



Quality System Document

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Title: Onsite Documents and Records Review List

In addition to those document sections indicated with an asterisk on the *AIHA LAP, LLC (AIHA LAP) 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 workstation 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 Accreditation Policy Modules and the *AIHA LAP Site Assessment Checklist*.

Note: All ISO requirements are incorporated by reference in AIHA LAP Accreditation Policies.

General Quality System and Technical Documents/Records

AIHA LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
2A.1		Authorized copy of the ISO/IEC 17025:2017 Standard.
	4.1.4	Records of identification of risks to impartiality.
	4.1.5	Records demonstrating how the laboratory eliminates or minimizes any identified risks to impartiality.
	4.2.1	Legally enforceable commitments (with both staff and customers) for the confidential management of all information obtained or created during the performance of laboratory activities.
	5.3	Definition and documentation of the range of laboratory activities for which the laboratory conforms with ISO/IEC 17025:2017.
	6.2.5 6.2.6	Records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel;



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		d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel.
	6.3.2	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	Procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.
	6.4.4	Verification that equipment conforms to specified requirements before being placed or returned into service.
	6.4.10	Records of intermediate checks necessary to maintain confidence in the performance of equipment.
	6.4.13 a-h	Records for equipment which can influence laboratory activities.
Appendix H, 5.2		External calibration certificates.
Appendix H, 5.4		Reference material certificates of analysis.
Appendix H, 5.5		In-house calibration records.
Appendix, H 5.7		Records of periodic verifications to demonstrate the continued validity of the calibration at specified intervals between calibrations.
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		Training records for laboratory staff performing in-house calibrations and verifications.
	6.6.2 a-d	Records for: a) defining, reviewing and approving the laboratory's requirements for externally



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		<p>provided products and services;</p> <p>b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;</p> <p>c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;</p> <p>d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.</p>
	6.6.3	<p>Evidence of communication of laboratory requirements to external providers for:</p> <p>a) the products and services to be provided;</p> <p>b) the acceptance criteria;</p> <p>c) competence, including any required qualification of personnel;</p> <p>d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.</p>
	7.1.1.c	Records of client notification/approval of subcontracting.
	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.
	6.4.3 7.2.1.2	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).
	7.2.1.5	Records of verification that the laboratory can properly perform methods before introducing them by ensuring that it can achieve the required performance.
	7.2.1.7	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.
	7.2.2.4	The following records of method validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics of the method; d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use.
	7.3.3. a-h	Records of sampling.
	7.4.3	Records of deviations from specified conditions upon receipt of test items and records of consultation with the customer for further instructions.
	7.4.4	Records of environmental conditions, when items need to be stored or conditioned under specific environmental conditions.
	7.5.1	Technical records containing the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original.
Appendix G, Section 5.1 Appendix G, Section 5.4	7.6.3	Demonstration of ability to evaluate measurement uncertainty for all accredited quantitative test methods in accordance with the laboratory procedure describing the process used to evaluate measurement uncertainty.
	7.7.1 a-k	Records of monitoring the validity of results in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results.
2A.7.7.1.3		Control charts or quality control databases used to record quality control data and compare them with acceptance limits.



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AIHA LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
2A.7.7.2 2A.7.7.3		Records of independent data review.
	7.8.2.1.p	Subcontracted test report and supporting data
	7.8.8.1	Amended or re-issued report.
	7.9.1 7.9.3 a-c	Complaints process on how the lab receives, evaluates and makes decision on complaints and associated records.
2A.7.10.1	7.10.2	Records of nonconforming work and actions as specified in 7.10.1, bullets b) to f) including outliers from all types of demonstrations of proficiency including third-party testing, round robin, or comprehensive internal PT program.
	7.11.2	Documentation and validation of laboratory information management systems developed by the laboratory. Validation of functionality of spreadsheet (e.g. Excel workbook) applications implemented by the laboratory.
	7.11.6	Records of checks of calculations and data transfers.
	8.4.1	Legible records to demonstrate fulfilment of the requirements in this document.
	8.5.1 a-c	Records of consideration of the risks and opportunities associated with the laboratory activities.
	8.5.3	Actions taken to address risks and opportunities.
	8.6.1	Opportunities for improvement and any necessary actions.
	8.6.2	Records of feedback, both positive and negative, from its customers..
	8.7.3	Records as evidence of: a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action.
	8.8.2.e	Records of the implementation of the internal audit program and the audit results.



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AIHA LAP Policy Module Reference	ISO/IEC 17025:2017 Reference	Document or Record
	8.9.2 a-o 8.9.3 a-c	Records of all inputs and decisions and actions related to required output elements of the management review.
2A.9		Chemical Hygiene Plan/Biosafety Plan
Module 6		Raw data and proficiency testing, comprehensive internal PT program, and/or round robin scored results and overall proficiency for corresponding FoTs to be accredited.

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.2.3		Records of annual 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
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.4.1		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.5.1.5		Records of quality control of culture media and analytical reagents per lot number for appropriate sterility, microbial growth and/or analytical reactions.
2D.5.2.2		Procedures for maintaining the cultures and using them for training and QC purposes.
2D.5.2.3		Records of monthly blind culture identifications.
2D.5.3.2		Two most recent spore trap round robin reports (Air Fungal Direct Examination FoT)
2D.5.3.3		Records of annual documentation of the traverse width or field of view to be used in calculations for each microscope, if applicable.