



Quality System Document

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In addition to those document sections indicated with an asterisk on the *AIHA-LAP, LLC Application Review and Site Assessment Checklist*, please confirm with your site assessor his/her preference to have the following documents and records pulled or otherwise pre-organized or readily available upon request for review during the on-site assessment to assist in expediting the assessment process. It is not necessary to submit any of these documents/records prior to the on-site assessment unless the assessor otherwise specifically requested them. For those organizations whose records are solely electronic, a work station must be provided for the assessor's review process; otherwise, printed copies will be requested on-site.

Please note that this is not a complete listing of documents and records that will be reviewed as part of the assessment. For a complete listing of relevant documents and record requirements, please consult the current AIHA-LAP, LLC Accreditation Policy Modules and the *AIHA-LAP, LLC Site Assessment Checklist*.

**Note:** All ISO requirements are incorporated by reference in AIHA-LAP, LLC Accreditation Policies.

**General Quality System and Technical Documents/Records**

AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
	8.3.2	List of controlled documents.
	7.1.8	Records of contract reviews and records of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.
	7.1.1.c	Records of client notification/approval of subcontracting.
	6.6.2	Procedure and example records for externally provided products and services and, where applicable, evidence of compliance with ISO/IEC 10725:2017 and AIHA-LAP, LLC requirements for the service in question.
	6.6.2.d 6.6.3	Records of actions taken to check compliance of supplies and services with specifications.
	6.6.1.a 6.6.2.a, b 6.6.3.a,b,c	Purchasing documents and records of review and approval for technical content prior to release.
	6.6.2.b, d	Records of evaluations and list of approved suppliers.



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AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
	7.9.1	Complaints process on how the lab receives, evaluates and makes decision on complaints. Provide examples.
	8.7.1.c 8.7.1.f 8.7.2 8.7.3	Documentation of any required changes resulting from corrective action investigations.
	8.7.1.b, c, f 8.7.2 8.7.3	Records of all nonconforming events/work, the determined cause(s), and corrective actions taken when required, including outliers from all types of demonstrations of proficiency including third-party testing, round robin, or comprehensive internal PT program.
	8.6.1 8.6.2	Opportunities for improvement and any necessary actions.
	7.11.3	Process or procedures used to protect the laboratory information management system from unauthorized use.
	8.8.2.e	Records of the implementation of the audit program and the audit results.
	8.9.3	Records of decision and actions related to the management review.
	6.2.2	Records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.
	6.3.1 6.3.2 6.3.5	Requirements for facilities and environmental conditions that can affect the validity of results.
	6.3.3 6.3.4.b	Records of environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.
	6.4.3 7.2.1.2 7.2.1.7	Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing. (Analytical Methods for all desired FoTs). Records documenting any deviations from test methods, the technical justification, authorization, and acceptance by the client.



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AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
	7.2.2.1 7.2.2.4	Records of validation of non-standard methods, laboratory- developed methods, and standard methods used outside their intended scope, or otherwise modified.
Appendix G, Section 5.4	7.6.3	Procedure describing the process used to evaluation measurement uncertainty.
	7.11.2 6.4.4 6.4.5	Documentation and validation of computer software developed by the laboratory.
2A.7.7.3		Records of data review.
	6.4.1 6.4.3 – 6.4.7	Calibration and maintenance procedure and records for equipment.
	6.4.3	Procedure for handling and maintenance of equipment.
	6.4.13	Records for equipment which can influence laboratory activities.
	6.4.10	Procedures for checks necessary to maintain confidence in the performance of equipment.
	6.4.1 6.4.3	Procedures for safe handling, storage and use of reference materials.
	7.3.3.h	Records of client required deviations, additions or exclusions from the documented sampling procedure.
Appendix H, Section 5.5		Documentation that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used for calibrations performed in-house, allowing for an overall uncertainty to be estimated for the in-house calibration.
Appendix H, Section 5.8		Procedures describing external and internal calibration and verification activities and frequencies, and the actions to follow if the equipment is found to be out of acceptable specification.
Appendix H, Section 5.9		Documented training for laboratory staff performing in-house calibrations and verifications.
	7.4.3	Records of deviations from specified conditions identified upon sample receipt. Records of discussions with the client regarding the suitability of an item for test, or when an item does not conform to the description provided, or when the test required is not specified in sufficient detail.



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	7.7.1	Data recorded in such a way that trends are detectable and, where practicable, statistical techniques have been applied to the reviewing of the results.
	7.8.1.2	Example test reports and supporting data (to be selected by the assessor on site)
	7.8.2.1.p	Subcontracted test report and supporting data
	7.8.8	Example amended test report
2A.9		Chemical Hygiene Plan
Module 6		Proficiency testing, comprehensive internal PT program, or round robin score results and overall proficiency for corresponding FoTs to be accredited.



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**IHLAP Specific Documents/Records**

AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
2B.2		Process for defining, establishing, verifying, and reporting of minimum reporting limits.
2B.2.1		Records of minimum reporting limit verifications

**ELLAP Specific Documents/Records**

LQSR/AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
LQSR 5.2.1.1.3 (Paint, Soil, Dust Wipes)		Records of a minimum of four (4) independent test runs of sample preparation and/or instrumental analysis for each FoT for each analyst and technician.
LQSR 5.4.4.1 (Paint, Soil, Dust Wipes)		Method Detection Limits (MDLs) records
2C.2.6 (Air)		
LQSR 5.3.1.1 (Dust Wipes)		Definition of the areas to be sampled and the level of acceptable contamination for quarterly wipe samples Results of quarterly wipe sampling to determine surface levels of lead in the laboratory and any corrective actions taken.



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**EMLAP Specific Documents/Records**

AIHA-LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
2D.2.1		Documented routine monitoring program to verify adequate contamination control.
2D.3.1.1.2		Records of annual ocular micrometer calibrations for non-fluorescence microscope(s)
2D.3.2.1		Records of annual certification of the Class II biological safety cabinet (BSC) to NSF Standard 49.
2D.5.1		SOPs addressing collection, transport, processing and analysis of samples; determining minimum reporting limits for each quantitative or semi-quantitative method; appropriate retention, waste treatment and disposal of environmental microbial samples; identification of fungi and/or bacteria; identification of fungal spores and structures; and biosafety and decontamination for the applicable FoT(s).]
2D.6.1.5		Records of quality control of culture media and analytical reagents per lot number for appropriate sterility, microbial growth and/or analytical reactions.
2D.6.2.2		Procedures for maintaining the cultures and using them for training and QC purposes.
2D.6.3.2		Two most recent spore trap round robin reports (Air Fungal Direct Examination FoT)