

# Licensing Analytical Laboratories for Sampling and Testing Cannabis

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# Creating Regulations for Cannabis Labs

- Not federally legal so no standard regulations for testing
- Basic analytical chemistry with a different matrix
- RI Regulation followed closely to Licensing Analytical Laboratories
  - Key contributor – Dr. Henry Leibovitz, RIDOH Lab - Chief of Environmental Section (retired - August 2023)
- Reviewed other state's regulations and various publications at the time and adjusted to Rhode Island's uniqueness of being a small state:
  - Require Indoor Grow Only (DBR Regulation)
  - Require Laboratories to perform the SAMPLING as well as TESTING
- September 2015 Original Regulation Promulgated
- September 2023 Revised Regulation Promulgated

# Sampling Requirements

- Registered lab agents collect representative samples of each production batch to test each regulated parameter.
  - Representative sample is defined as 0.3-0.5% of the batch size collected from various location of the bin/container.
- Samples are collected in the grow facility's controlled environment
  - Lab agents are usually gowned in Tyvek suits.
  - Use sterile techniques and sterile equipment(forceps, jars, etc)
  - Balances are checked for accuracy using certified weights.

# Testing Requirements

- Cannabis finished plant material including resins, kief and hashish
  - Potency - D9-tetrahydrocannabinol(D9-THC), D8-tetrahydrocannabinol(D8-THC), tetrahydrocannabinol acid (THCa), cannabidiol (CBD) and cannabidiolic acid(CBDa).
  - Microbiology – total viable aerobic bacteria, total coliforms, bile tolerant gram-negative bacteria, pathogenic E.coli, Salmonella, yeast and mold
  - Water Activity
  - Pesticides – residues of pesticides and growth regulators.
  - Metals - Arsenic, Cadmium, Lead, Mercury

# Testing Requirement continued..

- Cannabis extracts, resins, concentrates as-is or as components of Cannabis Infused Products(CIPS):
  - Potency - D9-tetrahydrocannabinol(D9-THC), D8-tetrahydrocannabinol(D8-THC), tetrahydrocannabinol acid (THCa), cannabidiol (CBD) and cannabidiolic acid(CBDa).
  - Solvents – residual solvent from production process.
  - Pesticides - residues of pesticides and growth regulators.
  - Metals - Arsenic, Cadmium, Lead, Mercury

# Testing Requirements continued..

- Cannabis Infused Products (CIPs)
  - Potency - D9-THC, D8-THC, THCa, CBD, CBDa
    - Potency testing of infused products may be waived if the potency of manufactured cannabis infused products remains consistently uniform from manufactured batch to batch.
    - The labs are certifying the “active ingredient” (extract/oil/concentrate) that is used for manufactured CIPs.
    - DBR approves the “recipe” for manufactured CIPs.

# Testing Requirements continued..

- Industrial Hemp and Hemp Products
  - According to USDA Establishment of a Domestic Hemp Production Program 7 C.F.R Part 990 Subpart B – State and Tribal Hemp Production Plans as incorporated in §§ 6.3© of this Part.
  - Testing for THC, CBD, and/or other material characters such as pesticides, heavy metals, and microbial concentration of a dry weight or per volume basis upon direction from DBR, The Rhode Island Department of Environmental Management (DEM) or RIDOH as applicable, as stated in § 230-RICR-80-10-1.9(D)(1)(a).

# RIDOH Licensing program ensures labs are Proficient and Their Data is Valid

- Qualified Personnel (All employees who handle Cannabis must have a testing agent card)
- Annual Blind Performance Evaluations for every test and every analyte
- Quality Assurance Manual (Sample handling, instrument calibrations, data reduction, PMs, internal audits, MDLs, Emergencies)
- Quality Control Program (Blanks, +/- Controls, Duplicates)
- Laboratory equipment (thermometers, weights, balances, pipets) are certified by qualified agencies. (NIST-National Institute of Standards & Technology) and checked regularly.
- RIDOH Approved Standardized Procedure Manuals (SOPs)
- Round Robin Testing (observed by RIDOH personnel)
- On-Site Audit by RIDOH Personnel (either scheduled or when necessary) to determine that the lab follows its SOP. (Lab says what they do and do what they say)
- All Data is collected in the State Seed to Sale tracking system - METRC



# Challenges

- Testing before licensing vs licensing before testing (Chicken or the Egg)
  - Regulation promulgated but must prove they are qualified and produce accurate results for each regulated parameter prior to being approved to test it for cannabis certification.
  - Rolled out enforcement whereby once a lab was approved, DBR would begin enforcement usually allowing time for the products to go through a grow cycle and preliminary testing.
  - Many pesticides have been added in current regulations. We are asking laboratories to obtain approval to test them. No enforcement for testing these additional pesticides in cannabis until the licensed laboratories are approved for them.

# Questions