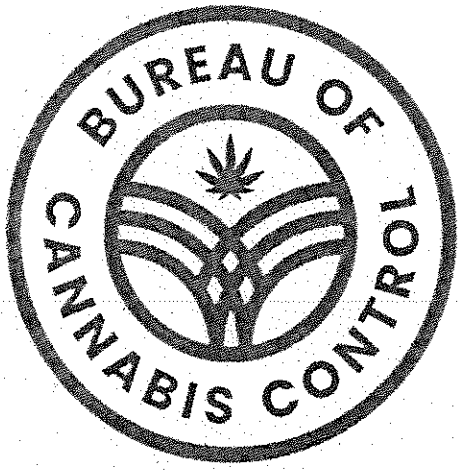
BUREAU OF CANNABIS CONTROL

DISCIPLINARY GUIDELINES



NOVEMBER 2017

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I. INTRODUCTION

Pursuant to Business and Professions Code section 26011.5, the protection of the public is of the highest priority for the Bureau of Cannabis Control (Bureau). In keeping with its mandate to protect the public, the Bureau has adopted these recommended uniform guidelines in order to promote consistency in disciplinary orders for similar offenses on a statewide basis. This document is intended for use by those involved in the administrative disciplinary process (e.g., Administrative Law Judges (ALJ), Deputy Attorneys General (DAG), Bureau licensees and their legal counsel, and other interested parties), and may be revised from time to time, and distributed to interested parties upon request.

The Bureau requests that the suggested disciplinary orders contained in these guidelines be levied consistently and appropriately, based on the nature and seriousness of the violation(s) confirmed in an administrative action. The Bureau recognizes that mitigating or aggravating circumstances, in addition to other factors, may necessitate departure from these recommended orders and terms of probation. If there are any deviations from the guidelines, the Bureau requests that the ALJ hearing the matter include an explanation in the Proposed Decision so that the circumstances can be better understood and evaluated by the Bureau before final action is taken.

Additionally, these guidelines only apply to formal administrative disciplinary processes. These guidelines do not apply to other alternatives available to the Bureau, such as administrative citations and fines, except in cases where an Accusation has been filed against a registrant or licensee for failure to pay an assessed administrative fine and/or comply with an order of abatement issued by the Bureau.

II. FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

In determining whether revocation, suspension, probation, fine, or a combination is to be imposed in a given case, factors such as the following should be considered:

1. Nature and severity of the act(s), offenses, or crime(s) under consideration.
2. Actual or potential harm to the public.
3. Actual or potential harm to any patient.
4. Prior disciplinary record.
5. Number and/or variety of current violations.
6. Mitigating evidence.
7. Rehabilitation evidence, including but not limited to, a statement of rehabilitation containing any evidence that demonstrates fitness for licensure, or a certificate of rehabilitation under Penal Code section 4852.01.
8. In case of a criminal conviction, compliance with conditions of sentence and/or court-ordered probation.
9. Overall criminal record.
10. Time passed since the act(s) or offense(s) occurred.
11. If applicable, evidence of expungement proceedings pursuant to Penal Code Section 1203.4.

III. DISCIPLINARY GUIDELINES

The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) specifies the offenses for which the Bureau may take disciplinary action. Following are samples of the codes and regulation numbers, titles of the offenses and the associated Bureau determined disciplinary recommendations. When filing an accusation, the Bureau or Office of the Attorney General are not limited to the violations listed herein. They may also cite any and all additional related statutes and regulations violated not listed below. The following is ***not*** a comprehensive list of potential violations and in no way, should limit the Bureau or the Attorney General's Office from asserting any relevant and applicable violation. The Bureau suggests that for cases with multiple violations, suspensions or other disciplines run concurrently. All standard terms of probation as stated herein shall be included for all probations.

As used herein, statutes and regulations are referenced as follows:
Business and Professions Code: (B&P)
Title 16, California Code of Regulations: (CCR)
Penal Code: (PC)

California Code of Regulations Disciplinary Order Guidelines - Tier 1

Minimum: revocation stayed, 5 to 15-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

Maximum: revocation

Tier 1 discipline is recommended for:

- violations which are potentially harmful

Violations of the following codes are representative of this category:

Violation Description	Authority
Failure to Surrender License	B&P § 119 (d) CCR § 5022
Failure to Notify the Bureau of Changes	CCR § 5023
Unauthorized Modification of Licensed Premises	B&P § 26055(c) CCR § 5027
Prohibited Commercial Cannabis Activity Between Medicinal and Adult-Use Licensees	CCR § 5032(b)
Unauthorized Storage of Inventory	CCR § 5033
Failure to Maintain Records	B&P § 26160 CCR §§ 5037(a), 5310, 5426, 5505-5506
Allowing the Unauthorized Use of the Track and Trace System and Failing to Maintain Track and Trace System Requirements	CCR §§ 5048-5050 and 5052
Failure to Properly Display and Post License	CCR § 5039

Failure to Comply with Advertising and Marketing Requirements	B&P §§ 26151- 26152 CCR §§ 5040-5041
Failure to Ensure Restricted Access to Limited-Access and Other Restricted Areas	B&P § 26070 CCR §§ 5042 and 5401
Failure to Comply with Security Requirements	CCR §§ 5043-5047 and 5403(b)(1)-(2)
Failure to Comply with Proper Cannabis Destruction and Waste Management	CCR §§ 5054-5055 and 5410(e)
Unauthorized Storage of Cannabis Goods and Storage-only Services	CCR §§ 5033 and 5300-5302
Failure to Comply with Packaging and Labeling Requirements	B&P § 26070 CCR §§ 5303 and 5412
Failure to Comply with Insurance Requirements	CCR § 5308
Failure to Comply with Inventory Documentation and Reconciliation Requirements	CCR §§ 5051, 5309 and 5423-5424
Failure to Comply with Transportation Requirements of Cannabis Goods	B&P § 26070 CCR §§ 5311-5312
Failure to Comply with Transport Personnel Requirements	CCR § 5313
Unauthorized Use of Distributor Transport Only License	CCR § 5315
Failure to Comply with Shipping Manifest Requirements	B&P §§ 26067 and 26070 CCR § 5314
Unauthorized Hours of Operation	CCR § 5403(a) and (b)(3), and 5422(b)
Unauthorized Sale of Cannabis Plants	CCR § 5408(a)-(b)
Use of Pesticide on Live Plants	CCR § 5408(c)
Unauthorized Furnishing of Free Cannabis Goods	CCR § 5411
Failure to Comply with Exit Packaging Requirements	B&P § 26070.1 CCR § 5413
Failure to Comply with Delivery Requirements	CCR §§ 5415-5418 and 5421
Failure to Provide Delivery Request Receipts	B&P § 26090 CCR § 5420
Unauthorized Receipt of Inventory Shipment	CCR § 5422
Failure to Record Sales to Customer	CCR § 5425
Failure to Comply with Requirements for Temporary Cannabis Event License	CCR § 5600 et seq.
Non-Permitted Use of License	B&P § 119(b)-(f)
Failure to Comply with Local Ordinance Regulating Commercial Cannabis Activity	B&P § 26030(f)
Failure to Comply with Operating Procedures	B&P § 26030(j)
Sale of Alcohol or Tobacco Products	B&P § 26054(a)
Failure to Record Commercial Cannabis Activity on Sales Invoice or Receipt	B&P § 26161
Failure to Exercise Care for Safety of Self or Others Due to Being Under the Influence of an Intoxicating Substance	PC § 647(f)

California Code of Regulations Disciplinary Order Guidelines - Tier 2

Minimum: revocation stayed, 15 to 30-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

Maximum: revocation

Tier 2 discipline is recommended for:

- Violations with a serious potential for harm
- Violations which involve greater risk and disregard of public safety

Violations of the following codes are representative of this category:

Violation Description	Authority
Exceeding License Privileges for Commercial Cannabis Activity	B&P §§ 26050 and 26053
Unauthorized Use and Operation of Designated Premises	CCR § 5025
Subletting of Premises	CCR § 5028
Failure to Comply with Track and Trace Reporting and System Reconciliation Requirements	CCR §§ 5049-5051
Failure to Comply with Video Surveillance System Requirements	CCR § 5044
Failure to Comply with Security Personnel Requirements	CCR § 5045
Failure to Verify Age of Customers and Unauthorized Access to Retail Areas	B&P § 26140 CCR §§ 5400 and 5402
Failure to Comply with Employee Age Restrictions	B&P § 26140 CCR § 5031
Sale or Furnish of Adult-use Cannabis Goods to Minors	B&P §§ 26030(g) and 26140 CCR § 5404
Consumption of Cannabis Goods by a Minor on Licensed Premises	B&P § 26200
Failure to Properly Display Cannabis Goods	CCR § 5405
Unauthorized Sale of Non-Cannabis Goods on Premises	CCR § 5407
Exceeding Daily Limits of Cannabis Goods Sales	CCR § 5409
Unauthorized Return of Cannabis Goods	CCR §§ 5053 and 5410
Consumption of Cannabis Goods During Delivery	CCR § 5419
Failure to Ensure Laboratory Testing Arrangements and Quality Assurance	CCR §§ 5304-5307
Failure to Comply with Microbusiness Operations Requirements	CCR § 5500
Failure to Comply with Laboratory Testing Requirements	CCR § 5700 et seq.
False or Misleading Declaration of Correction in a Notice to Comply	CCR § 5801
Prohibited Attire and Conduct	CCR § 5806

Prohibited Entertainers and Conduct	CCR § 5807
Allowing for the Copy or Display of a Fictitious License or a License that is Canceled, Revoked, or Altered	B&P § 119
Misdemeanor Offenses by Licensees	B&P § 125
Discipline by Another Agency	B&P § 141
Failure to Provide Safe Conditions for Inspection	B&P §§ 26030(i)

California Code of Regulations Disciplinary Order Guidelines - Tier 3

Minimum: revocation stayed, 45-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

Maximum: revocation

Tier 3 discipline is recommended for:

- Knowing or willfully violating laws or regulations pertaining to commercial cannabis activity
- Fraudulent acts relating to the licensee's commercial cannabis business

Violations of the following codes are representative of this category:

Violation Description	Authority
Failure to Notify the Bureau of a Change in Ownership	CCR § 5023 and 5024
Obtaining a License for Premises in Restricted Location	B&P § 26054 CCR § 5026
Conducting Commercial Cannabis Activity with Non-Licensees	CCR § 5032(a)
Failure to Notify the Bureau of Criminal Acts, Civil Judgments, and Revocation of a Local License, or Other Authorization after Licensure	CCR § 5035
Failure to Notify the Bureau of Significant Discrepancy, Theft, Loss, and Criminal Activity	B&P § 26070 (k) CCR § 5036
Restricting or Hindering the Examination of Books and Records	B&P §§ 26160-26161 CCR § 5037(b)-(c)
Obstruction of Inspections, Investigations, or Audits	CCR § 5800
Delivery or Transport of Cannabis Goods Outside of California or to a Publicly Owned or Leased Location	B&P § 26080 CCR § 5416(b)-(c)
Failure to Correct Any Objectionable Conditions on Premises	CCR § 5808(a)-(b)
Illegal Sale of Dangerous Drugs, or Other Controlled Substances	CCR § 5808(d)
Failure to Pay Fine	B&P § 125.9(b)(5)
Engage in Conduct that is Grounds for Denial of Licensure	B&P § 480(a)
False Statement in Application	B&P § 480(d)
Securing License by Fraud, Deceit, or Misrepresentation.	B&P § 498

Fine Formula

In instances where the Bureau allows a fine to be paid, the following method will be used to calculate the fine.

Gross Cannabis Sales divided by **Number of Days Open in Calculation Period = Average Daily Sale Amount**

Average Daily Sale Amount multiplied by **Number of Days of the Suspension = Potential Fine Amount**

The books and records of the licensee shall be kept in such a manner that the average daily sale amount and/or the loss of profits from commercial cannabis activity that the licensee would have suffered from a suspension can be determined with reasonable accuracy therefrom, and such books, records, and information shall be accessible to the Bureau to make an accurate and complete determination of any fine amount.

Minimum and Maximum Fine Amounts

The minimum and maximum fine amount is based on the tier the licensee falls into on annual license fee schedule listed in 16 CCR § 5015.

License Type	Operations ($Million Max. Per License)	Minimum Fine to Maximum Fine
Testing Laboratory	Up to 50 Million	$1,000 to $40,000
	Greater than 50 million to 500 Million	$2,000 to $90,000
	Greater than 500 Million	$4,000 to $180,000
Distributor	Up to 2 million	$1,000 to $2,400
	Greater than 2 million to 8 million	$2,000 to $10,000
	Greater than 8 million to 80 million	$4,000 to $72,000
	Greater than 80 million	$8,000 to $250,000
Distributor Transport Only Self-Distribution	Up to 2 million	$1,000 to $2,400
	Greater than 2 million to 8 million	$2,000 to $4,000
Distributor Transport Only	Up to 2 million	$1,000 to $2,400
	Greater than 2 million to 8 million	$2,000 to $5,000

Retailer	Up to .5 million	$1,000 to $8,000
	Greater than .5 million to 1.5 million	$2,000 to $24,000
	Greater than 1.5 million to 4.5 million	$4,000 to $72,000
	Greater than 4.5 million	$8,000 to $144,000
Microbusiness	Up to .5 million	$1,000 to $10,000
	Greater than .5 million to 1.5 million	$2,000 to $30,000
	Greater than 1.5 million to 4.5 million	$4,000 to $84,000
	Greater than 4.5 million	$8,000 to $240,000

IV. STANDARD CONDITIONS OF PROBATION

The protection of the public is the highest priority of the Bureau. In disciplinary matters where probation as been imposed, the Bureau believes conditions should be imparted to ensure public protection and to allow the probationer the opportunity to demonstrate rehabilitation. The following conditions of probation provide for consumer protection and establish a mechanism to monitor the rehabilitation progress of a probationer. Generally, the Bureau recommends a minimum of three (3) years' probation.

Introductory Language and Conditions 1-7 are required as follows:

1. OBEY LAWS

   Respondent shall obey all state and local laws. A full and detailed account of any and all violations of law shall be reported by the respondent to the Bureau in writing within seventy-two (72) hours of occurrence. To permit monitoring of compliance with this condition, respondent shall submit completed fingerprint forms and fingerprint fees within 45 days of the effective date of the decision, unless previously submitted as part of the licensure application process.

   CRIMINAL COURT ORDERS: If respondent is under criminal court orders, including probation or parole, and the order is violated, this shall be deemed a violation of these probation conditions, and may result in the filing of an accusation and/or petition to revoke probation.

2. SUBMIT WRITTEN REPORTS

Respondent, during the period of probation, shall submit or cause to be submitted such written reports/declarations and verification of actions under penalty of perjury, as required by the Bureau, but no more frequently than once each calendar quarter. These reports/declarations shall contain statements relative to respondent's compliance with all the conditions of the Bureau's Probation Program. Respondent shall immediately execute all release of information forms as may be required by the Bureau or its representatives.

3. REPORT IN PERSON

Respondent, during the period of probation, shall appear in person at interviews/meetings as directed by the Bureau or its representatives.

4. COMPLY WITH CONDITIONS OF PROBATION

Respondent shall fully comply with the conditions of probation established by the Bureau and cooperate with representatives of the Bureau in its monitoring and investigation of the respondent's compliance with the Bureau's Probation Program. Respondent shall inform the Bureau in writing within no more than 15 days of any address change. Upon successful completion of probation, respondent's license shall be fully restored.

5. POSTING OF SIGN

During the period of suspension, Respondent shall prominently post a sign or signs, provided by the Bureau, indicating the beginning and ending dates of the suspension and indicating the reason for the suspension. The sign or signs shall be conspicuously displayed in a location or locations open to and frequented by customers. The location(s) of the sign(s) shall be approved by the Bureau and shall remain posted during the entire period of actual suspension.

Additionally, the Respondent shall circulate a notice of the conditions of probation to all employees, and post the notice in a conspicuous place where notices to employees are posted or available to employees. New employees shall also be provided a copy of the notice of the conditions of probation.

6. MAINTAIN VALID LICENSE

Respondent shall, at all times while on probation, maintain a current and valid license with the Bureau, including any period during which suspension or probation is tolled.

7. COST RECOVERY

Respondent shall pay to the Bureau costs associated with its investigation and enforcement pursuant to Business and Professions Code Section 26031 in the amount of $_____ . Respondent shall be permitted to pay these costs in a payment plan approved by the Bureau, with payments to be completed no later than three months prior to the end of the probation term.

If respondent has not complied with this condition during the probationary term, and respondent has presented sufficient documentation of his or her good faith efforts to comply with this condition, and if no other conditions have been violated, the Bureau, in its discretion, may grant an extension of the respondent's probation period up to one year without further hearing in order to comply with this condition. During the one year extension, all original conditions of probation will apply.

8. LICENSE SURRENDER

During respondent's term of probation, if he or she ceases business or is otherwise unable to satisfy the conditions of probation, respondent may surrender his or her license to the Bureau. The Bureau reserves the right to evaluate respondent's request and to exercise its discretion whether to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances, without further hearing. Upon formal acceptance of the tendered license, respondent will no longer be subject to the conditions of probation. Surrender of respondent's license shall be considered a disciplinary action and shall become a part of respondent's license history with the Bureau.

9. VIOLATION OF PROBATION

If a respondent violates the conditions of his or her probation, the Bureau after giving the respondent notice and an opportunity to be heard, may set aside the stay order and impose the stayed discipline (revocation/suspension) of the respondent's license. If during the period of probation, an accusation or petition to revoke probation is filed against respondent's license, or the Bureau has served the respondent a notice of intent to set aside the stay, the Bureau shall have continuing jurisdiction, and the probationary period shall automatically be extended and shall not expire until final resolution of the matter.

VI. INTRODUCTORY LANGUAGE AND OPTIONAL TERMS AND CONDITIONS OF PROBATION

The following introductory language and all standard probation conditions are to be included in probationary decisions/orders. For applicants, cost recovery conditions do not apply. For licensees, all standard probation conditions apply. Optional terms and conditions may be included in orders of probation based upon violations.

INTRODUCTORY LANGUAGE FOR ALL ORDERS

IT IS HEREBY ORDERED that License Number _____ issued to Respondent_____ is [revoked/suspended/fined] [for/in the amount of] [days/amount], [however, the revocation is stayed] and respondent is placed on probation for _____ years on the following conditions.

SEVERABILITY CLAUSE – Each condition of probation contained herein is a separate and distinct condition. If any condition of this Order, or any application thereof, is declared unenforceable in whole, in part, or to any extent, the remainder of this Order, and all other applications thereof, shall not be affected. Each condition of this Order shall separately be valid and enforceable to the fullest extent permitted by law.

Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds

2nd Edition

US Food & Drug Administration
Office of Foods and Veterinary Medicine

April 2015

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Center for Food Safety and Applied Nutrition
Office of Applied Research and Safety Assessment
Office of Food Safety
Office of Regulatory Science

Center for Veterinary Medicine
Office of Research

National Center for Toxicological Research
Division of Microbiology

Office of Regulatory Affairs
Office of Regulatory Science
ORA Cadre of Microbiology Subject Matter Experts

Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Ed.

APPROVAL PAGE

This document is approved by the FDA Foods and Veterinary Medicine (FVM) Science and Research Steering Committee (SRSC). The FVM SRSC Project Manager is responsible for updating the document as change requirements are met, and disseminating updates to the SRSC and other stakeholders, as required.

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ORA, Member of the ORA Scientific Advisory Council

US Food & Drug Administration
Office of Foods and Veterinary Medicine

Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds
Second Edition

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1.0 INTRODUCTION

1.1 Purpose

The Foods and Veterinary Medicine (FVM) Enterprise within the U.S. Food & Drug Administration is responsible for ensuring the safety of the nation's food and feed supply. FDA accomplishes this through education; inspection; data collection; standards setting; prompt investigation of outbreaks; and, enforcement actions when appropriate. The effectiveness of the FVM Enterprise is highly dependent on the quality and performance of the laboratory methods used within the FDA. To ensure that all laboratory methods meet the highest analytical standards possible for their intended purpose, the FDA Office of Foods and Veterinary Medicine (OFVM) through the Science and Research Steering Committee (SRSC) has established these criteria by which all FVM microbiological methods shall be evaluated and validated.

1.2 Scope

These criteria apply to all FDA laboratories that develop and participate in the validation of analytical food and feed methods for Agency-wide implementation in a regulatory capacity. This includes all research laboratories, and ORA labs where analytical methods may be developed or expanded for potential regulatory use. At the time of final approval by the OFVM and the SRSC, this document will supersede all other intra-agency documents pertaining to food- and feed-related method validation criteria for microbial analytes. In addition, this guidance is a forward-looking document; the requirements described here will only apply to *newly*-developed methods and those for which significant modifications have been made to an existing method. Once a method has been validated, it can be implemented by other laboratories following the method verification process.

1.3 Administrative Authority and Responsibilities

All criteria established in this document for analytical method validation have been adopted and approved by the OFVM and the SRSC. As stated in the Methods Development, Validation and Implementation Program SOP (APPENDIX 3), The Method Validation Subcommittee (MVS) will have oversight responsibility for all collaborative validation studies (See Section 2.2.2.3).

1.4 The Method Validation Subcommittee

Under the authority of the SRSC, a Microbiology Methods Validation Subcommittee (MMVS) will oversee all microbiology method validation concerns. The MMVS is governed by the organizational structure, roles and responsibilities as detailed in its charter (See APPENDIX 2). Briefly, the MMVS will oversee and coordinate – in collaboration with the originating laboratory – all collaborative laboratory validation studies (planning and implementation) for microbiological methods developed within the FDA FVM Enterprise to support regulatory analytical needs. This includes the evaluation of Single Laboratory Validation (SLV) results and the evaluation of any subsequent collaborative validation study plan. Unless

otherwise stated, most correspondence between the method developer(s) and the MMVS will be by email using the following address: Microbiology.MVS@fda.hhs.gov.

1.5 General Responsibility of the Originating Laboratory

It is the responsibility of the originating (developing) laboratory to ensure proper adherence to all criteria described in the document. The originating laboratory must work in close consultation with the MMVS and/or its designated Technical Advisory Group (TAG) throughout the collaborative laboratory validation process. It will be the responsibility of the originating laboratory to include their respective QA/QC manager in all aspects of the validation process and to ensure proper adherence to all criteria described in this document.

1.6 Method Validation Definition

Method validation is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes:

- In one or more matrices to be analyzed.
- In one or more instruments or platforms.
- With a demonstrated sensitivity, specificity, accuracy, trueness, reproducibility, ruggedness and precision to ensure that results are meaningful and appropriate to make a decision.
- Reliably for its intended purpose. Intended purpose categories include, but may not be limited to emergency/contingency operations; rapid screening and high throughput testing; and confirmatory analyses.
- After the method developer has conducted experiments to determine or verify a number of specific performance characteristics that serve to define and/or quantify method performance.

1.7 Applicability

This document establishes evaluation criteria for methods to detect, identify, and quantify all microbial analytes that may now be, or have the potential to be associated with foods and feeds *i.e.* any microbiological organism of interest (target organism) or the genetic material *i.e.* DNA, RNA, toxins, antigens, or any other product of these organisms. If not specifically identified, all information contained in the accompanying tables should be extrapolated to the microbial analyte of interest. Such applicable areas of methods development and evaluation include, but are not limited to, the following:

- Qualitative assays *i.e.* detection assays
- Quantifiable assays *i.e.* real-time PCR
- Analyte-specific