



CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
Medical Use of Marijuana Program

99 Chauncy Street, 11th Floor, Boston, MA 02111

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-660-5370
www.mass.gov/medicalmarijuana

Title: Protocol for Sampling and Analysis of Environmental Media for
Massachusetts Registered Medical Marijuana Dispensaries

The Protocol contains the following sections:

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1.0 Purpose and Applicability

1.1 Purpose

The purpose of this protocol is to provide Massachusetts Registered Marijuana Dispensaries (RMDs) with requirements and best practices for the collection, handling, analysis, documentation, review, and reporting of environmental media samples to comply with Massachusetts regulation 105 CMR 725.000, Implementation of an Act for the Humanitarian Medical Use of Marijuana.

This protocol is subject to revision based on evolving best practices, updated scientific information or standards/guidelines, or other information relevant to the contents of the protocol.

1.2 Applicability

This protocol applies only to independent laboratory testing of environmental media (e.g., soils, solid growing media, and water) used in the cultivation of medical marijuana for contaminants by Massachusetts RMDs that have been issued Certificates of Registration. The protocol only addresses potential contaminants to protect the public health, in particular those contaminants from the environmental media which can accumulate in plant materials. All sampling and

analyses described are intended to demonstrate compliance with regulations, requirements, and guidance of the Massachusetts Department of Public Health (DPH) for certification and ongoing operation of a Massachusetts RMD.

Testing described in this protocol is not intended to apply to:

- Hardship Cultivation Registrations
- Measurement of nutrients, pH, or other contributors or detriments to healthy plant growth for cultivation purposes.
- Analysis of materials for disposal as may be required in agricultural or manufacturing practices.
- Testing of medical marijuana plant materials, concentrates/resins, finished marijuana products, or marijuana-infused products (MIPs) for contaminants or active ingredients for labeling, determination of product quality, or protection of public health.
- Real-time testing or monitoring devices, such as temperature or humidity meters that would be inspected by a DPH-appointed RMD inspector.
- Any internal RMD laboratory testing.
- Testing to evaluate or maintain product quality or verify system control.

Additional testing for optimizing cultivation, waste disposal compliance, product labeling, or quality assurance is at the discretion of the RMD. Additional testing performed including that not covered by this protocol is subject to routine inspection.

2.0 Definitions and Acronyms

Italicized terms are those defined in 105 CMR 725.004.

Aeroponics means process of cultivation in an air or mist environment without the use of soil or an aggregate medium and without liquid nutrient solution as a growing medium (i.e., hydroponics).

Certificate of Registration means the certificate issued by the Department that confirms that an RMD has met all requirements pursuant to the Act and 105 CMR 725.000 and is registered by the Department.

Cultivation Unit means soil plots, beds, individual plant containers, hydroponic chambers or other physical locations or equipment where marijuana plants are grown.

Cultivation Soils means soils in place in beds or containers at a RMD having passed initial source soil tests and actively used in marijuana cultivation. This definition excludes piles of soil which have passed initial source soil tests but are stored for future use in cultivation.

Dispensary Agent means a board member, director, employee, executive, manager, or volunteer of an RMD, who is at least 21 years of age. Employee includes a consultant or contractor who provides on-site services to an RMD related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of marijuana.

Environmental Media Evaluation Guides (EMEGs) are estimated contaminant concentrations based on Agency for Toxic Substances and Disease Registry (ATSDR) evaluation that are not expected to result in adverse health effects. EMEGs are based on ATSDR minimum risk levels (MRLs) and conservative assumptions about exposure, such as exposure frequency and duration, intake rate, and body weight.

Field Duplicates means two independent samples taken from and representative of the same material, stored in separate containers, but processed in parallel through all steps of the sampling and analytical procedures. Duplicate samples evaluate variance of the material sampled as well as introduced through the sampling and analysis procedure.

Flowering means the gametophytic or reproductive state of marijuana in which the plant produces flowers, trichomes, and cannabinoids characteristic of marijuana.

Hydroponics means the cultivation of plants in liquid nutrient solutions rather than in soil.

Hardship Cultivation Registration means a registration issued to a registered qualifying patient under the requirements of 105 CMR 725.035.

Marijuana means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; and resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil, or cake or the sterilized seed of the plant which is incapable of germination. The term also includes MIPs except where the context clearly indicates otherwise.

Marijuana-Infused Product (MIP) means a product infused with marijuana that is intended for use or consumption, including but not limited to edible products, ointments, aerosols, oils, and tinctures. These products, when created or sold by a RMD, shall not be considered a food or a drug as defined in M.G.L. c. 94, s. 1.

Massachusetts Maximum Contaminant Levels (MMCLs) means those limits of contaminants included under the drinking water regulations (310 CMR 22.00) promulgated by the Massachusetts Department of Environmental Protection. Under the Drinking Water Program (DWP), Massachusetts may adopt more stringent standards than the US EPA based on an independent review of primary or secondary data

Organic Fertilizer means soil additives derived from natural sources that increase the available plant nutrient content of soil and guarantee a minimum percentage of nitrogen, phosphate, and potash.

Propagation means the reproduction of marijuana plants by seeds, cuttings, or grafting.

Production Area means any limited access area within the RMD where marijuana is handled or produced in preparation for sale.

Public Water System (PWS) means a system for the provision to the public of water for human consumption through pipes or other constructed conveyances that is regulated by EPA or delegated states or tribes under the Safe Drinking Water Act.

Registered Marijuana Dispensary (RMD) means a not-for-profit entity registered under 105 CMR 725.100 that acquires, cultivates, possesses, processes (including development of related products such as edible MIPs, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to registered qualifying patients or their personal caregivers. Unless otherwise specified, RMD refers to the site(s) of dispensing, cultivation, and preparation of marijuana.

Soil Amendment means any material added to a soil to improve its physical properties, such as water retention, permeability, water infiltration, drainage, aeration and structure. Soil amendments do not include materials added to improve nutrients such as organic fertilizers. Soil amendments may include, for example coir, sphagnum peat moss, compost, or manure.

Solid Growing Media means any soil or solid substrate used for the cultivation of rooted marijuana plants. Soil growing media may contain soil and other solid materials amended to or used in replacement of soil including, but not limited to soil, sand, clay, compost, sphagnum peat moss, coir, newspaper, sawdust, perlite, or vermiculite.

Source Soil or Solids means any solid environmental media that originate outside of the RMD and are brought in for the purpose of cultivating medical marijuana.

3.0 Applicable Regulations

This protocol was developed to provide RMDs with guidance on complying with the 105 CMR 725.000 regulations. In particular, the detailed steps outlined in this protocol address requirements of the following sections of the regulations. Although the regulations are mandatory, this protocol includes recommendations to comply with the regulations that are not, themselves, necessarily mandatory. RMDs should be familiar with all applicable regulations to ensure full compliance.

725.105(A)(7)	Requirement of plans for quality control, including product testing for contaminants
725.105 (B)(1)(c-f)	Cultivation, Acquisition, and Distribution Requirements
725.105(C)(2)	Requirements for Handling and Testing Marijuana and for Production of MIPs

725.105(E)(2)	Labeling of marijuana (excluding MIPS)
725.105(E)(3)	Labeling of MIPS
725.105 (D)(1-5)	RMD Storage Requirements
725.105 (J)(1-5)	Waste Disposal
725.300 (E)	Inspection of Registered Marijuana Dispensaries
725.310	Plan of Correction

4.0 Sampling and Analysis Requirements

Sampling and analysis requirements apply to growing media to be used in the marijuana cultivation process, including soil, solid but non-soil growing media and water from public water supply (PWS) or non-PWS sources, such as private wells. This section identifies the types of environmental media sampling and analysis that are required for compliance with the 105 CMR 725 regulations. RMDs must ensure and be able to demonstrate to inspectors, that samples accurately represent cultivation conditions and analysis results accurately determine potential contaminants in all media used. All sampling and analysis is subject to inspection, review, and independent confirmation by inspectors according to the inspection guidelines and regulations.

The environmental media (soil, solids, and water) that must be sampled and analyzed depend on the materials used, previous testing performed on the media, and how the medical marijuana is cultivated. The sampling and analysis frequencies described below are considered the minimum requirements to comply with requirements under 105 CMR 725. Although cultivation generally is anticipated to involve traditional cultivation methods in soils, cultivation can involve solid growing media other than soil or hydroponics. Exhibit 1 illustrates the sampling and analysis requirements by media and cultivation approaches, including solids-based cultivation and hydroponics.

4.1 Solid Growing Media

Solid growing media include all soils including soil amendments or other solid materials used as a substrate for cultivation. Regulation 105 CMR 725.105 (B)(1)(e, f) states that soil for cultivation shall meet the ATSDR Environmental Media Evaluation Guidelines (EMEG) for residential soil levels and limits any pesticide residues. EMEG values have been determined for a number of contaminants of concern. Pesticides not permitted for use in organic agriculture are also prohibited for use in the cultivation of marijuana according to the regulations at 105 CMR 725.105 (B)(1)(d).

All soils and solid growing media must be sampled and analyzed 1) initially prior to use for cultivation of medical marijuana, and 2) at least annually¹, and within the quarter² if amended. Specifically:

- All source soils or solids must be sampled and analyzed prior to use in cultivation and whenever new soils or solids are received from a different source.
- Solid materials used in alternative, non-soil cultivation approaches such as hydroponics including but not limited to clay, rock wool, and vermiculite or other non-soil enhancements must be sampled and analyzed prior to being used for cultivation of medical marijuana and whenever received from a different source.
- All cultivation soils used in beds or containers to actively cultivate marijuana must be sampled and analyzed annually.
- In cases where cultivation soils (or other solid growing media) are amended with additional solid materials (excluding water and nutrient fertilizers), sampling and analysis in the quarter during which the soil was amended is required.

Section 5.1 below describes sample program design considerations for soil/solids. Exhibit 2 below summarizes the sampling frequency and required analyses for solid growing media with specific analytes and levels detailed in Section 7.

4.2 Water

Water used in marijuana cultivation generally requires analysis, however the frequency and sampling and analysis requirements are determined based on whether the water source is from a PWS already subjected to testing requirements and whether the cultivation approach relies on hydroponics. The term water is intended to include aqueous nutrient mixtures such as that used in hydroponic or aeroponic cultivation. Specifically:

- Water derived from a PWS and used in soil or solid growing media cultivation of medical marijuana is exempted from sampling and analysis requirements. If the water is derived from a PWS, the public records of the analysis must be maintained by the RMD and available to inspectors to demonstrate adequate analysis of the water and exemption from analysis.
- Water derived from non-PWS sources must be sampled and analyzed prior to use for cultivation of medical marijuana and quarterly thereafter.
- All water, regardless of source, used in hydroponic cultivation approaches must be sampled and analyzed prior to use for cultivation for medical marijuana and quarterly thereafter, at a minimum.

¹ Annually is determined based on calendar year during which a RMD maintains a Certificate of Registration.

² Quarters are determined based on calendar quarters within the calendar year with Quarters 1, 2, 3 and 4 beginning January 1, April 1, July 1, and October 1, respectively.

While hydroponic systems in particular are likely to require clean-out and analysis more frequently for optimizing cultivation, the quarterly analysis required in this protocol is designed to ensure and document protection of public health. Hydroponic growing systems use re-circulated water, so any additions of fertilizers, other nutrients, or pesticides will build up over time if the water is not somehow cleaned, filtered, or changed. For this reason, water in hydroponic systems must be tested more frequently than water used in soil production. In particular RMDs relying on hydroponic cultivation likely will require more frequent bacteriological sampling and analysis to maintain control of the systems and prevent failure of required testing. However, for that more frequent sampling and analysis, RMDs may utilize internal laboratory analysis. The RMDs are responsible for any and all sampling and analysis required to protect the public health given their expertise and specific knowledge of their cultivation approach and systems.

Section 5.2 below describes sample program design considerations for water sampling and analysis. Exhibit 3 below summarizes the sampling frequency and required analyses for solid growing media with specific analytes and levels detailed in Section 7.

5.0 Sampling Program Design

Sampling and analysis programs implemented by the RMD must meet the requirements of 105 CMR 725 as described in Section 4 as well as represent the best industry practices for protection of public health. The specific sample program design for environmental media at an RMD will depend on the agricultural approach, scale of the cultivation systems, RMD specific procedures, and physical set up of the RMD. In all cases, sample collection, design, and analytical analyses must be capable of demonstrating compliance with applicable regulations. Among these requirements are that the RMD is responsible for ensuring that samples collected and analyzed for compliance are representative (i.e., accurately represent the population of materials actually used). For example, collection of samples from selected containers or source soil piles repeatedly rather than collecting samples representing the actual range of containers or soil sources would be inadequate to comply with the requirements. Collection of water samples from sampling locations that do not represent water applied in cultivation would also be inadequate to comply with the requirements.

This section provides requirements and best practices for sampling program design for solids and water.

5.1 Solid Growing Media

Sources of solid growing media including soils must be sampled and analyzed prior to use in cultivation and, upon any change in the source of solids. Once cleared for use in cultivation, cultivation soils must be sampled and analyzed at least annually and within the quarter that soils are amended. The spatial distribution of samples must be considered to ensure representativeness across the entire cultivation operation. Sampling and analysis frequency, sample locations, and quality control (QC) samples are detailed below.

Minimum Sampling and Analysis Frequency.

Source Soils and Solids

- All source soils and solids shall be sampled and analyzed prior to use in cultivation.
- All source soils and solids shall be sampled and analyzed whenever a new source material is utilized (e.g., different source soil location or different source solid manufacturer).
- All source soils and solids for initial use must be sampled at the rate of one (1) sample per cubic yard of solid media/soil.
- Source soils and solids passing initial testing requirements may be stockpiled for later use without requiring re-analysis unless the stockpile has been contaminated or altered while stored. Situations for re-analysis may include but are not limited to soils that have been amended, mixed with other source soils/solids, subject to pesticide application, used for other purposes, or inundated by flood waters.

Cultivation Soils or Solids

- All cultivation soils and solid materials shall be analyzed at least annually during the calendar year of use. Solids tested initially as source soils or solids prior to use in cultivation do not require retesting until the following year (or quarter if amended as described below).
- If amended, the solid growing media/soil used in cultivation shall be sampled and analyzed during the quarter in which it was amended. Note that soil amendment includes any material added to a soil, including other soils, to improve its physical properties, such as water retention, permeability, water infiltration, drainage, aeration and structure. Note that soil amendment does not include addition of water or fertilizers added solely for nutrients. Materials such as compost or manure that is added for both nutrients and to change the character of the soil and that are added in bulk are considered soil amendments for the purpose of this protocol. Application of soil amendments must be consistent with all requirements of 105 CMR 725.000.
- For cultivation that utilizes beds or other broad area cultivation, solid growing media/soil samples shall be collected at the rate of 1 sample per discrete cultivation unit or at least 1 sample per 100 square feet of soil area for larger discrete cultivation units.
- For cultivation that utilizes individual plant containers (as opposed to beds or in-ground cultivation), solid growing media/soil samples shall be collected from a minimum of 5-percent of the total number of growing containers.

Sample Locations

- Solid growing media samples shall be collected to be representative of the horizontal and vertical conditions of the growing configuration.
- When collected prior to distribution among beds or containers, source soil or solids samples shall be taken to best represent the overall source soils (e.g., collected from different areas and depths of a stockpile).

- Cultivation soil and solid samples shall be collected to represent the broad range of cultivation units, growth stages, and soil and solid types whether from beds or containers.
- Samples shall be analyzed individually as grab samples unless the analysis methods used allow analytical reporting limits to be achieved on composite sample analyses that would demonstrate that any single sample in the composite would not exceed the contaminant limits described later in this protocol. In no case may more than five (5) primary samples be composited into a single sample for analysis. When analyzed as a composite, the laboratory results of the composite must demonstrate that each composite subsample is below the relevant contaminant limits, not just the composite itself. For example if the results of a five sample composite are reported as 1.0 mg/kg, any one subsample (20% of the total composite) could contain up to 5 mg/kg when accounting for the effective dilution of the other four subsamples (i.e., 1 sample at 5 mg/kg + 4 samples at 0 mg/kg = average of 1 mg/kg).
- Composite samples are not recommended but are allowable for RMDs to scale sampling and analysis to fit the cultivation scale and approach. However use of composite samples to demonstrate compliance would require corrective actions on all individual samples should the composite sample fail to achieve acceptable limits on any target analyte (see Section 8.0).

A diagram of the cultivation area, the sampling design, and the horizontal and vertical location of each sample shall be created for each sampling event, and maintained on file for review by inspection authorities.

Quality Control (QC) Samples

Field duplicate samples shall be collected at least annually and one (1) for every twenty (20) field samples of the solid samples collected to provide verification of field and laboratory procedures. Field duplicate samples shall be collected and analyzed for each analytical method performed on the samples. Field duplicate samples will not be identified to the laboratory (blind QC). Blank samples are required to provide important information on potential positive bias on any positive results in field samples.

Equipment rinsate blanks are required whenever non-disposable sampling equipment is used to collection samples at multiple locations such as in source soil testing or testing of hydroponic nutrient solutions. Equipment rinsate blanks must be collected at the rate of one per sampling event per sampling equipment type with at least 1 equipment rinsate blank for every 20 field samples of the same matrix. Where equipment rinsate blanks are not appropriate (i.e., use of disposable sampling equipment, collection of just one sample location, or direct collection into the sampling container), field blanks may be used to evaluate potential for contamination and potential positive bias at the same frequency of 1 per sampling event per sampling equipment type with at least 1 for every 20 field samples of the same matrix.

5.2 Water

Water that is used in both solid-based and hydroponic cultivation techniques shall be sampled and analyzed, although water derived from a PWS source and used in solids-based cultivation only is exempted from all sampling and analysis requirements. Sample locations must take into account both source water and, if utilized, on-site water treatment systems. Sampling and analysis described below is not intended to provide sufficient data for RMDs to manage optimum cultivation operations but rather to protect the public health. Additional sampling and analysis may be required to monitor nutrient levels, determine replacement of hydroponic solutions or water treatment filters, assess compliance with runoff/discharge requirements, or verify purity of waters used in MIPs.

Minimum Sampling and Analysis Frequency

- Non-PWS water that is used in soil or solid-based cultivation methods shall be sampled and analyzed prior to use for cultivation of marijuana and on a quarterly schedule thereafter.
- Water recycled from previous uses or otherwise not directly received from a PWS is considered non-PWS water for the purposes of this protocol.
- Water from a PWS source used in solid-based cultivation is exempt from sampling and analysis provided the RMD maintains publicly available records of the PWS analysis (i.e., the Consumer Confidence Report) and makes these records available to inspectors to demonstrate adequate analysis of the water. The RMD may choose to independently test their PWS water source and maintain the record of these analyses.
- All water used in non-solid cultivation systems including hydroponics requires quarterly sampling and analysis, regardless of whether it is a non-PWS or PWS system. The source water that is used in the hydroponic system shall be sampled and analyzed prior to use for cultivation of marijuana and on a quarterly schedule thereafter.

Sample Locations

- For traditional watering and irrigation of soil or solid based cultivation, water source samples shall be collected from the location as close as possible to the water use.
- In cases where a water treatment system is used, water samples must be collected both before entering and after leaving the water treatment system, as close as possible to the point of use. The sample collected and analyzed after the water leaves the treatment system reflects the water applied to the plants, while the sample collected and analyzed before entering the treatment system characterizes the water source. In cases where several individual water treatment systems are utilized rather than a central system located on a main water line, one sample representing the water source may be collected prior to entering the treatment systems, but separate samples must be collected after the water leaves each different water treatment system used in cultivation. Where multiple water treatment systems require multiple samples, there is no

requirement to collect water samples from different systems during the same sampling event: samples may be staggered throughout the quarter as long as all systems are tested within each quarter of the year.

- For all hydroponic cultivation systems (both closed and open loop systems) and any non-solid based cultivation technique, water samples shall be collected to represent each system independently. There is no requirement to collect all water samples from different systems during the same sampling event: samples may be staggered throughout the quarter as long as all systems are tested within each quarter of the year.
- The sampling design and layout of tanks sampled shall be retained and presented to the inspection authorities. A diagram of all water sampling locations shall be created for each sampling event and maintained on file for review by inspection authorities. Any major changes to the water system since the last sampling event must be noted in sampling design.
- Water samples shall be analyzed individually as grab samples unless the analysis methods used allow analytical reporting limits to be achieved on composite sample analyses that are protective of public health and in line with acceptance requirements. Under no circumstances shall samples collected prior to the water entering a treatment system be composited with samples collected after the water leaves a water treatment system. In no case may more than five (5) primary samples be composited into a single sample for analysis. When analyzed as a composite, the laboratory results of the composite must demonstrate that each composite subsample is below the relevant acceptance limits, not just the composite itself. For example if the results of a five sample composite are reported as 1.0 mg/L, any one subsample (20% of the total composite) could contain up to 5 mg/L when accounting for the effective dilution of the other four subsamples (i.e., 1 sample at 5 mg/L + 4 samples at 0 mg/L = average of 1 mg/L).
- Composite samples are not recommended but are allowable for RMDs to scale sampling and analysis to fit the cultivation scale and approach. However use of composite samples to demonstrate compliance would require corrective actions on all individual samples should the composite sample fail to achieve acceptable limits on any target analyte (see Section 8.0).

QC Samples

Field duplicate samples shall be collected at least annually and one (1) for every twenty (20) field samples of the water samples collected to provide verification of field and laboratory procedures. Field duplicate samples shall be collected and analyzed for each analytical method performed on the samples. Field duplicate samples will not be identified to the laboratory (blind QC). Blank samples are required to provide important information on potential positive bias on any positive results in field samples.

Equipment rinsate blanks are required whenever non-disposable sampling equipment is used to collection samples at multiple locations such as in source soil testing or testing of hydroponic nutrient solutions. Equipment rinsate blanks must be collected at the rate of one per sampling event per sampling equipment type with at least 1 equipment rinsate blank for every 20 field samples of the same matrix. Where equipment rinsate blanks are not appropriate (i.e., use of disposable sampling equipment, collection of just one sample location, or direct collection into the sampling container) field blanks may be used to evaluate potential for contamination and potential positive bias at the same frequency of 1 per sampling event per sampling equipment type with at least 1 for every 20 field samples of the same matrix.

6.0 Sample Collection Procedures

The RMD is responsible for performing sample collection and analysis that is compliant with regulations and capable of representative sample collection and accurate analysis. The following section provides guidance to support RMDs engaged in medical marijuana cultivation to collect environmental media samples for analysis and to package and send the samples to the laboratory. Section 6.1 provides procedures for collecting solid growing media/soil samples, Section 6.2 provides procedures for collecting water samples, and Section 6.3 provides instructions for handling, storing, packaging, and sending the samples to the analytical laboratory. All staff responsible for sample collection and sample handling must be trained in environmental sample collection. RMDs are responsible for maintenance of all training records and provision of the records to inspectors as required. Sampling and analysis staff must understand the sample collection plan, operation of sampling equipment, importance of ensuring representativeness and integrity of the samples, documentation, and chain-of-custody requirements.

6.1 Collecting Samples of Soil or Solid Growing Media

The sampling methods described are generally applicable to collection of soil and solid samples for cultivation methods anticipated to be used by RMDs. Characteristics of certain solid matrices such as cohesionless sands or non-uniformly distributed soil amendments may require adaptation for the specific situation encountered. Generally, samples may be collected from stockpiles or other sources prior to use in cultivation or from cultivation units such as beds or individual containers during ongoing cultivation. Solid growing media samples shall be collected that are representative of the horizontal and vertical conditions of the configuration.

Prior to Sample Collection. The RMD should assemble all equipment and information needed before beginning. Items to assemble before sampling include, but are not limited to, the following:

- Sample collection plan or diagram of locations to ensure representative sample collection

- Logbook or sample collection forms
- Chain-of-custody forms (COCs)
- Disposable gloves
- Decontaminated soil collection tool(s), such as a corer, spatula, or trowel
- Stainless steel bowl and implement to homogenize soil samples
- Clean, decontaminated plastic sheeting or other clean, non-porous surface for sample processing;
- Sample containers appropriate for the analyses required;
- Container labels and pen with indelible ink;
- Supplies to thoroughly clean, decontaminate and dry sampling equipment between samples; and
- A cooler with ice to keep samples cool until refrigeration or shipment to the laboratory.

Sample collection personnel should create a new entry for each sampling event in the sample collection logbook or prepare sample collection forms for documentation of sample collection. Sample collection documentation should identify the sample collection date and start time, participating personnel, a general description of the media and locations sampled, relevant environmental conditions, a description of the sampling procedures and equipment decontamination/cleaning used, and a record of plants or batches that would potentially be impacted should analysis results indicate unacceptable contamination.

Sample collection personnel shall identify or determine the number and location of soil or other solid growing media grab samples to be collected based on the requirements described in Section 5.1. Sample locations from containers, beds, or other cultivation units must be recorded in the sample collection logbook or forms. Record the sample location identifier (location ID) for each sample so that it can be utilized to identify the physical location of the cultivation unit. Location identifiers should be consistent across sampling events to allow tracking of repeated sample locations. The location IDs will be included on sample labels (unless the grab samples are used in a composite sample). In addition to the location ID, create a unique sample ID for each sample. Sample identifiers should be unique for a given sample event. Record the location and sample IDs in the sample collection logbook.

In some cases, a RMD might sample new solid growing media before placing it in cultivation units. In these circumstances, it is not necessary to record the locations within piles where the grab samples are collected. However, it is important to distribute the sample locations spatially so that they are representative of the whole volume of the media.

Any tools that contact the samples should be made of stainless steel or other inert material to avoid potential contamination of the sample. Sample containers should be made of suitable materials for the methods and analytes being analyzed. The sampler should avoid using insect repellents that may interfere with sample integrity.

Preparing sample labels and affixing them to sample containers immediately before sampling is recommended. Information to include on the label includes at a minimum the location and sample ID and date/time of collection. Additional information that must be recorded in documentation if not on the label includes sample collector's name, media type, collection method, whether the sample is a grab or composite sample, and soil or core depth (if applicable).

Sample Collection. Collect the planned samples from each sample location one at a time. Follow these basic steps for each sample:

1. Don gloves to mitigate potential for contamination of samples
2. Spread clean, decontaminated plastic sheeting or other nonporous surface near the sample location and lay out any tools and equipment needed.
3. Clear the surface of the location if necessary excluding detritus, dead leaves, stones, pebbles, or other debris from the soil or other solid growing media with a clean trowel or similar tool.
4. Collect the sample using an appropriate tool. Do not touch the sample with your hands or allow the sample to touch anything that might cause contamination.
5. Place the sample in the stainless steel bowl for homogenizing the sample using either the sample collection tool or separate clean, decontaminated implement.
6. Record the time each sample was collected and record any difficulties, inconsistencies with the sampling plan, or other remarks (e.g., environmental conditions) that might be relevant to data analysis or quality assurance.
7. To avoid cross contamination of samples, any tools or equipment that come in contact with the soil or growing media must be cleaned before moving to the next sampling location.
8. All samples should be placed in clean, airtight sample containers that are large enough to hold the prescribed sample quantity with minimal headspace. Sample containers must be firmly closed and appropriately labeled.
9. If grab samples are planned, place the homogenized sample into the appropriate container(s).
10. If the sample is to be composited with other locations, repeat the above steps to collect the other individual samples to be placed into the stainless steel bowl. Once the planned primary samples are collected, thoroughly homogenize the samples contained in the stainless steel bowl and place the homogenized composite sample into the appropriate container(s).

11. Excess soil collected but not shipped to the laboratory for testing should be returned to the cultivation area(s) where it was collected from (composite soils may be spread among the primary sample locations). It is not necessary to send the entire volume of the combined primary samples to the laboratory.
12. Samples should be refrigerated or maintained on ice until shipped to the analytical laboratory.
13. Chain-of-custody paperwork should be completed immediately prior to shipment.

6.2 Collecting Water Samples

The following sampling methods are generally applicable to collection of water samples for cultivation methods anticipated to be used by RMDs. Some RMDs may need to adapt the procedures described below to account for facility-specific design and operating details. It is the responsibility of the RMD to ensure, and be able to demonstrate to inspectors, that samples are fully and accurately representative of the presence of contaminants in the water or other aqueous media used. Generally samples may be collected from taps, spigots, hoses, or other connectors from water lines where the water is used for crop cultivation. In cases where RMDs operate purification or treatment systems, it is important to characterize both the untreated and treated water to document both expected contaminants that might be introduced into cultivation as well as the maximum or untreated levels. Water samples shall be collected to be representative of the process and water quality throughout the time period of sampling, although composite samples are not required. To achieve representativeness, samples should not be collected during any periods of unusual activity such as draining of water lines, immediately after changing treatment cartridges or replenishing of hydroponic nutrient solutions.

Prior to Sample Collection. The RMD should assemble all equipment and information needed before beginning. Items to assemble before sampling include, but are not limited to, the following:

- Sample collection plan or diagram of locations to ensure representative sample collection
- Logbook or sample collection forms
- Chain-of-custody forms (COCs)
- Disposable gloves
- Clean, decontaminated plastic sheeting or other clean, non-porous surface for sample processing;
- Sample containers appropriate for the analyses required;
- Preservatives as required for the analyses or pre-preserved containers
- Supplies (such as pH paper or meter) to verify adequate preservation
- Container labels and pen with indelible ink;

- Supplies to thoroughly clean, decontaminate and dry sampling equipment between samples; and
- A cooler with ice to keep samples cool until refrigeration or shipment to the laboratory.

Sample collection personnel should create a new entry for each sampling event in the sample collection logbook or prepare sample collection forms for documentation of sample collection. Sample collection documentation should identify the sample collection date and start time, participating personnel, a general description of the media and locations sampled, relevant environmental conditions, a description of the sampling procedures and equipment decontamination/cleaning used, and a record of plants or batches that would potentially be impacted should analysis results indicate unacceptable contamination.

Sample collection personnel shall identify or determine the number and location of water samples to be collected based on the requirements described in Section 5.1. Sample locations must be recorded in the sample collection logbook or forms. Record the sample location identifier (location ID) for each sample so that it can be utilized to identify the physical location of the sample location within the RMD. Location identifiers should be consistent across sampling events to allow tracking of repeated sample locations. The location IDs will be included on sample labels (unless the grab samples are used in a composite sample). In addition to the location ID, create a unique sample ID for each sample. Sample identifiers should be unique for a given sample event. Record the location and sample IDs in the sample collection logbook or forms as well as the volume of the sample, preservation, and associated sample containers.

Any tools that contact the samples should be made of stainless steel or other inert material to avoid potential contamination of the sample. In addition, all tools that come in contact with the sample media should be rinsed with deionized water between samples to reduce potential cross contamination. Sample containers should be clean and dry, and made of suitable materials appropriate for the methods and analytes being analyzed.

Preparing sample labels and affixing them to sample containers immediately before sampling is recommended. Information to include on the label includes at a minimum the location and sample ID and date/time of collection. Additional information that must be recorded in documentation if not on the label includes sample collector's name, media type, collection method, whether the sample is a grab or composite sample, and preservation (if applicable).

Sample Collection. Collect the planned samples from each sample location one at a time. Follow these basic steps for each sample:

1. Don gloves to mitigate potential for contamination of samples
2. Spread clean, decontaminated plastic sheeting or other nonporous surface near the sample location and lay out any tools and equipment needed.

3. Prepare the sample location by removing faucet aerators if connected. Note the location of any water treatment systems and remove if required to represent pre-treatment location.
4. For sample collection of water lines, purge the lines of standing water and note purge time in sample collection documentation. Generally for frequently used water 15 minutes run time is considered sufficient but actual time for purge depends on pipe volume and frequency of use. Note that pressurized lines may require additional system specific procedures. Sample collection personnel may monitor parameters including but not limited to temperature, pH, or turbidity for stability to assess sufficiency of purge.
5. For collection of water samples from tanks or other holding bins without valves or taps such as in some hydroponic systems, dip sampling may be used. However sample collection staff should be aware of potential for vertical distribution of additives and strive to take a sample representative of the overall tank or trough. In cases where contaminants of concern may be stratified and not distributed uniformly throughout a container, a discrete depth sampler such as a Kemmerer or van Dorn sampler may be recommended.
6. Open the pre-labeled sample containers appropriate for the analyses taking care to not allow errant drips or splashes off other surfaces to enter the caps or containers.
7. Samples for all analyses may be collected directly into sample containers or into a larger, inert vessel then poured into containers. During sample collection, make sure that the tap or spigot does not contact the sample container.
8. If water samples are to be composited to represent multiple hydroponic systems, repeat the steps above to collect the primary samples. The individual, primary samples should all be collected as unpreserved samples then combined volumetrically into a single composite sample.
9. Record the time each sample was collected and record any difficulties, inconsistencies with the sampling plan, or other remarks (e.g., environmental conditions) that might be relevant to data analysis or quality assurance.
10. Add preservatives according to the analytical methods as required.
11. Fill an extra sample container to verify adequate preservation and/or residual chlorine as required by analytical methods.
12. If a non-disposable sample collection tool other than the sample container (larger inert vessel, ladle, Kemmerer sampler, van Dorn sampler) is used, rinse the tool with deionized water between samples.
13. Excess sample collected but not shipped to the laboratory for testing should be disposed of properly recognizing that preserved samples may require disposal as hazardous materials. It is not necessary to send the entire volume of the combined primary samples to the laboratory.
14. Samples should be refrigerated or maintained on ice until shipped to the analytical laboratory.

15. Chain-of-custody paperwork should be completed immediately prior to shipment.

6.3 Sample Handling

After samples are properly collected and labeled, they should be delivered for analysis as soon as possible. This section describes how to handle, securely store, package, and ship the samples to the laboratory.

- Sample containers both empty and once containing samples should be stored in a contaminant-free environment to the degree possible. Sample containers should not be stored for more than one (1) year.
- Preservatives and pre-preserved sample containers may degrade after several months. Contact the laboratory to verify limits on sample container use.
- All samples should be collected and stored in containers of the appropriate materials based on the analysis method being performed.
- Until the samples are analyzed, they should be preserved to minimize chemical or physical changes according to the analytical method references.

Sample Storage.

- Samples should be refrigerated or maintained on ice (4 °C +/-2°C) until they are shipped to the analytical laboratory.
- Placing the samples in airtight containers with minimal headspace preserves samples by minimizing moisture loss and chemical exchange between the sample medium and air.
- In addition, protect the samples from excessive light exposure to minimize photochemical degradation. Samples can be protected from light by using an amber sample container, storing the samples in a closed box or other amber container, or in a dark storage location.
- To be considered valid, all samples must be analyzed prior to expiration of the technical holding time as defined in each analytical method. Note that the holding time for some biological components is very short; 24 to 48 hours from the time of collection,
- Note that all collected samples are considered under the custody of sample collection staff following collection and prior to shipment. Samples should be maintained either under the supervision of someone responsible for the integrity of the samples or locked to prevent mishandling.
- Chain of custody seals may be used by sample collection staff to ensure that samples are not tampered with following sample collection.

Packing and Shipping Samples. Many laboratories provide specific shipping or courier instructions to follow. In the absence of specific instructions from the laboratory, the following instructions, which are based on U.S. EPA (2002) guidance, may be used.

- Package the samples for shipping in a clean area free of contamination.

- Make sure that sample containers are clean, lids are tight and will not leak and that all samples are properly labeled as described above. Covering labels with clear tape is recommended for protection in the event of a leak or damage to the package.
- Conduct an inventory of sample IDs against the chain-of-custody documentation form to make sure that all samples and containers are present.
- Seal sample containers in clear plastic bags with labels visible.
- If the samples need to be kept cold during transport, pack the samples in a clean waterproof metal or hard plastic ice chest or cooler with double-bagged ice or ice packs. Samples should be maintained at 4 °C +/-2°C at all times. Be sure that the samples are already cool when packaged for shipping.
- When samples are shipped in a cooler, line the cooler with plastic (e.g., large heavy-duty garbage bag) before packing. If the cooler has an external drain, make sure it is plugged.
- Include noncombustible absorbent packing materials to protect the samples from damage.
- Enclose chain-of-custody forms and any other necessary documentation in a sealed waterproof plastic bag. If applicable, include instructions or a shipping label for return of the cooler.
- Remove the old shipping labels, if any, and seal the cooler, or other container, with strapping tape.
- Use package tracking, if available from the shipper.

7.0 Sample Analysis

All sample analyses described in this protocol shall be conducted by an independent laboratory that is either:

1. Accredited to International Organization for Standardization (ISO) 17025 by a third party accrediting body such as A2LA or ACLASS, or
2. Certified, registered, or accredited by an organization approved by the Massachusetts Department of Public Health.

For non-potable or potable water, any laboratory certified by the Massachusetts Department of Environmental Protection for analysis of the appropriate analytes and methods outlined in this protocol is acceptable to MDPH.

<http://www.mass.gov/eea/agencies/massdep/water/drinking/certified-laboratories.html>

For soils/solids, any laboratory certified by a National Environmental Laboratory Accreditation Program (NELAP) accrediting authority (e.g., currently, there are 13 individual states that are accrediting authorities, including New Hampshire and New

York) to conduct soils/solids testing for the appropriate analytes and methods outlined in this protocol is acceptable to MDPH.

<http://www.nelac-institute.org/>

Further requirements concerning the eligibility and responsibilities of analytical laboratories are provided in 105 CMR 725.105(C)(2).

In addition to the regulatory qualifications and requirements referenced above, the laboratory should have a demonstrated ability to perform the specific analytical methods required and to provide defensible documentation and quality assurance.

Exhibits 4 and 5 identify the analytical methods and analyses required for solid growing media and aqueous samples. For soils/solids, available ATSDR Environmental Media Evaluation Guidelines (EMEGs) are shown. EMEGs are required for concentration limits for soils/solids when they are available (105 CMR 725.105 (B)(1)(e, f)). Not all analytes listed in Exhibit 4 had available EMEGs. In those cases, DPH chose to use available ATSDR Cancer Rate Evaluation Guidelines (CREGs). If neither EMEGs nor CREGs were available, DPH chose to use US EPA Residential Soil Level (RSL) guidelines. Note that frequency of sample collection and conditions under which the analyses are required is covered in previous sections of this protocol.

Reporting limits are recommended based on the capabilities of appropriate methods.

All waters must demonstrate that waters used for cultivation meet the acceptable limits of the most recently promulgated Massachusetts Maximum Contaminant Levels (MMCLs) for metals, bacteriological, and pesticide residues.

8.0 Data Evaluation

RMDs are required under 105 CMR 725.105(C)(2)(c) to “have and follow a policy and procedure for responding to results indicating contamination, which shall include destruction of contaminated product and assessment of the source of contamination.” The analytical results provided by the laboratory, including those for environmental media samples discussed in this protocol, will be the primary means for RMDs to ensure compliance with this requirement.

The laboratory results shall include the following in the laboratory data package at a minimum.

- Case Narrative:
 - The narrative, written on laboratory letterhead, shall describe any sample receipt, preparation, or analytical issues encountered as well as any method nonconformances or exceeded QA/QC criteria.
 - The narrative shall identify the preparation and analytical methods utilized by the laboratory.

- The narrative shall include a signed statement by an authorized laboratory representative as to the accuracy, completeness, and compliance with the methods of the results presented.
- Chain of Custody information or other paperwork indicating requested analyses and documentation of sample collection and receipt.
- Summary of analytical results of samples including sample identifier, methods performed, target analytes analyzed for, result or reporting limit, proper qualifier according to laboratory standard procedures, units of measure, preparation date(s), where applicable, and analysis date(s).
- Complete final method verification and validation report with the data.

It is highly recommended that the laboratory data package also include sufficient data to evaluate the laboratory results including a summary of laboratory QA/QC results. The type of QA/QC results applicable differ by analysis method but can include surrogates or deuterated monitoring compounds, laboratory QC samples such as spikes, blanks, and duplicates, and calibration summaries. It is the responsibility of the RMD to maintain and provide upon request information sufficient to demonstrate that results are accurate and precise in accordance with method capabilities and program requirements.

Depending on the outcome of the analysis, the RMD may need to take action to address unacceptable levels of contamination or to perform follow-up investigation. Exhibits 6 and 7 describe the decision course of action the RMD should use in response analysis results. As discussed above, if any analysis fails to meet acceptable limits or data quality review demonstrates that the results are unreliable, then the suitability of the media for use in medical marijuana production cannot be confirmed. Media that are confirmed by a valid analysis to exceed acceptable levels of any contaminant shown in Exhibits 4 and 5 prior to use in cultivation of medical marijuana cannot be used in such cultivation until acceptable levels are demonstrated to be achieved (see Exhibit 6). If quality review demonstrates that results are not reliable then the media cannot be used until reliable results are obtained. Media that are confirmed by a valid analysis to meet all concentration limits can be used in the cultivation of medical marijuana.

As shown in Exhibit 7 the RMD is not necessarily required to discard marijuana plants or medical products derived from routine testing or testing after soil amendments solely due to media levels above acceptable levels. If finished medical marijuana products and MIPs are tested directly before they are to be dispensed and demonstrate levels of contaminants within the acceptance limits for those products, discarding or destruction of products or plants may not be required. Where environmental media fail ongoing monitoring acceptance limits, resulting products from those cultivation batches may only be used where analysis results of representative finished materials, intermediate products, and/or MIPs are tested and confirmed to be below acceptance limits for that product as defined in the companion protocol. As required

by 105 CMR 725.105(C)(2)(b), the RMD must maintain the results of all testing for no less than one year. These records must be available for inspection by DPH, upon request (105 CMR 725.105(I)), and maintained at the RMD's expense in a form and location acceptable to DPH for at least two years after closure (105 CMR 725.105(I)(7)).

9.0 References

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