INSTRUCTIONS
FORMS 6A THROUGH 6G – GENERAL AND PROGRAM-SPECIFIC REQUIREMENTS

OVERVIEW:

- Forms 6A through 6G are designed to assist the laboratory in becoming familiar with the requirements of AIHA LAP program(s) for which the laboratory is applying. The information requested on these forms will also help the site assessor to prepare for the on-site assessment of the laboratory.
- All laboratories applying for initial accreditation, reaccreditation, or a field of testing addition are required to submit the attachments as specified in Form 6A, General Quality Assurance Requirements.
- Forms 6B through 6G address the program-specific requirements and attachments to be submitted for each of the individual accreditation programs for which the laboratory is applying.
- The laboratory must submit the attachments as specified in Form 6A (General QA requirements) and program-specific Forms 6B through 6G, as applicable.

INSTRUCTIONS

A. Consult the AIHA LAP Policy Modules located here, each of which is incorporated by reference herein and is made a part hereof.

   1. The policy numbers included on Forms 6A through 6G correspond to the policy numbers in the AIHA LAP Policy Modules and/or ISO/IEC 17025:2017.
   2. Before completing this section of the application, the laboratory should read each applicable laboratory accreditation policy module carefully to ensure that the laboratory is in full compliance with all applicable program policies.

B. Attach an example of an actual, completed record for the "submission example required" – as specified by a "**X**" in the "Initial," "Reaccreditation", and/or "FoT Addition" columns to document that the laboratory is in full compliance.

   1. If the laboratory is not in compliance, then the laboratory should stop the application process and review and revise its procedures and practices as necessary. AIHA LAP suggests using the site assessor checklist as part of internal auditing.
   2. All required attachments submitted with the application must be in conformance with the current accreditation program policies prior to a site assessor being sent to the applicant laboratory. The site assessor will not schedule a site assessment of the laboratory until the submitted information indicates that the laboratory is in compliance and prepared for the site assessment.
   3. Several entries may require multiple attachments for the same topic depending on the laboratory's analytical activities. These should be compiled into one file or zipped folder to upload into the system.
   4. Highlighting or underlining portions of the attachment that demonstrate compliance with the applicable policy is recommended.
   5. Do not include documentation that is not requested.

C. **Electronic Submissions:** AIHA LAP requires electronic submissions of applications and all attachments. Application attachments shall be easily identifiable and navigable.

D. The document "Onsite Document and Records Review List" (located at: http://www.aihaaccreditedlabs.org) lists some of the additional documents and records that will be evaluated by the site assessor for conformance to the policy requirements during the laboratory's site assessment. Unlike the site assessment checklist, the laboratory is not required to submit the documentation requested within the Onsite Document and Records Review List with the formal application; however, it is recommended that the requested documentation be organized and readily available to the site assessor upon arrival to the laboratory in order to expedite the site assessment process.

For those organizations whose records are in electronic form only, a workstation must be provided for the assessor's review process; otherwise, printed copies will be requested on-site.

FORM 6A
GENERAL QUALITY ASSURANCE REQUIREMENTS *(Policy Module 2A)*

Policy Topic	Attachment Number	Submission Examples Required	AIHA LAP Policy or ISO Reference	Initial	Reaccreditation	FoT Addition
ISO/IEC 17025	**6A.1**	Proof of purchase (e.g., receipt or a signed affidavit stating that the laboratory purchased ISO/IEC 17025). See Form 9 for the affidavit. Required to obtain the checklist for submission 6A.2 below.	**All**	**X**	**X**	**X**
Site Assessment Checklist	**6A.2**	Current revision of the AIHA LAP Site Assessment Checklist with specific reference to laboratory-controlled document, section and/or page number, as applicable, for required policies, procedures and plans indicated with an asterisk (*) in the comments section of the checklist.	**All**	**X**	**X**	
Organization Chart	**6A.3**	A copy of the laboratory's current organization chart or description of the organization and management structure with the relationships between management and support personnel with personnel names.	**ISO 5.1, 5.5 a), 5.5 b)**	**X**	**X**	**X**
Document Control	**6A.4**	A copy or description of the laboratory's document control procedure/process.	**ISO 8.3.1**	**X**	**X**	
Document Control	**6A.5**	A list of controlled documents.	**ISO 8.3.2**	**X**	**X**	**X**
Nonconforming work / Corrective Action	**6A.6**	A copy of the laboratory's nonconforming work procedure. A copy or description of the laboratory's corrective action procedure/process.	**ISO 7.10.1, ISO 8.7.1**	**X**	**X**	
Improvements	**6A.7**	A copy or description of the laboratory's improvement procedure/process.	**ISO 8.6**	**X**	**X**	
Risks and Opportunities	**6A.8**	A description of how the laboratory addresses risk and opportunities in carrying out its activities.	**ISO 8.5**	**X**	**X**	
Internal Audit	**6A.9**	A copy of the most recent annual internal audit findings.	**ISO 8.8 2A.8.8.1**	**X**	**X**	
Management Review	**6A.10**	A copy of the laboratory's most recent annual management review findings.	**ISO 8.9 2A.8.9.1**	**X**	**X**	
Facilities	**6A.11**	Laboratory Floor Plan	**ISO 6.3**	**X**	**X**	**X**
Test Methods	**6A.12**	An internal test method/SOP for each field of testing (FoT) within the laboratory's scope of accreditation.	**ISO 7.2.1**	**X**	**X (Required when applying for FoT not previously accredited)**	**X**
Traceability	**6A.13**	A copy or description of the laboratory's procedure/process for demonstrating metrological traceability.	**ISO 6.5**	**X**	**X**	**X**

Policy Topic	Attachment Number	Submission Examples Required	AIHA LAP Policy or ISO Reference	Initial	Reaccreditation	FoT Addition
Measurement Uncertainty	**6A.14**	A copy or description of the laboratory's procedure/process for the evaluation of measurement uncertainty.	**ISO 7.6**	**X**	**X**	**X**
Proficiency Testing	**6A.15**	Initial: One passing round of data for each FoT in accordance with Policy Module 6 and the Scope/PT Table. Reaccred: Two rounds of data for each FoT in accordance with Policy Module 6 and the Scope/PT Table. If applying for FoodLAP w/AOAC recognition, please submit a 4-year PT plan. Contact any staff member for this form.	**Module 6**	**X (one passing round per FoT)**	**X (two rounds per FoT)**	**X**

FORM 6B
QUALITY ASSURANCE - IHLAP *(Policy Module 2B)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Analytical Methods (except Gravimetric & Asbestos)	**MRL**	**6B.1**	An example record of the annual reporting limit verification (using media spikes) for an analytical method in each applicable FoT within the laboratory's scope of accreditation.	**2B.2.3**	**X**	**X (An example reporting limit verification for each FoT not previously accredited)**	**X**
	LCS	**6B.2**	An example record documenting the use of multiple matrix-based Laboratory Control Samples for a method in each applicable FoT within the laboratory's scope of accreditation.	**2B.2.8**	**X**		**X**
Asbestos Analysis	**PCM Round Robin**	**6B.3**	OSHA asbestos regulation 29 CFR 1910.1001 (j) (8) (ii) (B) require results from semi-annual round robin participation with at least 2 other organizations. Provide results from the last 2 rounds.	**2B.3.1**	**X**	**X**	**X**
	Analyst Fibers (PCM)	**6B.4**	Certificate of completion of NIOSH (or equivalent) fiber counting course for all PCM analysts.	**2B.3.1.3**	**X**	**X (Only for new analysts since last AIHA LAP assessment)**	**X**
	Analyst Bulk (PLM)	**6B.5**	Certificate of completion of PLM course pertinent to asbestos fiber identification for all PLM analysts.	**2B.3.2.2**	**X**	**X**	**X**
	PLM Analysis Record	**6B.6**	An example of an analysis worksheet showing required fiber properties are documented.	**2B.3.2.8**	**X**	**X**	**X**

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Round Robin Results	**Compressed/ Breathing Air**	**6B.7**	Copy of results for most recent round of CAPT round robin PT program.	**6.6.1**	**X**	**X**	**X**
	Pharmaceutical	**6B.8**	Copy of results for most recent round of pharmaceutical round robin PT program.	**6.6.2**	**X**	**X**	**X**
Final Report	**IHLAP Final Report**	**6B.9**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT not previously accredited. **Initial**: A complete, signed final report for each FoT in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**

FORM 6C
QUALITY ASSURANCE – ELLAP *(Policy Module 2C)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy, ISO or LQSR Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Personnel	**Laboratory Staff**	**6C.1**	Submit Training records for all Pb analysts/technicians, including documentation of 4 independent test runs of 5 knowns for each matrix for each person.	**LQSR 5.2.1.1.3** **Lead in Air: N/A**	**X**	**X** **(Only for those new analysts/ technicians since the last AIHA LAP assessment)**	**X**
	Mobile and Field Operations	**6C.2**	For mobile and field operations, submit documentation of completion of the Inspectors training as pursuant to Section 402 of the TSCA and its implementing regulations.	**LQSR 5.2.1.2.1** **Lead in Air: N/A**	**X**	**X**	**X**
	Reporting Limits	**6C.3**	Include documentation that clearly indicates the Reporting Limit is greater than or equal to twice the MDL and equal to or less than 20% of the lowest regulatory level of concern. (50% for Dust wipes).	**LQSR 5.4.1** **Lead in Air: 2B**	**X**		**X**
	Method Detection Limits	**6C.4**	A current record of a statistically verified MDL study for <u>each</u> ELLAP matrix on each instrument for which you are performing analysis in-house, showing that the MDL was determined in accordance with 40CFR, Part 136, Appendix B.	**LQSR 5.4.4.1** **Lead in Air: 2B**	**X**		**X**
	Lowest Standard Determined	**6C.5**	For each matrix, an example (analysis record) of a matrix spike used for verification of stated Reporting Limit.	**LQSR 5.9.1.1** **Lead in Air:** **2B**	**X**		**X**
Internal QC	**Lab control sample (LCS)**	**6C.6**	A LCS analysis record for each matrix.	**LQSR 5.9.1.1** **Lead in Air: 2B**	**X**		**X**
	Acceptance Limits	**6C.7**	Acceptance limits for QC samples for each matrix in table form (Refer to LQSR Tables) Also list any current statistically generated limits.	**LQSR 5.9** **Lead in Air:2B**	**X**		**X**

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy, ISO or LQSR Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
	Contamination Control	**6C.8**	Most recent results of Pb wipe samples taken to document contamination control within the laboratory.	**LQSR 5.3.1.1**	**X**	**X**	**X**
Final Report	**ELLAP Final Report**	**6C.9**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT (or ELLAP matrix) not previously accredited. **Initial**: A complete, signed final report for each FoT (or ELLAP matrix) in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**

FORM 6D
QUALITY ASSURANCE – EMLAP *(Policy Module 2D)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	Attachment Number	Submission Examples Required	AIHA LAP Policy Reference	Initial	Reaccreditation	FoT Addition
Equipment	**Biological Safety Cabinet** (Culturable)	**6D.1**	Current certificate for a Class II biological safety cabinet documenting certification to NSF Standard 49 (or national equivalent outside the United States).	**2D.3.2.1**	X	X	X
	Magnification System	**6D.2**	Documentation of magnification system.	**2D.3.1.1.1, 2D.3.1.1.2**	X		X
QA/QC All Analyses	**Duplicates**	**6D.3**	Copy of QC database of duplicate (intra-analyst analyses for each Field of Testing and associated acceptance criteria	**2D.5.1.2, 2D.5.1.6**	X		X
	Replicates	**6D.4**	Copy of QC database of replicate (inter-analyst analyses for each Field of Testing and associated acceptance criteria	**2D.5.1.3, 2D.5.1.6**	X		X
QC Culturable and Fungal DE Bulk and Surface FoTs	**QC for Media and Reagents**	**6D.5**	Record showing quality control of culture media and analytical reagents per lot number for appropriate sterility, microbial growth and/or analytical reactions.	**2D.5.1.5**	X		X
QC Culturable FoTs	**Culture Collection**	**6D.6**	List of organisms in the microbial culture collection relevant to accreditation application (Copies of the listing of the organisms in the culture collection, and the dates they were placed in collection and the source).	**2D.5.2**	X	X	X
Fungal Direct Exam	**Reference Slides**	**6D.7**	A copy of a QC database showing daily use of reference slides for spore trap analysis. Also show acceptance criteria used.	**2D.5.3.1, 2D.5.1.6 (all culturable FoTs)**	X	X	X

FORM 6D - CONTINUED
QUALITY ASSURANCE – EMLAP *(Policy Module 2D)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	Attachment Number	Submission Examples Required	AIHA LAP Policy Reference	Initial	Reaccreditation	FoT Addition
Air Fungal Direct Exam	**Round Robin**	**6D.8**	Results of the most recent spore trap round robin showing participation with at least two other labs.	**2D.5.3.2**	**X**	**X**	**X**
QC Molecular FoTs / Technology	**Positive Control Collection**	**6D.9**	List of organisms in the control collection relevant to accreditation application (Copies of the listing of the organisms in the control collection and when they were placed in collection and the source)	**2D.5.4.1**	**X**	**X**	**X**
Final Report	**EMLAP Final Report**	**6D.10**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT not previously accredited. **Initial**: A complete, signed final report for each FoT in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**

FORM 6E
QUALITY ASSURANCE – Unique Scopes *(Policy Module 2E)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Analytical Methods	**Reporting Limit**	**6E.1**	For quantitative testing procedures, an example record of the annual reporting limit verification (using media spikes) for each analytical method.	**2E.3.1**	**X**	**X**	**X**
	Acceptance Limits	**6E.2**	Linear calibration acceptance limits, as specifically described in the applicable SOP, including date, applicable method, instrument identification, analysis date, analyte concentrations and instrument response.	**2E.3.4**	**X**	**X**	**X**
Internal QC	**Laboratory Control Spike**	**6E.3**	An LCS example for each method/analyte.	**2E.4**	**X**	**X**	**X**
	Matrix Spike	**6E.4**	For each method/analyte, an example (analysis record) of a matrix spike used for verification of stated Reporting Limit.	**2E.4**	**X**	**X**	**X**
	Duplicates	**6E.5**	Copy of QC database of duplicate (intra-analyst) analyses for each Field of Testing and associated acceptance criteria.	**2E.4**	**X**	**X**	**X**

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Final Report	**Unique Scopes Final Report**	**6E.6**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT **Initial**: A complete, signed final report for each FoT in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**

FORM 6F
QUALITY ASSURANCE – FoodLAP *(Policy Module 2F)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Equipment	**Biological Safety (Microbial analyses)**	**6F.1**	Certificate for a Class II biological safety cabinet documenting performance has been certified annually according to NSF Standard 49 (or national equivalent outside the United States).	**2F.2.1.3**	**X**	**X**	**X**
QA/QC	**Reference Cultures (Microbial analyses)**	**6F.2**	List of Reference Cultures (RC); Documentation of culture source; SOP on culture handling and maintenance; documentation of quality checks; and record showing use of RCs.	**2F.4.3**	**X**	**X**	**X**
	Reference Materials (Chemical analyses)	**6F.3**	Record showing use of Certified Reference Materials (CRM); Documentation of receipt and handling of CRM.	**2F.4.4**	**X**		**X**
AOAC Equipment	**Incubator(s) / Refrigerator(s)**	**6F.4**	Temperature Validation Records	**2F.6**	**X**	**X**	**X**
Final Report	**FoodLAP Final Report**	**6F.5**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT not previously accredited. **Initial**: A complete, signed final report for each FoT in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**

FORM 6G
QUALITY ASSURANCE – Be Field/Mobile *(Policy Module 2G)*

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Analytical Methods	**Reporting Limit**	**6G.1**	For quantitative testing procedures, an example record of the annual reporting limit verification (using media spikes) for each analytical method.	**2G.3.1**	**X**	**X**	**X**
	Acceptance Limits	**6G.2**	Calibration curve, acceptance limits, as specifically described in the applicable SOP, including date, applicable method, instrument identification, analysis date, analyte concentrations and instrument response.	**2G.3.4**	**X**	**X**	**X**
Internal QC	**LCS**	**6G.3**	An example record documenting the use of multiple matrix-based Laboratory Control Samples for a method in each applicable FoT within the laboratory's scope of accreditation.	**2G.3.7**	**X**	**X**	**X**

Policy Topic		General Accreditation Requirements					
	Sub-Topic	**Attachment Number**	**Submission Examples Required**	**AIHA LAP Policy Reference**	**Initial**	**Reaccreditation**	**FoT Addition**
Final Report	**Be Field/Mobile Final Report**	**6G.4**	**Reaccreditation**: • A complete, signed final report • A complete, signed final report for each new FoT **Initial**: A complete, signed final report for each FoT in which the laboratory participates.	**ISO 7.8, 2A.7.8**	**X**	**X**	**X**