A O A C INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, Pharmaceuticals, and Cannabis, February 2024 Working Document

AOAC ALACC 2024

ASSESSMENT INFORMATION	
Assessment Number	**Date(s)**
Enter Assessment Number Here	Enter Assessment Dates Here
CAB name:	Enter Name of the CAB Here
Lead Assessor:	Lead Assessor
Team Members:	Team Members
☐ Accreditation Assessment ☐ Reassessment ☐ EOA Reason:	
Location of Assessment: ☐ Onsite ☐ Virtual ☐ Remote Desk Review	

Instructions:

This checklist is to be used in conjunction with the LF-56 Supplement for the standard identified above and is to be used in conjunction with the ISO/IEC 17025 working document.

The assessment team is to use this checklist to evaluate the design and utilization of the management system as related to the standard requirements.

The checklist is a tool for recording the objective evidence used by the assessment team in the determination of conformance of standard requirements during the assessment.

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***** ON ACCREDITATION AND REACCREDITATION ASSESSMENTS, ALL CLAUSES OF THE STANDARD MUST BE COVERED AND DOCUMENTED ON THE THIS CHECKLIST *****

AOAC ALACC 2024 Working Document

Clause	Summary of Requirement	Document(s)	Conformity Determination	Objective Evidence Reviewed to Make Determination
	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
4	**General Requirements**			
ALACC 4.1.2	Are conflict-of-interest agreements established along with appropriate conflict-of-interest training programs for personnel?			
ALACC 4.1.2	Does training consist of initial and refresher training?			
ALACC 4.1.2	Does the laboratory define a schedule for refresher training and renewal of conflict-of-interest agreements?			
5	**Structural Requirements**			
ALACC 5.1	Is a cannabis or hemp testing laboratory registered as a legal business operating within and compliant with applicable regulatory requirements established by local, jurisdictional, state, provincial and/or federal specifications?			
ALACC 5.4 (a)	For cannabis laboratories, does the laboratory define quality management			

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	personnel to manage laboratory activities to ensure compliance, reduce and manage occurrences of nonconformances, and seek continual process improvement and effectiveness to the management system?			
ALACC 5.4 (b)	For cannabis laboratories, does the laboratory define quality management personnel to ensure that the management system implementation is effective and adheres to the requirements of its customers and federal, state, and local regulations?			
6	**Resource Requirements**			
ALACC 6.2.1	Does the laboratory meet any local, state, and/or federal-specific requirements for hiring specific laboratory personnel?			
ALACC 6.2.1	Does the laboratory supply appropriate information to allow employees to follow governmental (e.g., local, jurisdictional, state, provincial, federal, etc.) regulatory requirements and understand their importance to the position of the employee?			
ALACC 6.2.1	In the United States, does this include disclosing to employees and potential			

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	employees that although the laboratory is operating legally in the state, cannabis remains federally illegal?			
ALACC 6.2.2	In cases in which staff is qualified on only a portion of a method, do the training records indicate those parts upon which they have been trained?			
ALACC 6.2.3	For dietary supplements and pharmaceuticals, does the laboratory require a qualified person review complaints for possible failures and investigate where needed?			
ALACC 6.2.3	For dietary supplements and pharmaceuticals, does the laboratory define qualifications of staff handling complaints?			
ALACC 6.2.5	Do laboratory procedures specify the frequency to monitor the competence of personnel?			
ALACC 6.2.5	Does monitoring competence include demonstration(s) of competence for each activity?			
ALACC 6.2.5	Does the laboratory retain all data related to each monitoring activity?			
ALACC 6.2.5	For cannabis laboratories, does the laboratory document training specifically			

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	in the areas of safety, hazard, and emergency response?			
ALACC 6.3.3	Do laboratories use aseptic technique when conducting microbiological testing?			
ALACC 6.4.3	Are reference materials (e.g., RM, CRM, SRM) handled and stored according to instructions provided by material supplier/producer, unless valid reasons exist for not doing so?			
ALACC 6.4.3	Are deviations from these storage instructions and justification for the deviation recorded?			
ALACC 6.4.3	If deviations occur, is there evidence that the quality of the reference materials has been demonstrated?			
ALACC 6.4.3	Is documentation accompanying the reference material stored and available?			
ALACC 6.4.4	Does the laboratory determine and record expiration dates of reference materials after opening each purchased reference material when not provided by the manufacturer?			
ALACC 6.4.4	Are reagents, reagent solutions, sample solutions, and internal reference materials (including CRMs used as internal reference materials) used only within their expiration date, or is there			

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	documented verification of suitability if used beyond the expiration date?			
ALACC 6.4.4	Are certified reference materials used beyond their expiration date only when they have been appropriately qualified and designated for use as reference materials?			
ALACC 6.4.4	If dehydrated media is used past its expiration date, has the laboratory defined requirements for the necessary level of productivity and selectivity for the specific test, and can it demonstrate acceptable productivity and selectivity for each batch prepared from the expired media?			
ALACC 6.4.4	Does the laboratory define the use of the water and ensure the water is fit for that use?			
ALACC 6.4.8	Are reference materials labelled using an identification scheme that allows the laboratory to trace the lot of reference material used in any analysis?			
ALACC 6.4.8	Is each reference material labelled with the date received when the date is used for determining the expiration date?			
ALACC 6.6.1 (a)	Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities			

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	are used, when such products and services are intended for incorporation into the laboratory's own activities?			
ALACC 6.6.1 (b)	Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider?			
ALACC 6.6.1 (c)	Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services are used to support the operation of the laboratory?			
7	**Process Requirements**			
ALACC 7.2.1.1	Has the laboratory used an in-house method only when it has demonstrated acceptable performance or incorporates modern technology, and has the method been adequately validated as defined in the applicable documentation?			
ALACC 7.2.1.1	Are methods of analysis that are specified in law or regulation followed in full compliance with the applicable legal or regulatory requirements?			

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ALACC 7.2.1.1	Does the cannabis laboratory use specified test methods when they are identified or provided by the relevant regulatory body?			
ALACC 7.2.1.5	Has the laboratory confirmed through method verification that it can achieve the required performance for the intended purpose of the test method?			
ALACC 7.2.2.1	If the laboratory is required to fulfil ISO/IEC 17025 requirements prior to being legally authorized to possess cannabis materials, has a suitable surrogate matrix or matrices been selected to meet method validation requirements?			
ALACC 7.2.2.1	Once authorized to possess cannabis materials, does the laboratory demonstrate that the test method meets performance requirements using cannabis materials before analyzing customer sample?			
ALACC 7.2.2.4	Does the laboratory record the name of the representative who authorized the adoption of the method and the date of authorization?			
ALACC 7.3.1	When required to conduct field sampling of products, does the laboratory comply			

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	with the established procedures and applicable program requirements?			
ALACC 7.4.1	When not specified by the customer or regulations, does the laboratory communicate minimum sample retention periods to customers to ensure all parties are aware of the availability of the sample for retesting or retrieval?			
ALACC 7.4.1	If the laboratory tests only a portion of the received sample, is that portion unmistakably identified and traceable to the original sample?			
ALACC 7.4.1	Does the laboratory have documented procedures for subdividing, compositing, and/or homogenizing samples to ensure that a representative test portion is used for analysis?			
ALACC 7.5.1 (a)	Do laboratory records include the identity of the analyst(s) performing each step of the testing process?			
ALACC 7.5.1 (b)	Is analyst training documented with traceability to reference materials (RMs) and proficiency checks?			
ALACC 7.5.1 (c)	Are calibration records traceable to suitable reference materials (RMs)?			
ALACC 7.5.1 (d)	Is the column lot number and serial number recorded in laboratory records?			

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ALACC 7.5.1 (e)	Are data reviews documented in the audit trail?			
ALACC 7.5.1 (f)	Is equipment performance verified and recorded, including the use of CRMs, proficiency checks, and daily checks?			
ALACC 7.5.1 (g)	Are equipment qualification and maintenance activities documented?			
ALACC 7.5.1 (h)	Is the specific equipment used for testing identified in the laboratory records?			
ALACC 7.5.1 (i)	Is incubation time (time in and time out) recorded for incubators, ovens, and chambers where time at temperature is critical?			
ALACC 7.5.1 (j)	Is the identity of media, reagents, test kits, and reference materials recorded?			
ALACC 7.5.1 (k)	Is the open date of media, reagents, test kits, reference materials, and microorganisms recorded when it affects the expiration date?			
ALACC 7.5.1 (l)	Are expiration dates of media, reagents, test kits, reference materials, and microorganisms documented?			
ALACC 7.5.1 (m)	Are laboratory-assigned identification codes for media, reagents, test kits, reference materials, and microorganisms recorded?			

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ALACC 7.5.1 (n)	Are lot numbers for media, reagents, test kits, reference materials, and microorganisms documented?			
ALACC 7.5.1 (o)	Is the received date of media, reagents, test kits, reference materials, and microorganisms recorded?			
ALACC 7.5.1 (p)	Is the preparation date recorded for any prepared media or reagents?			
ALACC 7.5.1 (q)	Is the identity of the preparer documented for prepared media or reagents?			
ALACC 7.5.1 (r)	Are the components (identity, lot number, and amount) of prepared reagents recorded?			
ALACC 7.5.1 (s)	Are special instructions, hazards, or use restrictions associated with prepared reagents documented?			
ALACC 7.5.1 (t)	Is the concentration or purity of reagents recorded?			
ALACC 7.5.1 (u)	Are records maintained of reports issued, whether mailed or electronic?			
ALACC 7.5.1 (v)	Are test results clearly documented and traceable?			
ALACC 7.5.1 (w)	Are electronic transmissions (e.g., LIMS acquisitions) reviewed and documented?			

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ALACC 7.5.1 (x)	Are all reviews, including technical and quality reviews, recorded?			
ALACC 7.5.1 (y)	Is sample analysis documentation complete, including raw data such as chromatograms and standard curves?			
ALACC 7.5.1 (z)	Are sample handling and storage conditions recorded?			
ALACC 7.5.1 (aa)	Is sample preparation adequately documented?			
ALACC 7.5.1 (ab)	Is the receipt (log-in/check-in) of samples properly recorded?			
ALACC 7.5.1	When a method allows multiple testing options, does the laboratory record clearly indicate which option was followed, either through a work instruction, form, LIMS entry, or other documented means?			
ALACC 7.5.1	When strict chain of custody is requested by the customer does the laboratory have a documented policy and procedure that includes applicable licensing information for both the laboratory and the customer, as well as required sample weights?			
ALACC 7.5.1	Does the cannabis laboratory have a documented procedure that defines sample storage, retention, and disposal?			

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ALACC 7.6.3	When applicable, does the laboratory comply with regulatory requirements for evaluating and recording measurement uncertainty for specific test results?			
ALACC 7.7.1	Are quality control (QC) procedures defined for both quantitative and qualitative methods, including consideration of significant contributors to measurement uncertainty for the test method?			
ALACC 7.7.1	Do QC procedures include the use of quality control materials validated for use within the test method's matrix to demonstrate that the test functioned properly?			
ALACC 7.7.1	Is quality control sample data analyzed and shown to meet predefined acceptance criteria prior to the release of test results?			
ALACC 7.7.1	For enumeration assays, does the laboratory use a quantified quality control material?			
ALACC 7.7.1	In the absence of a certified reference material (CRM) or reference material (RM), does the laboratory obtain and justify the use of an alternative material with some level of consensus accuracy			

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	(e.g., through in-house testing, inter-laboratory comparison, or similar)?			
ALACC 7.7.1	Is the suitability of the quality control material used justified and documented by the laboratory?			
ALACC 7.7.1	Do the quality control requirements for each defined batch demonstrate that the laboratory's analysis is under control and produces data of known and documented quality that is fit for the intended purpose?			
ALACC 7.7.1	Is a quality control material included with each batch of samples analyzed, and is it tested in accordance with the entire method?			
ALACC 7.7.1	Is the quality control material processed from start to finish along with the batch of samples?			
ALACC 7.7.1	Has the laboratory defined and justified what constitutes a batch of samples?			
ALACC 7.7.1	Is method precision periodically evaluated by the laboratory, including consideration of significant contributors to measurement uncertainty?			
ALACC 7.7.1	Does the laboratory evaluate method precision over time using appropriate statistical process control techniques,			

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	including the use of replicate analyses of CRMs/RMs, positive samples, matrix spikes, LCSs, or other reference materials?			
ALACC 7.7.2	Has the laboratory obtained successful proficiency testing (PT) or interlaboratory comparison results to qualify each test method for which accreditation is being sought?			
ALACC 7.7.2	Does the laboratory demonstrate ongoing competence by participating in proficiency testing (PT) based on the scope of accreditation?			
ALACC 7.7.2	For a biological scope, does the laboratory participate in at least one PT event every 12 months for each method on its accredited scope?			
ALACC 7.7.2	For a chemical scope, does the laboratory participate in at least one PT event per year for each method on its scope, or provide documented justification for grouping methods with similar processes?			
ALACC 7.7.2	For chemical scopes using a method similarity justification, does the laboratory ensure that all methods are covered by PT participation within a four-year period?			

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ALACC 7.7.2	When a relevant and appropriate proficiency testing (PT) program is not available, does the laboratory document planned participation in other interlaboratory comparisons, where available and appropriate?			
ALACC 7.7.2	When no PT or interlaboratory comparison is available, has the laboratory developed and justified an alternative plan for monitoring the quality of its data?			
ALACC 7.7.2	Are PT samples analyzed using the laboratory's routine working practices?			
ALACC 7.7.2	Are PT samples rotated among qualified analysts to ensure comprehensive evaluation of staff competence?			
ALACC 7.7.2	Does the laboratory implement corrective action for any PT failures, including participation in the next available PT round for the failed method?			
ALACC 7.7.3	Does the laboratory have documented procedures defining acceptance criteria for quality control materials, including what constitutes a trend in statistical process control (SPC) data and consideration of significant contributors to measurement uncertainty?			

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ALACC 7.7.3	When QC material data do not meet acceptance criteria or indicate a trend, does the laboratory initiate appropriate procedures for addressing nonconforming work?			
ALACC 7.7.3	Does the laboratory have a procedure for evaluating data associated with a failing QC material and for determining appropriate actions to address it?			
ALACC 7.7.3	Does the laboratory treat data associated with failed QC material as suspect until properly evaluated?			
ALACC 7.7.3	For multianalyte test methods, does the laboratory's acceptance criteria acknowledge the probability of one or more analytes being out of limits and provide a balanced approach to avoid unnecessary corrective actions while identifying true nonrandom errors?			
ALACC 7.7.3	Do the laboratory's criteria for multianalyte methods account for analyte-specific behavior, including differences in variance or recovery performance, especially at lower concentrations?			
ALACC 7.7.3	Has the laboratory implemented an appropriate strategy or statistical approach to set control limits for			

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	multianalyte methods that reasonably balance false alarms and missed detections?			
ALACC 7.7.3	Does the laboratory evaluate proficiency testing (PT) results promptly upon receipt?			
ALACC 7.7.3	When acceptability limits and criteria are provided by the PT provider, does the laboratory apply criteria that are at least as stringent as those issued by the provider?			
ALACC 7.7.3	If the PT provider does not supply acceptability criteria, or if PT is conducted by alternative means, does the laboratory have documented procedures that define the acceptability of PT results?			
ALACC 7.7.3	When evaluating PT results, does the laboratory consider one or more of the following to establish the assigned value: SPC ranges for blinded LCSs, fortification values of prepared samples, assigned results from a previous round or set, or results from a group of two or more accredited laboratories that have demonstrated proficiency for the analyte?			

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ALACC 7.8.6.2	Does the cannabis laboratory include a disclaimer in the test report stating that decision rules, including pass or fail specifications, are established by the respective regulatory authority?			
ALACC 7.8.8.1	If an amendment includes a change to the sample description, does the report contain both the original and the updated descriptions?			
8	**Management System Requirements**			
ALACC 8.2.1	Does the quality manual (or equivalent management system documentation) for the multifunctional laboratory clearly identify and organize sections related to the special requirements of various analytes and/or techniques?			
ALACC 8.4.2	Are method validation and verification records retained for at least as long as the method remains in use by the laboratory?			
ALACC 8.4.2	Does the laboratory's retention of method validation and verification records comply with its documented policy on record retention?			
ALACC 8.4.2	Does the laboratory have a documented procedure for periodically confirming			

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	access to backup records, including those stored on instruments?			
ALACC 8.4.2	Is there evidence or a log of each periodic confirmation of access to backup records?			
ALACC 8.4.2	Are backup records stored in a separate location from the original records to protect against loss or damage?			
ALACC 8.5.2	Has the laboratory planned actions to address identified risks and opportunities, including those related to the implementation of ALACC Guidelines, and integrated these actions into its management system?			
ALACC 8.5.2	Is there a process in place to evaluate the effectiveness of these actions?			
ALACC 8.8.1	Prior to accreditation, has the laboratory completed internal audits for all parts of the quality system that fall within the requested scope of accreditation?			
ALACC 8.9.1	Does the laboratory's management review include a review of nonconforming work to identify and assess trends?			
ALACC 8.9.1	Are customer feedback, personnel feedback, and complaints reviewed			

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	during management review to identify recurring issues or trends?			
ALACC 8.9.1	Pre-accreditation: Has the laboratory completed a full management review that addresses all elements of ISO/IEC 17025 Section 8.9 prior to applying for accreditation?			
Appendix A	**Equipment**			
ALACC Appendix A	Has the equipment been calibrated and/or verified in accordance with the requirements outlined in the table below?			

Equipment/system	Action	Frequency	Compliant Y/N	Observation
Autoclaves	Calibrate temperature sensing system	At installation (or initial use)		
Autoclaves	Verify accuracy of temperature sensing system	Annually		
Autoclaves	Verify maximum temperature achieved	Each day		
Autoclaves	Verify performance with biological sterility indicator	Weekly		
Autoclaves	Uniformity of temperature [a]	At installation (or initial use) and annually thereafter		

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Autoclaves	Stability of temperature	At installation and annually as needed [b]		
Automated colony counters	Verify accuracy against manual count	Annually		
Analytical balances	Verify mass measurement	Each day of use		
Analytical balances	Calibrate [c]	Annually When moved to different location or after repair [d]		
Top-loading balances	Each day of use	Verify mass measurement		
Top-loading balances	Calibrate [c]	At a schedule and frequency determined by the laboratory based on documented risk assessment When moved to different location or after repair [d]		
Field balances [e]	Verify mass measurement	Each use		
Chromatographic systems (GC, IC, LC)	Verify detector response for the analytical methods [f]	At least once with each batch		
Dispensing equipment and vial fillers used in microbiology	Verify mass/volume measurement at each volume dispensed	At installation and each day of use		
Freeze-dryers, vacuum ovens	Verify ability to achieve and sustain vacuum	At installation and annually thereafter		

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Freeze-dryers, vacuum ovens	Verify vacuum gauges against traceable calibrated gauge	At installation and annually thereafter		
Hygrometer, reference	Calibrate	Every 2 years * Note: AOAC manual lists both Every year and every 2 years, defaulted to less stringent due to the conflicting requirements.		
Hygrometer, working	One-point comparison to reference hydrometer	Annually * te: AOAC manual lists both Every year and every 2 years, defaulted to less stringent due to the conflicting requirements.		
Microscopes used for measuring	Calibrate stage micrometer	At installation or initial use		
Moisture meters	Calibrate	Annually		
Moisture meters	Verify	Every 6 months		
pH meters ion selective, and related conductivity equipment [g]	Calibrate against reference buffer [h] or reference solution at level of use or bracketing range of use	Each day of use		
Temperature-controlled chambers used for storage (e.g., refrigerators and freezers)	Verify temperature	Frequency is dependent upon mechanism of monitoring [h]		

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Temperature-controlled chambers used for storage (e.g., refrigerators and freezers)	Uniformity of temperature [a] by mapping the chamber	At installation (or initial use) and after nonroutine maintenance [i]		
Temperature-controlled chambers used for testing (e.g., ovens, furnaces, incubators, heat blocks, water baths, and autoclaves)	Verify temperature	Minimum twice daily on each day of use with at least 4 hours between verifications [j]		
Temperature-controlled chambers used for testing (e.g., ovens, furnaces, incubators, heat blocks, water baths, and autoclaves)	Uniformity of temperature [a] by mapping the chamber	At installation (or initial use) and after nonroutine maintenance [i]		
Temperature sensing devices/systems, reference (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, automated monitors, etc.)	Calibrate temperature to the appropriate traceable standard	Every 2 years		
Temperature sensing devices/systems, working (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, automated monitors, etc.)	Verify temperature against reference device	Annually		

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Timers and internal timing devices [k]	Time	Verify working device annually against reference or against NIST time clock [l]		
UV-Vis spectrophotometer	Verify blank reading	Daily when in use		
UV-Vis spectrophotometer	Verify wavelength	At installation and annually		
Volumetric delivery devices: mechanical pipets, positive displacement pipets, mechanical burets, and liquid dispensers [m]	Verify accuracy using mass of water at a known temperature or by spectrophotometric method	As according to laboratory management system, minimum every 6 months		
Volumetric delivery devices: positive displacement syringes used for volumetric delivery [n]	Verify accuracy [O]	Upon receipt (manufacturer's certificate of accuracy may be accepted) [O]		
Volumetric nonclass A glassware: pipets, burets, positive displacement pipets, and volumetric flasks	Verify accuracy using mass of water at a known temperature by spectrophotometric method or by manufacturer's certificate of accuracy (provided the equipment is used under manufacturer's specified normal conditions)	Upon receipt		
Water Activity Meter	Verify water activity of known solutions	Daily when in use [g]		

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Water, used in all analyses to meet method requirements	Method-specific water quality attributes	Minimally every month		
Water, used for microbiological analyses	Acceptable levels of chlorine and aerobic plate count	Monthly		
Water used for pharmaceutical analyses	The eight types of water are as follows: 1. Nonpotable 2. Potable (drinkable) water 3. USP purified water 4. USP water for injection 5. USP sterile water for injection 6. USP sterile water for inhalation 7. USP bacteriostatic water for injection 8. USP sterile water for irrigation	Meet FDA Inspection Technical Guide Requirements [p]		
Weights, reference	Calibrate mass	Every 5 years [c]		
Weights, working	Verify mass against reference weights	Annually		

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[a] Uniformity may not be needed for low-capacity equipment. For example, a small muffle furnace with less than 1 ft3 capacity may be too small to detect variability. In these cases, the laboratory should have documented justification for not determining uniformity.
[b] Autoclaves equipped with a calibrated temperature sensing device that provides a record of temperature are considered to meet this requirement.
[c] All weights and balances shall be calibrated traceable to recognized national or international calibration units (i.e., National Institute of Standards and Technology, Bureau International des Poids et Mesures, Organisation Internationale de Métrologie Légale, or equivalent traceable weights). Accrediting bodies may require calibration by an ISO/IEC 17025-accredited calibration laboratory.
[d] A calibration is required when there has been a significant move (one involving packing and transport) to a different location or after a repair that requires significant disassembly and that produces a significant risk to the accuracy of measurements. A move to another lab bench or a minor repair would not necessarily trigger the need for a calibration.
[e] Balances or scales that are used in temporary locations outside of the laboratory.
[f] For quantitative methods, an analytical standard at the mid-range or lower of the calibration curve can verify detector response. For qualitative assessments, the appropriate response material must be used.
[g] When pH or water activity results are reported to the customer or may be a significant component of overall uncertainty of the measurand, the reference material (e.g., buffer or water activity analytical standard) must satisfy the requirements for metrological traceability (Clause 6.5.1). Accreditation bodies may require buffers obtained from an ISO 17034-accredited manufacturer.
[h] The intent is that the laboratory shall be able to verify that samples, reagents, reference materials, and other critical materials were stored at the proper temperature for the duration of storage. Automated monitoring with a calibrated and validated system meets this requirement. A min/max data logging thermometer would require verification at a frequency dependent upon the amount of data it can store.
[i] When determining mapping schedules, attention should be paid to extremes in laboratory ambient conditions(such as those brought on by seasonal changes) that can influence the performance of equipment. Initial and nonroutine maintenance monitoring can be done with no load.
[j] If a temperature-controlled chamber is only in use for a specified time less than 4 hours (e.g., waterbath, heat block), the laboratory can verify temperature at the beginning and end of use.
[k] Timers and internal timing devices only need to be verified when time is a critical factor in the test method. Time may not be a critical factor when time is not the reported result or a precise time is not required for the test method.

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[l] Accrediting bodies may require initial calibration by an ISO/IEC 17025-accredited calibration laboratory.

[m] Disposable serological pipets can be verified through receipt of manufacturer's certificate of accuracy.

[n] An acceptable alternative to weighing the mass of liquid delivered by a bottle top dispenser would be through measuring the dispensed volume of liquid. It is up to the lab to ensure the alternative to weighing is suitable for its intended use.

[o] Methods and frequency required to verify accuracy may be chosen based on how critical the exact volume delivery is to the test method. Acceptable methods may include, but are not exhaustive to, using a mass of water at a known temperature, by a spectrophotometric method, or comparing volumes dispensed against other calibrated pipets or glassware. An unexpired manufacturer's certificate of accuracy may also be accepted.

[p] https://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072925.htm

ALACC Appendix B	Microbiology			
ALACC Appendix B1	Are the organisms required for testing checked for purity (i.e., free from contamination by other organisms), enumeration, and relevant biochemical or biological characteristics, as appropriate for their intended application?			
ALACC Appendix B1	Is traceability of the organisms established and documented from the date of possession?			
ALACC Appendix B2.1	Is each batch of media examined to confirm its suitability for use?			
ALACC Appendix B2.1	For internally prepared media, are records maintained that include: • The components used and their respective amounts?			

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	• Traceability to the dehydrated media? • pH measurement and appearance? • Sterilization batch information? • Fill volumes (if applicable)? • Batch size and quantity?			
ALACC Appendix B2.2	Does each batch of media undergo quality control verification for: • Productivity (with positive culture)? • Selectivity (if applicable)? • Sterility?			
ALACC Appendix B2.2	Are verification records traceable to the individual who approved or rejected the media?			
ALACC Appendix B2.2	If quality control verification is performed concurrently with testing and the verification fails, does the laboratory treat all data generated with that batch as suspect and initiate the nonconforming work procedure?			
ALACC Appendix B3	Has the laboratory approved each lot of material prior to use?			
ALACC Appendix B3	Do the records for each approved or rejected lot include at least the date of approval and traceability to the			

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	individual who performed the approval or rejection?			
ALACC Appendix B3	For identification systems that speciate organisms (e.g., API 20E, VITEK, Biolog), does the laboratory verify the acceptability of the kit using a single appropriate control organism, unless there is a specific need to confirm identification of multiple organisms?			
ALACC Appendix B4	Autoclave Sterilization: Do autoclave records include the following information: • Date of the sterilization run? • Run number? • Autoclave identifier? • Description of the material or load sterilized? • Duration at the required temperature? • Traceability to the person(s) who performed the sterilization?			
ALACC Appendix B4	Other Sterilization Methods: 2. For sterilization methods other than autoclaving, do records include: • Date of sterilization? • Description of the material sterilized?			

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	• Confirmation of the sterilization procedure used (e.g., heating conditions, filtration, chemical denaturation)? • Traceability to the person(s) who performed the sterilization?			
Appendix C	**Chemistry**			
ALACC Appendix C	When applicable to the method, are acceptance criteria defined for the following elements: • Calibration curves? • Calibration checks? • Standard preparations? • Quality control samples? • Blanks? • Spikes? • Matrix spikes? • Duplicates?			
ALACC Appendix C	Does the laboratory have a documented policy or procedure describing how and when manual processing and/or integration of chromatographic data is permitted?			
Appendix D	**Pharmaceutical Analysis**			
ALACC Appendix D	Has the laboratory established scientifically sound and appropriate:			

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	• Specifications? • Standards? • Sampling plans? • Test procedures?			
ALACC Appendix D	Do these controls ensure that components, drug product containers, closures, in-process materials, labelling, and drug products conform to applicable standards of identity, strength, quality, and purity?			
ALACC Appendix E.1	Has the laboratory ensured that its analytical methods for dietary supplements are adequate and fit for purpose, considering the evolving nature of formulations, ingredients, and matrixes?			
Appendix E	**Dietary Supplement Laboratories**			
ALACC Appendix E.1	During method validation, does the laboratory use well-characterized, homogenized, and stable materials where possible?			
ALACC Appendix E.1	When available, does the laboratory utilize Certified Reference Materials (CRMs) and/or Standard Reference Materials (SRMs) to support method validation?			

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ALACC Appendix E.1	Does the laboratory obtain CRMs or SRMs from recognized sources, such as: • National Institute of Standards and Technology (NIST)? • United States Pharmacopeia (USP)? • British Pharmacopoeia (BP)? • European Pharmacopoeia (Ph. Eur.)? • American Herbal Pharmacopoeia (AHP)? • PhytoLab or other reputable providers?			
ALACC Appendix E.2	Has the laboratory documented a plan for participation in interlaboratory comparisons, given that appropriate proficiency testing (PT) programs may not be available for dietary supplement laboratories?			
ALACC Appendix E.2	Does the laboratory participate in recognized interlaboratory comparison or quality assurance programs, such as the NIST-established Health Assessment Measurements Quality Assurance Program (HAMQAP), where applicable?			
ALACC Appendix E.2	Does the laboratory evaluate its performance in such programs by reviewing metrics such as accuracy,			

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	precision, and concordance with peer laboratories?			
ALACC Appendix E.2	In cases where no interlaboratory comparison is available, has the laboratory developed and justified an alternative plan for monitoring the validity of its analytical data?			
ALACC Appendix E.3	Guidance Only			
ALACC Appendix E.4	Has the equipment qualified in accordance with the requirements outlined in the table below?			

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Equipment	Action	Frequency	Compliant Y/N	Observation
Detector response (UV, diode-array detection, fluorescence, electron ionization, RI, evaporative light- scattering detection, MS)	Verify detector response/linearity with at least three concentrations of analytical standard or certified reference standard if available. Concentrations should include the low, high, and mid-range of the calibration curve.	At least once with each batch Chromatographic systems (GC, ion chromatography, LC)		
Chromatographic systems (GC, ion chromatography, LC)	Pump flow accuracy and precision, column temperature accuracy and stability, wavelength accuracy, signal-noise and drift, injection precision, injection carry-over, gradient composition accuracy, gradient composition noise and drift, sample temperature accuracy	Annually, or after maintenance and repair		

Appendix F	Cannabis			
ALACC Appendix F 1.1	Are employees advised to follow all applicable local, state, and federal regulatory requirements, including being made aware that cannabis remains a federally prohibited substance?			

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ALACC Appendix F 1.2	Does the laboratory have a documented procedure describing how risks to impartiality are identified and evaluated?			
ALACC Appendix F 1.2	Does the laboratory's policy include potential actions to address any identified risks to impartiality?			
ALACC Appendix F 2.1	Does the laboratory have a documented procedure that specifies the frequency for monitoring the test environment for microbial contaminants?			
ALACC Appendix F 2.1	Does the procedure include measures to reduce the risk of cross-contamination?			
ALACC Appendix F 2.2	Does the laboratory have security measures in place to limit access to controlled areas, including the laboratory facility, cannabis waste storage, and cannabis-product storage areas?			
ALACC Appendix F 2.3	Does the laboratory have video surveillance in place to monitor key activities, including but not limited to: • Sample receiving? • Sample storage? • Sample weighing? • Sample destruction?			
ALACC Appendix F 2.4	When video surveillance equipment is used, does the laboratory verify that it meets specified requirements before			

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	being placed into service and after any repairs?			
ALACC Appendix F 2.5	When video surveillance equipment is used, does it include the following components at a minimum: • Digital or network video recorders? • A video monitor that allows clear identification of individuals performing work on behalf of the laboratory? • A still-photo printer? • Battery back-up?			
ALACC Appendix F 2.5	Does the video surveillance system maintain a digital archive of recordings for at least 45 days?			
ALACC Appendix F 2.5	If there is pending or expected litigation or an ongoing investigation, does the laboratory ensure that the digital archive is retained until the conclusion of the investigation or litigation?			
ALACC Appendix F 3.1	Does the laboratory have a quality manual that documents, describes, and/or references quality-related procedures and test methods?			

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ALACC Appendix F 3.2	Does the laboratory ensure employee commitment to support laboratory operations, including the following areas: • Maintaining confidentiality? • Upholding impartiality? • Implementing only approved and authorized procedures? • Refraining from falsifying or otherwise manipulating data? • Refraining from falsifying or otherwise manipulating records? • Refraining from unauthorized distribution or discarding of laboratory materials or information?			
ALACC Appendix F 3.3	Has the laboratory defined personnel responsible for quality management?			
ALACC Appendix F 3.3	Are laboratory activities managed to: • Ensure compliance with applicable requirements? • Reduce and manage the occurrence of nonconformances? • Promote continual process improvement? • Ensure the overall effectiveness of the management system?			

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ALACC Appendix F 4	Has the laboratory established and retained records documenting the storage conditions and shelf-life stability of all previously opened Certified Reference Material (CRM) source containers?			
ALACC Appendix F 5	Do quotations for laboratory work or Invitations for Bid (IFB) meet the process requirements specified in ISO/IEC 17025:2017, clause 7.1?			
ALACC Appendix F 6.1	Has the laboratory developed and implemented a chain-of-custody procedure, unless exempt due to valid reasons such as differing state regulations or pending litigation?			
ALACC Appendix F 6.1	Does the chain-of-custody documentation include the following details: • Laboratory name, physical address, and license number? • Producer's name, physical address, and license number? • Unique sample identification? • Date and time of sample collection (as available)? • Description and quantity of samples collected?			

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	• Estimated sample weights taken at the collection site? • Use of tamper-evident seals, where appropriate? • Printed and signed name(s) of the supplier? • Printed and signed name(s) of the sample collector? • Printed and signed name(s) of the transporter or courier from the supplier to the laboratory? • Printed and signed name of the laboratory personnel who received the sample(s)? • Printed and signed name of the laboratory personnel responsible for the sample destruction and the date of destruction?			
ALACC Appendix F 6.2	Upon receipt, are all samples compared against the chain-of-custody record by authorized laboratory personnel who were not involved in field sampling or transportation?			
ALACC Appendix F 6.2	Are any anomalies—such as discrepancies in quantity received or differences in recorded information—documented and reported to both			

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	laboratory management and the customer?			
ALACC Appendix F 6.3	Does the laboratory ensure that it does not accept samples that do not meet the minimum size or quantity requirements specified by either the regulatory body or the laboratory's analytical methods?			
ALACC Appendix F 6.3	If a sample is received that is smaller than required, do laboratory personnel: • Set the sample aside? • Notify the sampling personnel and laboratory management? • Ensure the issue is remedied before proceeding with any work, in accordance with ISO/IEC 17025:2017, clause 7.1?			
Appendix F 6.4	Does the laboratory maintain a record or set of records that reconciles the sample weight from the time of receipt through to destruction or disposal, including accounting for any loss?			
Appendix F 6.5	Is the chain-of-custody procedure and corresponding documentation implemented whenever a sample or any portion of a sample is outsourced for any reason?			
Appendix F 7	When regulatory procedures for sampling are not specified, does the			

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	laboratory have a documented sampling procedure that includes: • A list of contents for a sampling kit with all necessary equipment and supplies? • Chain-of-custody and sample submittal procedures? • A description of the types of products being sampled (e.g., flower, finished product)? • A description or photograph of the sampling environment (e.g., bins, containers, bags, rooms)? • A method for determining the overall field of samples and the quantity and/or number of samples collected? • A description of the sample collection method used to ensure equal opportunity for all product material to be sampled (e.g., random sampling, stratified random sampling, random-sequential sampling)? • A description of sample handling practices to prevent cross-contamination, based on the type of sample collected (e.g.,			

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	flower vs. distillate or packaged products)? • A description of the transportation process to ensure sample integrity during transit to the laboratory? • A procedure to record official sample weights in the laboratory using calibrated scales or balances, noting that weights taken at the collection site are estimates if noncalibrated scales are used?			
Appendix F 8.1	Does the laboratory ensure that all quantitative, semiquantitative, or qualitative test methods are appropriate for the specific matrix being tested, and not assume that a method validated for one matrix is suitable for other or different matrices?			
Appendix F 8.2	Does the laboratory have a documented procedure for the validation of quantitative analytical chemistry methods?			
Appendix F 8.2	Does the validation procedure include predetermined acceptance or rejection criteria for each of the following parameters, where applicable: • Specificity?			

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	• Sensitivity? • Method selectivity? • Limit of detection (LOD)? • Limit of quantitation (LOQ)? • Measurement range? • Linearity? • Repeatability? • Reproducibility? • Robustness? • Measurement bias?			
Appendix F 8.3	When extending a validated quantitative method to additional matrix or matrices, does the laboratory verify or validate the method to the extent necessary to demonstrate that it remains fit for its intended use (e.g., from cannabis flower to concentrates, edibles, or other specific commodities)?			
Appendix F 8.4	If a microbiological test kit was developed for a commodity other than cannabis, has the laboratory demonstrated that the kit is fit for use with cannabis matrices?			
Appendix F 8.4	Has the laboratory performed individual matrix studies to validate, to the extent necessary, the following parameters: • Matrix effects, including potential interferences and/or			

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	the presence of non-target microorganisms? • Minimum detection threshold for each target organism?			
Appendix F 8.5	Does the laboratory have a documented procedure to confirm the presence of target organism(s) during method validation?			
Appendix F 8.5	Are records of results retained for each matrix and for each target organism validated?			
Appendix F 9.1	Except for working standards, stock standards, or neat Certified Reference Materials (CRMs), are all quality control samples processed through the entire analytical procedure, including sample preparation?			
Appendix F 9.2	Does the laboratory ensure that sample fortification or spiking is performed at the initial stage of sample preparation?			
Appendix F 9.3	Does the initial calibration curve established by the laboratory represent the instrument's linear working range?			
Appendix F 9.3	Is an initial calibration verification (ICV) working standard from a second source used to verify the linearity of the calibration curve?			

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Appendix F 9.4	Does each sample batch include a matrix blank to ensure there is no analyte or contaminant carry-over?			
Appendix F 9.5	Does each sample batch include a continuous calibration verification (CCV) after every 10 non-quality control (non-QC) samples to ensure continued system suitability?			
Appendix F 9.5	If a CCV fails, does the laboratory immediately repeat the CCV and take appropriate corrective action as necessary?			
Appendix F 9.6	Does each sample batch include a laboratory control sample (LCS) containing known natural or fortified concentrations of designated analyte(s) in the same or a similar matrix or commodity?			
Appendix F 9.7	Does each quantitative assay have a corresponding quality control chart that includes defined warning and control limits?			
Appendix F 9.8	When quantitative or qualitative microbiological test methods are used outside their original validation parameters or matrices, does the laboratory ensure they meet			

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	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	predetermined quality control objectives, including the following: • Are uninoculated media controls (blanks) carried through the entire assay? • Are positive and negative control organisms included to detect atypical or no-media growth? • Are inclusivity and exclusivity studies performed, with organism concentrations at least 100 times the method's LD50? • Is the analyte concentration level appropriate for the specific matrix? • Are samples inoculated or confirmed to naturally contain low levels of the analyte to ensure positive detection? • Are samples inoculated or confirmed to naturally contain high levels (one log higher than the positive detection level) of the analyte? • Are matrix effects assessed, including interferences and the presence of non-target microorganisms?			

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Appendix F 9.9	When test kits are used, does the laboratory implement appropriate analytical quality control measures to supplement the kit's built-in controls and ensure the detection system operates within specifications?			
Appendix F 9.10	Does the laboratory have a documented procedure for determining expanded measurement uncertainty (k = 2, approximately 95% confidence level) for each reported test result?			
Appendix F 9.10	Are records of measurement uncertainty maintained for each test?			
Appendix F 9.10	Is the measurement uncertainty included with the results for each assay on the test report or Certificate of Analysis (COA)?			
Appendix F 9.11	In addition to the requirements of ISO/IEC 17025:2017 clause 7.8, does the test report include batch quality control results for each analyte?			
Appendix F 12.1	Does the laboratory conduct an internal audit of the management system at least once per year?			
Appendix F 12.2	Does the laboratory conduct an internal audit of its technical program—covering all methods on the Scope of Accreditation and any additional			

Clause	Summary of Requirement	Document(s)	Conformity Determination	Objective Evidence Reviewed to Make Determination
	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	supporting methods—at least once every two years?			
Appendix F 12.3	Are internal audits conducted by personnel who are qualified and authorized, in accordance with ISO/IEC 17025:2017 clause 6.3?			
Appendix F 12.4	Does the laboratory retain records of all internal audit findings, including but not limited to: • Completed checklists? • Audit procedures used? • Data reviewed? • Personnel interviewed? • Results of corrective actions taken?			
Appendix F 13	Does the laboratory conduct a review of the entire management system, in accordance with ISO/IEC 17025:2017 clause 8.9, at least once per year?			
Appendix F 13	Is the management review conducted either in a single session or across multiple sessions, as appropriate?			