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Environmental Laboratory Accreditation Program



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Protocol for Collecting Samples of Cannabinoid Products

ORELAP Sampling Subcommittee

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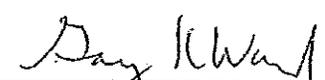
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Protocol for Collecting Samples of Cannabinoid Products

Introduction

Obtaining a representative cannabinoid product sample of a size suitable for the required regulatory testing connects a given batch of cannabinoid product with the laboratory for reliable labeling and information management. OAR 333-007-0310 defines a cannabinoid product, which essentially covers all cannabis products that are not defined therein as usable marijuana, an extract, a concentrate, or as industrial hemp. A laboratory report is dependent on the sample to accurately represent the process lot. Hence, the process of taking a representative sample is the beginning of laboratory analysis.

For the purposes of this document, a process lot is defined as “Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract, of which every portion is assumed to be uniform, within permitted tolerances, for factors which appear in the labeling.” OAR 333-007-0340 establishes requirements for testing cannabinoid products.

To reliably provide the laboratory with a representative sample, standard sampling methods must be applied with consistency. This controls variable factors in the sampling procedure, which may introduce error or bias resulting in a non-representative sample. A certain amount of random error is intrinsic to all measurements and may be minimized by close adherence to standard procedures.

Manufacturing error is the responsibility of the processor of the cannabinoid product and it is what is being evaluated by laboratory testing. Sampling error must be controlled to obtain a representative sample of the process lot. This is accomplished by maintaining the sample identity within the process lot, prevention of contamination of the sample, and consistent use of standard sampling methods and equipment. If proper controls are in place for sample collection, the laboratory report produced from the testing of the sample should reflect the quality of the process lot within recognized tolerances at the time of sampling.

There is a lack of reliable data on homogeneity and guidance for representative sampling protocols for cannabinoid products. In order to validate that the manufacturing process produces a uniform product assumed by the increment tables, three process validation studies must be performed or the increments must be analyzed separately if no process validation is performed.

The process validation study consisting of 20 increments analyzed for concentration of THC and must produce an RSD of results of less than 30% with no sample identified as an outlier using the Grubb’s outlier test evaluated with a significance level of 0.05 (only a 5 percent chance of error).

Once the processor has shown that the process produces a uniform product with successful completion of process validation, the required number of increments from each process lot can be combined to form one Field Primary Sample, and the same number of required increments can be combined to form one Field Duplicate sample for analysis. The Field Duplicate will act as ongoing Process Validation and if it fails the 20% RPD criteria, the waiver is invalidated and Process Validation must be performed again.

Incremental sampling techniques were adopted from reference and revised to be relevant to these

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unique products. If process validation is not performed, each increment sample is to be tested individually as a primary sample for attributes under test. As more data becomes available, the sampling requirements may be revised.

Accurate and thorough recordkeeping is another essential aspect of the sampling procedure to connect the batch to the sample and, eventually, the laboratory report. At a minimum, a sampling report should accompany the sample, which shows the sample information including product type, process lot size, process lot number, name and address of where sampled, the number of containers sampled, number of increments collected, number of primary samples collected, the sampler's name, and the date sampled. Additional information may include the origin of the batch and production date. It is always necessary for the sampler to keep a copy of the sampling report. A thorough record of the sample is best maintained on a form specifically designed for that purpose.

Representative sampling

When sampling a process lot, the sampler should check for any signs of non-uniformity. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed process lot numbers. During sampling, the sampler should look for differences in the cannabinoid products being sampled such as color, matrix variability and treatment. By definition, the process lot must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the process lot and that any sample drawn may not be representative for testing. The sampler must record these observations of the anomalies in the sample report.

General procedural guidelines that apply to all sampling include:

1. Use of appropriate sampling equipment and consistently following procedures;
2. Taking increments of an approximately equivalent quantity to form each primary sample;
3. Randomly or systematically taking increments to create composite primary samples throughout the process lot;
4. Obtaining a minimum number of increments, which will be based on process lot size;
5. Gaining access to the entire process lot.
6. Recording all observations and procedures used while collecting the sample on an appropriate sampling form.

Any exceptions to these guidelines must be noted in the sampling record. If a sample cannot be taken in a representative manner, it should either not be performed or the sample should be qualified as for "informational purposes only."

Random sampling

Sample increments should be randomly selected from different locations within a container or set of containers. Laboratories must develop procedures describing how to 1) assign location numbers within containers, 2) use a random number generator to determine which location to sample, and 3) document where each increment was sampled. Containers or items can be organized for sampling according to order of production where appropriate. Containers with depth should be sampled from the upper, middle, and lower locations within the container.

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Randomly select sample increments based on the answers to the following questions:

1. Is the sample ordered in time?
 - a. Group samples according to First (1), Middle (2), Last (3) where containers or individual units are numbered in order of production.
 - b. Where there is no existing production order of packaged items, arbitrarily number items according to number of containers or other relevant organization. Using a random number generator, select the numbered increments from their containers.
2. What is the shape of the container(s) to be sampled?
 - a. FLAT CONTAINERS – length x width only (examples: solids on a sheet, a single layer of flowers on a tray, or packaged edibles on a table)
 1. Assign 4 quadrants per container: Left, Right, Top, Bottom: LT (1), RT (2), LB (3), RB (4)
 2. Use a random number generator with the highest number equal to 4 for one container. Where there are multiple containers, use existing or arbitrary order of containers to assign numbers to quadrants and the total number of quadrants equals number of containers x 4.
 - b. DEEP CONTAINERS – length x width x height (examples: bulk liquid in a bucket, packaged edibles or bulk flower in a Tupperware bin)
 1. Reduce any distributional heterogeneity of the sample by mixing where practical.
 2. Assign 3 Quadrants per container: Upper (1), Middle (2), Lower (3) sections
 3. Use a random number generator with the highest number equal to 3 for one container. Where there are multiple containers, use existing or arbitrary order of containers to assign numbers to quadrants and the total number of quadrants equals number of containers x 3.
 - c. OTHER CONTAINERS (Bags etc.)
 1. The laboratory must have details in their SOP or Sampling Plan, from appropriate industry reference where possible, on how they will achieve random sampling in containers not addressed in this protocol.

Procedure

Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the matrix type and storage conditions, as this will determine the sampling plan. All sampling must be performed by personnel employed by an ORELAP accredited laboratory or sampling organization and must be in accordance with OAR 333-064-0100.

Refer to OAR 333-007-0340 and 333-07-0360, which describe requirements for sample collection and testing of cannabinoid products. Per Authority or client requests other analyses may require sampling and must be part of the planning process.

Post-cultivation processing of cannabis plant material to create any item can reasonably and justifiably be defined as an operating environment in which a continuing series of lots of are

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produced within the same operational parameters.

It is noted, the direct plant material that is utilized as primary raw material input may vary from lot-to-lot, with regards to 'strain' of cannabis plant being used. Also, various 'strains' may be combined together for a processing event. However, this variation in strain does not warrant a necessity for typical post-cultivation processing to be considered an operating environment where lots are manufactured in isolation.

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the matrix type and storage conditions, as this will determine the sampling plan. All sampling must be performed by personnel employed by an ORELAP accredited laboratory or sampling organization and must be in accordance with OAR 333-064-0100.

Equipment and Supplies

- Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
- Gloves (powder-free, nitrile, sterile)
- 70% Isopropyl alcohol – for surface cleaning sampling tools
- Teri-wipes, or equivalent
- Sample containers appropriate for analyses requested
- Field balance (Capable of 0.01 g measurements)
- Calibrated verification weights appropriate to verify field balance

Records and Documentation

Laboratories and/or sampling organizations shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

- The SOP shall be readily accessible to all pertinent personnel.
- The SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
- The sampling SOP shall use these protocols as minimum requirements and must include additional detail specific to laboratory procedures. Any changes, including use of a selected option, shall be documented and included on the sampling form. In cases where the published method has been modified or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.

The laboratory shall have SOP's for each sampling method.

- All documents shall be controlled and retained in accordance with the TNI standard.

The ORELAP accredited laboratory and/or the sampling organization shall maintain sampling plans (EL TNI 2009 V1M2 5.7). These documents must be made available at their location of use. Sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch. Standardized Sampling Plans can be included in the SOP, however

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specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.

Sampling Records/Field Data

In addition to collecting the sample, a sampling report form must be made for the process lot sampled and must include any observations made while taking the sample. This documentation shall include the following information:

- Name and address of processor, including licensee or registrant number;
- Product type;
- Unique laboratory Production Lot Number or ID #, METRC Lot ID #, and/ or OHA lot ID # as designated

Total mass or number of units in process lot;

- Total container number;
- Number of containers sampled;
- Total mass sampled;
- Number of increments and number of primary samples collected;
- Number and type of sample containers collected;
- Method of sampling and (SOP ID and revision)
- Description of equipment used;
- Place where sampled;
- Date sampled;
- Sampler's identification and/or signature;
- Name of responsible party for the process lot and transport information;
- Receiving laboratory and types of tests required or requested.

Note: In the event that the process lot or registrant number is not available, refuse to sample.

If any of the above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space. All sampling reports must be signed by the sampler. As part of the planning process, the laboratory must receive a manifest from the client regarding the batch to be sampled that includes the following information:

- Client Name
- Client License/Registration #(s)
- Facility address
- Process Lot Unique Identification number
- Storage conditions of the batch (if available, such as but not limited)

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- Temperature
- Humidity
- Containers
- Mass of process lot
- Requested Analyses
- Applicable Process Validation Certificates and Expiration Dates

While procuring the sample, in the absence of METRC procedures that contain the below information, the laboratory must create a Chain of Custody form with the following information:

Sampler's name

- Lab License Number
- Sample Identification (Lab ID number) if assigned before arrival at laboratory

Sampling Date/Time

- Mass and Location of increment samples
- Final Mass of composite sample
- Custody transfer signatures
- Custody Transfer Dates/Times

Note: Do not sample if the processing lot or registrant number is not available.

If any of the other above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space. All sampling reports must be signed by the sampler. Spell out chemical names and use CAS number as applicable since naming conventions are different in different industries.

Procedure: Process Validation Requirements

1. Take 20 increment samples for analysis following the procedures for selecting random locations. Process validation is required for THC analysis.
2. Each increment should be tested as a primary sample in each required analysis.
3. Calculate the RSD of the 20 sample results. If a sample result falls below the LOQ of the analysis, use the LOQ as the result in this calculation.
4. Apply the Grubb's outlier test to ensure that no samples qualify as an outlier.
5. If the RSD falls below 30% and there are no Grubb's outliers as defined, the Process Validation Study is considered acceptable.
6. Once three consecutive Process Validation Studies have been performed, submit the data to OHA of three consecutive ORELAP Process Validation studies to qualify for the reduction in necessary primary samples required for analysis to be reduced to one primary sample for all analyses.

Procedure: Sampling a Process Lot of Cannabinoid Product for Process Validation

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Study

1. Ensure that processor or processing site has completed the process validation requirements as per OAR 333-007-0440
2. Locate the process lot(s) of cannabinoid products to be sampled for the process validation study.
3. Review the process lot label information for process lot number and other pertinent information. Do not sample if a unique process lot number is not available or does not match the written request for process validation. Visually inspect the process lot to assess uniformity across units for sale.
4. Determine the expected number of units for sale in the process lot by reviewing the written request for process validation.
5. Determine the number of increments necessary based on total number of units for sale using Table 1 below. Each increment consists of an entire unit for sale. Additional increments may be required to ensure that sufficient quantity of material is available for all required tests.

Note: if an entire unit for sale is not a sufficient quantity of material available for all required tests, multiple units for sale can be combined to create a single increment.

Table 1 Number of increments required based on number of units for sale

Units for Sale	Increments (n)
3-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201-35,000	20
35,001-500,000	32
500,001 and above	50

6. Select the appropriate sampling tool(s).
7. Collection instruments, such as scoops and bags must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools should be cleaned at the laboratory and sealed to prevent contamination. Sampling tools which appear to be dirty or otherwise compromised shall not be used. The laboratory may choose to either field clean sampling equipment between batches or bring a lab-cleaned set for each batch sampled. Should the laboratory adopt the field cleaning procedure, the techniques adopted

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must be robust enough cleaning to prevent cross contamination during sampling.

Note: Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may field clean sampling equipment between samplings at a single facility, however, field cleaning between facilities is not appropriate. The sampler is required to bring enough sets of sampling equipment to use a new set at each site. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.

8. Each increment is collected into its own container and labeled as an independent laboratory sample.
9. Seal and label each laboratory sample with the following minimum requirements:
 - Sampling organization and/or laboratory licensee or registrant number;
 - Sampling organization unique identifier for sampling event;
 - Sampling date and name of sampler;
 - Processor's license or registration number;
 - Process lot and batch numbers;
 - Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12 point font

Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing.

10. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in 2009 TNI EL V1M2 5.8.1 through 5.8.7.
11. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
12. Record the sampling event in the OLCC seed to sale system under the licensee or registrant number for recreational marijuana and/or the OHA system for tracking medicinal marijuana

Procedure: Sampling a Process Lot of Cannabinoid Product – w/Process Validation Waiver

1. Ensure that processor or processing site has completed a written request for sampling and testing as per OAR 333-007-0315
2. Ensure that processor or processing site has an approved and valid Process Validation Waiver
3. Locate the process lot(s) of cannabinoid products to be sampled.
4. Review the process lot label information for process lot number and other pertinent information. Do not sample if a unique process lot number is not available or does not match the written request sampling and testing. Visually inspect the process lot to assess uniformity across units for sale.

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- Determine the expected number of units for sale in the process lot by reviewing the written request for process sampling and testing. Determine the number of increments necessary based on total number of units for sale using Table 2 below. Each increment consists of an entire unit for sale. Additional increments may be required to ensure that sufficient quantity of material is available for all required tests.

Table 2- Number of increments required based on number of units for sale.

Units for Sale	Increments (n)
2-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201-35,000	20
35,001-500,000	32
500,001 and above	50

- Select the appropriate sampling tool(s).
- Collection instruments, such as scoops and bags must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools should be cleaned at the laboratory and sealed to prevent contamination. Sampling tools which appear to be dirty or otherwise compromised shall not be used. The laboratory may choose to either field clean sampling equipment between batches or bring a lab-cleaned set for each batch sampled. Should the laboratory adopt the field cleaning procedure, the techniques adopted must be robust enough cleaning to prevent cross contamination during sampling.

Note: Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may field clean sampling equipment between samplings at a single facility, however, field cleaning between facilities is not appropriate. The sampler is required to bring enough sets of sampling equipment to use a new set at each site. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.

- Each increment is combined to create a single laboratory sample.
- Seal and label the laboratory sample with the following minimum requirements:
 - Sampling organization and/or laboratory licensee or registrant number;
 - Sampling organization unique identifier for sampling event;
 - Sampling date and name of sampler;
 - Processor's license or registration number;

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- Process lot and batch numbers;
- Label “PRODUCT NOT TESTED” in bold capital letters in minimum 12 point font

Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing.

10. Complete required documentation while at the sampling location as well as an appropriate chain of custody form as outlined in 2009 TNI EL V1M2 5.8.
11. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
12. Record the sampling event in the appropriate tracking database.

Sample Preservation, Handling and Storage

Submit the composite sample to the laboratory in its entirety. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

Containers for sample transport must be designed to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling should be appropriate for the sample matrix and the tests required. A tamper-proof seal is required and must be marked with the sampler’s name, date, and sample number.

Forward the composite sample to the laboratory or other designated location using packaging appropriate for secure transport. Protect the sample from moisture and temperature extremes. Include all documentation with the sample. Forward the sample by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody is accounted for to protect its integrity.

Quality Assurance/Quality Control

Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments and reducing sample heterogeneity. It is recommended that the number of increments prescribed in this protocol at a minimum are to be taken for the sample to be considered a representative decision unit for cannabis items.

The sampler must be prepared to collect adequate sample mass for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample for any quality control samples required by the laboratory, such as duplicates or matrix spikes.

Field QC

Field sampling equipment shall be certified clean prior to use by the laboratory. Cleaning techniques will vary depending upon the desired analysis. In general, sampling equipment must be sterile for microbiology samples when required and clean for chemistry samples. The laboratory

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shall perform cleanliness checks on each batch of sampling equipment cleaned prior to taking that equipment into the field. Should cleanliness checks fail, the sampling equipment must be re-cleaned and sterilized.

Field Duplicates

Field Duplicate are required for any sampling event that takes place with a Process Validation waiver or other waiver granted by the Authority or Commission in place. The Field Duplicate must be collected using the same procedure and contain the same number of increments as the Field Primary. Comparison of Field Primary and Field Duplicate results should fall within $\pm 20\%$ Relative Percent Difference (RPD). IF the 20% RPD is not met, the Authority must be notified and the Process Validation waiver is invalidated. Re-Sampling of the Batch is required to collect the appropriate amount of Primary Samples to be analyzed without a Process Validation Waiver.

Demonstration of Capability

Prior to acceptance and institution of each method for which data will be reported, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method, and, 2) when the method has not been performed by the laboratory or sampler within a 12-month period.

This procedure shall employ one of the following approaches to demonstrating capability:

- 1) Comparison of replicate samples within a defined RSD.
- 2) Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD.

Thereafter, ongoing continuing demonstration of capability (CDOC) as per the quality control requirements referenced in the method is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

Sampler qualifications

Recommended basic qualifications for samplers of usable marijuana are:

- Physically able to perform the duties of a sampler;
- No conflict of interest;
- Must be employed by an ORELAP accredited laboratory
- Pass initial and ongoing demonstrations of capability;
- Licensed to transport the required quantity of *marijuana items*

Education and training for samplers:

- Initial classroom training: 8-hours of training, including principles, procedures, and policies of sampling; Initial Training must be performed by an Instructor that has demonstrated competency in performing and instructing on the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.

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- Field or on-the-job training: 8-hours of training on various sampling techniques;
- Continuing education: 8-hours of periodic refresher training annually

Field Audits

The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits should be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.

When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.

Auditing checks

1. Using audit checklists:
 - a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol;
 - b. Observe the sampler conducting sampling procedures;
 - c. Obtain check samples taken by an auditor of harvest lot previously sampled by the sampler for evaluation and comparison of results.
2. Record any deficiencies and initiate corrective action.

References

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Appendix 1 – Definitions

Authority means Oregon Health Authority

Batch means a quantity of usable marijuana from a harvest lot or a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

Chain of Custody (CoC) The chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

Composite sample A sample containing all primary samples taken from a batch.

Container A container means a sealed, hard or soft bodied receptacle in which a marijuana item is placed or a physical division of a process lot of marijuana items for random sampling.

Decision Unit (DU) is the material from which the primary sample(s) is collected and to which the inference(s) is made.

Field Duplicate Sample means two samples taken in an identical manner from and representative of the sample marijuana item being sampled

Fundamental Sampling Error (FSE) results from compositional heterogeneity, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

Grower/Person Responsible for a marijuana grow site means a person who has been selected by a patient to produce medical or recreational marijuana for the patient, and who has been registered by the Authority or OLCC for this purpose.

Grow Site means a specific location registered by the Authority or licensed by OLCC and used by the grower to produce marijuana for medical or recreational use by a specific patient under ORS475B.420.

Harvest Lot means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices and harvested at the same time at the same location and cured under uniform conditions.

Heterogeneity the state or quality of being heterogeneous.

Heterogeneous Non-uniform or consisting of dissimilar parts or components.

Homogeneous Uniform in composition within recognized tolerances.

Increment means an individual portion of material collected by a single operation of a sampling device and combined with other increments to form a Laboratory Sample. Individual points randomly selected throughout any process lot where a sample is taken. Increments may be from bulk or packaged materials. Increments may be of various quantities. Total quantity of all increments must makeup total quantity necessary to perform all required testing and quality control. Increments may be combined into a composite if Process Validation Waiver is in effect for the Process Lot under inspection.

Label A tag or other device attached to or written, stamped, or printed on any container or

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accompanying any batch in bulk stating all required batch information.

Laboratory means a laboratory that is accredited under ORS 438.605 to 438.620 to conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS 475B.420.

Laboratory Sample means an amount of marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing. A Laboratory Sample may be made up of a single or multiple Increments.

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include industrial hemp, as defined in ORS 571.300.

Marijuana item means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

Process lot means:

- a. Any amount of cannabinoid concentrate or extract of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or
- b. Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract as defined in subsection (a) of this section.

Process Validation: Study performed on products or matrices of unknown homogeneity to assure required uniformity of product. Successful completion of process validation studies allow for the combination of required number of increments into a composite sample for analysis. . Failure to validate process requires separate analysis of each increment with each result subject to action limits.

Producer means a grower, marijuana processing site, or a medical marijuana dispensary.

Registrant means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.420, 475B.435 or 475B.450.

Relative Percent Difference: used to compare two quantities while taking into account the "sizes" of the things being compared. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

$$RPD = \frac{(sample\ result - duplicate\ result)}{(sample\ result + duplicate\ result / 2)} \times 100\%$$

Relative standard deviation: the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

$$\% RSD = \frac{S}{x} \times 100\%$$

Protocol for Collecting Samples of Cannabinoid Products

$$s = \sqrt{\sum_{i=0}^n \frac{(x_i - \bar{x})^2}{(n - 1)}}$$

where:

s = standard deviation,

n = total number of values,

x_i = each individual value used to calculate mean, and

\bar{x} = mean of n values

Representative Sample means a Laboratory Sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample Quality Criteria (SQC) is a series of statements that clarify program technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed Secured to provide authenticity or integrity.

Sterilization means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

Unit for sale means an individually packaged cannabinoid product intended to be sold or transferred to a customer, patient or designated primary caregiver.

Usable marijuana means the dried leaves and flowers of marijuana. Usable marijuana does not include the seeds, stalks and roots of marijuana or waste material that is a by-product of producing or processing marijuana.