net weight of the lot of final form raw single serving units created in accordance with this paragraph cannot exceed the net weight of the batch of cannabis plant material used to create the final product.
  - **(3) Blended Batch Raw Single Serving Units.**
    - **(a)** A processor **may** combine batches a cannabis plant material to create the lot of final form raw single serving units in accordance with the following:

- **(i)** The blended batch of plant material must be tested for cannabinoid potency prior to creating the final form product.
- **(ii)** The blended batch cannot exceed the net weight of 35,000 production units of the final form raw single serving units destined solely for direct customer sale.
- **(iii)** The minimum allowable sample size for each blended batch of plant material is ten (10) grams
- **(iv)** Each sample increment equals one (1) gram.
- **(v)** Each test sample shall be tested for cannabinoid potency at the processor, including, at a minimum, the following:
    - **(A)** Delta-9-tetrahydrocannabinolic acid (THCA);
    - **(B)** Delta-9-tetrahydrocannabinol;
    - **(C)** Delta-8-tetrahydrocannabinol;
    - **(D)** Cannabidiolic acid (CBDA);
    - **(E)** Cannabidiol (CBD);
    - **(F)** Tetrahydrocannabivarin (THCV);
    - **(G)** Cannabinold (CBN);
    - **(H)** Cannabigerolic acid (CBGA);
    - **(I)** Cannabigerol (CBG);
    - **(J)** Cannabichromenic acid (CBCA);
    - **(K)** Cannabichromene (CBC);
    - **(L)** Cannabidivarinic acid (CBDVA);
    - **(M)** Cannabidivarin (CBDV); and
    - **(N)** Any other cannabinoid determined by the division.

- **(4) Final Form Raw Single Serving Units.**
    - **(a)** After the cannabis plant material meets all standards for cannabinoid potency, the processor **shall** produce the final form raw single-serving units, including any filter or paper.
    - **(b)** Each lot of final form raw single serving units must undergo additional state-required testing in accordance with this paragraph.
    - **(c)** The net weight of the lot cannot exceed the net weight of 35,000 production units of the final form raw single serving units destined solely for direct customer sale.
    - **(d)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot, or twenty-three (23) grams, whichever is larger.
        - **(i)** Each sample increment equals one (1) gram.
    - **(e)** Each test sample shall be tested, at a minimum, for the following:
        - **(i)** Microbial contaminants, including:
            - **(A)** Total yeast and mold;
            - **(B)** Total Enterobacteriaceae;
            - **(C)** Salmonella;
            - **(D)** Shiga toxin-producing E. Coli (“STEC”); and
            - **(E)** Any other contaminant the division deems necessary;
        - **(ii)** Mycotoxins;
        - **(iii)** Moisture content;
        - **(iv)** Water activity;
        - **(v)** Foreign matter contamination;

- **(vi)** Heavy metals;
- **(vii)** Pesticide, herbicides, and growth regulators;
- **(viii)** Terpenes, including, at a minimum:
    - **(A)** Alpha-bisabolol;
    - **(B)** Alpha-humulene;
    - **(C)** Alpha-pinene;
    - **(D)** Terpinolene;
    - **(E)** Beta-caryophyllene;
    - **(F)** Beta-myrcene;
    - **(G)** Beta-pinene;
    - **(H)** Caryophyllene oxide;
    - **(I)** Limonene; and
    - **(J)** Linalool

- **(f)** Unless otherwise authorized by division 1301:18 of the Administrative Code, the associated certificate of analysis for each lot of final form raw single-serving units is to reflect the results for cannabinoid potency obtained from the associated batch dried cannabis plant material created pursuant to this rule.

- **(G) Bulk Cannabis Distillate and bulk cannabis extract destined solely for further production into cannabis-infused edibles and cannabis-infused beverages.**
    - **(1)** Unless otherwise specified by this rule, each lot of bulk cannabis distillate destined solely for use as an ingredient in a cannabis-infused edible or cannabis-infused beverage, is limited to the distillate created within a 72-hour period, using the same extraction method, same operating procedures, and same batch or batches of starting plant material. The 72-hour period begins when the lot of cannabis extract is submitted to distillation.
    - **(2)** Each lot of bulk solvent-based cannabis extract destined solely for use as an ingredient in a cannabis-infused edible or cannabis-infused beverage shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and not exceed fifty pounds.
    - **(3)** Each lot of bulk distillate or bulk cannabis extract used as an ingredient in a cannabis product must be tested as follows:
        - **(a)** The minimum allowable test sample size for bulk distillate is 0.5% of the net weight of the lot of bulk distillate, or ten (10) grams, whichever is larger.
            - **(i)** Each sample increment equals one (1) gram.
        - **(b)** Each test sample shall be tested, at a minimum, for the following:
            - **(i)** Mycotoxins;
            - **(ii)** Heavy metals;
            - **(iii)** Pesticides, herbicides, and growth regulators; and
            - **(iv)** Residual solvents.
- **(H) Cannabis-Infused Edibles:** For each lot of cannabis-infused edibles destined solely for direct customer sale at a dispensary, the following applies:
    - **(1)** Prior to creating the final form cannabis-infused edibles, the **processor** is to ensure:
        - **(a)** Each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided by this rule;
        - **(b)** Each lot of bulk cannabis distillate or cannabis extract meets all standards for state-required testing as outlined under this rule; and

        - **(c)** All non-cannabis ingredients meet all standards as outlined under rule 1301:18-6-06 of the Administrative Code prior to use as an ingredient in the final form cannabis product.
    - **(2) Final form testing.** Each lot of final form cannabis-infused edibles is to adhere to the mandates outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed 35,000 production units.
    - **(3)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot of the final form cannabis-infused edibles, or ten (10) grams, whichever is larger.
        - **(a)** Each sample increment equals one (1) gram.
    - **(4)** Each test sample shall be tested, at a minimum, for the following:
        - **(a)** Microbial contaminants, including:
            - **(1)** Total yeast and mold;
            - **(2)** Total Enterobacteriaceae;
            - **(3)** Salmonella;
            - **(4)** Shiga toxin-producing E. Coli ("STEC"); and
            - **(5)** Any other contaminant the division deems necessary;
        - **(b)** Foreign Matter Contamination;
        - **(c)** Cannabinoid potency including, at minimum:
            - **(1)** Delta-9-tetrahydrocannabinolic acid (THCA);
            - **(2)** Delta-9-tetrahydrocannabinol;
            - **(3)** Delta-8-tetrahydrocannabinol;
            - **(4)** Cannabidiolic acid (CBDA);
            - **(5)** Cannabidiol (CBD);
            - **(6)** Tetrahydrocannabivarin (THCV);
            - **(7)** Cannabinold (CBN);
            - **(8)** Cannabigerolic acid (CBGA);
            - **(9)** Cannabigerol (CBG);
            - **(10)** Cannabichromenic acid (CBCA);
            - **(11)** Cannabichromene (CBC);
            - **(12)** Cannabidivarinic acid (CBDVA);
            - **(13)** Cannabidivarin (CBDV); and
            - **(14)** Any other cannabinoid determined by the division.
        - **(d)** Water activity; and
        - **(e)** Homogeneity verification.
        - **(f)** In addition to the state-required test panels and associated analysis outlined in this paragraph, a licensee **may** also submit the test sample for terpene testing, including:
            - **(1)** Alpha-bisabolol;
            - **(2)** Alpha-humulene;
            - **(3)** Alpha-pinene;
            - **(4)** Terpinolene;
            - **(5)** Beta-caryophyllene;
            - **(6)** Beta-myrcene;
            - **(7)** Beta-pinene;
            - **(8)** Caryophyllene oxide;
            - **(9)** Limonene; and

        - **(10)** Linalool.
    - **(5)** Unless otherwise authorized by division 1301:18 of the Administrative Code, the associated certificate of analysis for each lot of final form cannabis-infused edibles is to reflect the results for the following obtained from the **bulk cannabis distillate or bulk cannabis extract** created pursuant this rule:
        - **(a)** Mycotoxins;
        - **(b)** Heavy metals;
        - **(c)** Pesticides, herbicides, and growth regulators; and
        - **(d)** Residual solvents.
    - **(6)** In the event the final form cannabis-infused edibles fail to meet all standards for state-required testing, the licensee shall not remediate the associated lot.
        - **(a)** The licensee shall immediately destroy the associated lot of cannabis-infused edibles in accordance with rule 1301:18-3-12 of the Administrative Code.
- **(I) Cannabis-Infused Beverages.** For each lot of cannabis-infused beverages destined solely for direct customer sale at a dispensary, the following applies:
    - **(1)** Prior to creating the final form cannabis-infused beverage destined for direct customer sale, the **processor** is to ensure:
        - **(a)** Each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided by this rule;
        - **(b)** Each lot of bulk cannabis distillate or cannabis extract meets all standards for state-required testing as outlined under this rule;
        - **(c)** All non-cannabis ingredients meet all standards as outlined under rule 1301:18-6-06 of the Administrative Code prior to use as an ingredient in the final form cannabis product.
        - **(d)** Each lot of final form cannabis-infused beverages shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and not exceed 35,000 production units.
    - **(2)** Each lot of final form cannabis-infused beverages shall adhere to the mandates outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed 35,000 production units.
    - **(3)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot of final form cannabis beverages, or ten (10) grams, whichever is larger.
        - **(a)** Each sample increment equals one (1) gram.
    - **(4)** Each test sample shall be tested, at a minimum, for the following:
        - **(a)** Microbial contaminants, including:
            - **(i)** Total yeast and mold;
            - **(ii)** Total Enterobacteriaceae;
            - **(iii)** Salmonella;
            - **(iv)** Shiga toxin-producing E. Coli (“STEC”); and
            - **(v)** Any other contaminant the division deems necessary;
        - **(b)** Foreign Matter Contamination;
        - **(c)** Cannabinoid potency including, at minimum:
            - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
            - **(ii)** Delta-9-tetrahydrocannabinol;
            - **(iii)** Delta-8-tetrahydrocannabinol;
            - **(iv)** Cannabidiolic acid (CBDA);

- **(v)** Cannabidiol (CBD);
- **(vi)** Tetrahydrocannabivarin (THCV);
- **(vii)** Cannabinold (CBN);
- **(viii)** Cannabigerolic acid (CBGA);
- **(ix)** Cannabigerol (CBG);
- **(x)** Cannabichromenic acid (CBCA);
- **(xi)** Cannabichromene (CBC);
- **(xii)** Cannabidivarinic acid (CBDVA);
- **(xiii)** Cannabidivarin (CBDV); and
- **(xiv)** Any other cannabinoid determined by the division.

▪ **(d)** pH; and
▪ **(e)** Homogeneity verification.
▪ **(f)** In addition to the state-required test panels and associated analysis outlined in this paragraph, a licensee **may** also submit the test sample for terpene testing, including:

- **(i)** Alpha-bisabolol;
- **(ii)** Alpha-humulene;
- **(iii)** Alpha-pinene;
- **(iv)** Terpinolene;
- **(v)** Beta-caryophyllene;
- **(vi)** Beta-myrcene;
- **(vii)** Beta-pinene;
- **(viii)** Caryophyllene oxide;
- **(ix)** Limonene; and
- **(x)** Linalool.

o **(5)** Unless otherwise authorized by division 1301:18 of the Administrative Code, the associated certificate of analysis for each lot of final form cannabis-infused beverages is to reflect the results for the following obtained from the lot of **bulk cannabis distillate or bulk cannabis extract** created pursuant to this rule:
▪ **(a)** Mycotoxins;
▪ **(b)** Heavy metals;
▪ **(c)** Pesticides, herbicides, and growth regulators; and
▪ **(d)** Residual solvents.

o **(6)** In the event the lot of final form cannabis-infused beverages fail to meet all standards for state-required testing, the licensee shall not remediate the associated lot. The licensee shall immediately destroy the associated lot of cannabis-infused beverages in accordance with rule 1301:18-3-12 of the Administrative Code.

- **(J) Final Form Vaporization Solution**
  - **(1)** Prior to creating the final form vaporization solution destined for direct customer sale, the **processor** is to ensure each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided this rule.
  - **(2)** After creating the lot of bulk distillate or lot of bulk cannabis extract, a processor **shall** combine the lot with non-cannabis ingredients that meet all mandates with rule 1301:18-6-06 of the Administrative Code and adhere to the following:

- **(a)** Each lot of final form vaporization solution shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and not exceed 35,000 production units.
- **(b)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot of final form vaporization solution, or ten (10) grams, whichever is larger.
    - **(a)** Each sample increment equals one (1) gram.
- **(c)** Each test sample shall be tested, at a minimum, for the following:
    - **(a)** Microbial contaminants, including:
        - **(i)** Total yeast and mold;
        - **(ii)** Total Enterobacteriaceae;
        - **(iii)** Salmonella;
        - **(iv)** Shiga toxin-producing E. Coli ("STEC"); and
        - **(v)** Any other contaminant the division deems necessary;
    - **(b)** Mycotoxins;
    - **(c)** Foreign matter contamination;
    - **(d)** Heavy metals;
    - **(e)** Pesticides, herbicides, and growth regulators;
    - **(f)** Cannabinoid potency including, at minimum:
        - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
        - **(ii)** Delta-9-tetrahydrocannabinol;
        - **(iii)** Delta-8-tetrahydrocannabinol;
        - **(iv)** Cannabidiolic acid (CBDA);
        - **(v)** Cannabidiol (CBD);
        - **(vi)** Tetrahydrocannabivarin (THCV);
        - **(vii)** Cannabinold (CBN);
        - **(viii)** Cannabigerolic acid (CBGA);
        - **(ix)** Cannabigerol (CBG);
        - **(x)** Cannabichromenic acid (CBCA);
        - **(xi)** Cannabichromene (CBC);
        - **(xii)** Cannabidivarinic acid (CBDVA);
        - **(xiii)** Cannabidivarin (CBDV); and
        - **(xiv)** Any other cannabinoid determined by the division.
    - **(g)** Terpenes, including, at a minimum:
        - **(i)** Alpha-bisabolol;
        - **(ii)** Alpha-humulene;
        - **(iii)** Alpha-pinene;
        - **(iv)** Terpinolene;
        - **(v)** Beta-caryophyllene;
        - **(vi)** Beta-myrcene;
        - **(vii)** Beta-pinene;
        - **(viii)** Caryophyllene oxide;
        - **(ix)** Limonene; and
        - **(x)** Linalool; and
    - **(h)** Residual solvents.
- **(3)** In the event the test sample fails to meet the standards for state-required testing the following applies:

        - **(a)** The licensee may remediate the lot of final form vaporization solution if the test sample fails for either of the following:
            - **(i)** Cannabinoid potency; or
            - **(ii)** Residual solvents.
        - **(b)** For all other state-required testing, the licensee shall immediately destroy the associated lot of vaporization solution in accordance with rule 1301:18-3-12 of the Administrative Code.
- **(K) Final Form Combination Inhalable Products**
    - **(1)** Prior to creating the final form combination inhalable products destined for direct customer sale, the **processor** is to ensure each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided by this rule.
    - **(2)** A **processor may** combine the batches of plant material to create a lot of final form combination inhalable products.
    - **(3)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot of the final form combination inhalable product, or twenty-three (23) grams, whichever is larger.
        - **(a)** Each sample increment equals one (1) gram.
    - **(4)** Each lot shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and not exceed 35,000 production units.
    - **(5)** Each test sample shall be tested, at a minimum, for the following:
        - **(a)** Microbial contaminants, including:
            - **(i)** Total yeast and mold;
            - **(ii)** Total Enterobacteriaceae;
            - **(iii)** Salmonella;
            - **(iv)** Shiga toxin-producing E. Coli (“STEC”); and
            - **(v)** Any other contaminant the division deems necessary;
        - **(b)** Mycotoxins;
        - **(c)** Moisture content;
        - **(d)** Water activity;
        - **(e)** Foreign matter contamination;
        - **(f)** Heavy metals;
        - **(g)** Pesticides, herbicides, and growth regulators;
        - **(h)** Cannabinoid potency, including, at a minimum:
            - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
            - **(ii)** Delta-9-tetrahydrocannabinol;
            - **(iii)** Delta-8-tetrahydrocannabinol;
            - **(iv)** Cannabidiolic acid (CBDA);
            - **(v)** Cannabidiol (CBD);
            - **(vi)** Tetrahydrocannabivarin (THCV);
            - **(vii)** Cannabinold (CBN);
            - **(viii)** Cannabigerolic acid (CBGA);
            - **(ix)** Cannabigerol (CBG);
            - **(x)** Cannabichromenic acid (CBCA);
            - **(xi)** Cannabichromene (CBC);
            - **(xii)** Cannabidivarinic acid (CBDVA);
            - **(xiii)** Cannabidivarin (CBDV); and

- **(xiv)** Any other cannabinoid determined by the division.
- **(i)** Terpenes, including, at a minimum:
  - **(i)** Alpha-bisabolol;
  - **(ii)** Alpha-humulene;
  - **(iii)** Alpha-pinene;
  - **(iv)** Terpinolene;
  - **(v)** Beta-caryophyllene;
  - **(vi)** Beta-myrcene;
  - **(vii)** Beta-pinene;
  - **(viii)** Caryophyllene oxide;
  - **(ix)** Limonene; and
  - **(x)** Linalool.
- **(j)** Residual solvents if a **solvent-based extract** is used as an ingredient in the combination inhalable product, including solvents used during winterization.

- **(L) Final Form Cannabis Concentrates.** Each lot of final form cannabis concentrates destined solely for direct customer sale at a dispensary shall adhere to the following:
  - **(1)** After each batch of dried cannabis plant material meets all standards in accordance with this rule, a **processor may** combine the batches of plant material to create a lot of final form cannabis concentrates.
  - **(2)** Each lot shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed ten pounds (4536g) of cannabis concentrate created using the same extraction method, same operating procedures, and same batch or batches of starting plant material.
  - **(3)** The minimum allowable test sample size for each lot of is 0.5% of the net weight of the lot of the final form cannabis extract, or ten (10) grams, whichever is larger.
    - **(a)** Each sample increment equals one (1) gram.
  - **(4)** Each test sample shall be tested, at a minimum, for the following analytes:
    - **(a)** Microbial contaminants, including:
      - **(i)** Total yeast and mold;
      - **(ii)** Total Enterobacteriaceae;
      - **(iii)** Salmonella;
      - **(iv)** Shiga toxin-producing E. Coli (“STEC”); and
      - **(v)** Any other contaminant the division deems necessary;
    - **(b)** Mycotoxins;
    - **(c)** Foreign matter contamination;
    - **(d)** Heavy metals;
    - **(e)** Pesticides, herbicides, and growth regulators;
    - **(f)** Cannabinoid potency including, at minimum:
      - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
      - **(ii)** Delta-9-tetrahydrocannabinol;
      - **(iii)** Delta-8-tetrahydrocannabinol;
      - **(iv)** Cannabidiolic acid (CBDA);
      - **(v)** Cannabidiol (CBD);
      - **(vi)** Tetrahydrocannabivarin (THCV);
      - **(vii)** Cannabinold (CBN);
      - **(viii)** Cannabigerolic acid (CBGA);
      - **(ix)** Cannabigerol (CBG);

- **(x)** Cannabichromenic acid (CBCA);
- **(xi)** Cannabichromene (CBC);
- **(xii)** Cannabidivarinic acid (CBDVA);
- **(xiii)** Cannabidivarin (CBDV); and
- **(xiv)** Any other cannabinoid determined by the division.

(g) Terpenes, including, at a minimum:

- **(i)** Alpha-bisabolol;
- **(ii)** Alpha-humulene;
- **(iii)** Alpha-pinene;
- **(iv)** Terpinolene;
- **(v)** Beta-caryophyllene;
- **(vi)** Beta-myrcene;
- **(vii)** Beta-pinene;
- **(viii)** Caryophyllene oxide;
- **(ix)** Limonene; and
- **(x)** Linalool. and

(h) Residual solvents if a solvent-based extract is used to create the lot of final form cannabis concentrate including solvents used during winterization.

- **(M) Final Form Topical Cannabis Products.** Each lot of final form topical cannabis products destined solely for direct customer sale at a dispensary shall adhere to the following:
  - **(1)** After each batch of dried cannabis plant material meets all standards in accordance with this rule, a **processor may** combine the batches of plant material to create a lot of final form cannabis concentrates.
  - **(2)** Each lot shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed 35,000 production units.
    - **(a)** The net weight of the lot cannot exceed the net weight of 35,000 production units of the final form cannabis products destined solely for direct customer sale.
  - **(3)** The minimum allowable test sample size for each lot of cannabis products is:
    - **(a)** 0.5% of the net weight of the lot of the cannabis product; or
    - **(b)** 0.5% of the total number of production units.
    - **(c)** Notwithstanding the requirements outlined in this paragraph, a minimum of ten (10) grams of the lot of final form cannabis products must be obtained for all state-required testing.
  - **(4)** Each test sample shall be tested, at a minimum, for the following:
    - **(a)** Microbial contaminants, including:
      - **(i)** Total yeast and mold;
      - **(ii)** Total Enterobacteriaceae;
      - **(iii)** Salmonella;
      - **(iv)** Shiga toxin-producing E. Coli (“STEC”); and
      - **(v)** Any other contaminant the division deems necessary;
    - **(b)** Water activity;
    - **(c)** Foreign matter contamination;
    - **(d)** Pesticides, herbicides, and growth regulators;
    - **(e)** Cannabinoid potency, including, at a minimum:
      - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
      - **(ii)** Delta-9-tetrahydrocannabinol;
      - **(iii)** Delta-8-tetrahydrocannabinol;

- **(iv)** Cannabidiolic acid (CBDA);
- **(v)** Cannabidiol (CBD);
- **(vi)** Tetrahydrocannabivarin (THCV);
- **(vii)** Cannabinold (CBN);
- **(viii)** Cannabigerolic acid (CBGA);
- **(ix)** Cannabigerol (CBG);
- **(x)** Cannabichromenic acid (CBCA);
- **(xi)** Cannabichromene (CBC);
- **(xii)** Cannabidivarinic acid (CBDVA);
- **(xiii)** Cannabidivarin (CBDV); and
- **(xiv)** Any other cannabinoid deemed necessary by the division.

▪ **(f)** Terpenes, including, at a minimum:

- **(i)** Alpha-bisabolol;
- **(ii)** Alpha-humulene;
- **(iii)** Alpha-pinene;
- **(iv)** Terpinolene;
- **(v)** Beta-caryophyllene;
- **(vi)** Beta-myrcene;
- **(vii)** Beta-pinene;
- **(viii)** Caryophyllene oxide;
- **(ix)** Limonene; and
- **(x)** Linalool.

▪ **(g)** Residual solvents if the extract is a solvent-based extract, including solvents used during winterization.

- **(N) Final Form Cannabis Products.** Unless otherwise specified by this rule, each lot of final form cannabis products destined solely for direct customer sale at a dispensary shall adhere to the following:
  - **(1)** After each batch of dried cannabis plant material meets all standards in accordance with this rule, a **processor may** combine the batches of plant material to create a lot of final form cannabis products.
  - **(2)** Each lot shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed 35,000 production units.
    - **(a)** The net weight of the lot cannot exceed the net weight of 35,000 production units of the final form cannabis products destined solely for direct customer sale.
  - **(3)** The minimum allowable test sample size for each lot of cannabis products is:
    - **(a)** 0.5% of the net weight of the lot of the cannabis product; or
    - **(b)** 0.5% of the total number of production units.
    - **(c)** Notwithstanding the requirements outlined in this paragraph, a minimum of ten (10) grams of the lot of final form cannabis products must be obtained for all state-required testing.
  - **(4)** For final form cannabis products administered **via inhalation**, each test sample shall be tested, at a minimum, for the following:
    - **(a)** Microbial contaminants, including:
      - **(i)** Total yeast and mold;
      - **(ii)** Total Enterobacteriaceae;
      - **(iii)** Salmonella;
      - **(iv)** Shiga toxin-producing E. Coli (“STEC”); and

- **(v)** Any other contaminant the division deems necessary;
- **(b)** Mycotoxins;
- **(c)** Water activity;
- **(d)** Foreign matter contamination;
- **(e)** Heavy metals;
- **(f)** Pesticides, herbicides, and growth regulators;
- **(g)** Cannabinoid potency, including, at a minimum:
  - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
  - **(ii)** Delta-9-tetrahydrocannabinol;
  - **(iii)** Delta-8-tetrahydrocannabinol;
  - **(iv)** Cannabidiolic acid (CBDA);
  - **(v)** Cannabidiol (CBD);
  - **(vi)** Tetrahydrocannabivarin (THCV);
  - **(vii)** Cannabinold (CBN);
  - **(viii)** Cannabigerolic acid (CBGA);
  - **(ix)** Cannabigerol (CBG);
  - **(x)** Cannabichromenic acid (CBCA);
  - **(xi)** Cannabichromene (CBC);
  - **(xii)** Cannabidivarinic acid (CBDVA);
  - **(xiii)** Cannabidivarin (CBDV); and
  - **(xiv)** Any other cannabinoid determined by the division.
- **(h)** Terpenes, including, at a minimum:
  - **(i)** Alpha-bisabolol;
  - **(ii)** Alpha-humulene;
  - **(iii)** Alpha-pinene;
  - **(iv)** Terpinolene;
  - **(v)** Beta-caryophyllene;
  - **(vi)** Beta-myrcene;
  - **(vii)** Beta-pinene;
  - **(viii)** Caryophyllene oxide;
  - **(ix)** Limonene; and
  - **(x)** Linalool.
- **(i)** Residual solvents if a **solvent-based extract** is used as an ingredient in the final form cannabis products, including solvents used during winterization.

- **(5)** Unless otherwise required by these rules or authorized by the division, for all other final form cannabis products, each test sample shall be tested, at a minimum, for the following:
  - **(a)** Microbial contaminants, including:
    - **(i)** Total yeast and mold;
    - **(ii)** Total Enterobacteriaceae;
    - **(iii)** Salmonella;
    - **(iv)** Shiga toxin-producing E. Coli ("STEC"); and
    - **(v)** Any other contaminant the division deems necessary;
  - **(b)** Mycotoxins;
  - **(c)** Water activity;
  - **(d)** Foreign matter contamination;

- **(e)** Heavy metals;
- **(f)** Pesticides, herbicides, and growth regulators;
- **(g)** Cannabinoid potency, including, at a minimum:
    - **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
    - **(ii)** Delta-9-tetrahydrocannabinol;
    - **(iii)** Delta-8-tetrahydrocannabinol;
    - **(iv)** Cannabidiolic acid (CBDA);
    - **(v)** Cannabidiol (CBD);
    - **(vi)** Tetrahydrocannabivarin (THCV);
    - **(vii)** Cannabinold (CBN);
    - **(viii)** Cannabigerolic acid (CBGA);
    - **(ix)** Cannabigerol (CBG);
    - **(x)** Cannabichromenic acid (CBCA);
    - **(xi)** Cannabichromene (CBC);
    - **(xii)** Cannabidivarinic acid (CBDVA);
    - **(xiii)** Cannabidivarin (CBDV); and
    - **(xiv)** Any other cannabinoid deemed necessary by the division.
- **(h)** Residual solvents if the extract is a solvent-based extract, including solvents used during winterization.
- **(i)** In addition to the state-required test panels and associated analysis outlined in this paragraph, a licensee **may** also submit the test sample for terpenes, including, at a minimum:
    - **(i)** Alpha-bisabolol;
    - **(ii)** Alpha-humulene;
    - **(iii)** Alpha-pinene;
    - **(iv)** Terpinolene;
    - **(v)** Beta-caryophyllene;
    - **(vi)** Beta-myrcene;
    - **(vii)** Beta-pinene;
    - **(viii)** Caryophyllene oxide;
    - **(ix)** Limonene; and
    - **(x)** Linalool.

OAC 1301:18-4-14: Minimum Testing Requirements for Hemp-Derived Ingredients

- **(A)** In accordance with rule 1301:18-6-02(I)(3) of the Administrative Code, except for vaporization solutions, prior to use of any extracted hemp-derived ingredient in a manufactured cannabis product, each lot of hemp-derived ingredients shall be tested for the following, at a minimum, prior to use in the cannabis product:
    - **(1)** For each shipment of hemp-derived ingredient received:
        - **(a)** The test sample size is 0.5% of the net weight of the hemp-derived ingredients; and
        - **(b)** Sample increment equals one (1) gram
    - **(2)** Each test sample shall be tested, at a minimum, for the following analytes:
        - **(a)** Mycotoxins;
        - **(b)** Heavy metals;
        - **(c)** Pesticides, herbicides, and growth regulators;
        - **(d)** Cannabinoid potency, including, at a minimum:

- **(i)** Delta-9-tetrahydrocannabinolic acid (THCA);
- **(ii)** Delta-9-tetrahydrocannabinol;
- **(iii)** Delta-8-tetrahydrocannabinol;
- **(iv)** Cannabidiolic acid (CBDA);
- **(v)** Cannabidiol (CBD);
- **(vi)** Tetrahydrocannabivarin (THCV);
- **(vii)** Cannabinold (CBN);
- **(viii)** Cannabigerolic acid (CBGA);
- **(ix)** Cannabigerol (CBG);
- **(x)** Cannabichromenic acid (CBCA);
- **(xi)** Cannabichromene (CBC);
- **(xii)** Cannabidivarinic acid (CBDVA);
- **(xiii)** Cannabidivarin (CBDV); and
- **(xiv)** Any other cannabinoid determined by the division.

▪ **(e)** Residual solvents; and
▪ **(f)** Any other analyte that the division deems necessary.

OAC 1301:18-4-15: Failure to Meet all standards for state-required testing – immediate destruction

- **(A) Unless otherwise authorized by the division of cannabis control or these rules**, each licensee shall establish, maintain, and comply with written policies and procedures to ensure all cannabis that fails to meet all standards for state-required testing adheres to the following:
  - **(1) Immediate Destruction Required:**
    - **(a)** A batch or lot of cannabis that fails for any of the following shall be immediately destroyed in accordance with rule 1301:18-3-12 of the Administrative Code:
      - **(i)** Microbial contaminants, including:
        - **(A)** Salmonella;
        - **(B)** Shiga toxin-producing E. Coli ("STEC"); or
        - **(C)** Any other microbial contaminant the division deems necessary.
      - **(ii)** Mycotoxins;
      - **(iii)** Foreign matter contamination;
      - **(iv)** Heavy metals; and
      - **(v)** Pesticides, herbicides, and growth regulators, approved by the division in accordance with rule 1301:18-5-03;
    - **(b)** Any cannabis that fails to meet the standards for these analytes cannot be remediated or re-retested.
  - **(2) Notification and Quarantine Required:**
    - **(a)** A batch or lot of cannabis that fails for any of the following is to adhere to all mandates as outlined under this rule:
      - **(i)** Any pesticide, growth regulator, or herbicide that is not approved by the division in accordance with rule 1301:18-5-03 of the Administrative Code.
      - **(ii)** Any solvent or similar chemical utilized during the extraction process that is not approved by the division in accordance with rule 1301:18-6-06 of the Administrative Code.

        - **(b)** Upon determination that a batch or lot of cannabis fails for these analytes, each licensee shall do the following:
            - **(i)** The laboratory must immediately do the following:
                - **(A)** Upload the results for the test sample in the state inventory tracking system;
                - **(B)** Quarantine the remainder of the test sample; and
                - **(C)** Notification in a manner prescribed by the division.
            - **(ii)** The cultivator must immediately do the following:
                - **(A)** Quarantine the associated batch of plant material; and
                - **(B)** Notification in a manner prescribed by the division.
        - **(c)** Upon receipt of such notification, the division will provide further guidance on how to proceed.
- **(B)** Except as provided by this rule, a licensee seeking to re-test a batch or lot of cannabis for any state-required testing must submit a written request to the division prior to submitting a test sample to re-testing.
    - **(1)** A licensee shall not submit any batch or lot to re-testing unless and until receipt of written approval by the division to proceed.
    - **(2)** A licensee seeking to re-test a batch or lot of cannabis shall submit the request in a manner prescribed by the division, and include the following:
        - **(a)** The associated certificate of analysis for the batch or lot tested;
        - **(b)** The state-inventory tracking number;
        - **(c)** The specific state-required test that did not pass testing;
        - **(d)** The extenuating circumstances, including quality control, or other equipment malfunction, which give rise to such request; and
        - **(e)** Any other information requested by the division.
    - **(3)** Upon receipt of a request pursuant to this paragraph, the division may:
        - **(a)** Conduct an inspection at the licensed premises of the licensee requesting the re-testing or the testing laboratory;
        - **(b)** Approve the application;
        - **(c)** Approve the application subject to certain mandates or limitations, including submission of the failed batch or lot to a specific testing laboratory to complete the re-testing as determined by the division;
        - **(d)** Advise the licensee in writing that the applicant failed to meet all application requirements and request additional information; or
        - **(e)** Deny the application.

Processor Rules

OAC 1301:18-6-06 Manufacturing Cannabis Products

- **(A)** Unless otherwise authorized by the division of cannabis control, each processor shall establish, maintain, and comply with written policies and procedures to ensure that all cannabis products are manufactured, processed, and distributed in accordance with all mandates and limitations outlined in this rule. A processor's written policies and procedures for cannabis products shall ensure:
    - **(1)** Prior to the issuance or renewal of a certificate of operation, each processor completes both of the following:

- **(a)** An inspection with the Ohio department of agriculture, or an equivalent body, evidencing compliance with the manufacturing standards established by the division.

- **(2)** Only the following methods, equipment, solvents, and gases are used to manufacture cannabis products:
  - **(a)** Hydrocarbon solvent-based extraction methods in a spark-free and properly ventilated environment, isolated from any open flame or ignition source, and may use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade, closed-loop extraction system designed to recover the solvents:
    - **(i)** Propane;
    - **(ii)** N-butane;
    - **(iii)** Isobutane;
    - **(iv)** Heptane; or
    - **(v)** Other solvents exhibiting minimal potential toxicity to humans with the approval of the division.
  - **(b)** Carbon dioxide-based extraction methods using food grade carbon dioxide at a minimum of ninety-nine per cent purity in a professional grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.
  - **(c)** Ethanol at a minimum of ninety-nine per cent purity to produce extracts for use in the manufacture of cannabis products.
  - **(d)** Food grade glycerin, ethanol, and propylene glycol in the manufacture of cannabis products.
  - **(e)** Non-solvent based extraction methods involving the mechanical separation of cannabinoids from plant material to produce cannabis extracts for use in the manufacture of cannabis products.
- **(3)** No potentially hazardous foods as defined by section 3715.01 of the Revised Code are manufactured at the licensed premises;
- **(4)** Any cannabis product that is divided into portions, serving sizes, or units, adheres to the following:
  - **(a)** Each portion of cannabis is clearly demarked in a way that enables a reasonable person to intuitively determine the amount of product that constitutes a single portion;
  - **(b)** Each portion of cannabis contains not less than ninety percent or no more than one hundred ten percent of the concentration of target THC content indicated in the product registration application;
  - **(c)** Each portion is to be affixed with the universal THC symbol on each portion of the cannabis product;
  - **(d)** If the cannabis product is presented as separate single portions, the processor is to apply the universal symbol to each single portion;
  - **(e)** If the cannabis product is presented as a single unit comprised of more than one portion, the processor creates clearly visible lines of demarcation between portions and apply the universal symbol to each portion; and
  - **(f)** The size of the universal symbol marking is determined by the size of the portion instead of the overall product size, and shall not be less than one-fourth inch by one- fourth inch.

- **(B) Non-Cannabis Ingredients**
    - **(1)** Notwithstanding any other provision, the division may prohibit the use of certain non-cannabis ingredients if the division determines that there is reasonable probability that use in the manufacture of cannabis products is, or would be, in violation of Chapters 3780 or 3796. of the Revised Code or use or exposure to the ingredient may constitutes a risk to public health or safety.
    - **(2)** Except as restricted pursuant to this rule, non-marijuana ingredients may be used in the manufacture of cannabis products provided they meet the following conditions:
        - **(a)** The non-cannabis ingredients are obtained from licensed and regulated sources that comply with the requirements of federal and state laws and regulations;
        - **(b)** The non-cannabis ingredients are nontoxic and safe for human consumption; and
        - **(c)** The non-cannabis ingredients were not prepared or stored in a private residence.
    - **(3)** Hemp-derived ingredients may be used in the manufacture of cannabis products provided they meet the following conditions:
        - **(a)** The ingredients meet the definition for hemp, as defined by rule 1301:18-1-01 of the Administrative Code and ensure the total THC concentration does not exceed 0.3% per the total THC equation (0.877 x THCA) + delta-9 THC + delta-8 THC.
        - **(b)** The ingredients are obtained from a licensed and regulated source that comply with all applicable federal and state laws and regulations; and
        - **(c)** Prior to receipt of any hemp-derived ingredient, each processor is to ensure the following:
            - **(i)** All ingredients were extracted, processed, and manufactured by an appropriate source outlined under this rule and the processor receives the ingredients in extracted form; and
            - **(ii)** Each shipment of hemp-derived ingredients, is recorded in the state inventory tracking system as hemp.
        - **(d)** Within forty-eight hours of receipt of an ingredient pursuant to this paragraph, the processor ensures the following:
            - **(i)** The ingredients contain an accompanying certificate of analysis evidencing compliance with all state-required testing as outlined under rule 1301:18-4-15 of the Administrative Code; or
            - **(ii)** The ingredients are submitted and adhere to all mandates for state-required testing as outlined under rule 1301:18-4-15 of the Administrative Code; and
            - **(iii)** The associated certificate of analysis is uploaded in the state inventory tracking system.
        - **(e)** In the event a processor determines after receipt of a hemp-derived ingredient it fails to meet any mandates outlined under this paragraph, the processor shall immediately:
            - **(i)** Notify the division in writing;
            - **(ii)** Quarantine and separate the ingredient from all other viable ingredients and inventory; and
            - **(iii)** Preclude use of the ingredient in any product.

- **(C)** Notwithstanding preclusions outlined under rule 1301:18-3-18 of the Administrative Code, a processor may remove plant material packaged for direct customer sale if the plant material meets the following standards:
    - **(1)** It is not damaged, defective, or adulterated upon receipt;
    - **(2)** The plant material is to be used to create a cannabis extract;
    - **(3)** It meets all standards established by the division for Salmonella and shiga toxin-producing E. Coli ("STEC") outlined under 1301:18 of the Administrative Code prior to extraction; and
    - **(4)** Any extract from the plant material must meet all standards for state-required testing prior to use as an ingredient in any product.

Testing Laboratory Rules

OAC 1301:18-7-02: Testing Laboratory Operating Procedures and Quality Assurance

- **(A)** Each testing laboratory shall establish, maintain, and comply with written policies and procedures for the daily operation and testing of cannabis. The testing laboratory's standard operating policies and procedures shall ensure the safe, secure, proper, and impartial testing of cannabis and compliance with all mandates under division 1301:18 of the Administrative Code.
- **(B) Major Modifications**
    - **(1)** Any proposed major renovation or modification of the licensed premises shall be submitted to the division of cannabis control prior to implementation.
    - **(2)** The division will review the proposed modification and may do any of the following:
        - **(a)** Approve the submission;
        - **(b)** Deny the submission; or
        - **(c)** Mandate updates to the submission to ensure compliance with 1301:18 of the Administrative Code.
    - **(3)** The division may inspect the licensed premises pursuant to any proposed major renovation or modification.
    - **(4)** A testing laboratory shall not proceed with any major modification unless and until the division provides the testing laboratory written approval to do so.
    - **(5)** For purposes of this paragraph, this includes any new instrumentation or changes to instrumentation already maintained at the licensed premises but does not include the purchase of a duplicate instrument that has already been approved by the division.
- **(C)** Each testing laboratory shall ensure the licensed premises:
    - **(1)** Conforms with all relevant local ordinances, zoning and planning requirements, and fire codes;
    - **(2)** Prominently displays its certificate of operation and license seal issued by the division;
    - **(3)** Contains sufficient lighting to ensure visibility, security, and proper surveillance;
    - **(4)** Maintains proper cleanliness, ventilation, temperature control, and sanitation of the facility to ensure safe and consistent testing of cannabis;
    - **(5)** All chemicals, cleaning solutions, and other sanitizing agents are approved for use in testing laboratories and stored in a manner that protects against contamination;
    - **(6)** Standardizes all analytical test instrumentation using commercially available reference materials traceable to reference material producers accredited to ISO/IEC 17034 "General Requirements for the Competence of Reference Material Producers" or the national metrology institute (NMI), where available;
    - **(7)** Retains all test instrumentation data and any other associated information indefinitely;

- **(8)** Conducts routine calibration of all scales, balances, or other weight or mass measuring devices using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least annually, by an independent third party in accordance with all applicable ISO requirements, or as approved by the division;
- **(9)** Implements a safety program which meets all applicable mandates of the Laboratory Safety Guidance published by the Occupational Safety and Health Administration of the United States Department of Labor; and
- **(10)** Documents the chain of custody of all cannabis at the licensed premises in the state inventory tracking system.

- **(D) General Sanitary Requirements**
  - **(1)** Each facility must provide employees with adequate, readily accessible toilet facilities.
    - **(a)** Toilet facilities are to be kept clean and cannot be a potential source of contamination of cannabis.
  - **(2)** Each facility is to contain a sink fully stocked with the following:
    - **(a)** Disposable, single-use paper towels in a mounted dispenser;
    - **(b)** Hand washing soap contained in a dispenser; and
    - **(c)** A trash can conveniently located near the sink.
  - **(3)** Waste is to be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of cannabis.
- **(E) Designated Areas within the Facility.**
  - **(1)** Each testing laboratory shall designate areas within the facility that are compartmentalized based upon function and restrict movement between the different areas by personnel based on access credentials assigned by the facility.
  - **(2)** Each testing laboratory shall maintain the following designated, secure limited access areas accessible only by authorized registered employees:
    - **(a)** Test sample storage areas including the following:
      - **(i)** An area for testing samples awaiting analysis;
      - **(ii)** An area for testing samples prepared for analysis; and
      - **(iii)** An area for test samples that have completed all testing.
    - **(b)** Microbiology and PCR testing areas;
    - **(c)** A security area for all security and surveillance systems and equipment;
    - **(d)** A cannabis destruction and disposal area that complies with rule 1301:18-3-12 of the Administrative Code; and
    - **(e)** An area for receipt of all cannabis transported and other deliveries to the facility.
- **(F) Testing Methodologies.**
  - **(1)** The division will publish guidance that must be followed by testing laboratories for test method selection, validation, performance, and quality control requirements.
    - **(a)** All test method validations must be submitted in a manner prescribed by the division for approval.
    - **(b)** The division may at any time amend, modify, or rescind approval for any test method.
  - **(2)** Each testing laboratory shall utilize analytical testing methodologies that meet the following requirements:
    - **(a)** Have been validated for cannabis testing in the relevant cannabis matrix by an independent third party;

        - **(b)** Have been certified in cannabis matrix by an internationally recognized accredited body; and
        - **(c)** Have been internally verified by the laboratory according to the requirements specified by the division.
        - **(d)** If a method that is certified in cannabis is unavailable, test methods must be chosen from standard methods that have been published by a nationally known, authoritative entity and must be fully validated in accordance with division requirements.
    - **(3)** Each testing laboratory shall maintain all records and any other associated information related to testing methodologies for the life of the method or five calendar years, whichever is longer.
- **(G)** Each licensee shall adhere to all of the following and are hereby incorporated by reference:
    - **(1)** Occupational Safety and Health Administration. (2011). Laboratory Safety Guidance (OSHA Guidance 3404-11R.) Retrieved from
        - https://www.osha.gov/sites/default/files/publications/OSHA3404laboratory-safety-guidance.pdf.
    - **(2)** International Organization for Standardization. (2017). General requirements for the competence of testing and calibration laboratories (ISO/IEC Standard 17025.)
    - **(3)** AOAC International. (2024). Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals. An Aid to Interpretation of ISO/IEC 17025:2017.

OAC 1301:18-7-03 Testing Laboratory Employee Training Requirements

- **(A)** Prior to commencing employment, each testing laboratory shall ensure all employees are registered with the division of cannabis control pursuant to rule 1301:18-3-09 of the Administrative Code and receive adequate education and training on standard operating procedures and as mandated by rule 1301:18-3-10 of the Administrative Code.
- **(B)** In addition to the mandates outlined under rules 1301:18-3-09 and 1301:18-3-10 of the Administrative Code, each testing laboratory is to establish, maintain, and comply with written policies and procedures to ensure compliance with this rule and as follows:
    - **(1)** All registered employees display their employee badge at all times during working hours.
    - **(2)** A registered responsible party as outlined by rule 1301:18-3-09 of the Administrative Code is present at the licensed premises at least twenty hours per week.
    - **(3)** Each testing laboratory employs a scientific director responsible for supervising all laboratory employees and ensuring that the laboratory achieves and maintains quality standards of practice.
        - **(a)** Each testing laboratory's scientific director is to meet the following minimum qualifications:
            - **(i)** A doctorate degree in chemical, environmental, or biological sciences from an accredited college or university and two years of post-degree laboratory experience;
            - **(ii)** A master's degree in chemical, environmental, or biological sciences from an accredited college or university and four years of post-degree laboratory experience; or

        - **(iii)** A bachelor's degree in chemical, environmental, or biological sciences from an accredited college or university and eight years of post-degree laboratory experience.
    - **(4)** All individuals employed at a testing laboratory meet the education and experience guidelines pursuant to ASTM D8347 21a: "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries" and incorporated by reference.
    - **(5)** Each testing analyst demonstrates acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls) as part of their competency assessment.
        - **(a)** Determination of competency is to be evaluated for each test performed and documented for all analysts (including backup analysts) according to the following schedule:
            - **(i)** Prior to testing independently;
            - **(ii)** At least every six months during the first year;
            - **(iii)** At least annually thereafter; and
            - **(iv)** Any time there is reason to question competency.
        - **(b)** If the scientific director also participates in testing, the scientific director is to be included in competency assessment for each test they may perform.

OAC 1301:18-7-07: State-Required Testing Analysis Generally

- **(A)** Each testing laboratory shall establish, maintain, and comply with written policies and procedures to ensure all business practices and testing operations lead to safe, compliant, and impartial testing. A testing laboratory's written policies and procedures for state-required testing is to apply to all cannabis cultivated, produced, manufactured, transferred, sold, and distributed pursuant to Chapters 3780 and 3796. of the Revised Code and include the following:
    - **(1)** All cannabis is tested for all test panels and analytes as mandated pursuant to division 1301:18 of the Administrative Code;
    - **(2)** All cannabis meets all testing guidance, directives, mandates, and standards as established by the division of cannabis control;
    - **(3)** Complies with all applicable mandates for cannabis testing outlined under division 1301:18 of the Administrative Code;
    - **(4)** Ensures all cannabis test samples are collected pursuant to rules 1301:18-7-08 and 1301:18-7-09 of the Administrative Code and Chapter 1301:18-4 of the Administrative Code; and
    - **(5)** In accordance with the requirements outlined under ISO, create a unique certificate of analysis for each batch or lot tested, that includes all information outlined under and rule 1301:18-4-16 of the Administrative Code.
- **(B)** Unless otherwise authorized by these rules, a testing laboratory shall:
    - **(1)** Only collect test samples and conduct testing on cannabis obtained directly from a cultivator or processor licensed pursuant to division 1301:18 of the Ohio Administrative Code.
    - **(2)** Accurately record all test samples and tests performed on all cannabis received and maintained at the licensed premises; and
    - **(3)** Not conduct any state-required testing more than once on a single batch or lot.
    - **(4)** Request additional sample material in excess of the amounts outlined in these rules if necessary for completion of any state-required test.

- **(5)** Within thirty calendar days of completion of all analysis performed on any given test sample, dispose of any cannabis waste or excess cannabis not used during the sample analysis and in accordance with rule 1301:18-3-12 of the Administrative Code.

OAC 1301:18-7-08: Test Sample Collection Generally

- **(A)** Each testing laboratory shall establish, maintain, and comply with written policies and procedures to ensure all test samples are collected in a safe, consistent, impartial, and compliant manner. A testing laboratory's written policies and procedures for test sample collection shall ensure:
  - **(1)** All test sample collection policies and procedures are readily available to, and maintained by, each test sample collector while conducting any test sample collection;
  - **(2)** Sampling procedures prevent and mitigate:
    - **(i)** Any damage to the batch or lot during the collection of a test sample;
    - **(ii)** Cross-contamination of pathogens or other organisms or substances between facilities; and
    - **(iii)** Cross-contamination between test samples.
  - **(3)** Any surface utilized for the test sample collection procedure is maintained in a clean and sanitary condition to mitigate concerns of cross-contamination or adulteration of the cannabis subject to testing;
  - **(4)** All sample equipment is the following:
    - **(i)** Appropriate and specific for the applicable sample matrix;
    - **(ii)** One of the following:
      - **(A)** Manufactured with stainless steel or other material that can be sterilized; **and**
      - **(B)** Cleaned and sanitized in between each test sample collection using ethanol, 70% or equivalent; **or**
      - **(C)** Sterile, individually wrapped, and single-use per batch or lot sampled; **and**
    - **(iii)** If a test sample collector is obtaining test samples from more than one licensee during any given transport, the test sample collector is to utilize only one set of single-use or sanitized sampling equipment per facility.
  - **(5)** Each test sample collector:
    - **(i)** Maintains appropriate personal protective equipment throughout the sample collection; and
    - **(ii)** Utilizes aseptic sampling techniques, including donning unused single-use, sterile gloves prior to collecting a test sample;
  - **(6)** All laboratory field balances comply with all mandates outlined under rule 1301:18-7-02(C)(7) and the following:
    - **(a)** At least once per calendar year, calibrated for the entire range of expected test sample weights;
    - **(b)** Calibrated using verification weights prior to collecting a test sample; and
    - **(c)** Capable of producing measurements up to 0.01g.
    - **(d)** All mandated field balance calibrations are recorded and maintained pursuant to rule 1301:18-3-14 of the Administrative Code.
  - **(7)** The test sample collector completes a written **sampling report for each test sample,** as prescribed by the division;
  - **(8)** All test samples are weighed by the test sample collector at the facility of the originating licensee and contemporaneously with the sample collection;

- **(9)** Upon receipt of a test sample, a laboratory employee immediately:
  - **(a)** In accordance with rule 1301:18-4-16 of the Administrative Code, captures a photograph of each test sample to be included on the corresponding certificate of analysis; and
  - **(b)** Documents each test sample in the state inventory tracking system.
- **(10)** Adequate identification is provided on all test sample containers throughout all phases of testing.
  - **(a)** The sample identifier(s) on any sample container are to be indelible, legible, and able to withstand all stages of processing and conditions of storage.
- **(11)** After conducting any testing pursuant to these rules, a laboratory employee immediately:
  - **(a)** Documents any and all tests performed on each test sample; and
  - **(b)** Uploads the certificate of analysis for each sample tested with all information outlined under rule 1301:18-4-16 of the Administrative Code.

- **(B)** All transfers of samples, aliquots, and extracts referred to another testing laboratory in the event of subcontracted testing including, but not limited to aliquots, dilutions, tubes, slides, culture plates, extracts, data files, images, and other secondary samples created during the processing or testing of a sample are to be recorded.
- **(C)** All procedures, and other documents required by this rule are maintained at the licensed premises and pursuant to 1301:18-3-14 of the Administrative Code and available for immediate review and duplication upon the division's request.

OAC 1301:18-7-09: Test Sample Collection Procedure

- **(A)** In addition to, and in accordance with, the mandates outlined in rule 1301:18-7-08 of the Administrative Code, each testing laboratory's test sampling procedure shall adhere to the following protocol:
- **(B)** Prior to collecting a test sample, the test sample collector is to:
  - **(1)** Review all identifying information outlined on the container of cannabis to ensure it coincides with the information provided by the originating licensee pursuant to rule 1301:18-4-10 of the Administrative Code;
    - **(a)** Each container in a batch or lot is to outline at least the state inventory tracking number and one other positive identifier that correlates with the batch or lot.
    - **(b)** If a container or tray in a batch or lot is not identified, the test sample collector is to note this in the sample collection report and not collect the test sample until all containers are positively identified.
  - **(2)** The test sample collector shall not proceed and collect a test sample if:
    - **(a)** The batch or lot size outlined in the information provided by the licensee pursuant to rule 1301:18-4-10 of the Administrative Code appears inaccurate compared to visual observation.
    - **(b)** The licensee does not provide the batch or lot size.
    - **(c)** The batch or lot size exceeds the allowable amount pursuant to rule 1301:18-1-01 of the Administrative Code.
- **(C)** In accordance with rule 1301:18-4-13 of the Administrative Code, the test sample collector next determines the minimum test sample size and number of sample increments to retrieve a representative test sample from each batch or lot and as follows:
  - **(1)** In order to create a representative sample of the batch or lot and comply with all mandates for state-required testing, the total test sample size is dependent upon the net weight of the batch or total number of units contained within the lot.

    - **(2)** In order to determine the representative test sample size necessary to complete all state-required testing, the test sample collector is required to adhere to the guidance established by the division and retrieve the appropriate number sample increments.
- **(D)** To achieve a representative sample, the test sample collector is to acquire each test sample in a manner to ensure:
    - **(1)** Sample increments are taken from multiple areas of each container or tray (i.e., the upper, middle, and lower sections).
        - **(a)** If the batch or lot is stored in multiple containers or trays, the test sample must be comprised of increments from each container or tray as equally as possible.
    - **(2)** For large containers, bales or bags, sample increments are taken from a depth of at least 10 cm or 3.9 in.
    - **(3)** Shatter, wax, or other concentrate slab(s) which demonstrate varying degrees of thickness are to be sampled such that different regions of thickness are included in a manner representative of the batch.
    - **(4)** Liquid cannabis concentrates are:
        - **(a)** Brought to at least room temperature prior to sampling; and
        - **(b)** Mixed by inverting the container completely at least three times.
            - **(ii)** If the oil is too viscous or the container that holds the oil cannot be inverted, a sterile tool may be used to help with making it more homogeneous by stirring.
- **(E)** The test sample collector then combines all sample increments collected for one batch or lot into one test sample. The entire combined test sample is homogenized prior to testing.
    - **(1)** Sample increments or samples collected from different batches or lots may not be combined.
    - **(2)** The test sample collector may allocate half the combined sample into another sterile container for the purposes of microbial testing.
- **(F)** The sample collector is to seal the entire sample within a tamper-resistant package or in a package that is sealed with tamper resistant tape immediately after the sample is placed in the package.
- **(G)** The coordinating state-inventory tracking system number for the test sample is to be affixed to the exterior of the sample package.
- **(H)** The test sample collector then transports all test samples in compliance with rule 1301:18-3-13 of the Administrative Code and in a manner that prevents degradation, contamination, commingling, and tampering of any test sample during transit.

OAC 1301:18-7-10 Testing Laboratory Prohibited Activities

- **(A)** In addition to the prohibitions outlined under rule 1301:18-9-03 of the Administrative Code, each testing laboratory shall not do any of the following:
    - **(1)** Maintain a direct or indirect financial interest with a physician certified by, or who has applied for certification to, the state of Ohio medical board under section 4731.30 of the Revised Code to recommend medical cannabis:
    - **(2)** Maintain a physician certified by, or who has applied for certification to, the state of Ohio medical board under section 4731.30 of the Revised Code to recommend medical cannabis as an officer, board member, administrator, employee, agent, or other person who may control the activities of a testing laboratory;
    - **(3)** Maintain or transport cannabis in quantities greater than that which is necessary to perform required analysis;

- **(4)** Certify, endorse, advertise, or make any claims on behalf of any cultivator, processor, dispensary, brand, or strain of cannabis, or brand or type of cannabis product;
- **(5)** Publish or release to the public any results of any tests performed pursuant to division 1301:18 of the Administrative Code, except aggregate data obtained as part of a research plan approved by the division; or
- **(6)** Offer a different fee schedule, refund, rebate, waiver of payment, or return of payment in the form of alternate compensation in the event of failing or otherwise undesirable test results.

Dispensary Rules

OAC 1301:18-8-13 Dispensaries Prohibited Activities

- **(A)** In addition to the prohibitions outlined under rule 1301:18-9-03 of the Administrative Code, each dispensary shall not do any of the following:
  - **(1)** Sell, transfer, or distribute cannabis to a person under the age of twenty-one years old, or eighteen years old for registered patients;
  - **(2)** Allow a recommending physician to conduct a physical examination or follow up care on or at the dispensary's licensed premises;
  - **(3)** Allow intoxicating liquor or beer as defined in section 4301.01 of the Revised Code onto its licensed premises;
  - **(4)** Dispense expired, damaged, deteriorated, misbranded, adulterated, or opened cannabis;
  - **(5)** Possess or dispense any cannabis requiring refrigeration or hot-holding or other any potentially hazardous food; or
  - **(6)** Provide free samples of cannabis to any person.

Enforcement Rules

OAC 1301:18-9-02: General Requirements

- **(A) Change of Operation.** Prior to any change in operation, each licensee shall apply in a manner prescribed by the division for review and approval prior to implementation of any proposed change.
- **(B) Duty to Report**
  - **(1)** Within twenty-four hours of discovery, each licensee shall provide written notification in a manner prescribed by the division of the following:
    - **(a)** An individual registered pursuant to rule 1301:18-3-09 of the Administrative Code is arrested for activities that, if convicted, would constitute a disqualifying offense as defined by 1301:18-1-01 of the Administrative Code;
    - **(b)** The sale, transfer, or distribution in any manner, cannabis to any unauthorized persons occurred at the licensed premises;
    - **(c)** The licensee violated any mandate outlined under 1301:18 of the Administrative Code;
    - **(d)** For the following the licensee shall also submit a written report within ten days:
      - **(i)** Any fire or other hazardous materials related incident or any incident requiring an emergency response to the licensed premises;
      - **(ii)** An alarm activation or other event that requires response by public safety personnel occurs;

- **(iii)** A breach of security; or
- **(iv)** The failure of the security alarm system due to a loss of electrical support or mechanical malfunction.

- **(e)** If a licensee has reason to believe that unauthorized access to or an actual loss, theft, or diversion of cannabis occurred at the licensed premises, a designated responsible party shall provide a signed statement that details the estimated time, location, and circumstances of the event, including an accurate inventory of the quantity and type of cannabis unaccounted for due to diversion or theft.
- **(f)** Within ten days of a report submitted under paragraph (B)(1)(d) of this rule, the licensee shall:
  - **(i)** Review and secure video surveillance footage during the time of the suspected theft or diversion;
  - **(ii)** Conduct an internal investigation to determine the cause of the loss, theft, or diversion;
  - **(iii)** Conduct an audit of the facility's actual inventory maintained with the inventory reflected in the state inventory tracking system;
  - **(iv)** Submit in a manner prescribed by the division the following information:
    - **(A)** The names and identification numbers of every employee at the facility at the time of the event;
    - **(B)** The findings of the internal investigation and audit conducted pursuant to this rule;
    - **(C)** A revised plan to secure the facility's inventory and measures that will be taken to prevent future loss, theft, or diversion; and
    - **(D)** Identify all the records at the facility and potential evidence outside the facility, including video surveillance footage, that will be sealed and prevented from being destroyed until a full investigation is conducted by the division or law enforcement.

- **(2)** Within ten business days of discovery, each licensee shall notify the division of the following:
  - **(a)** The licensee, or any person who is an owner, officer, board member, employee or agent of licensee, is named as a party in any pending administrative, criminal, or civil action pertaining to cannabis or any activity related to licensee's business or other activities related to licensee's business;
  - **(b)** The licensee, or any person who is an owner, officer, board member, employee or agent of licensee, is notified by the applicable state or territory of the United States or any foreign jurisdiction of a pending administrative or criminal investigation involving the licensee or above-outlined person associated with licensee.
  - **(c)** In addition to the disclosure requirements outlined under this paragraph, each licensee shall notify the division within fourteen days of the date of any final order or judgment entry pertaining to the actions outlined under this paragraph and provide the division with a copy of the final order or judgment entry.
- **(3)** Within ten business days of receipt, each licensee shall notify the division of a complaint received alleging the cannabis cultivated, processed, tested, or dispensed at

the licensed premises, directly caused a negative health or adverse event resulting in serious bodily harm to the complainant.

1301:18-9-03: Prohibited Activities

- **(A)** Any of the following shall be considered threats to the public health, welfare, or safety and shall be sufficient cause for a provisional license, certificate of operation, or provisional employee badge or employee badge certificate of a cultivator, processor, testing laboratory, or dispensary, or any combination thereof, or employee to be denied, suspended with or without a hearing, revoked, fined, have conditions placed upon such license, or subject to other actions authorized pursuant to rule 1301:18-9-05 of the Administrative Code, or any combination of such actions necessary to ensure the division's administration, implementation, and enforcement:
    - **(1)** Except as permitted under chapter 1301:18-10 of the Administrative Code, the sale, transfer, or distribution of cannabis to a person under the age of twenty-one years old at the licensed premises;
    - **(2)** Selling, distributing, transferring in any manner, or giving cannabis to any person not authorized under Chapters 3780 or 3796. of the Revised Code;
    - **(3)** Cannabis has been diverted across state lines in a manner prohibited by either state;
    - **(4)** Trafficking of illegal drugs or illegal activities occurred on or at the licensed premises;
    - **(5)** Illegal or unauthorized possession or use of a firearm at a facility;
    - **(6)** Driving while drugged or otherwise intoxicated;
    - **(7)** Drug or alcohol abuse;
    - **(8)** Consumption or administration of cannabis in any form on or at the licensed premises;
    - **(9)** Acceptance of cannabis from any person not authorized by the division;
    - **(10)** Revenue from the sale of cannabis has gone to criminal enterprises;
    - **(11)** Discriminating in price between different processor or dispensary facilities that are purchasing a like grade, strain, brand, quality, and quantity of cannabis;
        - **(a)** Nothing herein shall prevent price differentials based on differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which the medical marijuana is sold or delivered.
    - **(12)** Offer a different fee schedule, refund, rebate, waiver of payment, or return of payment in the form of alternate compensation in the event of failing or otherwise undesirable test results;
    - **(13)** Exchange, or offer to exchange, of anything of value with another licensed entity, or any of their representatives, agents, or employees, in an effort to induce or reward their business or referral of business;
    - **(14)** Providing dispensary employees rebates, discounts, or other incentives, monetary or otherwise, to purchase or sell cannabis from the particular licensee;
    - **(15)** Aiding or assisting another person in violating any provision of Chapter 3780 or 3796. of the Revised Code or the rules promulgated in accordance with Chapter 3780 or 3796. of the Revised Code;
    - **(16)** Permitting another person to use the licensee's license;
    - **(17)** Failure to comply with all mandates outlined under Chapters 3780 and 3796. of the Revised Code:
        - **(a)** Possessing, maintaining, cultivating, manufacturing, producing, processing, packaging, labeling, advertising, transporting, testing, distributing, transferring, or selling cannabis in violation of Chapter 3780 or 3796. of the Revised Code or the rules promulgated in accordance with Chapter 3780 or 3796. of the Revised Code;

- **(18)** Cooperation with Division of Cannabis Control
  - **(a)** Failure to cooperate or give information to the division, law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at any cultivator, processor, or testing laboratory;
  - **(b)** Failure to respond to a written request for information by the division within ten business days, unless otherwise stated;
  - **(c)** Failure to comply with a subpoena issued by the division;
  - **(d)** A finding by the division that the cannabis entity, after having the license suspended or subject to mandatory corrections under any rules promulgated in accordance with Chapters 3780 or 3796. of the Revised Code, has violated the terms of the suspension or failed to perform the mandatory corrections;
- **(19)** Other licensure:
  - **(a)** Any civil or disciplinary action is taken, or has been taken, against any persons relating to a professional license;
  - **(b)** The licensee was denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the inappropriate prescribing dispensing, administering, supplying or selling a controlled substance or other dangerous drug other than medical marijuana dispensed;
  - **(c)** Discipline, including, but not limited to, denial, suspension or revocation of a license, by any state or any territory of the United States or any foreign jurisdiction;
  - **(d)** Failure to report to the division within fourteen days of any adverse final action taken against a license in any state or any territory of the United States or any foreign jurisdiction, any governmental agency, any law enforcement agency or any court;
  - **(e)** Division of remuneration during the cultivation, processing, testing, dispensing, purchase or sale of medical marijuana with any licensed health professional certified to recommend medical marijuana;
  - **(f)** Sharing office space with, compensate, receive compensation from, or refer patients to a physician holding a certificate to recommend issued by the state medical board under section 4731.30 of the Revised Code;
- **(20)** Licensing
  - **(a)** Failure to immediately notify the division in writing of a change of any of the following for any person affiliated with a licensee:
    - **(i)** Full legal name;
    - **(ii)** Telephone number that may be utilized during normal business hours;
    - **(iii)** Electronic mail address; and
    - **(iv)** Mailing address.
    - **(v)** All information provided must be in working order and readily available to receive voice messages, electronic messages, or other communication as applicable.
  - **(b)** Failure to adhere to any and all mandates outlined in an application, as prescribed by the division;
  - **(c)** False or misleading statements in or involving any application submitted to the division;
- **(21)** Compliance

- **(a)** A finding by the division of a substantial discrepancy in a division inspection of any records and the subject matter of any records that are required under any rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code;
- **(b)** Failure to maintain effective controls and security measures designed to ensure compliance with the law or protect the facility, patients, caregivers, consumers, employees, and cannabis;
- **(c)** Knowing material misstatements or omissions in the inventory tracking system, where, in the exercise of reasonable diligence, the person should have obtained such knowledge prior to the misstatement or omission;
- **(d)** Falsifying, changing, modifying, or otherwise altering in any way the results of quantitative or other analyses performed on cannabis test samples or the corresponding certificates of analysis;
- **(e)** Cultivating, manufacturing, processing, testing, or maintaining cannabis in excess of the quantity required for normal, efficient operation based on population and consumption reported in the inventory tracking system.
- **(f)** Cultivating, manufacturing, processing, testing, selling, or distributing cannabis outside the appropriate designated area(s) at the licensed premises;
- **(g)** Knowingly or intentionally altering, obliterating, or otherwise destroying any cannabis container, package intended for direct customer sale, or label attached to a container or package;
- **(h)** Failure to continuously escort an otherwise unauthorized person within an area designated by the facility as a controlled access area, unless that person is an investigator or employee of the division, authorities from local licensing authority or any state or law enforcement agency;
- **(i)** Allowing cannabis, or cannabis byproduct or scrap, to be used or disposed of in a manner not consistent with Chapter 3796. of the Revised Code or the rules promulgated in accordance with Chapter 3796. of the Revised Code;
- **(j)** Failure to keep accurate records in accordance with any rules promulgated in accordance with Chapters 3780 or 3796. of the Revised Code;
- **(k)** Disclosure of patient, caregiver, or customer names, personal information or protected health information in violation of these rules or any state or federal law;
- **(l)** Discontinuance of business for more than ninety days, unless the division approves an expansion of such period for good cause shown, upon a written request;

- **(22)** Misc.
  - **(a)** Operating in a manner inconsistent with the public health, safety, and welfare standards of the local governmental authority;
  - **(b)** A fraudulent or deceptive practice, transaction, representation or omission to the public, law enforcement or a representative of the division, regardless of whether anyone relied on such practice, transaction, representation or omission;
  - **(c)** Operational failures that endanger public health, create a likelihood of contamination or diversion, or a pattern of deviation of standard operating procedures; or
  - **(d)** Failure to maintain a good business repute. For purposes of this rule and making a determination of a failure to maintain good business repute, the division shall consider if the person has engaged in any conduct which would reflect on the reputation for honesty, integrity, and competence in business and personal

dealings of the person. These would include, but not limited to, if the person has been determined to have engaged in forgery, embezzlement, nondisclosure, incomplete disclosure, misstatement of material facts, and manipulative or deceptive practices, or if the person has established a reputation for honesty, integrity, and competence.