Oregon Environmental Laboratory Accreditation Program

3150 NW 229th Ave. Ste. 100
Hillsboro, Oregon 97124
Voice (503) 693-4122
FAX (503) 693-5602
TTY (503) 731-4031

ORELAP

Executive Board Programs:
Department of Agriculture, Laboratory Division
Department of Environmental Quality, Laboratory Division
Oregon Health Authority, Public Health Laboratory

Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, and Products

ORELAP-SOP-002 Rev 3.0

ORELAP Executive Board and Program Approval Signatures:

For Brian Boling, DEQ Laboratory Program Manager — Date: 12/1/2016

John Fontana Ph.D., Public Health Laboratory Director — Date: 12/01/2016

Kathleen Wickman, ODA Laboratory Manager — Date: 12/01/16

Gary Ward, ORELAP Administrator — Date: 12/1/2016

Scott Hoatson, ORELAP QA Officer — Date: 12/1/2016

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Acknowledgements

Version 1.0 of this document was authored by Cannabis Sub-Committee with input from Technical Experts and approved by the ORELAP Executive Board. Revision 3.0 was authored and reviewed by NEFAP/GLP sampling experts. See Revision 2.0 for original committee authorship.

Technical Expert Authorship:

Kim Watson, RQAP-GLP
Stone Environmental
TNI NEFAP committee

Justin Brown
Environmental Monitoring and Technologies Inc.
TNI NEFAP committee

Technical Expert Input and Review Revision 3.0
Shannon Swantek
Oregon Health Authority
ORELAP Compliance Specialist

Scott Hoatson
Oregon DEQ Laboratory
ORELAP Quality Officer

Marlene Moore
Advanced Systems Inc.
TNI NEFAP committee

ORELAP Executive Board

Brian Boling
Oregon DEQ Laboratory and Assessment Division
Laboratory Manager

Kathleen Wickman
Oregon Department of Agriculture Laboratory
Laboratory Manager

John Fontana
Oregon Health Authority Public Health Lab
Laboratory Manager

Introduction and Scope

Laboratory analysis relies on sampling to characterize a larger batch. Hence, the process of collecting a representative sample is the beginning of the analytical process.

For the purposes of this document, a batch is defined as "a quantity of cannabinoid concentrate, extract, or cannabinoid product from a process lot" identified by a batch number or other unique identifier, every portion of which is assumed to be uniform within permitted tolerances. The testing requirements for cannabinoid concentrates, extracts and products are in Oregon Administrative Rules (OAR) 333-007-0330 to 333-007-0345.

To reliably provide the laboratory with a representative sample, standard sampling methods must be applied with consistency. In addition, sampling practices and devices must be "correct" for the matrix. 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 well documented standard procedures.

Manufacturing error is the responsibility of the processor of the *Cannabis* product (concentrate, extract or product). Sampling error must be controlled in order to obtain a representative sample of the defined batch. This is accomplished by maintaining the sample identity within the defined batch, 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 batch within recognized tolerances at the time of sampling.

This protocol will focus on standard and correct sampling practices and sampling devices. The laboratory must meet the client needs for uncertainty, risk, and liability in the sampling contract. It is strongly recommended that the laboratories encourage clients to mitigate risk of uncertainty in representativeness by increasing the number of individually analyzed sample increments for each test. The specifications in the contract are met by creating a site specific sampling plan or process specific sampling plan that uses statistical design for each project to meet the confidence interval requested by the client. Unless the contract states otherwise, a laboratory need only collect the minimum number of sample increments required in OAR 333-007-0360. Samples taken for a control study may not be combined. After a control study is performed and certified by either the Authority or the Commission, the laboratory can combine the required sample increments into one Field Primary Sample and must also collect an equivalent number of sample increments that can be combined into one Field Duplicate Sample for ongoing validation of the control study.

Incremental and Representative Sampling design

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 site specific or process specific sampling plan and a project specific

sampling report should accompany the sample, which shows the sample information including product type, batch size, batch number, name and address of where sampled, the number of containers sampled, number of primary samples collected, the sampler's name, and the date sampled. Additional information may include the origin of the batch, production date, and other information needed for choosing increments (small volume of material removed in a single operation of the sampling device, or any deviation of the product making the state minimum at higher risk than normal. 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. In your sampling plan, the correct sample for analysis would be the sample that has the mean analyte concentration representative in the volume of sample needed for analysis. The sample may be a structured composite sampling made up of increments randomly selected over a containerized cannabis concentrates, and extracts and products.

Equipment and Supplies

The minimum equipment and supplies are listed in this protocol, however, lab procedures and sampling plans should have all equipment (sampling devices) necessary to take a consistent representative sample. The lab must also have procedures on cleaning the equipment or dedicated sampling disposal devices. The cleaning procedures must effectively eliminate carryover by removing any analyte of interest regardless of concentration of the analyte. This cleaning procedure must be validated initially and validated at any time the procedure, materials, or analyte of interest change, or there is evidence of contamination in samples.

Sampling equipment such as spoons, spatulas, forceps, syringe or transfer pipettes, or other matrix specific tools:

- Gloves (powder-free, nitrile, sterile)
- Sodium Hypochlorite (bleach) – for surface cleaning sampling tools for microbiology
- 70% Isopropyl alcohol – for surface cleaning sampling tools for pesticides and potency
- Teri-wipes, or equivalent
- Amber Glass containers
- Field balance (Capable of 0.01 g measurements)
- Calibrated Verification Weights appropriate to verify field balance Chain of Custody
- Custody Seals
- Sample Labels
- Sample Cooler/Ice (if thermal preservation required)
- Permanent Ink Pen
- Equipment Logbook (if balance used in field)

Procedures for Sampling Concentrate and Extract Products.

Planning

Prior to initiating a sampling event, a written sampling plan will be generated detailing the requirements and project. A sampling plan will detail sampling event(s) with specific specifications for the sampling event(s). The sampling plan should be as complete as possible before arriving on the sample site included such information as sampling devices and number of increments and size. If the sampling plan is a repeat event, based on a contract with a client, there should be a project plan with the information that will stay consistent.

For the sampling plan, whether with client-provided information or site information, the sampler shall survey the site and sampling locations to identify the matrix type and storage conditions of defined batch to be sampled. The sampling plan should identify, at a minimum, the quantity of samples to be collected, sample size, the sampling locations, the analysis to be performed, the sampling methodology required, and any other pertinent information regarding the sampling event. The sampling plan and any other supporting documents (i.e. SOP, protocols, forms, maps, etc.) must be readily available to the sampler at time of sampling event.

The sampling plan shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the representativeness of the sample(s) collected. Factors such as storage, environmental conditions, heterogeneity of the batch or sample, all must be considered and addressed in the sampling plan. Any deviation from the standard sampling process, or addition to the sampling plan must be documented in detail and shall be included in the final report.

All sampling must be performed by qualified personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and 333-064-0100.

Cannabinoid concentrates and extracts must be tested in accordance with OAR 333-007-0330. Cannabinoid products, depending on what they are, must be tested in accordance with OAR 333-007-0340 or 333-007-0345. Per Authority or Commission request, or client request, additional analyses may be required, and will be specified by the laboratory in the written sampling plan. The sampling plan shall address representativeness of the individual, or composite sample collected; the sampling locations must be selected at random, and designed so that the composite sample reflects the total composition of the product. The sampling plan will address volume of sample to be collected from each sampling location. This specification will ensure that adequate sample volume is collected for the analyses required, including all required quality control samples as well as any potential confirmation analysis.

Representative sampling

Data is only useful to the degree which the sample(s) collected represent the batch being analyzed. Based on client specifications and/or regulatory requirements, the sampler should identify sampling location(s) that represent the batch sufficiently to

meet data quality objectives.

When sampling a batch, the sampler should check for any signs of non-uniformity or anomalies that may result in deviation from sampling plan or may affect sample collection/analytical results. Examples of potential indicators may be different types, or sizes of containers, variations in marks and labels, or mixed batch numbers. Discrepancies shall be noted in the field record. During sampling, the sampler should look for differences in the *Cannabis* products being sampled such as size, color, matrix variability and treatment. The batch must be uniform for all factors identified in the sampling plan; product variations observed may indicate a lack of uniformity and sample collected may not be representative of the batch. The sampler must record these observations of the anomalies, and any preventative measures taken in the sample report .

General guidelines that apply to all sampling include:

- Use appropriate sampling equipment or devices, and thoroughly clean to prevent contamination;
- Follow all applicable procedures and the sampling plan;
- Taking equal increments as specified in the sampling plan to form each primary sample and duplicate or individual sample as required;
- Randomly or systematically take increments throughout the batch to create primary composite sample;
- Obtaining a minimum number of samples, as specified in the sampling plan;
- Recording all observations and procedures used while collecting the sample on an appropriate sampling record containing at a minimum the components described in the "Sampling Records/Field Data" section of this protocol. Any exceptions to these guidelines or deviations from the sampling plan must be noted in the field record. If a representative sample cannot be collected, the appropriate authority (client or regulatory) should be contacted immediately or the sample should be clearly identified as "for informational purposes only". Should the representativeness be in question, the sample should be collected and all pertinent data and observations, including those which may validate or invalidate the representativeness, shall be documented and submitted with the sampling record.

Random sampling

As specified in the sampling plan, 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 and the volume collected from each increment.

Assign divisions based on the type of container in the site specific sampling plan. Use a random number generator with the higher number equal to the number of divisions for

the container. When there are multiple containers, use existing or arbitrary order of containers to assign numbers to the total of "divisions multiplied by total number of containers" (divisions x # containers = total number of random increments) and record in the sampling report.

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 unclear decision unit.

Records and Documentation

Laboratories 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 laboratory needs to keep thorough records of each part of the process. The sampling plan, the sampling record, and chain of custody are required for each batch. If there is a quality assurance project plan for the client, the sampling plan can be abbreviated to include the client and lab information and any variation or modification that occurred in the particular sampling event.

Site Specific or Process Specific Sampling Plan/Project Plan/Request for Analysis

The laboratory shall maintain site and/or project specific sampling plans (2009 TNI EL 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 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.

In some cases, especially when an on-going project plan is in place, the lab may wish to combine the sampling plan and sampling record. If this is the case, as much information about the site specific plan should be collected before sampling and there must be enough room on the record to record any deviations from the plan; including but not limited to number and orientation of containers to be sampled, mass, environmental

conditions and any other factors that cannot be determined before arriving on-site. It must be clear on the combined sampling plan/record which information was recorded during planning and which information was recorded on-site with signatures of any applicable personnel.

As part of the planning process, the laboratory must receive a manifest or Request for Analysis from the client regarding the specific batch to be sampled (even if a project plan is in place). It is recommended that there be a compliant contract in place in addition to a sampling plan to define client quality objectives. A sampling plan should include:

- Client Contract Record
- Analyses requested
- Sample designation (Medical or Recreational)
- If applicable, standing or individual subcontract agreements by the client and subcontract lab
- Sampling schedule and transport schedule
- Personnel assigned to sampling and transport
- Name and address of processor, including licensee or registrant number
- Any certifications of Control Study and expiration date issued by OHA or the Commission
- Product type
- Unique laboratory Project Number or ID #, METRC Lot ID #, and/ or OHA lot ID # as designated
- Total Mass or number of units in process lot
- Applicable SOPs for sample type
- Statistical methods or calculators used for sampling design
- List of necessary equipment

Sampling Records/Field Data

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. Any deviations and amendments to the sampling plans or SOPs must be well documented at the time of occurrence and, when possible should be agreed upon by the client preferably before sampling occurs. Sampling records must include at least the following:

- 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 number of containers
- Sample containers collected (Type and Number)
- Total mass sampled
- Number of increments
- If applicable, number of increments combined into primary and duplicate samples collected
- Number of total primary and duplicate samples
- Sampling Methodology (Reference and lab SOP IDs and revision)
- Description and IDs of equipment used;
- Balance identification and calibration information (where applicable)
- Identify any environmental conditions or other considerations that may impact data
- Identify any deviations from the sampling plan or SOP
- Sampling locations
- Date sampled
- Sampler's identification and signature
- Name of responsible party for the production lot and transport information
- Receiving laboratory and types of tests required or requested
- *Note: In the event that the production lot* or *registrant number is not available, refuse to sample.*
- Client Name
- Client License/Registration #(s)
- Facility address
- Batch Unique Identification number
- Storage conditions of the batch (if available, such as but not limited to)
- Temperature
- Humidity
- Containers
- Mass of batch or production lot
- Requested Analyses
- Applicable Control Study Certificate, agency documentation, and expiration dates of these.

If any of the above information requested on the sampling report is unavailable, indicate "N/A" in the appropriate space. All sampling reports must be signed by the sampler.

Chain of Custody

While procuring the sample, in the absence of METRC procedures and print-outs 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
- Sample IDs and container ID of increment or composite samples
- Final Mass of each sample ID
- 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 chain of custody forms must be signed by the sampler.

Sampling process for the Control Study required in OAR 333-007-0440

1. Ensure that processor or processing site has completed the control study requirements under OAR 333-007-0440(1).
2. Locate the batch of cannabis product to be sampled for the control study.
3. Review the batch label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot number is not available or does not match the written request for the control study.
4. Visually inspect the batch to assess uniformity across units for sale.
5. Determine the size of batch by reviewing the written request for the control study.
6. Determine the number of increments necessary based on total size of the batch. The minimum increments necessary are in OAR 333-007-0360, Exhibit B. 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.
7. Additional information and requirements for sampling concentrates, extracts and products is in the section below.
8. Sample increments taken for a control study may not be combined into a

composite sample.

Once a process lot of a product has successfully completed a control study and the control study has been certified by the Authority or the Commission, sample increments collected from future process lots of that product can be combined for testing as specified in OAR 333-007-0360 and 333-007-0440. Sample increments for a field duplicate must also be obtained as described below in this protocol.

The number of sample increments required to be collected for a control study and for ongoing testing must be at least the minimum number of sample increments specified in OAR 333-007-0360, Exhibit B, except that the client can request that additional sample increments be taken in accordance with the sampling plan.

Sampling for concentrates, extracts and products

1. Locate the cannabis product batch to be sampled.
2. Review the container label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot number is not available.
3. Determine if the sample matrix is a liquid, semi liquid, or solid either in bulk form or in packaged units. Determine and record the total batch weight or volume and the number of containers comprising the batch. If the product is already in final packaging, determine and record the total number of final package units. Visually inspect the batch for uniformity and/or deviations from the manifest or elements that call the site specific or process specific sampling plan into question. Do not sample if there are deviations from the manifest or questions about the statistical certainty of the sampling plan.
4. Establish which tests will be performed. Ensure sufficient sample increments are taken to meet sample size requirements determined sampling plan and record the number of increments collected. The minimum sample amount is determined by the analytical method(s) being performed but can be no less than number of increments in OAR 333-007-0360, Exhibit B. Ensure that appropriate equipment and containers are used for the tests being performed. For residual solvent analysis, use glass amber containers that can be properly sealed to prevent the loss of solvent gas and minimize the headspace remaining in the sample container.
5. Select the appropriate sampling tool to ensure that it reaches all portions of the batch.
6. Collection instruments must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools which appear to be dirty or otherwise compromised shall not be used. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling.
    a. *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 clean sampling equipment in the field*

between samplings at a single facility. However, the sampler is required to bring enough sets of sampling equipment to use a new set at each facility visited. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.

7. Once taken, seal and label the primary or composite sample with the following minimum requirements:
    a. Laboratory licensee number
    b. Unique identifier for sampling event
    c. Sampling date and name of sampler
    d. Processor's license or registration number
    e. Process lot and batch numbers
    f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12 point font
8. Apply a custody seal to the sample container in a manner that prevents the product from being tampered with prior to testing.
9. 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.
10. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
11. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational extracts and concentrates and document under the registrant number for tracking medicinal extracts and concentrates.
12. Apply the following guidelines when taking **Solid** and **Semi Solid** samples:
    a. Establish the total batch weight or volume. If the batch is in final product packaging, determine how many units there are and the total batch mass.
    b. Each sample increment should be taken from a randomly chosen position in the batch, as far as practically possible. A sample increment should be taken from each container if possible. If more containers exist than sample increments required, sample from as many as possible to obtain composite primary sample and field duplicate.
    c. The primary samples should consist of sufficient material to perform the required laboratory methods. 1 gram +/- 0.2g is offered as guidance, however if this does not supply sufficient mass for required analysis, the mass of the increments can be increased or decreased as long as they are equivalent to each other.
    d. The minimum number of sample increments is in OAR 333-007-0360 but more sample increments may be collected at client request based on the statistical design in the site specific sampling plan. If not using the minimum requirements in rule the laboratory shall use its statistical design

training, procedures, and calculators to determine the increments needed for a confidence interval that meets the client request.

e. Store each increment or combine all sample increments as specified in the site specific sampling plan for each sample in an amber glass container to form the test sample. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the increments are combined into a field primary sample, complete the same procedure with a second set of equivalent increments to form the field duplicate sample.

13. Apply the following guidelines when taking **Liquid** samples:

a. If the sample is to be taken from a bulk container, ensure proper homogenization of the product prior to taking the sample by mixing the container thoroughly and employing any process for homogenization that the processor would use to disperse the sample into packaging. Use an appropriate sample device for sampling bulk liquid in a container. Sample the appropriate number of increments based on the site specific sampling plan for the client.

b. Store each increment or combine all sample increments as specified in the site specific sampling plan for each sample in an amber glass PTFE screw top container to form the test sample. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the increments are combined into a field primary sample, complete the same procedure with a second set of equivalent increments to form the field duplicate sample.

Sample Preservation, Handling and Storage

Preparation of the samples

Transport the sample increments or composite sample to the analysis laboratory following OLCC licensee rules for transport. Note: Current law does not permit shipping in any form such as USPS or FedEx.

The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.

Submit the sample increments or 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.

Forwarding samples to the primary and/or re-testing laboratory

Forward the sample increments or composite sample to the laboratory using packaging appropriate for secure transport.

Protect the sample increments or composite sample from moisture and temperature extremes.

Include all sampling records and field data with the sample increments or composite sample.

Forward the samples by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the batch 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 requires a sampling plan that includes enough representative and random increments to meet the client-specified confidence intervals and the minimum regulation. The most common way to achieve this is by increasing the number of sample increments and reducing sample heterogeneity. The minimum number of sample increments required to be taken are prescribed in OAR 333-007-0360.

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 mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.

Field QC

Field sampling equipment and devices 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 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

A Field Duplicate Sample is required for any sampling event that takes place after a control study has been certified according to OAR 333-007-0440. The Field Duplicate must be collected using the same procedure and contain the same number of sample increments as the Field Primary. Comparison of Field Primary and Field Duplicate results should fall within ±20% Relative Percent Difference (RPD)[1]. IF the 20% RPD is not met, the Authority or the Commission must be notified and the control study waiver

[1] Standard Methods 20th Edition; 1020 B Quality Control, 11. QC Calculations, f. Duplicate Sample.

is invalidated. Re-Sampling of the Batch is required to collect the appropriate amount of sample increments to be analyzed without a certified control study.

Equipment Blanks

Equipment rinse blank samples provide a QC check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning.

The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.

The Equipment Blank must pass the required analysis at <LOQ for cleaning validation. If the Equipment Blank is collected at the sampling event, the lab must have detail in the sampling plan or procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

Transport Blank

A Transport Blank is required as part of a sampling plan that includes collection for solvent analysis. A single Transport Blank must be collected per trip regardless of amount of sampling events and each event's samples must be linked to the acceptability of its result. The Transport Blank must pass solvent analysis at <LOQ for the sampling event to be considered valid.

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 within a 12-month period.

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

- Comparison of replicate samples within defined %RSD acceptance criteria.
- Comparison of a sample collected to that of one collected by personnel with an existing IDOC within defined %RPD acceptance criteria.

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
- 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.

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

Using audit checklists:

- Review sampling and performance records from the preceding year for

deficiencies in the application of sampling protocol.

- Observe the sampler conducting sampling procedures.
- Obtain check samples taken by an auditor of harvest lot previously sampled by the sampler for evaluation and comparison of results.
- Record any deficiencies and initiate corrective action.

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Appendix 1 – Definitions

Authority means Oregon Health Authority

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

CBD means Cannabidiol.

Chain of Custody means the chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

Commission means the Oregon Liquor Control Commission.

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

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

Control Study means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through sampling and testing as described in OAR 333-007-0440.

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

Equipment blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate cleaning procedure or between sampling batches to demonstrate lack of contamination.

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

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 means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

Homogeneous means uniform in composition within recognized tolerances.

Increment means a sampling unit that is used to produce a primary sample.

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

sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS475B.420.

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.

ORELAP means the Oregon Environmental Laboratory Accreditation Program.

Primary Sample means a sample composed of sample increments and tested for the required analysis methods.

Registrant means a person registered with the Authority under ORS 475B.420, 475B.435, or 475B.450.

Relative Percent Difference means comparing 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.

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

Relative standard deviation means 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.

$$\%\ RSD = \frac{s}{\bar{x}} \times 100\%$$

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

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

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.

Representative Sample means a 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. In essence, the sample must mimic the population in every way, including distribution of the individual items or members of the population.

Sample means an amount of marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

Sample Quality Criteria (SQC) means 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 means secured to provide authenticity or integrity.

Test Batch means a group of samples that are collectively submitted to a laboratory for testing purposed. A test batch *does not mean* a combination of marijuana flowers, marijuana leaves, cannabinoid products, or cannabinoid concentrate or extract.

Test sample means anything collected by an individual authorized by the Authority to collect a sample from a licensee or registrant that is provided to a laboratory for testing, including but not limited to marijuana items, soil, growing medium, water, solvent or swab of a counter or equipment.

THC means **tetrahydrocannabinol**

Transport Blank means a sample of analyte-free media which has been carried to the field and returned to the lab used to demonstrate that the process did not add volatile contamination in solvent analysis.

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.