White Paper
Management and Support to Facilitate Accreditation of Vet-LIRN Laboratories

Date: August 15, 2022

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This work was supported by the Veterinary Investigation and Response Network, Center for Veterinary Medicine, Food and Drug Administration grant 1U18FD007236-01.

1 Introduction and Background

The Food Safety Modernization Act (FSMA), signed into law on January 11, 2011, was designed to enable the Food and Drug Administration to better protect public health by helping ensure safety and security of the food and animal feed supplies. One of the goals of FSMA is to ensure there is sufficient capacity of high-quality laboratories in the United States to provide food safety and animal feed testing as well as effective response to outbreaks. The FSMA TITLE II, SEC, 202, Laboratory Accreditation of Analyses of Foods identifies the following key goals.

- Establishment of a program for testing of food and feed products by accredited laboratories
- Establishment of a publicly available registry of accreditation bodies and laboratories recognized accredited
- Recognition of laboratory accreditation bodies that meet established criteria
- Increase in the number of qualified laboratories and the provision of model laboratory standards that accredited labs must meet.

The Veterinary Laboratory Investigation and Response Network (Vet-LIRN) was established by The Department of Health and Human Services, Center for Veterinary Medicine (CVM) in accordance with FDA's Strategic Priorities: Strategic Goals and Long-Term Objectives

- 3.2.3 Advance Animal Drug Safety and Effectiveness Animal Drugs and Feeds Program,
- 3.2.3.5 Enhance response to food/feed and drug safety events, and the FDA Food Safety Modernization Act (FSMA).

The FDA formally partnered with veterinary diagnostic laboratories across the USA in 2012 to achieve these goals through the formation of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). The overall mission of the Vet-LIRN is to advance the CVM mission of protecting human and animal health by coordinating a network of veterinary diagnostic laboratories. Veterinary diagnostic laboratories enhance public health by providing non-regulatory testing of animal food for chemical and microbial contaminants, including zoonotic pathogens. Vet-LIRN labs respond to requests for testing as directed by FDA resulting from consumer complaints, and participate in method development activities and proficiency exercises. Currently 46 veterinary diagnostic laboratories are members of the Vet-LIRN program.

The accreditation requirements included in the Food Safety Modernization Act (FSMA) TITLE II, SEC, 202, (6) Model Laboratory Standards for laboratories engaged in food safety and animal feed testing are the following:

- appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate,
- internal quality systems are established and maintained,
- procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited, and
- individuals who conduct the sampling and analyses are qualified by training and experience to do so.

Most veterinary diagnostic laboratories are accredited by the American Association of Veterinary Laboratory Diagnostician (AAVLD) Accreditation Program, which has accredited veterinary diagnostic laboratories in North America (USA and Canada) since 1969. There are currently 65 AAVLD accredited laboratories (61 in USA and 4 in Canada). The AAVLD Requirements for Accreditation of Veterinary Medical Diagnostic Laboratories is congruent with the international laboratory accreditation standard ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories". Most Vet-LIRN laboratories are accredited by the AAVLD Accreditation Program.

In 2016, a joint FDA-AAVLD White paper was published detailing the alignment of the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 2016-07 with ISO/IEC 17025:2005 (Management and Support to Facilitate Accreditation of Vet-LIRN Laboratories; FDA-SOL-1130894). The purpose of the current white paper is to update the 2016 document by comparing the updated and current version of "AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 2021.01" with ISO/IEC 17025:2017, the updated and current version of "General requirements for the competence of testing and calibration laboratories". The overall goal is to continually evaluate accreditation bodies and quality standards that laboratories should meet in order to be compliant with the Food Safety Modernization Act (FSMA) TITLE II, SEC, 202 and to determine the best fit of accreditation bodies and standards for veterinary diagnostic laboratories within the Vet-LIRN network.

2 Evaluation of Accreditation Standards for Animal Health Laboratories

2.1 Overview:

Laboratory Accreditation is a voluntary, third party-reviewed process by a certifying body providing formal recognition of laboratory competence and quality. As part of accreditation, a laboratory's quality management system is thoroughly evaluated on a regular basis to ensure continued management and technical competence and compliance with appropriate laboratory quality management system standards. The accreditation process requires ongoing maintenance of the Quality Management System (QMS) by the laboratory, as well as surveillance audits performed by a certifying body. The desired outcomes of this process are assurance of credible laboratory results for clients, and the expectation of continual improvement of the accredited laboratory's processes. Accreditation standards based on ISO/IEC 17025 are those which most testing labs follow to demonstrated management and technical competence. Many countries have testing accreditation programs that are based upon the International Organization of Standards (ISO) 17025 document and recognize it as their official guide to acceptable standards for laboratory accreditation.

Animal disease diagnosis, surveillance and food safety in the United States is the combined responsibility of publicly funded state and federal veterinary diagnostic laboratories. Ensuring quality diagnostic and surveillance efforts is essential to safeguarding the health and well-being of our national herds and flocks, companion animals, wildlife, zoo and exotic species as well as public health. Ensuring the quality of test results has been a priority for veterinary diagnostic for a number of years. The World Organization for Animal Health is one of the founding international organizations in animal health. It was formed in 1924 as the Office International

Epizooties (OIE). It is an intergovernmental organization with a mandate from its 181 member countries and territories to improve animal health worldwide. Detection and reporting the presence of disease within nations is dependent upon the prompt and accurate testing of their animal and animal products for disease and pathogens that may be of socioeconomic importance to other nations receiving those animals and animal products. In 1999, the (OIE) released a draft of the Standard of Management and Technical Requirements of Laboratory Conducting Tests of Infectious Animal Disease, written by the Standards Commission of the OIE. This document described international standards for management and technical competence that served as the basis for accreditation of laboratories that conduct diagnostic tests for infectious diseases of animals as well as the detection of zoonotic pathogens. This standard was based on ISO/IEC 17025 and was intended to be a foundation document from which further interpretations and application specific to veterinary diagnostics could be made. The official document became the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008. Laboratory accreditation standards for global animal health testing laboratories based upon ISO/IEC 17025 are also accepted by the Food and Agricultural Organization of the United Nations (FAO), and national laboratory disease surveillance networks of USDA-APHIS (National Animal Health Laboratory Network) and FDA (Veterinary Laboratory and Investigation Network).

2.2 Comparison of American Association of Veterinary Laboratory Diagnosticians and ISO/IEC 17025 Laboratory Accreditation Standards

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) was formed in 1958 to promote improvement of veterinary diagnostic laboratories by advancing the discipline of veterinary diagnostic laboratory science. AAVLD has facilitated the attainment and maintenance of healthy herds and flocks in the United States and the assurance of food safety throughout the world. It has also been instrumental in the achievement of accurate diagnosis and reporting of animal diseases. The importance of standardized quality management systems for animal and food safety pathogens has been recognized by AAVLD, many federal agencies, as well as international trading partners.

Since 1969 the AAVLD has had a robust accreditation program developed and administered by the AAVLD Accreditation Committee. The AAVLD Accreditation Committee recognized the value of the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases and adopted that reference as the basis for their standard in 2006. The current "AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory" ensures laboratories meet or exceed the standards of the World Organization for Animal Health described in the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases (2nd edition, 2008) and the current version of ISO/IEC 17025.

In 2016, a joint FDA-AAVLD White paper was published detailing the alignment of the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 2016-07 with ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" (White Paper, Management and Support to Facilitate Accreditation of Vet-LIRN Laboratories,FDA-SOL-1130894.). Both standards were divided into Management and Technical requirements sections, and address the same areas, including organization,

personnel, physical facilities, equipment, records, communication, and laboratory quality assurance. Overall, the AAVLD Accreditation Requirements (current version at that time) included 96% of the elements found in ISO 17025:2005. Some of the more significant differences between the ISO 17025 and AAVLD laboratory accreditation standards were:

- ISO 17025 includes standards for calibration laboratories where AAVLD does not, (AAVLD accredited labs are not calibration laboratories but animal health testing laboratories)
- AAVLD Requirements included sections addressing Administrative Requirements which specify the types of laboratories that are eligible for AAVLD Accreditation, expertise of top management and expectation of financial resources required for offering quality services, which were not included in ISO 17025.
- AAVLD Requirements had requirements for biosafety, biocontainment, and biosecurity which are not included in ISO 17025. These requirements were critical due to the infectious nature of samples being submitted to veterinary diagnostic laboratories but not critical to calibration labs.
- ISO 17025 as a standard for calibration laboratories addressed measurement uncertainty while AAVLD requirements did not. Results for most of the tests offered by AAVLD labs were qualitative rather than quantitative in nature.

An updated version of ISO/IEC 17025:2005 was published in 2017 (ISO/IEC 17025:2017). The revised standard provided updates primarily in:

- Fewer mandatory procedures;
- Process approach (greater reference to process)
- Expansion of mandatory requirements from two to five (management requirements plus expanded technical requirements into separate sections regarding general, structural, resource, and process requirements);
- Greater emphasis on evidence containing records versus mandatory records;
- Usage of recent and updated IT technology (mainly use of systems and provision of electronic test results and records; and
- Concept of risk-based thinking (actions to address risk and opportunities for improvement);

In order to remain aligned with ISO 17025:2017, the AAVLD Accreditation Program undertook a 3-year process to update the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory. This update allows labs accredited by AAVLD to continue to serve client needs for global recognition of laboratory quality assurance / quality control and test results. The process included a detailed “cross walk” of ISO 17025:2017 with the AAVLD Requirements 2016-07, determining appropriate additions and subtractions, drafting a revision AAVLD Accreditation Requirements, seeking input from AAVLD membership, publishing the revised AAVLD Requirements, training auditors to the updated AAVLD Requirements, and lastly implementation of accreditation evaluations under the new AAVLD Requirements (version 2021.01). The process is complete and the AAVLD Accreditation Program began auditing laboratories under the revised AAVLD Requirements in CY2021. The revised standard provided updates primarily in:

- Expanded client-centric processes for impartiality and client complaints, and handling of specimens;

- Concept of risk-bases thinking (actions to address risk and opportunities for improvement);
- Expanded inclusion of requirements for IT technology (laboratory information systems, and electronic records, test results, and documents);
- Expansion of management review to include risk assessment and continual improvement;
- Clarification of specific authorization of personnel; and
- Expanded test verification and validation fit-for-purpose and planned review of validity of test results

A direct, detailed comparison of AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 2021-01 and ISO/IEC 17025:2017 is provided in Table 1 which is a cross-reference between the two laboratory accreditation standards. Similar to the comparison of previous versions of the two standards done in 2016, the revised AAVLD accreditation requirements included 96% of the elements found in ISO 17025:2017 (out of a total of 212 standard elements analyzed). Both standards include management and technical requirements that address major general, structural, resource, process, and management requirements including organization, communication, document control, review of contracts, purchasing, client complaints, non-conforming work and corrective actions, records, management review, personnel, physical facilities, test methods, equipment, specimen handling, and reporting or results. The major differences between the two standards were in the following areas:

- ISO 17025 as a standard for calibration laboratories includes requirements for calibration laboratories where AAVLD does not. (e.g. calibration certificates, calibration statement of conformity, measurement uncertainty)
- AAVLD Requirements includes sections addressing Administrative Requirements which specify the types of laboratories that are eligible for AAVLD Accreditation, expertise and qualifications of management personnel, and expectation of financial resources required for offering quality services.
- AAVLD Requirements include biosafety, biocontainment, and biosecurity which are not included in ISO 17025. These physical and process requirements are critical due to the biological infectious nature of samples being submitted to veterinary diagnostic laboratories.
- ISO 17025 specifically addresses measurement uncertainty while AAVLD requirements do not. Measurement uncertainty, the summation of errors inherent within the process of production of calibration products, is critical to calibration, chemistry and drug testing laboratories. Test results for most of the tests offered by AAVLD laboratories are qualitative rather than quantitative in nature. Also, for quantitative test results the AAVLD Requirements address tolerance through a requirement for acceptance criteria of test results within test methods.

3 Evaluation of Accreditation Bodies for Animal Health Laboratories

An accreditation body is an independent third-party entity which declares that specified requirements within an accreditation standard have been met. Accreditation bodies currently engaged in accrediting veterinary diagnostic laboratories in North America include the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and the American Association of Laboratory Accreditation (A2LA). The A2LA accredits using the ISO 17025 and OIE standard. The Canadian Standards Council is an accreditation body for veterinary diagnostic labs in Canada. This body does not conduct audits outside of Canada. A description of the AAVLD and A2LA accreditation bodies is provided below. Table 2 provides a comparison of these two laboratory accrediting bodies.

3.1 American Association of Veterinary Laboratory Diagnosticians Accreditation Program

The AAVLD Accreditation Committee is the ruling body for determining the accreditation status under the AAVLD Accreditation Program. AAVLD provides accreditation to public veterinary diagnostic laboratories in North America per the written standard AAVLD Requirements of Veterinary Medical Diagnostic Laboratories, and uses peer-inspection (practicing veterinary diagnostic laboratory professionals and discipline-specific subject matter experts) in assessing laboratory compliance and physical facilities for determining accreditation status. The most recent version of this standard is publicly available at https://aavld.memberclicks.net/accreditation-requirements-page . AAVLD is the most recognized and longstanding accreditation body of veterinary diagnostic labs within the United States.

The AAVLD Accreditation Committee has the responsibility of reviewing and updating the standard, conducting site visits, and awarding accreditation for laboratories following review of the site visit report. The committee is comprised of a least 2 members from each of the 7 AAVLD regions throughout the United States and Canada. Committee members serve on a voluntary basis and are selected from practicing Laboratory Directors, Pathologists, Microbiologists, Molecular Biologists, Immunologists, Toxicologists and Quality Assurance Officers. The USDA National Animal Health Laboratory Network (NAHLN) Coordinator serves as an ad hoc member of the Accreditation Committee. The Committee has 3 meetings a year during which audit reports and responses are reviewed and accreditation decisions are made.

Laboratories eligible for AAVLD accreditation include those state funded facilities that provide a full range of diagnostic services year-round in a majority of the following essential disciplines: necropsy, histopathology, bacteriology, virology, mycology, parasitology, serology and toxicology. Full service laboratories must offer necropsy, histopathology, bacteriology and virology on-site. The scope of accreditation for AAVLD includes the entire laboratory (all laboratory tests and activities), which is a departure from accrediting bodies that award accreditation on a test by test or technology basis.

Laboratories may be awarded either full accreditation for 5 years (contingent upon an acceptable response to a laboratory audit) or provisional accreditation. Provisional accreditation is awarded to labs that do not meet all of the requirements but show intent to do so. A provisionally

accredited lab is given a specified time period by the Accreditation Committee to correct deficiencies noted and are required to document progress through periodic assessments and reports. Provisional accreditation is typically awarded for one year.

3.1.1 Training of AAVLD Accreditation Body Members

The Accreditation Committee organizes and sponsors training, in concert with the AAVLD Quality Assurance Committee and USDA NALHN. Biennial quality assurance symposia are held at the annual AAVLD conferences. The Committee also receives annual training from an external trainer versed in the current version of ISO/IEC 17025. The Committee also selects, trains and evaluates and Auditor Pool of practicing veterinary professional diagnosticians from across the United States and Canada to serve as subject matter experts who participate in site visits with Accreditation Committee members. The Committee and Auditor Pool Members receive annual training on auditing to the AAVLD Requirements and quality system management implementation.

3.1.2 Recognition of AAVLD Accreditation (Domestic and International)

The AAVLD laboratory accreditation program historically provided the only accreditation services for publicly supported veterinary diagnostic laboratories in the United States for several decades. During that time the Organization International Epizooties (OIE) and the United States trading partners recognized AAVLD accreditation as evidence of quality diagnostics. This recognition was further supported by a Memorandum of Understanding between the United States Department of Agriculture, Animal Plant Health Inspection Services (USDA APHIS) and AAVLD that was initiated in 2001 and subsequently modified in 2006, 2011, and 2017 to recognize the AAVLD accreditation standard and process. Key elements of the 2001 USDA/AAVLD MOU include the following:

- "… AAVLD shall cooperate with the USDA National Veterinary Services Laboratory as our federal partner in the U.S. diagnostic services. Such cooperation should result in a memorandum of understanding to be presented and considered for formal adoption at the 2001 House of Delegates."
- "…. the Accreditation Committee shall investigate the feasibility of utilizing ISO 17025 as part of the accreditation of AAVLD labs and the feasibility of utilizing an appropriate accreditor to assist with accreditation responsibilities for AAVLD under AAVLD/NVSL advisement.

In 2006 the MOU was modified to strengthen support of the AAVLD Accreditation process and its ties to the OIE/ISO 17025 standard with the addition of the following language:

- ".. AAVLD, as of 2006, incorporates OIE guidelines in the accreditation process, therefore AAVLD requests that USDA/NVSL formally recognize and notify OIE that the AAVLD accreditation process is consistent with the World Trade Organization Guidelines for Quality Management in Veterinary Testing Laboratories, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and, as such, meet OIE requirements".

In 2011 the MOU was updated again to its current form which includes the following language:

- "NVSL agrees to continue to recognize AAVLD-accredited veterinary diagnostic laboratories as an integral part of the national animal health diagnostic system in the United States. This includes, depending on mutual agreement by Veterinary Services, participation in foreign animal disease testing and/or domestic surveillance an international/interstate regulatory testing."

In 2017 the MOU stated the following updated language:

- "NVSL agrees to Continue to recognize AAVLD-accreditation as verification of an implemented quality management system in veterinary diagnostic laboratories that become an integral part of the national animal health diagnostic system in the United States. This includes, depending on mutual agreement by Veterinary Services, participation in foreign animal disease testing and/or domestic surveillance and international/interstate regulatory testing, primarily through the NA HLN."
- "Work with AAVLD, through collaborative training programs and laboratory site visits to meet quality standards developed based on ISO 17025 standards for AAVLD accreditation."

The recognition by USDA of AAVLD Accreditation Requirements and process is significant. Veterinary diagnostic test results are frequently required by countries importing animals or animal products from the United States. This recognition supports international trade by deeming AAVLD Accredited labs to be technically competent and test results to be credible which supports the movement of animals and animal products national and international trade markets.

3.2 American Association of Laboratory Accreditation (A2LA)

A second accreditation body for veterinary diagnostic laboratories in the US is A2LA and is provided as an example of a private for-profit accrediting body serving veterinary diagnostic laboratories. A2LA was established in 1978 as a private, non-profit organization that offers laboratory accreditation for fields such as acoustics and vibration, biological, calibration, chemical, construction materials, electrical, environmental services and a variety of others. A2LA services are available to both private and government organizations. They currently offer veterinary laboratory accreditation as a sub-program to the general biological field. The program requirements currently include:

- ISO-IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
- ASLA R216 – Specific Requirements-Veterinary Laboratory Accreditation Program
- NAHLN Quality Standard-Harmonization of AAVLD and ISO 17025:2017

In addition to the accreditation and training services for testing and calibration laboratories, A2LA offers accreditations and training for inspection bodies, proficiency testing providers, reference material produces, and product certification bodies. A2LA has formal written agreements of recognition or documented endorsement with federal agencies, state agencies, and private sector parties. Examples include but are not limited to the federal agencies such as 1) US Environmental Protection Agency (EPA), 2) US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), 3) Centers for Medicare and Medicaid Service (CMS), 4) US Federal Aviation Administration (FAA), and 5) National Institute of Standards and

Technology (NIST). A2LA also has Mutual Recognition Arrangements (MRA) with international bodies such as 1) International Laboratory Accreditation Cooperation (ILAC), 2) Asia Pacific Laboratory Accreditation Cooperation (APLAC), 3) Inter-American Accreditation Cooperation (IAAC), and 4) International Accreditation Forum (IAF).

3.3 Food Safety Modernization Act Criteria for Evaluating Accreditation Bodies

The criteria for the evaluation of accreditation bodies for Vet-LIRN network laboratories as specified in solicitation FDA-SOL-1130894, include:

- Accreditation processes
- Cost effectiveness of obtaining accreditation
- Added value of obtaining accreditation by various accreditation bodies

3.3.1 AAVLD and A2LA Accreditation Processes

A comparison of accreditation bodies currently available to veterinary diagnostic laboratories in the US regarding the criteria stated above follows.

The general process that AAVLD and A2LA follow for evaluating veterinary diagnostic laboratories in the US are similar and typically include the following steps:

1) The applicant completes and returns the application for accreditation including all required supporting documentation.
2) The accrediting body reviews the application documents and appropriate assessors (site team) are assigned, with the applicant's concurrence. The site team is comprised of 2-4 auditors.
3) A tentative date for the audit is selected.
4) The laboratory being audited may be asked to provide additional documents and records to the accreditation body. If the materials are found to be acceptable, the audit date is confirmed.
5) Audits typically are scheduled for 2-4 days, depending on the size of the lab and number of sites to be visited. An agenda is proposed by the site visit team with input from the lab being audited.
6) The site visit is conducted which typically includes a pre-audit meeting, review of additional records and an observation of analysts who are conducting assays. The goal is to verify the compliance of a lab that to the policies and procedures of its quality management system. If departures are observed, they are shared with the laboratory staff (typically the quality assurance officer) and a non-conformance may be written.
7) The site visit team holds an exit interview with all of the lab staff.
8) A report is provided to the laboratory which includes all findings, including nonconformances. The laboratory provides a response to the accrediting body including documentary evidence regarding the resolution of non-conformances. The accreditation body awards the laboratory accreditation based on the site team report response provided by the lab. The period of accreditation can be from 1 to 5 years (A2LA accreditation cycle is up to 2 years). Additional information from the lab may be required by the accreditation body during this time period.

3.3.2 Cost Effectiveness of Obtaining Accreditation

The cost of AAVLD accreditation is less than that provided by private accreditation bodies. This is due to several factors, including that AAVLD Accreditation Committee members serve on a voluntary basis. Preparation time, travel time, on-site time and report preparation time is donated by AAVLD assessors, all of whom are active members of the veterinary diagnostic medicine profession. Site visit expenses are supported by AAVLD Accreditation funds provided through annual lab dues. These dues are higher for the year(s) in which a laboratory's site visit is conducted (see Table 2). Hotel costs are frequently paid directly by the lab being assessed. The transportation and per diem costs for AAVLD assessors is reimbursed through AAVLD Accreditation funds.

Assessor costs charged by private accreditation agencies include preparation time, travel time, on-site time and report preparation time. Additional site visit costs for private assessors include transportation, hotel and per diem costs. The costs are also impacted by the frequency of the on-site visits. Some agencies require onsite assessments on a biennial basis. The frequency required for on-site assessments for AAVLD accredited labs can be as often as every year but can extend to once every 5 years for fully accredited labs provided there have been no significant changes to the facility or laboratory management. Fees or lab dues are paid for AAVLD and private agencies for intervening years but typically AAVLD fees are lower. A costs comparison for AAVLD vs A2LA lab is provided in Table 2. Costs for the actual audit process can vary depending on the size and scope of the laboratory. Scope specific A2LA costs are significantly higher than those of laboratory wide AAVLD audits. For example, A2LA costs per 2-year audit cycle under a single scope are estimated at approximately $14,000 for annual fees plus the certification audits (annualized at $7,000 per year). AAVLD costs per 5-year audit cycle under a whole laboratory scope are estimated at $12,000 for annual fees plus the certification audit (annualized at $2,400 per year). The cost accreditation by A2LA could be prohibitively expensive for many Vet-LIRN labs receiving base infrastructure grant funds from the FDA-CVM.

3.3.3 Added Value of Obtaining Accreditation by Accreditation bodies

Formal laboratory accreditation does not certify a product or service, rather it attests that a laboratory adheres to documented processes and quality controls in conformance with ISO-based international standards. Conformance to standards inherently contributes to higher quality, safety, reliability, and consistency of services. This increases a laboratory's marketability, customer satisfaction, and acquisition of new customers. The increased credibility associated with formal laboratory accreditation leads to advantages such as:

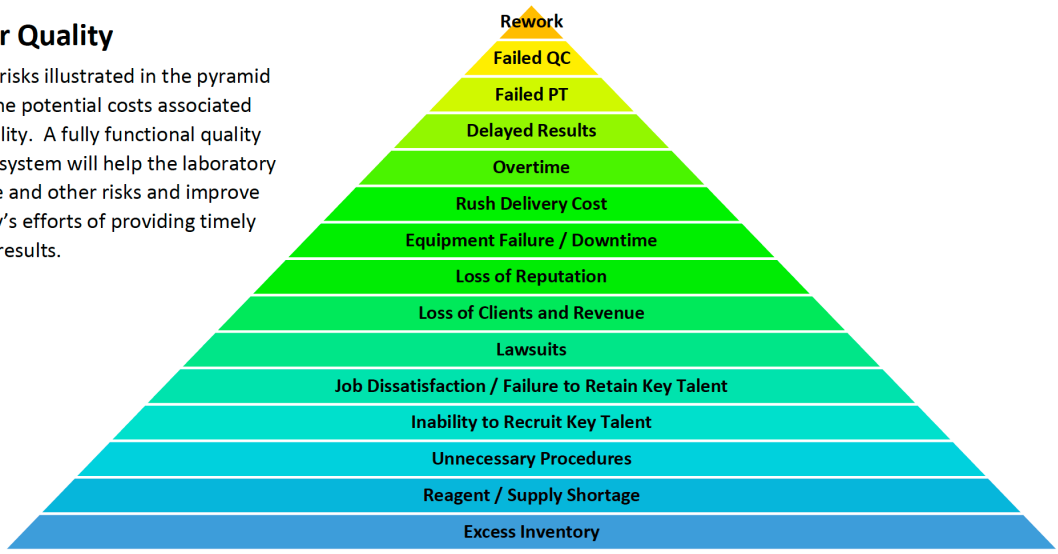
- Decreased operating expenses from retesting;
- Enhanced management control through management review participation;
- Reduced product liability risk resulting from robust QMS;
- Increased customer satisfaction as a result of customer focused QMS;
- Increased marketability from the commitment to meeting internationally accepted quality standards;
- Participation in funded national and international programs for foreign animal disease detection, animal/zoonotic/and emerging disease surveillance, and export testing;

- Expanding customer ability to reach international markets; and
- Ability to provide documentary evidence (records) of the whole laboratory test process.
- Meet the priorities of the Food Safety Modernization Act of 2011 by enhancing the safety of human and animal foods by increasing the capacity and capability of laboratories across the Vet-LIRN to perform network case investigations or surveillance efforts through implementation quality assurance/quality control processes that lead to laboratory reliable and accurate laboratory test results.

Some expanded and prioritized benefits of Vet-LIRN laboratory accreditation are shown below.

Cost of Poor Quality

The potential risks illustrated in the pyramid are some of the potential costs associated with poor quality. A fully functional quality management system will help the laboratory mitigate these and other risks and improve the laboratory's efforts of providing timely accurate test results.



4 Conclusion

The most recent two versions of the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory and ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories accreditation standards are 96% congruent, when directly compared by cross referencing all elements in each standard in both 2016 and 2022. The AAVLD and private accreditation bodies have similar missions, authority, recognition, audits processes and outcomes. The differences noted were associated primarily with the intended scope of laboratory accreditation of the two standards as shown below.

Scope of Laboratory Accreditation	
ISO 17025:2017	***AAVLD Requirements:2021-01***
Scope defined by laboratory upon application	Scope defined by requirements
Testing and calibration laboratories	Publicly funded veterinary diagnostic laboratories
Scopes relevant to veterinary testing laboratories • Microbiological testing • Biological testing • Chemical testing	Full-service laboratory scope • Necropsy, histopathology, clinical pathology, mycology, parasitology, serology, toxicology

	• Necropsy, histopathology, bacteriology and virology "on-site"

The most significant crucial requirements included in the AAVLD Requirements compared to the ISO/IEC 17025 standard are: 1) AAVLD requirement to address biosafety, biocontainment, and biosecurity at the facility (environment) and procedural levels. These physical and process requirements are critical and essential for routine veterinary diagnostic laboratory testing and disease surveillance activities due to the infectious nature of samples being submitted to veterinary diagnostic laboratories, which may contain emerging and zoonotic pathogens; and 2) AAVLD requirements to specify expertise and qualifications of personnel at the management and technical levels to help ensure workforce competency.

From a practical perspective the cost of the AAVLD laboratory accreditation is estimated to be approximately 1/3 the cost of private laboratory accreditation. This difference has been beneficial to publicly funded veterinary diagnostic laboratories by allowing them to establish a continuous improvement model which meets the domestic and international expectations of laboratory clients. For Vet-LIRN laboratories, the majority of which are supported in large part by tax-payers dollars, the lower cost paired with equivalent rigor in accreditation requirements directed at the Vet-LIRN required service needs, justifies AAVLD Accreditation as an appropriate fit for the Vet-LIRN.

Table 1. Cross-reference between "*AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory-2021*" and *"ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories-2017"*

AAVLD Requirement	ISO 17025:2017	Comments
2. ADMINISTRATIVE REQUIREMENTS		
2.1 Organization, Management and Personnel		
2.1.1 Diagnostic laboratories reviewed for accreditation shall be administered by a State/Provincial Department of Agriculture, a University, an Agricultural Experiment Station, a State/Provincial Department of Health, or by various combinations of such public institutions. The committee does not review commercial laboratories, or laboratory animal diagnostic laboratories supported by the National Institutes of Health.		No equivalent in ISO 17025
2.1.2 The laboratory personnel shall be able to provide competence in all management and technical groups evaluated for accreditation. Minimum training levels are listed by laboratory position in Appendix I, Personnel Qualifications.		No equivalent in ISO 17025
2.2 Finance and Budget		
2.2.1 The overall budget will be evaluated on the basis of salaries for personnel, operations, equipment, maintenance, travel, information technology and continuing education. The laboratory shall have sufficient resources to meet the requirements for accreditation as indicated in the support for the various disciplines and the overall administrative function of the laboratory.		No equivalent in ISO 17025
2.2.2 As diagnostic laboratories are a vital part of disease surveillance and monitoring, finances must be available to sustain these assignments. Since these laboratories serve the public good, surveillance resources are not intended to be self-sufficient financially and require public financial support commensurate with the public good derived.		No equivalent in ISO 17025
3. ACCREDITATION PROCESS – see *AAVLD REQUIREMENTS FOR AN ACCREDITED VETERINARY DIAGNOSTIC LABORATORY*		
4. MANAGEMENT REQUIREMENTS		
4.1 **Organization and Management**		
4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.	5.1. The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.	ISO 17025 and AAVLD requirements are similar
4.1.2 The laboratory shall be organized and shall operate in such a way that it meets the requirements of this Standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.	5.4. Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility. 6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
4.1.3 The laboratory shall have a clearly defined organizational system and structure. This shall be supported with organizational charts and job descriptions. Organizational charts shall indicate key personnel and the laboratory's place within the larger organization. Relationships between management, technical operations, support services and quality activities shall be specified.	5.5. The laboratory shall: 5.5.a. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; 5.5.b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;	ISO 17025 and AAVLD Requirements are similar
4.1.4 The laboratory shall:		
4.1.4.1 have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures;	5.6. The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: 5.6.a. implementation, maintenance and improvement of the management system; 5.6.b. identification of deviations from the management system or from the procedures for performing laboratory activities; 5.6.c. initiation of actions to prevent or minimize such deviations;	ISO 17025 and AAVLD Requirements are similar
4.1.4.2. have policies and procedures to ensure the ongoing impartiality of its management and personnel such that they are free from any undue internal or external commercial, financial or other pressures and influences that may adversely affect the quality of their work or diminish confidence in their competence, judgment or operational integrity.	4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality. 4.1.2 The laboratory management shall be committed to impartiality. 4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality. 4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality 4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. 6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.	ISO 17025 and AAVLD Requirements are similar
4.1.4.3. have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results. These procedures shall ensure: 4.1.4.3.1. Policies are extended to external personnel who have access to confidential client information.	4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
4.1.4.3.2. Client complaints are kept confidential. 4.1.4.3.3. The client is notified when information is required to be released for any reason, except when released to federal, state, or provincial, or local regulatory agencies.	the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. 4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided. 4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source. 4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.	
4.1.4.4. specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of tests;	5.5. the laboratory shall: 5.5.a. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; 5.5.b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;	ISO 17025 and AAVLD Requirements are similar
4.1.4.5. provide adequate supervision of testing staff, including trainees, by persons familiar with the tests, their purpose and the analysis of the test results;	5.5. The laboratory shall: 5.5.b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;	ISO 17025 and AAVLD Requirements are similar
4.1.4.6. have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;	5.5. The laboratory shall: 5.5.b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;	ISO 17025 and AAVLD Requirements are similar
4.1.4.7. appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;	5.2. The laboratory shall identify management that has overall responsibility for the laboratory. 5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:	No equivalent in ISO 17025 to require a Quality Manager.

AAVLD Requirement	ISO 17025:2017	Comments
	5.6.d. reporting to laboratory management on the performance of the management system and any need for improvement; 5.6.e. ensuring the effectiveness of laboratory activities.	
4.1.4.8. appoint backups or deputies for key managerial personnel such as the quality manager.		
None	5.3. The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.	No equivalent in AAVLD
Note: In laboratories with a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for every function.		
4.2 Quality System		
4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and volume of testing it undertakes. The laboratory management shall document its policies, systems, programs, procedures and instructions to enable the laboratory to ensure to the extent possible the quality of the test and diagnostic interpretations it generates. Documentation used in this quality system shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	5.5. The laboratory shall: 5.5.c. document its procedures to the extent necessary to assure the consistent application of its laboratory activities and the validity of the results. 6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. 8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purpose of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. 8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.	ISO 17025 and AAVLD Requirements are similar
4.2.2. The laboratory management shall define and document the policies and objectives to be achieved by implementing the quality system. The laboratory management shall ensure that these policies and objectives are documented in a quality manual.	5.6. The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: 5.6.a. implementation, maintenance and improvement of the management system; 8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purpose of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. 8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.	No equivalent in ISO 17025 to require a Quality Manual or quality policy statement.

AAVLD Requirement	ISO 17025:2017	Comments
Note: The quality policy statement and manual should be concise.		
4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.	5.5. The laboratory shall: 5.5.c. document its procedures to the extent necessary to assure the consistent application of its laboratory activities and the validity of the results. 8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	No equivalent in ISO 17025 to require a Quality Manual
4.2.4 The quality manual shall define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the AAVLD Standard.	5.5. the laboratory shall: 5.5.a. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; 5.5.b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; 6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. 8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.	No equivalent in ISO 17025 to require a Quality Manual or Quality Manager
4.3 Document Control	8.3 Control of Management System Documents (Option A)	
4.3.1 The document control system shall ensure that only the current version of the correct document is in use in the laboratory, and that documents needed for staff to perform their work are available at the work location.	8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. 8.3.2 d. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). 7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	7.11.5. The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.	
4.3.2 The laboratory shall have documented policy, procedures and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived, and discarded. Procedures shall be reviewed and approved by authorized, qualified staff.	8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. 8.3.2 The laboratory shall ensure that: a) documents are approved for adequacy prior to issue by authorized personnel; b) documents are periodically reviewed, and updated as necessary; f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.	ISO 17025 and AAVLD Requirements are similar ISO 17025 Option A does require policies for the management system as defined in 8.2.1 but does not require a procedure
4.3.3 Changes to documents shall be identified clearly and reviewed and approved by an authorized, qualified officer, administrator or supervisor having access to pertinent background information concerning the change.	8.3.2 The laboratory shall ensure that: a) documents are approved for adequacy prior to issue by authorized personnel; c) changes and the current revision status of documents are identified;	ISO 17025 and AAVLD Requirements are similar
4.3.4 Documents shall be uniquely identified and accurately cross-referenced.	8.3.2 The laboratory shall ensure that: e) documents are uniquely identified; 8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.	ISO 17025 and AAVLD Requirements are similar
4.3.5 Documents shall include page numbers and total number of pages and/or a mark to signify the end of the document,	No equivalent	No equivalent in ISO 17025
Note: In this context "document" means any information or instructions, in any format or medium, that have direct bearing on or affect the quality of test results, and includes not only the quality manual, policy, procedures, and instructions but also test methods, worksheets, forms, international standards, and regulations	Under 8.3.1 NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, textbooks, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.	No equivalent in ISO 17025 for document control of forms and worksheets
4.4 Review of requests or contract		
4.4.1 The laboratory shall have a documented policy and procedures that describe how the laboratory ensures that it is capable of and has the capacity for doing particular testing. The procedures shall ensure adequate review of the proposed work with laboratory staff and the client. The laboratory shall keep a record of the review and of client agreement.	7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: a) the requirements are adequately defined, documented and understood; b) the laboratory has the capability and resources to meet the requirements; **[c. covered in AAVLD 4.4.2 below]**	ISO 17025 and AAVLD Requirements are similar.

AAVLD Requirement	ISO 17025:2017	Comments
	d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way. 7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date. 7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.	
	7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results. 7.1.5 The customer shall be informed of any deviation from the contract. 7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel. 7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. NOTE Such cooperation can include: a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities; b) preparation, packaging, and dispatch of items needed by the customer for verification purposes. 7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.	
4.4.2 The review shall also cover any work that is subcontracted or referred by the laboratory. The laboratory shall advise the client what laboratory the sample/specimen will be sent to for testing. Advisement can occur pre or post submission (e.g. phone, website, fee schedule, test report)	7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval; NOTE 1 It is recognized that externally provided laboratory activities can occur when:	ISO 17025 and AAVLD Requirements are similar.

AAVLD Requirement	ISO 17025:2017	Comments
	— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; — the laboratory does not have the resources or competence to perform the activities.	
NOTE: Please refer to the AAVLD Glossary of Terms for definitions of Subcontracted and Referral tests.		
4.5 Subcontracting of test services	**6.6 Externally provided products and services**	
4.5.1 When a laboratory offers tests that are subcontracted, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting or agency arrangements) this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with the AAVLD Requirements or ISO 17025 for the work in question.	6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of the laboratory NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services. 6.6.2 The laboratory shall have a procedure and retain records for: a) defining, reviewing and approving the laboratory's requirements for externally provided products and services; b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; 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; d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.	ISO 17025 and AAVLD Requirements are similar.
	6.6.3 The laboratory shall communicate its requirements to external providers for: a) the products and services to be provided; b) the acceptance criteria; c) competence, including any required qualification of personnel; d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.	

AAVLD Requirement	ISO 17025:2017	Comments
4.5.2 The laboratory shall advise the customer of the arrangement.	7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval; NOTE 1 It is recognized that externally provided laboratory activities can occur when: — the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; — the laboratory does not have the resources or competence to perform the activities.	ISO 17025 and AAVLD Requirements are similar
4.5.3 The laboratory is not responsible for documenting that the subcontractor is competent when the customer or a regulatory authority specifies which subcontractor is to be used.	**6.6.1** The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of the laboratory	ISO 17025 and AAVLD Requirements are similar
4.5.4 The laboratory shall maintain a list of all subcontractors that it uses for tests.	N/A	No equivalent in ISO 17025
4.6 Purchasing services and supplies		
The laboratory shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results. These procedures shall include a description of the criteria for selection, evaluation, use, handling, and storage of materials and reagents having an effect or potential effect on test results.	6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of the laboratory. NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services. 6.6.2 The laboratory shall have a procedure and retain records for: a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;	ISO 17025 and AAVLD Requirements are similar. 17025:2017, 6.6 incorporates any external service and products that "support the operation of the laboratory", including purchasing (and others – subcontracting, proficiency testing, equipment maintenance and calibration, support testing. Additionally, in 17025:2017, the lab must communicate it's requirements (and have record of) to external providers. No equivalent in AAVLD.

AAVLD Requirement	ISO 17025:2017	Comments
	b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; 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;	
	d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers. 6.6.3 The laboratory shall communicate its requirements to external providers for: a) the products and services to be provided; b) the acceptance criteria; c) competence, including any required qualification of personnel; d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.	
4.7 Complaints	7.9 Complaints	
4.7.1. The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties and shall ensure that:	4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source. 7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.	ISO 17025 and AAVLD Requirements are similar
	7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.	ISO 17025 and AAVLD Requirements are similar
4.7.1.1. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.	7.9.3 The process for handling complaints shall include at least the following elements and methods: a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	b) tracking and recording complaints, including actions undertaken to resolve them; c) ensuring that any appropriate action is taken.	
	7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint	ISO 17025 and AAVLD Requirements are similar
4.7.1.2. The client shall be kept informed of the progress made on the complaint and of its resolution.	7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome. 7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.	ISO 17025 and AAVLD Requirements are similar
4.7.1.3. All complaints are reviewed and approved by someone not involved in the original laboratory activity in question.	7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. NOTE This can be performed by external personnel.	ISO 17025 and AAVLD Requirements are similar
4.8 Control of nonconforming testing and test results		
4.8.1. The laboratory shall have a policy and procedures that ensure that nonconforming testing (conditions that exist which have or could adversely affect the reliability of test results) is detected and promptly corrected. The procedure shall ensure that: 4.8.1.1. Clients are notified if questionable or incorrect test results have been reported. 4.8.1.2. An evaluation of the impact on previous work is assessed. 4.8.1.3. The responsibility and authority to stop work, withhold test results, implement corrective action and authorize resumption of work is defined.	7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that: a) the responsibilities and authorities for the management of nonconforming work are defined; b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; d) a decision is taken on the acceptability of the nonconforming work; e) where necessary, the customer is notified and work is recalled; f) the responsibility for authorizing the resumption of work is defined.	ISO 17025 and AAVLD Requirements are similar
4.8.2. The laboratory shall retain records of nonconforming work and actions taken.	7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).	ISO 17025 and AAVLD Requirements are similar
4.8.3. When a serious issue or a risk to the quality of test results is identified the laboratory shall ensure that appropriate corrective action procedures given in 4.9 shall be promptly implemented.	6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	examine the effect of the defect or deviation from specified requirements and shall **initiate the management of nonconforming work** procedure (see 7.10). **7.10 Nonconforming work** See also 7.10.1 above 7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.	
	8.7 Corrective actions (Option A) 8.7.1 When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the management system, if necessary.	
4.9 Corrective action, Risk assessment and Improvements		
4.9.1. **Corrective Action** The laboratory shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure:	**7.10 Nonconforming work (see above)** 7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory **shall implement corrective action.** 7.11.3 The laboratory information management system(s) shall: e) include recording system failures and the appropriate immediate and corrective actions.	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	8.6 Improvement (Option A) 8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions. NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, **corrective actions,** management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. **Management Requirements 8.1** **8.1.2 Option A** As a minimum, the management system of the laboratory shall address the following:	
	— management system documentation (see 8.2); — control of management system documents (see 8.3); — control of records (see 8.4); — actions to address risks and opportunities (see 8.5); — improvement (see 8.6); — **corrective actions (see** 8.7); — internal audits (see 8.8); — management reviews (see 8.9).	
	8.7 Corrective actions (Option A) 8.7.1 When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken;	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	e) update risks and opportunities determined during planning, if necessary; f) make changes to the management system, if necessary.	
	8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.	
4.9.1.1. designation of appropriate authorities responsible for implementation of corrective action(s);	5.5 The laboratory shall: a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; 5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance and improvement of the management system; b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimize such deviations; d) reporting to laboratory management on the performance of the management system and any need for improvement; e) ensuring the effectiveness of laboratory activities.	ISO 17025 and AAVLD Requirements are similar
4.9.1.2. investigative procedures are implemented to determine the root cause(s) of the problem;	8.7.1 When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur;	ISO 17025 and AAVLD Requirements are similar
4.9.1.3. upon identification, appropriate corrective action(s) are implemented;	c) implement any action needed;	ISO 17025 and AAVLD Requirements are similar
4.9.1.4. documentation of any required changes to operational procedures;	8.7.3 The laboratory shall retain records as evidence of:	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action.	
4.9.1.5. once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and	8.7.1 When a nonconformity occurs, the laboratory shall: d) review the effectiveness of any corrective action taken;	ISO 17025 and AAVLD Requirements are similar
4.9.1.6. when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11.	8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system: a) conforms to: — the laboratory's own requirements for its management system, including the laboratory activities; — the requirements of this document; b) is effectively implemented and maintained.	No equivalent in ISO 17025 for audit in response to Corrective Action-
Note: Special internal audits need only be initiated when a serious issue of risk to the quality of test results or integrity of the quality system has been the subject of corrective action.		
4.9.2. **Risk Assessment**		
4.9.2.1. The laboratory shall consider the risks and opportunities associated with its activities in order to: 4.9.2.1.1. assure the quality management system can achieve its intended results; 4.9.2.1.2. enhance opportunities to achieve the purpose and objectives of the laboratory; 4.9.2.1.3. prevent, or reduce, undesired impacts and potential failures in the laboratory activities; 4.9.2.1.4. achieve improvement.	**8.5 Actions to address risks and opportunities (Option A)** 8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to: a) give assurance that the management system achieves its intended results; b) enhance opportunities to achieve the purpose and objectives of the laboratory; c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d) achieve improvement.	ISO 17025 and AAVLD Requirements are similar
4.9.2.2. The laboratory shall plan: 4.9.2.2.1. actions to address these risks and opportunities; 4.9.2.2.2. how to integrate and implement the actions into its quality management system; 4.9.2.2.3. how to evaluate the effectiveness of these actions.	8.5.2 The laboratory shall plan: a) actions to address these risks and opportunities. b) how to: — integrate and implement these actions into its management system; — evaluate the effectiveness of these actions. **8.6 Improvement (Option A)**	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
4.9.2.3. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.		ISO 17025 and AAVLD Requirements are similar
4.9.3. **Improvement**		
4.9.3.1. The laboratory shall identify and select opportunities for improvement and implement any necessary actions.	8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions. NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.	ISO 17025 and AAVLD Requirements are similar
4.9.3.2. The laboratory shall seek feedback, both positive and negative, from its clients. The feedback shall be analyzed and used to improve the quality management system, laboratory activities and customer service.	8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.	ISO 17025 and AAVLD Requirements are similar
Note: Preventive action is a pro-active process. Identification of specific technical areas requiring preventive action often involves the ongoing monitoring and review of the validity of the test methods and the competence of the laboratory.	Preventive actions fall under opportunities for improvements (8.6)	ISO 17025 and AAVLD Requirements are similar
4.10 Records		
All laboratory records must be maintained in an effective retrieval system, and must be accurate, contemporaneous, attributable and legible. This retrieval system should include a system of classification of diseases. Records shall be preserved in accordance with requirements for individual jurisdictions.		
4.10.1 General. The laboratory shall have a records management system.	8.4.1. The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.	ISO 17025 and AAVLD Requirements are similar
4.10.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as corrective and preventive action records.	8.4.2. The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available	ISO 17025 and AAVLD Requirements are similar
4.10.1.2. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention of records shall be consistent with contractual obligations.	8.4.1. The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document. 8.4.2. The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.	ISO 17025 and AAVLD Requirements are similar
Note: Records may be in the form of various types of media, such as hard copy or electronic media.		
4.10.1.3 All records shall be held secure and in confidence.	8.4.2 Access to these records shall be consistent with the confidentiality commitments	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
4.10.1.4 The laboratory shall have procedures to protect and back-up data and records held on computers at all times and to prevent unauthorized access to or amendment of data or records on computers.	7.11.3. The laboratory information management system shall: a. be protected from unauthorized access; b. safeguarded against tampering and loss;	ISO 17025 and AAVLD Requirements are similar (LIMS covered in AAVLD 4.10.2.4)
4.10.2 Technical Records		
4.10.2.1 The laboratory shall retain for a defined period of time, original observations, derived data, calibration records, staff records, a copy of each test report issued, and any other information necessary to recreate the activity. The records for each test shall contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.	7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement results and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.	ISO 17025 and AAVLD Requirements are similar
4.10.2.2 Observations, data and calculations shall be clearly and permanently recorded and identifiable to the specific test at the time they are made.	7.5.2 Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.	ISO 17025 and AAVLD Requirements are similar
4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible or deleted) and the correct value entered alongside. All such alterations to records shall be dated, signed or initialed by the person making the correction. In the case of computer-collected data, similar measures shall be taken to avoid loss or change of original data.	7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.	ISO 17025 and AAVLD Requirements are similar
4.11 Internal audits		
4.11.1 The laboratory shall periodically and in accordance with a predetermined schedule and procedure conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the AAVLD Standard. The internal audit program shall address all elements of the quality system, including testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit can be carried out.	8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system: a) conforms to: — the laboratory's own requirements for its management system, including the laboratory activities; — the requirements of this document; b) is effectively implemented and maintained. 8.8.2 The laboratory Shall a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; b) define the audit criteria and scope for each audit; c) ensure that the results of the audits are reported to relevant management;	ISO 17025 and AAVLD Requirements are similar
Note: In laboratories with a small number of personnel, effective internal audits may not be feasible. In such cases, it may be appropriate for two or more laboratories to cooperate in auditing each other.		
4.11.2 When audit findings cast doubt on the effectiveness of the operations or on the quality of the laboratory's test results, the laboratory shall take timely and effective corrective and where appropriate preventive action, and	8.8.2 The laboratory shall: d) implement appropriate correction and corrective actions without undue delay;	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
shall notify clients in writing if investigations show that the laboratory results may have been affected (see 4.8).		
4.11.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these corrective actions are discharged within an appropriate and agreed-upon time-frame.	8.8.2 The laboratory shall: d) implement appropriate correction and corrective actions without undue delay; e) retain records as evidence of the implementation of the audit programme and the audit results.	ISO 17025 and AAVLD Requirements are similar
4.12 Management reviews		
4.12.1 The quality system and test related activities shall be reviewed by management at least once per year.	5.7. Laboratory management shall ensure that: 5.7.a. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; 5.7.b. the integrity of the management system is maintained when changes to the management system are planned and implemented. 8.9.1. The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document	No equivalent in ISO 17025 for management review to be completed once per year.
4.12.2 The laboratory shall have a procedure for performing a Management Review. The review shall take into consideration:	8.9.2. The inputs to management review shall be recorded and shall include information related to the following:	ISO 17025 and AAVLD Requirements are similar
4.12.2.1. suitability of policies and procedures;	c. suitability of policies and procedures	ISO 17025 and AAVLD Requirements are similar
4.12.2.2. reports from managerial and supervisory personnel;	a. changes in internal and external issues that are relevant to the lab	ISO 17025 and AAVLD Requirements are similar
4.12.2.3. status of actions from previous management reviews;	d. status of actions from previous management reviews	ISO 17025 and AAVLD Requirements are similar
4.12.2.4. reports of recent internal audits;	e. outcome of recent internal audits	ISO 17025 and AAVLD Requirements are similar
4.12.2.5. corrective actions;	f. corrective actions	ISO 17025 and AAVLD Requirements are similar
4.12.2.6. assessments by external bodies;	g. assessments by external bodies	ISO 17025 and AAVLD Requirements are similar
4.12.2.7. results of inter-laboratory comparisons or proficiency tests;	n. outcomes of the assurance of the validity of results	ISO 17025 and AAVLD Requirements are similar
4.12.2.8. changes in the volume and type of work;	h. changes in the volume and type of the work or in the range of lab activities	ISO 17025 and AAVLD Requirements are similar
4.12.2.9. client feedback;	i. customer and personnel feedback	ISO 17025 and AAVLD Requirements are similar
4.12.2.10. complaints;	j. complaints	ISO 17025 and AAVLD Requirements are similar
4.12.2.11. improvements;	k. effectiveness of any implemented improvements b. fulfilment of objectives	ISO 17025 and AAVLD Requirements are similar
4.12.2.12. risk assessment;	m. results of risk identification	ISO 17025 and AAVLD Requirements are similar
4.12.2.13. other relevant factors, such as quality control activities, resources, and staff training.	l. adequacy of resources o. other relevant factors, such as monitoring activities and training.	ISO 17025 and AAVLD Requirements are similar
4.12.3 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed-upon timeframe.	5.7. Laboratory management shall ensure that: 5.7.a. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;	No equivalent in ISO 17025 for actions from the management review to be completed within an

AAVLD Requirement	ISO 17025:2017	Comments
	5.7.b. the integrity of the management system is maintained when changes to the management system are planned and implemented. 8.9.3. The outputs from the management review shall record all decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; d) any need for change.	appropriate and agreed-upon timeframe
4.12.4 This review and subsequent activities shall ensure the continuing suitability and effectiveness of the quality management system and shall ensure the introduction of necessary changes and improvements.	5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: 5.6.e. ensuring the effectiveness of laboratory activities. 5.7. Laboratory management shall ensure that: 5.7.a. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; 5.7.b. the integrity of the management system is maintained when changes to the management system are planned and implemented. 8.9.3 a. The effectiveness of the management system and its processes b. improvement of the laboratory activities related to the fulfilment of the requirements of this document c. provision of required resources d. any need for change.	ISO 17025 and AAVLD Requirements are similar
5. TECHNICAL REQUIREMENTS		
5.1 General		
5.1.1 Many factors can affect the reliability of test results. The extent to which these factors contribute to the reliability of test results differs between tests. The laboratory shall take account of these factors in developing or adopting test methods and related procedures for routine use, in the training and qualification of personnel, in the selection and calibration of equipment, and in the assessment of materials and reagents to be used in testing.	N/A	Removed.
5.2 Personnel	**6.2 Personnel**	
5.2.1. The laboratory shall ensure:		
5.2.1.1. the initial and ongoing competence of laboratory personnel to do their assigned work using objective criteria. *NOTE: Examples of objective criteria include proficiency testing, inter-laboratory comparisons, reference sample panels, replicate testing of quality control materials and continuing education.*	6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.	ISO 17025 and AAVLD Requirements are similar (AAVLD covers impartiality of personnel in 4.1.4.2)
5.2.1.2. laboratory personnel understand the significance of deviation from laboratory procedures.	6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
5.2.2. The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and diagnostic interpretation, and the management shall authorize only staff who are documented as qualified and competent to do testing and related work.	6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. 6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: a) development, modification, verification and validation of methods; b) analysis of results, including statements of conformity or opinions and interpretations; c) report, review and authorization of results.	ISO 17025 and AAVLD Requirements are similar
5.2.3. The laboratory shall have a system which ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.	6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system. 6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. 6.2.5 The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel.	ISO 17025 and AAVLD Requirements are similar
5.2.4. The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: 5.2.4.1. develop, modify, verify and validate methods and any planned deviations; 5.2.4.2. analyze results, including statements of conformity or opinions and interpretations; and; 5.2.4.3. review, authorize and report results.	6.2.5 The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel.	ISO 17025 and AAVLD Requirements are similar
5.3 Accommodation and environmental conditions		
All aspects of the physical facilities must provide an appropriate environment for the conduct of the activities of all disciplines required for laboratory accreditation.		No equivalent in ISO 17025 (to "incorporate safety, biosafety, biocontainment

AAVLD Requirement	ISO 17025:2017	Comments
Laboratories, offices, storage space and animal holding rooms shall be clean, maintained in good repair and be adequate in number and size for intended function of the laboratory. Adequate lighting and ventilation shall be provided. Safety biosafety, biocontainment and biosecurity features shall be incorporated as a part of the physical facility.		and biosecurity features as part of the physical facility")
5.3.1 Laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of tests. The laboratory shall ensure that the environment does not invalidate the results or adversely affect the required quality of any testing activity.	6.1 The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities. 6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. 6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. 6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.	ISO 17025 and AAVLD Requirements are similar
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results. Due attention shall be paid, for example, to the biological sterility, dust, electromagnetic interference, radiation, humidity, airflow, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Test activities shall be stopped when the environmental conditions jeopardize the test results.	6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results. 6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: 6.3.4.b. prevention of contamination, interference or adverse influences on the laboratory activities;	ISO 17025 and AAVLD Requirements are similar
5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.	6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: 6.3.4.c. effective separation between areas with incompatible laboratory activities.	ISO 17025 and AAVLD Requirements are similar
5.3.4 Access to and use of areas affecting test results shall be controlled.	6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: 6.3.4.a. access to and use of areas affecting laboratory activities;	ISO 17025 and AAVLD Requirements are similar
5.3.5 The laboratory shall ensure the establishment and maintenance of safety, biosafety, biocontainment, and biosecurity programs relevant to present and anticipated needs. The programs will provide staff training and address all necessary elements to ensure a safe work environment.		No equivalent in ISO 17025
5.4 Test methods		
5.4.1 General		
5.4.1.1 The laboratory shall use appropriate test methods and related procedures for all animal disease diagnostic testing activities. Consideration shall be given to all factors that impact on the relevance of the test method and test results to a specific diagnostic interpretation or application. These factors include the suitability of the test method, its acceptability by the scientific and regulatory communities, its acceptability to the client, and its feasibility given available laboratory resources. See 5.4.3.1 note.	7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: 7.1.1.d. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. 7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	measurement uncertainty as well as statistical techniques for analysis of data. 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). 7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. 7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment are recommended. Laboratory-developed or modified methods can also be used. 7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	
5.4.1.2 Test methods shall be approved for use by qualified, authorized personnel, according to established procedures.		ISO 17025 and AAVLD Requirements are similar
5.4.1.3 Tests shall be appropriately controlled.		ISO 17025 and AAVLD Requirements are similar
5.4.1.4 The laboratory shall have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment, and the collection, handling, transport and storage of specimens and preparation of samples for testing.	6.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration. 6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.	ISO 17025 and AAVLD Requirements are similar
5.4.1.5 Laboratories using test methods prepared by national and international standards-setting bodies and other external technical organizations shall have a system to receive updates of these methods in a timely manner.		No equivalent in ISO 17025
Note: International, regional or national standards or other recognized specifications that contain sufficient and concise information on any of the above subjects do not need to be rewritten as internal procedures if these		

AAVLD Requirement	ISO 17025:2017	Comments
standards are published in a way that they can be used as published by the operating staff in a laboratory. Consideration may need to be given to providing additional documentation for optional steps in the assay or additional details. As with all test methods, they shall be subject to document control (see 4.3).		
5.4.2 Selection of methods		
5.4.2.1 The client shall be informed of the test method chosen and if required, the laboratory shall provide the client with the rationale used in making this choice (see 5.4.1.1).	7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date. 7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment are recommended. Laboratory-developed or modified methods can also be used. 7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.	ISO 17025 and AAVLD Requirements are similar
5.4.2.2. The laboratory shall demonstrate, using objective criteria, that it can properly perform standard methods prior to introducing diagnostic tests. Records of verification shall be retained. If the standard methods change, the verification must be repeated.	7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. 7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.	ISO 17025 and AAVLD Requirements are similar
5.4.2.3 Test methods shall contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to information sources outside the laboratory's document control system. In addition, they shall include as appropriate:		No equivalent in ISO 17025 requiring specific test method components
5.4.2.3.1. evidence of document control;		
5.4.2.3.2. relevant references;		
5.4.2.3.3. a description of intended analyte(s) (e.g., antibody) and any quantities or ranges to be determined (e.g., titer);		
5.4.2.3.4. any reference standards or reference materials required (e.g., reference strains, reference standards for antibody);		
5.4.2.3.5. a description of the appropriate matrix or specimen for testing, including species (e.g., bovine serum);		
5.4.2.3.6. safety considerations, including biocontainment level needed;		No equivalent in ISO 17025
5.4.2.3.7. a list of and specifications for equipment, materials and reagents, including software;		

AAVLD Requirement	ISO 17025:2017	Comments
5.4.2.3.8. conditions for acceptance of specimens as fit for testing;		
5.4.2.3.9. conditions for specimen identification, collection, handling, transportation and storage;		
5.4.2.3.9. conditions for specimen identification, collection, handling, transportation and storage;		
5.4.2.3.11. a description of the controls used and their acceptance limits;		
5.4.2.3.12. checks to be made prior to beginning the test procedure (e.g., equipment checks and calibrations);		
5.4.2.3.13. acceptance criteria for results;		
5.4.2.3.14. data to be recorded and the method of analysis/transformation, presentation, and/or interpretation (e.g., how an absorbance reading is transformed and interpreted as a positive or negative result relative to a cut-off) and recording; and		
5.4.2.3.15. the most current description of the test procedure.		
5.4.2.4 The test method shall be validated before it is incorporated into the routine diagnostic activities of the laboratory. The same prerequisite applies to an existing assay that has been modified if the modification affects the performance characteristics of the assay (see 5.4.3).	7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.	ISO 17025 and AAVLD Requirements are similar
5.4.3 Validation of test methods		
5.4.3.1. A test method, whether an international or national standard method, a harmonized method or developed in-house, shall be considered appropriate for routine diagnostic purposes if it has been validated, where possible, according to the principles outlined in the OIE Manual of Standards for Diagnostic Tests and Vaccines or other related OIE references. It is preferred for all methods, whether developed in-house or drawn from reputable collections of standard methods, that the laboratory should be able to define, at least through reference to public or private documentation, the analytical sensitivity and specificity, accuracy and precision, diagnostic sensitivity and specificity and other parameters relevant to the use of the test method in the user's laboratory. The user is not required to re-validate international or national standard methods.	6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: 6.2.6.a. develop, modify, verify and validate methods and any deviations; 7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized. 7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. 7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed. 7.2.2.3 The performance characteristics of validated methods as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.	ISO 17025 and AAVLD Requirements are similar
Note: Test methods may be classified as "validate for use" by meeting the following criteria:		

AAVLD Requirement	ISO 17025:2017	Comments
5.4.3.1.1. Ongoing documentation of internal or inter-laboratory performance using known reference standard(s) for the species and/or diagnostic specimen(s) of interest, AND one or more of the following:		No equivalent in ISO 17025
5.4.3.1.2. Endorsed or published by reputable technical organization (e.g.: OIE Manual of Standards for Diagnostic Tests and Vaccines, US Food and Drug Administration's Bacteriologic Analytic Methods, Bergey's Manual of Determinative Bacteriology, American Society of Microbiology Manual of Clinical Laboratory Immunology, American Association of Avian Pathologists Isolation and Identification of Avian Pathogens, EPA protocols, American Fisheries Society Bluebook, AOAC, NAHLN);		No equivalent in ISO 17025
5.4.3.1.3. Published in a peer-reviewed journal with sufficient documentation to establish diagnostic performance and interpretation of results;		No equivalent in ISO 17025
5.4.3.1.4. Documentation of internal or inter-laboratory comparison to an accepted methodology or protocol.		No equivalent in ISO 17025
5.4.3.2. Validation data, including all original observations, calculations, equipment monitoring and calibration records, archived procedures used to formulate performance characteristics, and a statement on validity of the method, detailing its fitness for the intended use shall be retained by the laboratory for at least as long as the assay is used for diagnostic purposes and for at least seven years after the assay has been retired from use.	7.2.2.4 The laboratory shall retain the following records of validation: 7.2.2.4.a. the validation procedure used; 7.2.2.4.b. specification of the requirements; 7.2.2.4.c. determination of the performance characteristics of the methods; 7.2.2.4.d. results obtained; 7.2.2.4.e. a statement on the validity of the method, detailing its fitness for the intended use.	ISO 17025 and AAVLD Requirements are similar
Note: Depending on client needs, the laboratory may be required to define other diagnostic performance indicators such as positive and negative predictive values of the test. Such indicators may be particularly relevant to certain diagnostic applications or test populations.		
5.4.4 Control of data		
5.4.4.1 The laboratory shall ensure, using appropriate procedures that all data resulting from test validation and all data relating to test results are secure, retrievable, and approved for use by specified, qualified personnel.	7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities. 7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation. 7.11.3 The laboratory information management system shall: 7.11.3.a. be protected from unauthorized access; 7.11.3.b. be safeguarded against tampering and loss; 7.11.3.c. be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;	ISO 17025 and AAVLD Requirements are similar

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	7.11.3.d. be maintained in a manner that ensures the integrity of the data and information; and 7.11.3.e. include recording system failures and the appropriate immediate and corrective actions. 7.11.4 When laboratory information management system are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.	
5.4.4.2 Manual calculations and data transfers shall be subject to appropriate checks in a systematic manner.	7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.	ISO 17025 and AAVLD Requirements are similar
5.4.4.3 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:		
5.4.4.3.1. computer software, modified or developed by the user, is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use, i.e., the laboratory shall implement and document changes to control procedures such that these activities can be recreated and an audit trail is established;	7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.	ISO 17025 and AAVLD Requirements are similar
5.4.4.3.2. The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any additions or deletions of functionality, they shall be authorized, documented and validated before implementation. This includes extensions to commercial off-the-shelf software.	7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.	ISO 17025 and AAVLD Requirements are similar
5.4.4.3.3. procedures are established and implemented for protecting the security, integrity, and retrievability of data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;		ISO 17025 and AAVLD Requirements are similar
5.4.4.3.4. computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.	7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.	ISO 17025 and AAVLD Requirements are similar
5.4.4.4. The laboratory information management system(s) shall be:	7.11.3 The laboratory information management system shall: 7.11.3.a. be protected from unauthorized access; 7.11.3.b. be safeguarded against tampering and loss; 7.11.3.c. be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides	

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	conditions which safeguard the accuracy of manual recording and transcription; 7.11.3.d. be maintained in a manner that ensures the integrity of the data and information; and 7.11.3.e. include recording system failures and the appropriate immediate and corrective actions.	
5.4.4.4.1. protected from unauthorized access;		ISO 17025 and AAVLD Requirements are similar
5.4.4.4.2. safeguarded against tampering and loss;		ISO 17025 and AAVLD Requirements are similar
5.4.4.4.3. operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;		ISO 17025 and AAVLD Requirements are similar
5.4.4.4.4. maintained in a manner that ensures the integrity of the data and information.		ISO 17025 and AAVLD Requirements are similar
5.4.4.5. Failures in the laboratory information management system to operate as expected are subject to the non-conforming work process.		ISO 17025 and AAVLD Requirements are similar
5.4.4.6. When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure the provider or operator of the system complies with all applicable requirements of this document.	7.11.4 When laboratory information management systems are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.	ISO 17025 and AAVLD Requirements are similar
NOTE: Commercial software, excluding LIMS, in general use within its designed application range may be considered sufficiently validated.		
	7.6 Measurement Uncertainty	
None	7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty all contributions which are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.	No equivalent in AAVLD
	7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.	No equivalent in AAVLD
	7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.	No equivalent in AAVLD
5.5 Equipment	**6.4 Equipment**	
The laboratory shall possess or have access to all equipment necessary for the correct performance of all services. All equipment shall be identified, properly maintained and calibrated with maintenance and calibration procedures documented.	6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.	ISO 17025 and AAVLD Requirements are similar
5.5.1 The laboratory shall be furnished with all items of test and related equipment required for the correct performance of the tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the requirements of this AAVLD standard are met.	6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	ISO 17025 and AAVLD Requirements are similar
5.5.2 Equipment and its software used for diagnostic activities shall be capable of achieving the accuracy required and shall comply with specifications relevant to the procedures concerned. Calibration programs shall be	6.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper	ISO 17025 and AAVLD Requirements are similar

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established for key equipment where those properties have a significant effect on the results.	functioning and to prevent contamination or deterioration. 6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. 6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. 6.4.6 Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE Types of equipment having an effect on the validity of the reported results can include: — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; — those used to make corrections to the measured value, e.g. temperature measurements; — those used to obtain a measurement result calculated from multiple quantities. 6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.	
5.5.3 Equipment shall be operated by authorized, qualified personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.	6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system. 6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. 6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. **6.2.5** The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel.	ISO 17025 and AAVLD Requirements are similar

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	6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. **7.2 Selection, verification and validation of methods** 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).	
5.5.4 Each item of equipment used for test activities significant to a test result shall be uniquely identified.	6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. 6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: a) the identity of equipment, including software and firmware version; b) the manufacturer's name, type identification, and serial number or other unique identification; c) evidence of verification that equipment conforms with specified requirements; d) the current location;	ISO 17025 and AAVLD Requirements are similar
5.5.5 Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:	6.4.13 see above	
5.5.5.1. identity of the item of equipment;	a) the identity of equipment, including software and firmware version	ISO 17025 and AAVLD Requirements are similar
5.5.5.2. manufacturer's name, type identification, and serial number or other unique identification;	b) the manufacturer's name, type identification, and serial number or other unique identification;	ISO 17025 and AAVLD Requirements are similar
5.5.5.3. verification that equipment complies with the specification;	c) evidence of verification that equipment conforms with specified requirements;	ISO 17025 and AAVLD Requirements are similar
5.5.5.4. the current location, where appropriate;	d) the current location;	ISO 17025 and AAVLD Requirements are similar
5.5.5.5. the manufacturer's instructions, if available	6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).	ISO 17025 and AAVLD Requirements are similar
5.5.5.6. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;	6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;	ISO 17025 and AAVLD Requirements are similar

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5.5.5.7. maintenance carried out to date and the maintenance plan;	6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;	ISO 17025 and AAVLD Requirements are similar
5.5.5.8. damage, malfunction, modification or repair to the equipment.	6.4.13 h) details of any damage, malfunction, modification to, or repair of, the equipment.	ISO 17025 and AAVLD Requirements are similar
5.5.6 Maintenance procedures shall be established.	6.4.13 g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; **6**.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.	ISO 17025 and AAVLD Requirements are similar
5.5.7 Equipment calibrations shall be performed by qualified personnel using procedures appropriate to intended use, accuracy and precision required, and at appropriate intervals as historical data indicate.	6.4.6 Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. 6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or 6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or **6.6 Externally provided products and services** 6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of the laboratory.	ISO 17025 and AAVLD Requirements are similar
	NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance	

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	services, proficiency testing services and assessment and auditing services. 6.6.2 The laboratory shall have a procedure and retain records for: a) defining, reviewing and approving the laboratory's requirements for externally provided products and services; b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; 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; d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.	
5.5.8 Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and shall institute the "Control of nonconforming work" procedure (4.8).	6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).	ISO 17025 and AAVLD Requirements are similar
5.5.9 Whenever practical, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration or verification and the date when the next calibration or verification is due.	6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.	ISO 17025 and AAVLD Requirements are similar
5.5.10 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.	6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met. 6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results. 6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.	ISO 17025 and AAVLD Requirements are similar
5.5.11 Test equipment, including both hardware and software, shall be safeguarded from adjustments which could invalidate the test results.	6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.	ISO 17025 and AAVLD Requirements are similar
5.6 Measurement traceability		
5.6.1 Where indicated and when possible, the laboratory shall have traceability of all measurements, including the calibration of equipment, to Standard International (SI) units.	6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. 6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:	ISO 17025 and AAVLD Requirements are similar

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	a) calibration provided by a competent laboratory; or b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	
5.6.2 Where traceability of SI units of measurement is not possible, the best available means for providing confidence in the results shall be applied such as:	6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.: a) certified values of certified reference materials provided by a competent producer; b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.	ISO 17025 and AAVLD Requirements are similar
5.6.2.1. the use of suitable reference standards or materials certified to give a reliable characterization of the material;	6.5.3. a) certified values of certified reference materials provided by a competent producer	ISO 17025 and AAVLD Requirements are similar
5.6.2.2. mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned;	6.5.3 b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.	ISO 17025 and AAVLD Requirements are similar
5.6.2.3. participation in a suitable program of inter-laboratory comparisons or proficiency testing.	6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	ISO 17025 and AAVLD Requirements are similar
5.6.3 Reference equipment, standards or materials used in conjunction with testing activities shall be handled, maintained, and stored in a manner that ensures proper performance and/or accuracy.	**7.4 Handling of test or calibration items** 7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed. 7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.	ISO 17025 and AAVLD Requirements are similar
5.6.4 Biological reference materials shall, where possible, be traceable to accepted international standards or to OIE reference materials (e.g., International Standard Sera).	6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or	ISO 17025 and AAVLD Requirements are similar

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	b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	
5.6.5 Checks needed to maintain confidence in the status of working standards and reference materials shall be carried out according to defined procedures and schedules.	**7.4 Handling of test or calibration items** 7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed. 7.7 Ensuring the validity of results 7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to: a) use of reference materials or quality control materials; d) use of check or working standards with control charts, where applicable;	ISO 17025 and AAVLD Requirements are similar
5.6.6 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.	**7.4. Handling of test or calibration items** 7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.	ISO 17025 and AAVLD Requirements are similar
5.7 Specimens		
5.7.1 General: The lab shall have procedures for the collection of specimens to ensure that they are both appropriate to the test being undertaken and suitable for testing.	7.3.1. The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.	ISO 17025 and AAVLD Requirements are similar
Note: This applies to veterinary diagnostic laboratories only when the laboratory is directly responsible for sample collection.		

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5.7.1.1 The laboratory shall have procedures for the collection, processing where indicated and preservation of specimens. Collection and related procedures shall be available at the location where collection is undertaken.	7.3.1. The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.	ISO 17025 and AAVLD Requirements are similar
5.7.1.2 The laboratory shall have procedures for recording relevant data and operations relating to specimen collection that forms part of the test that is undertaken, whether the collection is performed by laboratory staff or by the client. Records shall include the collection procedure used, identification of the collector, environmental conditions (if relevant) and diagrams or other means to identify the collection location as necessary (e.g., in the case of tissue specimens) and, if appropriate, the statistics that sampling procedures are based upon.	7.3.3 The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant: a Reference to the sampling method used d. identification of the personnel performing sampling f. environmental or transport conditions g. diagrams or other equivalent means to identify the sampling location, where appropriate.	ISO 17025 and AAVLD Requirements are similar
5.7.1.3 When sampling from populations, as appropriate, the laboratory shall have a statistically defined plan for sample collection.	7.3.1. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods	No equivalent in ISO 17025
Note: While the laboratory may provide relevant scientific and/or statistical input into the development of sampling plans for the testing of animal populations, the development of these plans does not fall within the AAVLD Accreditation Requirements.		
5.8 Handling of Specimens		
5.8.1. The laboratory shall have procedures which ensure the integrity of specimens. These shall include transportation, receipt, handling, protection, retention and/or disposal of specimens. Handling instructions provided by the client with the specimen shall be considered.	7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.	ISO 17025 and AAVLD Requirements are similar
5.8.2 The laboratory shall have a system for identifying specimens that ensure no confusion between specimens or derived samples. The identification shall be retained throughout the life of the specimen and its derived samples in the laboratory, and linked to the test report (5.10).	7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.	ISO 17025 and AAVLD Requirements are similar
5.8.3. Upon receipt of the specimen, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, shall be recorded. If there has been a departure from specifications, then the samples should not be considered fit to test. However, if the client requests an item to be tested after acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.	7.4.3. Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. (cont'd)	ISO 17025 and AAVLD Requirements are similar
5.8.4 When there is any doubt as to the suitability of a specimen for testing purposes, or when a specimen does not conform to the description provided, or if the test method required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the facts and results of that discussion.	7.4.3 (cont'd) When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions,	ISO 17025 and AAVLD Requirements are similar

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	the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation	
5.9 Ensuring the quality of test results		
5.9.1 The laboratory shall have quality control procedures for monitoring the validity of test results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to: a) use of reference materials or quality control materials; b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; f) replicate tests or calibrations using the same or different methods; g) retesting or recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; j) intralaboratory comparisons; k) testing of blind sample(s).	ISO 17025 and AAVLD Requirements are similar
5.9.1.1. internal quality control schemes using statistical techniques (e.g., control charts);	d) use of check or working standards with control charts, where applicable;	ISO 17025 and AAVLD Requirements are similar
5.9.1.2. where applicable, use of international reference reagents for preparation of national and/or working standards for internal quality control;	a) use of reference materials or quality control materials;	ISO 17025 and AAVLD Requirements are similar
5.9.1.3. when practical, replicate tests using the same or different methods;	f) replicate tests or calibrations using the same or different methods;	ISO 17025 and AAVLD Requirements are similar
5.9.1.4. correlation of results for different characteristics of a specimen or sample;	h) correlation of results for different characteristics of an item;	ISO 17025 and AAVLD Requirements are similar
5.9.1.5. re-testing of retained specimens or samples;	g) retesting or recalibration of retained items;	ISO 17025 and AAVLD Requirements are similar
5.9.1.6. participation in interlaboratory comparison or proficiency testing programs;	j) intralaboratory comparisons; 7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following: a) participation in proficiency testing; b) participation in interlaboratory comparisons other than proficiency testing.	ISO 17025 and AAVLD Requirements are similar
5.9.1.7. functional check(s) of measuring and testing equipment;	c) functional check(s) of measuring and testing equipment;	ISO 17025 and AAVLD Requirements are similar
5.9.1.8. intermediate checks on measuring equipment;	e) intermediate checks on measuring equipment;	ISO 17025 and AAVLD Requirements are similar
5.9.1.9. review of reported results;	i) review of reported results;	ISO 17025 and AAVLD Requirements are similar

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5.9.1.10. testing of blind sample(s);	k) testing of blind sample(s).	ISO 17025 and AAVLD Requirements are similar
5.9.1.11. use of alternative instrumentation that has been calibrated to provide traceable results.	b) use of alternative instrumentation that has been calibrated to provide traceable results;	ISO 17025 and AAVLD Requirements are similar
5.9.2. Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.	7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.	ISO 17025 and AAVLD Requirements are similar
Note: The validity of test results is influenced by both technical competence and assay performance characteristics. If the validity of test results is called into question, it is important to be able to distinguish between the two. A test may demonstrate appropriate process control but poor diagnostic performance or vice versa.		
5.10 Reporting test results	7.8	
5.10.1. The results of each test performed by the laboratory shall be reported accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test method or contract. The results shall be reviewed and authorized prior to reporting.	7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records. NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively. NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.	ISO 17025 and AAVLD Requirements are similar No AAVLD equivalent to the following which are specific to calibration laboratories: 7.8.4 Calibration certificates 7.8.6 Statement of conformity
5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:	7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:	NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.
5.10.2.1. a title (e.g., "Test Report")	7.8.2.1 a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");	ISO 17025 and AAVLD Requirements are similar
5.10.2.2. name and address of laboratory, and if different, the location where the tests were performed;	7.8.2.1 b) the name and address of the laboratory c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;	ISO 17025 and AAVLD Requirements are similar
5.10.2.3. unique identification (see 5.8.2.) at the beginning and on each page of the test report to ensure that the page is recognized as a part of the test report and a clear identification of the end of the report;	7.8.2.1 d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;	ISO 17025 and AAVLD Requirements are similar
5.10.2.4. name and address of the client placing the order;	7.8.2.1	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	e) the name and contact information of the customer;	
5.10.2.5. description and unambiguous identification of the specimen(s) tested;	7.8.2.1 g) a description, unambiguous identification, and, when necessary, the condition of the item;	ISO 17025 and AAVLD Requirements are similar
5.10.2.6. unique identification of the test method(s) used;	7.8.2.1 f) identification of the method used;	ISO 17025 and AAVLD Requirements are similar
5.10.2.7. date of receipt of specimen(s) where relevant to the validity and application of the results;	7.8.2.1 h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;	ISO 17025 and AAVLD Requirements are similar
5.10.2.8. the date(s) of performance of the laboratory testing where relevant to the validity and application of results;	7.8.2.1 i) the date(s) of performance of the laboratory activity;	ISO 17025 and AAVLD Requirements are similar
5.10.2.9. test results;	7.8.2.1 m) the results with, where appropriate, the units of measurement;	ISO 17025 and AAVLD Requirements are similar
5.10.2.10. reference to specimen collection procedures used by the laboratory or by the client where these are relevant to the validity or application of the results;	7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results. 7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.	ISO 17025 and AAVLD Requirements are similar
5.10.2.11. where appropriate and needed, opinions and diagnostic interpretations of the test results;	7.8.3.1 d) where appropriate, opinions and interpretations (see 7.8.7);	ISO 17025 and AAVLD Requirements are similar
5.10.2.12. the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report.	7.8.2.1 o) identification of the person(s) authorizing the report;	ISO 17025 and AAVLD Requirements are similar
5.10.3 Where applicable, the test report shall also include:	7.8.5 Reporting sampling – specific requirements Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results: 7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following: a) information on specific test conditions, such as environmental conditions;	ISO 17025 and AAVLD Requirements are similar

AAVLD Requirement	ISO 17025:2017	Comments
	b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: — it is relevant to the validity or application of the test results; — a customer's instruction so requires, or — the measurement uncertainty affects conformity to a specification limit; d) where appropriate, opinions and interpretations (see 7.8.7); e) additional information that may be required by specific methods, authorities, customers or groups of customers.	
5.10.3.1. date of specimen collection;	7.8.5. a) the date of sampling;	ISO 17025 and AAVLD Requirements are similar
5.10.3.2. unambiguous identification of specimen source;	7.8.5. b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);	ISO 17025 and AAVLD Requirements are similar
5.10.3.3. location of collection, including any diagrams, sketches or photographs;	7.8.5. c) the location of sampling, including any diagrams, sketches or photographs;	ISO 17025 and AAVLD Requirements are similar
5.10.3.4. reference to sampling plan used (see 5.7.1.3.);	7.8.2.1 k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; 7.8.5. d) a reference to the sampling plan and sampling method;	ISO 17025 and AAVLD Requirements are similar
5.10.3.5. details of any environmental condition during collection that may affect the interpretation of the test results;	7.8.3.1 a) information on specific test conditions, such as environmental conditions; 7.8.3.1 b) where relevant, a statement of conformity with req specifications (see 7.8.6); 7.8.5 e) details of any environmental conditions during sampling that affect the interpretation of the results;	ISO 17025 and AAVLD Requirements are similar
5.10.3.6. identification of the collection procedure or technique.	7.8.5. d) a reference to the sampling plan and sampling method;	ISO 17025 and AAVLD Requirements are similar
5.10.4 When opinions and diagnostic interpretations are included in the test report, the laboratory shall document the basis upon which the opinions and interpretations have been made.	7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.	ISO 17025 and AAVLD Requirements are similar No equivalent in AAVLD for ISO 17025 7.8.7.3 (record of dialogue)

AAVLD Requirement	ISO 17025:2017	Comments
	7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such. 7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained	
Note: When the results of a battery of tests are considered in formulating an opinion or making a diagnostic interpretation, it may be necessary to describe, for the client, the rationale behind the sequence of testing and the decision making process (e.g. presumptive vs. definitive tests or screening vs. confirmatory tests).	NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.	
5.10.5 When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.	p) clear identification when results are from external providers.	ISO 17025 and AAVLD Requirements are similar
5.10.6 Transmission of test results and/or interpretations whether in hardcopy or electronic format shall meet the requirements of the AAVLD Standard.	None	No equivalent in ISO 17025
5.10.7 The report format shall be designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.	None	No equivalent in ISO 17025
5.10.8 When a battery of tests is to be performed and results reported as available, interim test reports shall be issued to the client. These reports shall indicate tests completed and tests pending. Such reports shall be uniquely identified as interim test reports, shall contain a reference to any and all preceding interim reports and shall meet all the requirements of the AAVLD Standard. Upon completion of all testing, a final test report shall be issued that is uniquely identified and shall contain a reference to any and all interim reports that it replaces.	None	No equivalent in ISO 17025
5.10.9. When an issued report needs to be changed, or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.	7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.	ISO 17025 and AAVLD Requirements are similar
5.10.9 When a material amendment to a test report that has been issued is necessary, a supplement to the test report shall be issued to the client. Such amendments shall be uniquely identified as a supplement, shall contain a reference to the original test report and shall meet all the requirements of the AAVLD Standard.	7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording. Such amendments shall meet all the requirements of this document.	ISO 17025 and AAVLD Requirements are similar
5.10.10 When it is necessary to issue a new test report, it shall be uniquely identified and shall contain a reference to the original that it replaces.	7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.	ISO 17025 and AAVLD Requirements are similar

Table 2: Comparison of AAVLD Accreditation Program and ISO 17025 Accreditation Bodies

Feature	AAVLD Accreditation	ISO 17025 Accreditation
Mission	Accredit public veterinary diagnostic laboratories in North America relative to technical and operational competence compatible with appropriate standards, and to provide an administrative assessment; peer review with self-help aspect to advance the profession	Accredit laboratories to an international standard relative to technical and operational competence
Auditing Body	AAVLD Accreditation Program	National ISO 17025 accrediting bodies, e.g., American Association for Laboratory Accreditation (A2LA, in USA), Standards Council of Canada (SCC)
Authority	The AAVLD Accreditation Program Accreditation Committee is an appointed Standing Committee of AAVLD. AAVLD represents its individual members independent of their laboratories.	Authorized as ISO 17025 accreditors via International Laboratory Accreditation Cooperation (ILAC)
Recognition	Recognized as meeting the international standard for veterinary laboratories by the Chief Veterinary Officer (CVO) of the United States. It meets all requirements for international trade of animals and live animal products. Recognized by USDA-NAHLN and FDA Vet-LIRN.	Recognized as the international standard for laboratory accreditation
Standard	AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 2021.01	ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
Frequency of Audits	Minimum of once every 5 yrs. Intervening year audits as determined by Accreditation Committee. Records and documents may be requested by Accreditation Committee for non-site visit years.	Biennial on site audit. Intervening year, paper audit.
Format of Audits	Laboratory-wide sampling audit of all services Site visit team of 1 or more trained auditors / subject matter experts	Restricted to specific methods or declared scope of testing. Procedural audit, site visit team of 1 or more trained auditors
Estimated Cost (Costs vary by accreditation scope and laboratory size (multiple sites)	Annual Lab dues - $1,200/year Audit year - $1,000 for single lab plus $600/branch lab. Local transportation and hotel expenses provided by labs during site visits - $4,000	Annual Lab dues - $1,300/year -Biennial full audit for single scope - $10,000* -Intervening year audit fees - ~$5,000* *including on-site expenses
Outcomes	Report with non-conformances, Requirements and Observations to lab director with timeline for responses Documentary evidence of correction of non-conformances required Accredited labs posted on AAVLD website, certificate issued	Report of non-conformances, Requirements and Observations to lab director with timeline for responses Documentary evidence of correction of non-conformances required Scope of testing of accredited labs posted on A2LA/SCC website, certificate issued