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Protocol for Collecting Samples of Usable Marijuana

ORELAP-SOP-001 Rev. 3.0

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Acknowledgements

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Introduction and Scope

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

For the purposes of this document, a batch is defined as "a definite quantity of usable marijuana from a harvest lot" identified by a batch number or other unique identifier, every portion of which is assumed to be uniform, within permitted tolerances." Oregon Administrative Rule (OAR) 333-007-0320 describes the testing requirements for Usable Marijuana.

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.

Production error is the responsibility of the producer of the Usable Marijuana 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 samples required in OAR 333-007-0360 and as recommended in this protocol.

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, to the laboratory report. At a minimum, a sampling report shall accompany the sample, which shows the batch information including cultivator, 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 and harvest 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 batch, the sampler shall 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 batch numbers. During sampling, the sampler shall look for differences in the usable marijuana products being sampled such as color, shape, size, and treatment. By definition, the batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the batch and that any sample drawn may not be representative for testing. The sampler shall note as a comment and details of these anomalies in the sample collection report.

General procedural guidelines that apply to all sampling include:

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

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 its SOP or Sampling Plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

Procedures for Sampling Usable Marijuana

Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the Usable Marijuana is being kept, as this will determine the sampling plan. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in

accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for Usable Marijuana are in OAR 333-007-0320. The requirements for sampling and sample size are in OAR 333-007-0360. Per Authority or Commission request or client request, other analyses may require sampling and must be part of the planning process.

In cases where Usable Marijuana will be sold or transferred to a processor or processing site, analysis may occur prior to the drying and curing steps. To ensure representativeness, the sampling plan must be designed such that each flower bud in the batch has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required, but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 10 lbs**.

Equipment and Supplies

- Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
- Tongs
- Corers
- Teri-wipes, or equivalent
- Field balance (Capable of 0.01 g measurements)
- Calibrated Verification Weights appropriate to verify accuracy of field balance
- Cleaning supplies – solvent, bleach, 70% Ethanol
- Gloves (powder-free, nitrile, sterile)
- Mylar Bags (For final sample transport and storage) And/Or
- Amber Glass jars (For final sample transport and storage)

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.
- All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-007-0310.

The ORELAP accredited laboratory shall maintain sampling plans (2009 TNI ELV1M2 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.

Sampling Records/Field Data

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

- Name and address of producer (cultivator), including licensee or registrant number;
- Product type;
- Total mass of batch;
- Unique laboratory batch ID#,METRC batch ID #, and/or OHA batch ID#; as designated
- Total container number;
- Number of primary samples;
- Number of containers sampled;
- Number of sample containers collected;
- Total mass sampled;
- Sampling plan ID and revision date;
- Sampling Procedure ID and revision date;
- Description of equipment used;
- Place where sampled;
- Date sampled;
- ORELAP Laboratory Identification number;
- Sampler's identification and/or signature;
- Name of responsible party for the batch and transport information;
- Receiving laboratory and types of tests required or requested.

Note: Do not sample if the harvest lot or licensee or registrant number is not available. Until January 1, 2017, a laboratory may sample for a processing site listed on the Authority's website, http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Pages/processors-pending.aspx.

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

Sampling a Batch of Usable Marijuana

1. Locate the batch to be sampled.
2. Review the container label information for harvest lot number, cultivator, and other pertinent information. Each harvest lot must be separated into batches of 10 lbs. or less and must be assigned a unique batch number by the grower. Do not sample if a unique batch number is not available.
3. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container. Do not sample if the batch size is unavailable or exceeds 10 lbs. for a container.
4. Determine the number of containers from which test samples must be collected (Appendix 2).
5. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
6. Collection instruments must be clean 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. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. Decontamination waste must be collected and properly disposed of if not used for analysis.

   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. Where aseptic technique is required, apply the FDA Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6) when taking samples:

7. Visually inspect each test sample to assess uniformity;
8. If non-uniformity is identified, record observation in the sampling report. It is expected with Usable Marijuana to have variable sizes of flowers. When drawing test sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected.
9. Combine all test sample increments to form the composite test sample.
10. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
11. Seal and label the composite sample with the following minimum requirements:
    - Laboratory license number
    - Unique identifier for sampling event
    - Sampling date and name of sampler
    - Producer's license or registration number
    - Harvest lot and batch numbers
    - Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12 point font.
12. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the laboratory sample identification number.

13. 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.
14. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
15. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational marijuana or record in the laboratory's records the registrant number for tracking medicinal marijuana.
16. Field duplicates are recommended for any Usable Marijuana sampling event, but not required. The laboratory must have documentation of the client request for a field duplicate with any quality objectives. Field duplicates must be collected using the same procedures, must contain the same sample increments as the field primary sample and precision limits must meet the client's need.

Sample Preservation, Handling and Storage

Preparation of the Composite Sample

1. Transport the sample to the analysis laboratory following OLCC license regulation for transport. Note: The existing regulation does not permit shipping in any form such as USPS or FedEx.
2. 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.
3. Submit the composite sample to the laboratory in its entirety.
4. 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 is a glass, amber jar with a PTFE-lined lid or a Mylar bag. 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

1. Forward the composite sample to the laboratory or other designated location using packaging appropriate for secure transport.
2. Protect the sample from moisture and temperature extremes.
3. Include all documentation with the sample.
4. 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 to compensate for normal batch heterogeneity. It is recommended that a minimum of seven (7) increments be taken for the sample to be considered a representative decision unit for Usable Marijuana.

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 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 and clean for chemistry samples. The laboratory shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.

Field Duplicates

Field Duplicates are recommended for any Usable Marijuana sampling event, but not required. The Field Duplicate must be collected using the same procedure and contain the same number of increments as the Field Primary. The lab must have documentation of the client request for a Field Duplicate with any client specified Quality objectives. A Field Duplicate must be collected using the same procedures and contain the sample increments as the Field Primary sample and precision limits must meet the client's need.

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.

Demonstration of Capability

Prior to acceptance and institution of any 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 Relative Standard Deviation (%RSD)[1].
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 Usable 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 must 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.

[1] Standard Methods 20th Edition; 1020 B Quality Control, 11. QC Calculations, a. Initial Calibration.

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. Have the auditor and sampler collect samples from the same harvest lot for evaluation and comparison of results.
2. Record any deficiencies and initiate corrective action.

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Oregon Administrative Rules (2016), *Marijuana Labeling, Concentration limits, and Testing,* Chapter 333, Division 7.

Oregon Administrative Rules (2016), *General Requirements Applicable to all Marijuana Licensees,* Chapter 845, Division 25.

Standard Methods 20th Edition (1998); 1020 Quality Assurance

Appendix 1 – Definitions

Authority means Oregon Health Authority

Batch means a quantity of Usable Marijuana from a harvest lot.

Chain of Custody means the chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample. (Sample tracking document)

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 a marijuana batch for random and representative sampling.

Decision Unit (DU) 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).

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 licensed by 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 cultivated utilizing the same growing practices and harvested within a 48-hour period 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 an individual portion of material collected by a large single operation of a sampling device. Increments are created by the sampling operation and are usually taken from parts of a lot separated in time or space. Increments may be reduced individually or tested either individually or combined with other increments with the resulting composite reduced in size and tested as a single unit.

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.560.

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.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.420.

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

Registrant means a person registered with the Authority under ORS475B.420, 475B.435, or ORS 475B.450.

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.

Sample means an amount of marijuana item collected by sampling 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.

Usable Marijuana means the dried and cured 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.

Appendix 2 – Recommended Sampling Guidelines

Sample size

Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required, but shall in no case be less than 0.5% of the weight of the batch. Per OAR 333-007-0350, the maximum batch size is 10 lbs.

The required sample size for a given batch size based on OAR 333-007-0360 varies depending upon the size of the batch (Table 1).

Table 1 – Sample size requirements based on size of batch.

Batch size	**Required sample size**		
	Pounds (lbs)	**Ounces (oz)**	**Grams (g)**
≤1 lbs	0.005	0.08	2.3
1.01 ≤2 lbs	0.010	0.16	4.5
2.01 ≤3 lbs	0.015	0.24	6.8
3.01 ≤4 lbs	0.020	0.32	9.1
4.01 ≤5 lbs	0.025	0.40	11.3
5.01 ≤6 lbs	0.030	0.48	13.6
6.01 ≤7 lbs	0.035	0.56	15.9
7.01 ≤8 lbs	0.040	0.64	18.1
8.01 ≤9 lbs	0.045	0.72	20.4
9.01 ≤10 lbs	0.050	0.80	22.7

Sampling a batch

1. When collecting a primary sample from a batch, a minimum of seven (7) increments shall be collected. Collect the increments by following different paths through the batch container or by taking the increments systematically at well-separated points along a heptagonal pattern.
2. As the batch increases in size, it is necessary to collect additional increments to make up the primary sample (Table 2). Collect seven increments plus additional increments based on 10% of the weight of batch. Do not collect more than 9 increments.

Table 2 - Number of increments for the primary sample based on batch size.

Size of batch (lbs)	≤ 2	≤ 4	≤ 6	≤ 8	≤ 10
No. of increments	7	7	8	8	9