

Q1: When are AIHA LAP accredited laboratories required to conform to the new standard?

A: AIHA LAP policies were published July 2, 2018 with an immediate effective date. Laboratories are required to conform to these new policies and ISO/IEC 17027:2017 during any assessments conducted after July 2, 2018. All AIHA LAP accredited laboratories will have been assessed to the new standard by November 30, 2020.

Q2: If my laboratory is not accredited to the new standard by November 2020, what will be the impact?

A: AIHA LAP will not recognize laboratories that have not been assessed and accredited to ISO/IEC 17025:2017 by November 2020. Any laboratory not accredited to the new standard by then will be suspended.

Q3: I understand that ISO/IEC 17025:2017 no longer requires a quality manual. Can we still submit our quality manual as part of our AIHA LAP application?

A: Yes, by all means. A quality manual is no longer required by the standard, which provides further flexibility and less prescriptive requirements regarding the manner in which the laboratory documents its quality management system. The laboratory may retain and submit a quality manual to AIHA LAP (as part of its accreditation application) to demonstrate that it has a quality management system as required. Many of our accredited laboratories tell us that they intend to retain existing systems.

Q4: ISO/IEC 17025:2017 no longer specifies a quality manager. Can we still keep that title and associated responsibilities?

A: Yes. A designated quality manager is no longer required by the standard, but the laboratory may retain its existing personnel structure, titles, and responsibilities if it wishes to do so. Again, feedback indicates that many laboratories intend to retain existing personnel structure.

Q5: It appears that ISO/IEC 17025:2017 does not require as many policies and procedures as the 2005 standard. What does AIHA LAP expect to see?

A: That is correct. The 2017 standard does not specifically require as many policies and procedures as the 2005 standard. AIHA LAP requires controlled documents in all instances where the standard indicates “policy, procedure, documented process, programme, or method.”

Q6: New language in the revised standard deals with risk-based thinking. What does AIHA LAP expect to see?

A: As indicated in Q3, the standard was rewritten to provide further flexibility and less prescriptive requirements. Because of this, the laboratory must consider risks and opportunities associated with its operations and plan actions to address those risks and opportunities. Because ISO/IEC 17025:2005 was more prescriptive, conformity with that standard reduced many of the risks for the laboratory. The 2017 standard also specifically requires that risks to impartiality are identified on an ongoing basis. These risks can be affected by new customers, suppliers, personnel, personnel relationships, organizational changes, or service offerings. The standard specifically states: “NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.” AIHA LAP will expect its laboratories to have documented evidence of considering risks and opportunities associated with its operations (e.g., results of meetings, brainstorming, and/or risk assessment and management reviews) and plans to address identified risks and opportunities.

Q7: How will labs be assessed under Option B vs. Option A?

Option A assessments would require that the lab submit the accreditation application and all applicable attachments, and the assessment would progress as it always had: with an onsite assessment of the laboratory, a review of the quality management system, and the technical witnessing of the laboratory’s testing activities.

Option B applies to ISO 9001 organizations. For a lab that is an ISO 9001 certified organization, we would need, at a minimum, a copy of the final report to show that the laboratory aspects were covered under the certification. In the event that the report cannot substantiate that the certification covers laboratory aspects, then the lab would need to provide all attachments requested in the application and will likely need to apply under option A. Although a lab may opt to demonstrate compliance to the management system through option B, doing so does not exclude the applicant’s management system from review by AIHA LAP, LLC during the accreditation process (see Policy Module 2A.8.10). So, the site assessor may request additional documentation if the lab submits the report from its certification body. In addition, the assessor will ensure that the certification body is accredited by a signatory to the International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA).

Q8: Are there new record requirements in the new standard?

A: Yes, there are number of new record requirements throughout the standard. AIHA LAP requires records in all instances where the standard indicates “record, define, document (v), specify, and identify.”

Q9. Sampling is now considered a laboratory activity under ISO/IEC 17025:2017. Does that mean AIHA LAP will accredit sampling organizations?

A: Yes, sampling that is associated with subsequent accredited laboratory testing is now an activity that can be accredited. AIHA LAP is considering the establishment of a standalone sampling program or at minimum including new sampling fields of testing (FoTs) under current accreditation programs to accommodate testing laboratories that want to have their sampling activities accredited.

Q.10 How has the complaint process changed?

A: New language found in section 7.9 of ISO/IEC 17025:2017 requires, among other things, that laboratories describe the handling process for complaints available to interested parties, record all complaints, and communicate the outcome of complaints to the complainants. The communicated outcome of a complaint must be made by, or reviewed and approved by, an individual independent of the complaint activities.

Q11. Once my laboratory is accredited to ISO/IEC 17025:2017, will we receive a different accreditation symbol?

A: Yes. All AIHA LAP laboratories successfully assessed to the new standard will receive the 2017 version of the AIHA LAP accreditation symbol (designed for each program) after signing a new Licensing Agreement. These symbols, which are used in conjunction with lab identification numbers, have been updated to include ISO/IEC 17025:2017 in the rim of the symbol. Until your laboratory is assessed and accredited to the new standard, you should continue to use the previously issued accreditation symbol.

Q12: Will AIHA LAP training be available for laboratories?

A: AIHA LAP has prepared a recorded webinar on changes in the new standard. The webinar is available to AIHA LAP accredited labs at no charge. Additional webinars are planned for 2019.

Q13: When do I need to conduct an internal audit against the ISO/IEC 17025:2017 standard?

A: AIHA LAP requires annual internal audits. Since July 2, 2018 was the effective date of the 17025:2017 standard and AIHA LAP policies for accredited laboratories, any internal audit efforts on or after that date must be against the current standard and policies. Initial and renewal assessments conducted on or after July 2, 2018 will look for evidence of audits against the 2017 standard and current AIHA LAP policies. Surveillance assessments from July 2, 2018 forward will look for evidence of audits against the 17025:2017 standard and current AIHA LAP policies according to the laboratory's internal audit schedule.

Q14: When do I need to conduct a management review in conformity with the ISO/IEC 17025:2017 standard?

A: AIHA LAP requires annual management reviews. As in question 13, any management review performed on or after July 2, 2018 must be in conformity with the current standard and policies. Initial and renewal assessments conducted on or after July 2, 2018 will look for evidence of management reviews conducted in conformity with the 2017 standard and current AIHA LAP policies. Surveillance assessments from July 2, 2018 forward will look for evidence of management reviews in conformity with the 17025:2017 standard and current AIHA LAP policies according to the laboratory's management review schedule.

Q15: The note in 17025:2017 Section 4.1 states that a relationship that threatens the impartiality of the laboratory can be based on payment of a sales commission or other inducement for the referral of new customers. Is it a risk to impartiality for a laboratory to pay a salesperson a wage/salary/commission to obtain new clients?

A: There are many potential risks. Paying a sales commission is one potential risk, but whether it is a real risk depends on many factors. The lab needs to decide if there is a risk, and, if so, how it will eliminate or minimize the risk. These risks may be minimized by limiting authorizations and laboratory review and approval processes.

Q16: ISO/IEC 17025:2017 no longer specifies that top management conduct the management review. Can top management continue to conduct the reviews?

A: That is correct. The requirement for top management to conduct the management review (MR) has been removed. It is up to the laboratory to determine the appropriate level of management to conduct the MR, although AIHA LAP suggests that top management is an integral part of this process. Note that there are additional considerations for the MR in the 2017 standard and more inputs and outputs (findings) must be recorded.

Q17: Are there any remaining requirements for a technical manager or quality manager?

A: ISO/IEC 17025:2017 does not reference technical management or a quality manager, and AIHA LAP has removed any specific requirements for technical manager or quality manager with one exception. The designation of a technical manager and quality manager and associated responsibilities are still requirements of the EPA National Lead Laboratory Accreditation Program Laboratory Quality System Requirements (LQSR Revision 3.0) administered under the AIHA LAP ELLAP program (AIHA LAP Policy Module C).

Q18: What procedures and records will AIHA LAP expect regarding risk?

A: There are no specific process or procedural requirements related to risk although laboratories will often document their risk process(es). Records of risk identification and mitigation or elimination are required for risks to impartiality on an ongoing basis (Sections 4.1.4, 4.1.5). Records of risk identification and any actions taken to address risk are also required (Section 8.5). The management reviews require records of inputs related to the results of risk identification (Section 8.9.2.m).

Q19: What is expected with regard to opportunities in section 8.6 of the standard?

A: Laboratories are expected identify and select opportunities for improvement and implement any necessary action. These requirements do not vary substantially from the service to the customer, improvement, and preventive action requirements of the 2005 standard. Records regarding the identification and selection of opportunities for improvement and records of actions taken are expected, as well as records of feedback solicited from customers.

Q20: Are the decision rule requirements in section 7.1.3 of the standard applicable to AIHA LAP accredited laboratories?

A: If the customer requests results to be used to evaluate conformity with (e.g., pass/fail or above/below) a permissible exposure limit (PEL), action level (AL), or recommended exposure level (REL or TLV), the decision rule requirements are applicable, and uncertainty and the appropriate coverage factor must be discussed with the customer and included on the report with a clear statement of conformity. If the laboratory provides relevant "information" on the report such as the HUD limits, OSHA PEL or AL, REL, or TLV, but the customer has not requested a statement of conformity from the laboratory (e.g., pass/fail or above/below) and the laboratory does not provide such a statement, then the decision rule requirements do not apply.