Materials for 11/21/2024 Meeting

DCC is proposing updates to its laboratory testing regulations. The proposed regulatory package will update the Department's laboratory regulations to address regulatory loopholes, areas of confusion that lead to non-compliance, and emerging issues.

*Items marked with ** were previously recommended by the Cannabis Advisory Committee*

15700 – Definitions

- **New**
  - Add definitions for audit trail, Delta-8 THC, Delta-10 THC, percent accuracy, reference lab, sample injection, THCV, THCVA.
- **Clarifying**
  - Update definitions for: Certified Reference Material (CRM), Laboratory Control Sample, Matrix spike sample, Representative sample, and total THC calculations.

15701. General Laboratory License Requirements.

- **New**
  - Adds Vitamin E acetate to the list of testing for which a licensed lab must maintain ISO/IEC 17025 accreditation.

15702. Laboratory License Application.

- **Clarifying**
  - Add Vitamin E acetate to the existing requirement that laboratories must submit a valid certificate of accreditation with the application.
  - Add specific reference to the criteria in 15711 into the standard operating procedures for test methods.
  - Add specific reference to the criteria in 15713 into method validation reports for testing methods.
  - Add specific reference to the criteria in 15704 for the standard operating procedures for the sampling of cannabis or cannabis products.

15706 – Chain of Custody

- **New**
  - Require that the sampler affix one package tag directly to the COC form and the corresponding package tag to the packaged sample at the time the batch is sampled for compliance testing. (This will ensure there is a direct reconciliation of the UID in the system, the UID on the physical sample, and the UID on the COC document.)

15708 – Cannabis Product Batch and Pre-Roll sampling

- **Clarifying**
  - Add clarification that each sample increment consists of 1 packaged unit in its final form. This is important for testing because sometimes the rolling paper is what has the contaminants on it.

15713 – Validation of Test Methods

- **Clarifying**
  - Update two FDA guidance reference documents to the most current one (3rd edition).
  - Update the number of target organisms, and non-target organisms, to 5 species reported for microbial analyses of samples.
  - Update the requirements for validating test methods for chemical analyses of samples.
  - Require a narrative describing the experimental approach, laboratory acceptance criteria, and conclusions regarding each criterion listed in section 15713(b) for a microbial method validation report or 15713(c)(1) for a chemical method validation report.
  - Require validation reports to include raw data and instrument raw data, for each test method, printed directly from the instrument.
  - Require validation reports to include the signature of the supervisory or management laboratory employee who reviewed and approved the validation report for each test method and the date the report was signed.
  - Require that prior to the use of new test methods or altered test methods, the licensee must submit a validation report to the Department for review and approval.
- **New**
  - Require licensed laboratories to use at least one (1) representative matrix each for dried flower, inhalable cannabis concentrates, and edible cannabis products when validating test methods for chemical analyses of samples. **
  - Require licensed laboratories to analyze all required laboratory quality control samples specified in section 15730 with each analytical batch, when validating test methods for chemical analysis of samples.
  - Add Vitamin E Acetate to the list chemical analysis that must be done using certified reference materials.
  - Add calibration point accuracy and acceptance criteria i.e. 50-150% for the lowest calibration point, 70-130% for all other calibration points. (This is basic scientific principle to calibrate instrumentation appropriately.)
  - Establishes the criteria that the Department will use to approve and review test method validations.

15715 –Vitamin E Acetate Testing

- **New**
  - Require licensed laboratories to analyze at minimum 0.25 grams of the representative sample of an inhalable cannabis product to determine whether vitamin E acetate is present.
  - Sets the action levels for vitamin E acetate at 1.0 µg/g.
  - Includes a six-month delayed implementation for testing requirements in order for labs to develop and validate test methods and for the Department to approve the methods.

15719 – Residual Pesticides Testing – *PLACEHOLDER*

The Department of Pesticide Regulation (DPR) is finalizing recommendations to DCC regarding pesticide residues pursuant to Business and Professions Code section 26060(c). Upon receipt from DPR, DCC will review the recommendations in accordance with Business and Professions Code section 26100(d)(2) and propose any amendments to section 15719 that are determined to be necessary for consistency.

15720 – Microbial Impurities

- **New**
  - Set minimum incubation time of 24 hours. **
  - Require sterile sample prep techniques.
  - Require identification of the particular aspergillus species on the COA.

15724 – Cannabinoid Testing

- **Clarifying**
  - Clarify that the testing of the cannabinoid profile must include CBDA, CBD, CBG, CBN, THC, delta-8 THC, delta-10 THC, THCA, THCV, and CBC. It must also include a percentage and weight or volume measurement for each tested cannabinoid.
- **New**
  - Add specification as to what is deemed acceptable variance and what is deemed inaccurate when a licensed lab's testing is compared to the reference lab. Currently there is no explicit threshold. This change will establish a standard for potency inflation.

15726 – Certificate of Analysis (COA)

- **New**
  - Require Metrc Testing Sample UID be included on the COA. This will connect the sample collection, the chain of custody, and the COA.
  - Prohibit the use of alternative calculations for cannabinoid analyte concentration results.

15729 – Lab Quality Assurance (LQA) Program

- **Clarifying**
  - Require LQA manual to include standard operating procedures for each step of the testing process.
  - Laboratory training must now include integration training.
- **New**
  - Require all analytical equipment to include audit trail documentation capabilities. Each user of the analytical instrument must have a unique username and password. Usernames and passwords may not be shared between laboratory employees. If any paper records are created during testing, the transcription of those records must be reviewed by another laboratory employee and approved by a supervisory or management employee.

15730 – Laboratory Quality Control (LQC) Samples

- **Clarifying**
  - Define peak requirements, including specific signal to noise requirements.
- Continuing Calibration Verification (CCV) clarification to LQC sample section (i.e. every 10 'sample injections, and at the end of each analytical sequence)
  - Strengthen section (g) (see below) to avoid the labs from re-prepping and passing the failed sample. Add Initial Calibration Verification (ICV) and Calibration Curve Point to QC sample methods along with their respective acceptance criteria and corrective actions.
- **New**
  - Laboratories must have a valid calibration curve that meets the requirements of section 15713, for each chemical analysis.

15731 – Limit of Detection (LOD) & Limit of Quantitation (LOQ) for Quantitative Analyses

- **Clarifying**
  - Eliminates the ability for labs to choose from a variety of methods to establish LOD. Require labs to use the specified calculation only. **
  - Clarify that for chromatographic analyses, the LOD must have a minimum signal-to-noise ratio of 3:1, and must verified by visual inspection. For non-chromatographic analyses, the LOD must have a minimum signal-to-noise ratio of 3:1, and must verified by software analysis or mathematical calculation.
  - Clarify that for chromatographic analyses, the LOQ must have a minimum signal-to-noise ratio of 10:1, and must verified by visual inspection. For non-chromatographic analyses, the LOQ must have a minimum signal-to-noise ratio of 10:1, and must verified by software analysis or mathematical calculation.
  - Specify that If the LOD or LOQ is outside the specified acceptance criteria, the laboratory shall remedy the problem until the result is within the acceptance criteria.

15733 – Required Proficiency Testing.

- **Clarifying**
  - Clarify that proficiency testing programs must be completed within one calendar year.
  - Add Vitamin E acetate to the list of proficiency tests a licensed laboratory must participate in.

15737 – Supervisor or Management Responsibilities and Qualifications.

- **New**
  - Adds "reviewing and approving of COAs" to the list of duties of the laboratory supervisor or manager.
  - Require a lab to notify the Department when a new supervisor or management-level employee is hired and to provide evidence of the individual's qualifications.