Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Independent Testing Laboratory
Guidance for Third-Party ISO Accreditation

Revised – December 1, 2017

This document was issued originally by the Department of Public Health (DPH). As part of the transfer of the medical-use of marijuana program on or before December 31, 2018, the Commission adopted this document. We suggest that before you rely on the contents of this document, you check the applicable medical-use marijuana laws, which include M.G.L. c. 94I and 935 CMR 501.000, as they may provide or clarify the legal requirements related to this document. We also suggest that you periodically check for revisions to this document. Questions with regards to this document may be directed to CannabisCommission@Mass.gov.

INSTRUCTIONS

This Guidance for Third-Party ISO Accreditation "*Intake Form*" has been prepared to assist with evaluating laboratories for compliance with ISO/IEC 17025:2005 standards when operating as an Independent Testing Laboratories (ITL) in accordance with established policies outlined by the Cannabis Control Commission (Commission).

Specifically, this *Intake Form* lists the specified testing that a third-party ISO accreditor should evaluate when assessing your technical competence to perform when conducting the testing of medical marijuana consistent with Commission Testing Protocols (see Section E).

A laboratory applicant is expected to make available the documentation specified in the "CHECKLIST" section of this *Intake Form* to the third party accrediting body that is providing the third-party ISO accreditation. All information must be maintained at the laboratory, to be made available to the Commission upon request. A laboratory is expected to maintain this documentation, as well as supporting information specified in this *Intake Form.*

QUESTIONS

If additional information is needed regarding the ITL registration process, please contact the Medical Use of Marijuana Program at 833-869-6820 or MedicalMarijuana@State.MA.US.

CHECKLIST

The items listed below or an approved explanation of omission must be maintained by a laboratory applicant, as outlined above:

☐ A fully and properly completed Commission ITL Application, signed by an authorized signatory of the laboratory

☐ The laboratory quality management plan/manual

☐ Resume or curriculum vitae of all key technical and management personnel

☐ Current organization chart, indicating reporting relationships and functional area for laboratory personnel

☐ Facility floor plan, to include square footage and location of key equipment (including fume hoods, refrigerators/freezers/incubators)

☐ A master list of all analytical and non-analytical (e.g. safety and training) Standard Operating Procedures (SOPs) indicating the latest revision/review dates and current effective dates

☐ The laboratory SOPs for all sample receiving, handling, storage, and waste disposal

☐ The last internal QA/QC audit and a report on the status of response/corrective actions

☐ The last management review/audit and a report on the status of response/corrective actions

☐ Current list of analyte-specific accreditations and copies of certificates relevant to ITL methods

☐ Last two performance evaluation analyses (proficiency testing) and scores/results

☐ Demonstrations of competency and method performance for the methods listed below. Should include both:
Demonstration of method validations (i.e., precision, accuracy and sensitivity)
Staff competency

☐ A copy of a complete laboratory results report meeting all Commission requirements for reporting results to RMDs

☐ The laboratory preparative and analytical SOPs for the tests performed at your facility (See table below)

TEST PARAMETER	MATRIX
Metals	Finished plant material, cannabis resin, cannabis concentrates, environmental media, water
Pesticides	Finished plant material, environmental media, water

Cannabinoid Profile	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products
PCBs	Environmental media, water
Residual Solvents	Cannabis resin, cannabis concentrates
Mycotoxins	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, and CO_2/solvent-based extracts
Total Viable Aerobic Bacteria	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water
Total Yeast and Mold	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water
Total Coliforms	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water
Bile-tolerant Gram-Negative Bacteria	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water
E. Coli (pathogenic strains)	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water
Salmonella spp.	Finished plant material, cannabis resin, cannabis concentrates, marijuana-infused-products, CO_2/solvent-based extracts, water

Independent Testing Laboratory Guidance for Third-Party ISO Accreditation

SECTION A: INDEPENDENT TESTING LABORATORY INFORMATION (REQUIRED)		
1.Laboratory name:	2. Laboratory tax ID number:	
3. Organization name:	4. Laboratory telephone number: ( )	5. Laboratory fax number: ( )
6. Laboratory business address 1:	7. Laboratory business address 2:	
8. City:	9. State:	10. Zip code:
11. Laboratory mailing address 1:	12. Laboratory mailing address 2:	
13. City:	14. State:	15. Zip code:

Please indicate with "N/A" for any items that are not applicable and provide an explanation.

SECTION B: INDEPENDENT TESTING LABORATORY CONTACT PERSON INFORMATION (REQUIRED)	
16. Last name of contact person:	17. First name of contact person:
18. Phone number of contact person: ( )	19. Alternate phone number of contact person: ( )
20. Email address of contact person:	
21. Last name of laboratory director:	22. First name of laboratory director:
23. Last name of laboratory quality assurance manager:	24. First name of laboratory quality assurance manager:

SECTION C: INDEPENDENT TESTING LABORATORY COMPANY INFORMATION (REQUIRED)

25. Date current company or holding company founded:	26. Total years operating in current facility:
27. Primary accrediting authority:	28. Total square footage of current facility:
29. Business hours of operation: _____AM to _____PM	30. Operating hours of operation: _____AM to _____PM

31. Sample receipt schedule:

_____AM to _____PM ☐Mon ☐Tues ☐Wed ☐Thurs ☐Fri ☐Sat ☐Sun

_____AM to _____PM ☐Mon ☐Tues ☐Wed ☐Thurs ☐Fri ☐Sat ☐Sun (if applicable)

_____AM to _____PM ☐Mon ☐Tues ☐Wed ☐Thurs ☐Fri ☐Sat ☐Sun (if applicable)

_____AM to _____PM ☐Mon ☐Tues ☐Wed ☐Thurs ☐Fri ☐Sat ☐Sun (if applicable)

32. Total company personnel employed (full- and part-time): _____total employed personnel	33. Technical personnel employed: ____full-time personnel ____ part-time personnel

34. What is the turnover rate of personnel at your facility (within last calendar year)?

35. How many dedicated quality assurance (QA) personnel (FTEs) are employed at your facility?

36. What is the date of your last accrediting audit(s)?

37. What other certifications and accreditations do you currently possess? Please list state and/or accrediting bodies and provide certificates as an attachment.

38. Over the past year, what changes have occurred at your facility (*e.g.,* added/dropped certifications, methods, equipment, key personnel, major suppliers/vendors, utilities, LIMS, building facilities)?

39. What is the process by which updated Standard Operating Procedures (SOPs) are distributed and previous versions are retrieved?

40. Please list the methods and matrices for which your laboratory has developed Standard Operating Procedures (SOPs):

41. What security system(s) are employed at your facility (*e.g.,* burglar and fire alarm)?

42. Does your facility have a sign-in/sign-out requirement for visitors?

43. How many total entrances does your facility have?
44. How many building entrances are unlocked during business hours?
45. Which entrances are unlocked during business hours?
46. Does your facility have an uninterrupted power supply (UPS)? If yes, please describe what it is used for:
47. Does your facility use a deionization water system? If yes, please specify how many systems are in place:
48. Please specify the final water quality classification for each water system in use:
49. Please specify any analytical instruments in your facility that are maintained under service contract:

SECTION D: LABORATORY INFORMATION MANAGEMENT SYSTEM INFORMATION (REQUIRED)	
50. Laboratory information management system (LIMS) currently in use:	51. LIMS platform currently in use:
52. Total number of information technology (IT) personnel employed at your facility:	53. Is the LIMS on-site? ☐Yes ☐No
54. If LIMS is on-site, specify name of person responsible for maintenance:	55. Processing software used for organic analysis:

SECTION E: INDEPENDENT TESTING LABORATORY ANALYTICAL METHODS (REQUIRED)				
TEST PARAMETER	**METHOD(S) IN USE**	**SPECIFY METHOD(S)** *(if applicable)* **(e.g., ICP-MS)**	**SPECIFY ANALYTE(S)** *(if applicable)* **(e.g., cadmium)**	**METHOD(S) REFERENCE** *(if applicable)* **(e.g., USP Monograph)**
Metals	56. ☐Yes ☐No	57.	58.	59.
Pesticides	60. ☐Yes ☐No	61.	62.	63.
Cannabinoid Profile	64. ☐Yes ☐No	65.	66.	67.
Residual Solvents	68. ☐Yes ☐No	69.	70.	71.
Mycotoxins	72. ☐Yes ☐No	73.	74.	75.
Total Viable Aerobic Bacteria	76. ☐Yes ☐No	77.	78.	79.
Total Yeast and Mold	80. ☐Yes ☐No	81.	82.	83.
Total Coliforms	84. ☐Yes ☐No	85.	86.	87.
Bile-tolerant Gram-Negative Bacteria	88. ☐Yes ☐No	89.	90	91.
E. Coli (pathogenic strains)	92. ☐Yes ☐No	93.	94.	95.
Salmonella spp.	96. ☐Yes ☐No	97.	98.	99.

SECTION F: INDEPENDENT TESTING LABORATORY CERTIFICATION OF INFORMATION PROVIDED (REQUIRED)	
By signing below, I hereby certify that the above information is correct and complete.	
100. Signature of Contact Person:	101. Date Signed (mm/dd/yyyy): / /

IMPORTANT: Please include documentation specified in the "CHECKLIST" section above when maintaining this Intake Form.