



Onsite Documents and Records Review List

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 Application Review and Site Assessment Checklist*.

Note: References beginning with just a number (e.g. 4.1.4) are ISO/IEC 17025:2005 references; references beginning with a number and letter combination (e.g. 2A.4.11) are AIHA-LAP, LLC Accreditation Policy references. All ISO requirements are incorporated by reference in AIHA-LAP, LLC Accreditation Policies.

General Quality System and Technical Documents/Records

1. (4.3.2.1) Master list of controlled documents.
2. (4.4.2) 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.
3. (4.5.2) Records of client notification/approval of subcontracting.
4. (4.5.4) Register of all subcontractors and a record of the evidence of compliance with ISO/IEC 10725:2005 and AIHA-LAP, LLC requirements for the work in question
5. (4.6.2) Records of actions taken to check compliance of supplies and services with specifications.
6. (4.6.3) Purchasing documents and records of review and approval for technical content prior to release.
7. (4.6.4) Records of evaluations and list of approved suppliers.
8. (4.8) Records of all complaints and of the investigations and corrective actions taken by the laboratory.



9. (4.11.3) Documentation of any required changes resulting from corrective action investigations
10. (2A4.9.1 and 2A.4.11.1) Records of all nonconforming events/work, the determined cause(s), and corrective actions taken when required, (2A4.9.2, 2A.4.11.2) including outliers from proficiency testing, round robin, or demonstration of competency.
11. (4.12.1, 4.12.2) Preventive action procedure and preventive actions plans.
12. (4.13.1.4) Procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.
13. (4.14.3) Records of internal audit findings and corrective actions that arise from them.
14. (4.15.2) Records of findings from management reviews and the actions that arise from them.
15. (2A.4.15.3) Most recent quarterly QAC report to management.
16. (5.2.5) Records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.
17. (2A.5.2.1.3) Demonstrations of proficiency for analysts.
18. (5.3.1) Technical requirements for accommodation and environmental conditions that can affect the results of tests.
19. (5.3.2) Records of environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.
20. (2A.5.3.2) Records of ventilation hood face velocity checks.
21. (5.4.1) 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).
22. (5.4.1) Records documenting any deviations from test methods, the technical justification, authorization, and acceptance by the client.
23. (5.4.5.2) Records of validation of non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplification and modifications of standard methods.
24. (App G 5.4; 5.4.6.2) Procedure describing the process used to estimate measurement uncertainty.
25. (5.4.7.2 a) Documentation and validation of computer software developed by the laboratory.



26. (2A.5.4.7) Records of data review.
27. (5.5.2) Calibration and maintenance program/records for testing and support equipment.
28. (5.5.3) Instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment).
29. (5.5.5) Records of each item of equipment and its software significant to the tests performed.
30. (2A.5.5.6) Where appropriate, cleaning procedures for glassware and apparatus
31. (5.6.3.3) Procedures and schedules for checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials.
32. (5.6.3.4) Procedures for safe handling, storage and use of reference standards and reference materials.
33. (2A.5.6.1) Requirements for reagents and standards to ensure the quality of testing.
34. (5.7.2) Records of client required deviations, additions or exclusions from the documented sampling procedure.
35. (2A.5.7.1) Information regarding sampling materials, sampling containers, preservatives, and shipping instructions.
36. (App H 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.
37. (App H 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.
38. (App H 5.9) Documented training for laboratory staff performing in-house calibrations and verifications.
39. (5.8.3) Records of abnormalities or departures from normal or specified conditions identified during sample receipt.
40. (5.8.3) 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.
41. (5.9.1) Quality control data recorded in such a way that trends are detectable and, where practicable, statistical techniques have been applied to the reviewing of the results.
42. (5.10.1) Example test reports and supporting data (to be selected by the assessor on site)



43. (5.10.6) Subcontracted test report and supporting data
44. (5.10.9) Example amended test report
45. (2A.6) Chemical Hygiene Plan
46. (Mod 6) IHPAT, ELPAT, EMPAT, BAPAT, NVLAP, BePAT, Direct Exam, and/or other relevant third-party proficiency testing, internal demonstration of competency or round robin score results and overall proficiency for corresponding FoTs to be accredited

IHLAP Specific Documents/Records

1. (2B.3.2.1) The criteria and training requirements for laboratory personnel.
2. (2B.3.2.1) Description of the training program content, duration of training, qualifications of the trainer, and objective evidence that the analyst/technician has successfully analyzed unknown reference samples of the matrices/analytes of concern within specified acceptance limits.
3. (2B.4) Process for defining, establishing, verifying, and reporting of minimum reporting limits.
4. (2B.4.1) Records of minimum reporting limit verifications
5. (2B.5.1.1.h) Two most recent PCM round robin reports

ELLAP Specific Documents/Records

1. (2C.3.2.4) 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.
2. (2C.4.3.2) Method Detection Limits (MDLs) records
3. (2C.4.12) Records indicating that each batch of composited wipe samples and associated quality control (QC) samples contain the same number of wipes, i.e. composited wipes that contain two wipes are to be analyzed in a batch containing QC samples to which two wipes were added as matrix
4. (2C.5.10) Definition of the areas to be sampled and the level of acceptable contamination for quarterly wipe samples.
5. (2C.5.10) Results of quarterly wipe sampling to determine surface levels of lead in the laboratory and any corrective actions taken.

EMLAP Specific Documents/Records

1. (2D.2.1) Documented routine monitoring program to verify adequate contamination control.



2. (2D.3.1.2.2) Records of annual ocular micrometer calibrations for non-fluorescence microscope(s)
3. (2D.3.2.1) Records of annual certification of the Class II biological safety cabinet (BSC) to NSF Standard 49.
4. (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).
5. (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.
6. (2D.6.2.2) Procedures for maintaining the cultures and using them for training and QC purposes.
7. (2D.6.3.2) Two most recent spore trap round robin reports (Air Fungal Direct Examination FoT)