White Paper
Management and Support to Facilitate Accreditation of Vet-LIRN Laboratories
FDA-SOL-1130894

Introduction

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.

Veterinary diagnostic laboratories are valuable resources for achieving these goals. They enhance public health by providing surveillance testing of food and animal feed products for zoonotic pathogens. These labs also provide pathogen and chemical toxin testing in response to food borne and animal feed-associated illnesses. The FDA has partnered with veterinary diagnostic labs to achieve these goals through the formation of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Vet-LIRN labs respond to requests for testing as directed by FDA resulting from consumer complaints, participate in surveillance studies, method development activities and proficiency tests. Most member laboratories are accredited by the American Association of Veterinary Laboratory Diagnosticians. Currently 36 veterinary diagnostic laboratories are members of the Vet-LIRN program.

The purpose of this white paper, as described in FDA-SOL-1130894 -Management and Support to Facilitate Accreditation of Vet-LIRN Laboratories, is to 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. The specific goal is to determine the best fit for accreditation bodies and standards for veterinary diagnostic laboratories within the Vet-LIRN network.

Section 1: Background

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 Vet-LIRN's mission is to maintain an integrated national and international network of veterinary diagnostic laboratories that can investigate and respond to biological or chemical contamination or adulteration of animal feeds or drugs. The program has been in place since 2011. Vet-LIRN member labs participate in a variety of activities including method development, proficiency programs for biological and chemical agents, surveillance of pets and pet food for pathogenic agents including *Salmonella,* and providing diagnostic services in response to client complaints and case investigations as directed by the FDA. Diagnostic services provided by Vet-LIRN labs include necropsy and histopathological evaluations of animals, as well as the detection and identification of pathogens and/or chemical toxins in animal tissues, feed and food. State funded veterinary diagnostic laboratories are uniquely qualified to do this work because of their expertise across multiple scientific disciplines and the longstanding role they play in the protection of animal health in the United States. To ensure the quality of the Vet-LIRN laboratories, the Center for Veterinary Medicine's Office of Research Vet-LIRN Program proposed an evaluation of the most appropriate accreditation standards and accreditation bodies for the Vet-LIRN which may be engaged in veterinary diagnostic activities during active FDA case investigations.

Section 2: Laboratory Accreditation Standards

Laboratories use quality standards to implement a quality management system aimed at improving their ability to produce consistently valid and accurate results. These standards are the basis for accreditation from an accreditation body. The standards based on ISO/IEC 17025 are those which most testing labs follow and must meet to be deemed technically competent. Many countries have testing accreditation programs that are based upon the International Organization of Standards (ISO) 17025 document and accept it as their official guide to acceptable standards for laboratory accreditation. Some organizations recommend ISO 17025 standards and additionally provide guidance documents and requirements which are specific to their scientific discipline. These organizations include the Association of Official Analytical Chemists, Association of American Feed Control Officials, the Racing Medication Testing Consortium, as well as others.

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*.

A. Evaluation of Accreditation Standards for Animal Health Laboratories

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) and is still known by the initials of the original organization's name. It is an intergovernmental organization with a mandate from its 172 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, Organization International Epizooties (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 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**.**

B. American Association of Veterinary Laboratory Diagnosticians and ISO 17025 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). Both standards are divided into Management and Technical requirements sections, and address the same areas, including organization, personnel, physical facilities, equipment, records, communication, and laboratory quality assurance. Within each section are multiple requirements which accredited laboratories must meet. The standards included in ISO 17025, the OIE Standards and Guideline, and the AAVLD Requirements are virtually identical.

As OIE does not have an associated accrediting body, a comparison of the two standards, *AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory* and *ISO Guide 17025* is provided in Table 1 which is a cross-reference between the requirements specified by ISO 17025 and those of AAVLD. The table includes all elements of both of the standards and provides comments in areas where they differ. Some of the more significant differences between the ISO 17025 and AAVLD standards are:

- ISO 17025 includes standards for calibration laboratories where AAVLD does not, (AAVLD labs are not calibration laboratories)
- AAVLD includes 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.
- AAVLD has requirements for safety, biosafety, and biosecurity which are not included in ISO 17025. These are critical due to the infectious nature of samples being submitted to veterinary diagnostic laboratories.
- ISO 17025 addresses measurement uncertainty while AAVLD requirements do not. Results for most of the tests offered by AAVLD labs are qualitative rather than quantitative in nature.

Overall, AAVLD includes 96% of the elements found in ISO 17025. AAVLD Requirements have been widely adopted in veterinary diagnostic laboratories throughout Northern America. As of 2015, there are 42 labs in the US and 2 Canadian provinces that are accredited to the AAVLD standard. FMSA requirements for lab accreditation are included in both of AAVLD and ISO 17025.

Section 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 bodies.

A. American Association of Veterinary Laboratory Diagnosticians Accreditation Committee

The Accreditation Committee is the ruling body for determining the accreditation status of AAVLD laboratories. AAVLD provides accreditation to public veterinary diagnostic laboratories in North America per the written standard AAVLD *Requirements of Veterinary Medical Diagnostic Laboratories,* and uses veterinary diagnostic laboratory and discipline-specific expertise in assessing laboratory compliance and physical facilities for determining accreditation status. The most recent version of this standard is attached. 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. Committee members serve on a voluntary basis and include 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 face-to-face meetings a year during which audit reports and responses are reviewed and accreditation decisions are made.

Labs 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 lab, which is a departure from some accrediting bodies which award accreditation on a test by test or technology basis.

Labs may be awarded either full 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 reports. Provisional accreditation is typically awarded for one year.

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 selects and trains diagnosticians from across the United States to serve as subject matter experts who participate in site visits with Accreditation Committee members. The Committee and Audit Pool Members receive annual training on quality system management implementation.

2. Recognition of AAVLD Accreditation (Domestic and International)

The AAVLD laboratory accreditation program historically provided the only accreditation services for publically 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 and 2011 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."

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.

B. American Association of Laboratory Accreditation (A2LA)

A second accreditation body for veterinary diagnostic laboratories in the US is A2LA. A2LA was established in 1978 as a private, non-profit organization who 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 standards to which labs are accredited by A2LA are ISO-IEC 17025:2005 and the OIE Standard.

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.

1. Recognition of A2LA Programs (Domestic and International)

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).

Section 3: FSMA 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

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

A. Accreditation Processes

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 non-conformances. The laboratory provides a response to the accrediting body including documentary evidence regarding the resolution of non-conformances.
9) 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. Additional information from the lab may be required by the accreditation body during this time period.

B. 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 bases. 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 on-site 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 can vary depending on the size and scope of the laboratory. A2LA costs are significantly higher than those of AAVLD. For example, A2LA costs can range from $ 5000 to $ 10,000 per year while AAVLD costs are $ 800 per year (annual dues) and $ 1300 for years in which a site visit occurs. The cost accreditation by A2LA would be prohibitively expensive for many VetLIRN labs which receive a total of $ 16,500 per year for infrastructure grant funds from the FDA.

C. Added value of obtaining accreditation by various accreditation bodies

The value of accreditation and the implementation of a quality management system to veterinary diagnostic laboratories in the US today is increased confidence in results by clients and regulatory authorities. AAVLD accreditation is recognized by veterinarians, state and federal health officials and international trading partners. Additional benefits of accreditation include increased efficiencies and improved laboratory operations through the process of continuous improvement. These benefits are similar whether the accreditation body is AAVLD or another internationally-recognized accreditation body. Achieving and maintaining lab accreditation has become the expectation of numerous organizations and agencies throughout the United States and world.

Section 4: Conclusion

The AAVLD and ISO accreditation standards are virtually identical. The AAVLD and private accreditation bodies have similar missions, authority, recognition, audits processes and outcomes. A significant difference between AAVLD and other accreditation processes, particularly for publicly-funded laboratories, is the cost. This difference has been beneficial to publicly funded labs 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 the best fit for the Vet-LIRN.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
2. ADMINISTRATIVE REQUIREMENTS	**2. ADMINISTRATIVE REQUIREMENTS**	
Not Applicable	**2.1 Organization, Management and Personnel**	This section describes the type of labs that are eligible for AAVLD accreditation and the educational requirements for top management and supervisors. This clarification ensures that labs seeking accreditation employ the scientists with expertise in the areas needed.
Not Applicable	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.	
Not Applicable	2.1.2 The director/chief administrative officer shall be a veterinarian. The laboratory personnel shall be able to provide competence in all testing groups evaluated for accreditation. Minimum training levels are listed in the section on personnel qualifications in Appendix I.	
Not Applicable	**2.2 Finance and Budget**	This section ensures that laboratories are financially stable and able to offer quality services to support agribusiness, animal and public health.
Not Applicable	2.2.1 The overall budget shall be evaluated on the basis of salaries for personnel, operations, equipment, maintenance, travel, library resources 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.	
Not Applicable	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	

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
	intended to be self-sufficient financially and require public financial support commensurate with the public good derived.	
Not Applicable	**3. Accreditation Process** See AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory.	This is an advantage for the AAVLD standard because it educates applicants on the steps that are required to meet accreditation within the document.
4. MANAGEMENT REQUIREMENTS:		
4.1 Organization	**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.	4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.	ISO and AAVLD requirements are the same.
4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.	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.	ISO and AAVLD requirements are similar.
4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.		
4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.	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.	ISO and AAVLD requirements are similar.
4.1.5 The laboratory shall	4.1.4 The laboratory shall:	
a) have managerial and technical personnel who, irrespective of other	a) have managerial and technical personnel with the authority and	ISO and AAVLD requirements are

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);	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;	similar.
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;	b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;	ISO and AAVLD requirements are similar.
c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;	c) 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;	ISO and AAVLD requirements are similar.
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;	d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;	ISO and AAVLD requirements are similar.
e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;	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.	ISO and AAVLD requirements are similar.
f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests	4.1.4.e) specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
and/or calibrations;	the quality of tests;	
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;	4.1.4.f) provide adequate supervision of testing staff, including trainees, by persons familiar with the tests, their purpose and the analysis of the test results;	ISO and AAVLD requirements are similar.
h) 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;	4.1.4.g) 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;	ISO and AAVLD requirements are similar.
i) appoint a member of staff as management manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality 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;	4.4.1.h) 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;	ISO and AAVLD requirements are similar.
j) appoint deputies for key managerial personnel (see note).	i) appoint backups or deputies for key managerial personnel such as the quality manager	ISO and AAVLD requirements are similar.
k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.	4.1.3. ….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. 4.2.2. c. a requirement that all laboratory personnel familiarize themselves with the quality documentation and implement the policies and procedures in their work. 4.2.4 The quality manual shall define the roles and responsibilities of technical management and the	AAVLD does not have a specific section as in ISO but they do address the relationships between personnel and their quality activities shall be specified and the personnel shall familiarize themselves with the quality policies and procedures and implement them in their work.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
	quality manager, including their responsibility for ensuring compliance with the AAVLD Standard.	
4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.	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.	AAVLD addresses this element under the Management Review section that specifies that management shall ensure suitability, effectiveness, changes if necessary and improvements of the management system.
4.2 Management system	**4.2 Quality System**	
4.2.1 The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the management of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	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.	ISO and AAVLD requirements are similar.
4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:	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. The overall objectives shall be set out in a quality policy statement in the quality manual, stating the standard of performance to be achieved and maintained. The	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
	quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:	
a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;	d) the laboratory management's commitment to good professional practice and quality of its diagnostic services to its clients; and	ISO and AAVLD requirements are similar.
b) the management's statement of the laboratory's standard of service;	a) a statement of the laboratory management's intentions with respect to the standard of service it will provide;	ISO and AAVLD requirements are similar.
c) the purpose of the management system related to quality;	b) the purpose of the quality system;	ISO and AAVLD requirements are similar.
d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and	c) a requirement that all personnel concerned with testing activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;	ISO and AAVLD requirements are similar.
e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of management system.	e) the laboratory management's commitment to compliance with the AAVLD Standard.	ISO and AAVLD requirements are similar.
4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.	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.	AAVLD addresses these elements under the Management Review section that specifies that management shall ensure suitability, effectiveness, changes if necessary and improvements of the management system.
4.2.4 Top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.		
4.2.5 The management manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.	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.	ISO and AAVLD requirements are similar.
4.2.6 The roles and responsibilities of	4.2.4 The quality manual shall	ISO and AAVLD

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.	define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the AAVLD Standard.	requirements are similar.
4.2.7 Top management shall ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.	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.	AAVLD addresses this comment under the Management Review section that specifies that management shall ensure suitability, effectiveness, changes if necessary and improvements of the management system.
4.3 Document control	**4.3 Document Control**	
4.3.1 General		
The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.	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.	ISO and AAVLD requirements are similar.
4.3.2 Document approval and issue		
4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.	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.	ISO and AAVLD requirements are similar. ISO specifies a master list, AAVLD requires a written document.
4.3.2.2 The procedure(s) adopted shall ensure that:	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	ISO and AAVLD requirements are similar.
a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the		

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
laboratory are performed;	the work location.	
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.	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. 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.	ISO and AAVLD requirements are similar. Note: ISO details in bullet form the requirement where AAVLD makes a singular statement covering the same items.
4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority (ies).	4.3.4 Documents shall be uniquely identified and accurately cross-referenced. 4.3.5 Documents shall include page numbers and the total number of pages or a mark to signify the end of the document.	ISO and AAVLD requirements are similar.
4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.	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.	ISO and AAVLD requirements are similar.
4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.	Note: under 4.3.5. 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.	ISO and AAVLD requirements are similar.
4.4 Review of requests, tenders and contracts	**4.4 Review of requests or contract**	
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that: a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); b) the laboratory has the capability and resources to meet the requirements; c) the appropriate test and/or calibration method is selected and capable of meeting the customers' requirements (see 5.4.2). Any differences between the request or tender and the contract shall be	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 the client agreement.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer. 4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.		
4.4.3 The review shall also cover any work that is subcontracted by the laboratory.	4.4.2 The review shall also cover any work that is subcontracted by the laboratory.	ISO and AAVLD requirements are similar.
4.4.4 The customer shall be informed of any deviation from the contract.	4.4.1 The laboratory shall have 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.	ISO and AAVLD requirements are similar.
4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.	Not Applicable	AAVLD does not require this element.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.5 Subcontracting of tests and calibrations	**4.5 Subcontracting of test services**	
4.5.1 When a laboratory subcontracts work 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, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	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.	ISO and AAVLD requirements are similar.
4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.	4.5.2 The laboratory shall advise the customer of the arrangement.	ISO and AAVLD requirements are similar.
4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.	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.	ISO and AAVLD requirements are similar.
4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.	4.5.4 The laboratory shall maintain a list of all subcontractors that it uses for tests.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.6 Purchasing services and supplies	**4.6 Purchasing services and supplies**	
4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations. 4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained. 4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release. 4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.	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.	ISO and AAVLD requirements are similar.
4.7 Service to the customer		
4.7.1 The laboratory shall be willing to 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, provided that the laboratory ensures confidentiality to other customers.	4.12.2 The laboratory shall have a procedure for performing a Management Review. The review shall take into consideration: ……. h) client feedback	AAVLD does not have a specific section entitled Service to the customer however AAVLD Management Review 4.12.2.h requires client feedback.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.		Also, during an actual on-site audit AAVLD auditors meet with clients one-on-one to discuss client satisfaction without laboratory personnel present. This provides direct feedback to auditors and is not required by ISO 17025.
4.8 Complaints	**4.7 Complaints**	
The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).	4.7.1 The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.	ISO and AAVLD requirements are similar.
4.9 Control of nonconforming testing and/or calibration work	**4.8 Control of nonconforming testing and test results**	
4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that: a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified; b) an evaluation of the significance of the nonconforming work is made; c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work; d) where necessary, the customer is notified and work is recalled;	4.8.1 The laboratory shall have a policy and procedures that ensure that non-conforming testing (conditions that exist which have or could adversely affect the reliability of test results) is detected and promptly corrected. The laboratory shall have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client. These procedures shall describe who has the authority to withhold test results, implement corrective action, and authorize resumption of work.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
e) the responsibility for authorizing the resumption of work is defined.		
4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.	4.8.2 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 promptly be implemented.	ISO and AAVLD requirements are similar.
4.10 Improvement		
The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	4.9.2. The laboratory shall identify potential sources of non-conformances and potential needs for improvement, either technical or with the quality system.	ISO and AAVLD requirements are similar. .
4.11 Corrective action	**4.9 Corrective and Preventive Action**	
4.11.1 General The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.	4.9.1 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: a) designation of appropriate authorities responsible for implementation of corrective action(s);	ISO and AAVLD requirements are similar.
4.11.2 Cause analysis The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	b) Investigative procedures are implemented to determine the root cause of the problem;	ISO and AAVLD requirements are similar.
4.11.3 Selection and implementation of corrective actions. Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the	c) upon identification, appropriate corrective action(s) are implemented; d) documentation of any required changes to operational procedures;	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
magnitude and the risk of the problem. The laboratory shall document (and document) and implement any required changes resulting from corrective action investigations.		
4.11.4 Monitoring of corrective actions The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and	ISO and AAVLD requirements are similar.
4.11.5 Additional audits Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.	f) when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11. NOTE: Special internal audits need only be initiated when a serious issue or risk to the quality of test results or integrity of the quality system has been the subject of corrective action.	ISO and AAVLD requirements are similar.
4.12 Preventive action	**4.9 Corrective and Preventive Action**	
4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.	4.9.2 The laboratory shall identify potential sources of nonconformance and potential needs for improvement, either technical or with the quality system. Preventive action procedures shall include: a) identification and evaluation of potential nonconformance or improvement; b) development and implementation of an action plan, including appropriate controls; and c) monitoring of effectiveness in reducing likelihood of nonconformance or in addressing specific needs for improvement.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.12.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.	b) development and implementation of an action plan, including appropriate controls; and	ISO and AAVLD requirements are similar.
4.13 Control of records	**4.10 Records**	
4.13.1 General		
4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.	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.	ISO and AAVLD requirements are similar.
4.13.1.2 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 times of records shall be established.	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 time of records shall be established.	ISO and AAVLD requirements are similar.
4.13.1.3 All records shall be held secure and in confidence.	4.10.1.3 All records shall be held secure and in confidence.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.13.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	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.	ISO and AAVLD requirements are similar.
4.13.2 Technical records		
4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	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.	ISO and AAVLD requirements are similar.
4.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.13.2.3 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 signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.	4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible nor 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.	ISO and AAVLD requirements are similar.
4.14 Internal audits	**4.11 Internal audits**	
4.14.1 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 management system and this International Standard. The internal audit program shall address all elements of the management system, including the testing and/or calibration 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.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.	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 shall notify clients in writing if investigations show that the laboratory results may have been affected (see 4.8).	ISO and AAVLD requirements are similar.
4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. 4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.	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.	ISO and AAVLD requirements are similar.
4.15 Management reviews	**4.12 Management reviews**	
4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:	4.12.1 The quality system and test related activities shall be reviewed by management at least once per year. 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. 4.12.2 The laboratory shall have a procedure for performing a Management Review. The review shall take into consideration:	AAVLD specifies a time frame for management reviews as once per year which is an advantage for the laboratories to know the specific time frame. ISO does not specify a time frame.
the suitability of policies and procedures;	a) the suitability of policies and procedures;	ISO and AAVLD requirements are similar.
reports from managerial and supervisory personnel;	b) reports from managerial and supervisory personnel;	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
the outcome of recent internal audits;	c) reports of recent internal audits;	ISO and AAVLD requirements are similar.
corrective and preventive actions;	d) corrective and preventive actions;	ISO and AAVLD requirements are similar.
assessments by external bodies;	e) assessments by external bodies;	ISO and AAVLD requirements are similar.
the results of inter-laboratory comparisons or proficiency tests;	f) the results of inter-laboratory comparisons or proficiency tests;	ISO and AAVLD requirements are similar.
changes in the volume and type of the work;	g) changes in the volume and type of work;	ISO and AAVLD requirements are similar.
customer feedback;	h) client feedback;	ISO and AAVLD requirements are similar.
complaints;	i) complaints;	ISO and AAVLD requirements are similar.
recommendations for improvement; other relevant factors, such as quality control activities, resources and staff training.	j) other relevant factors, such as quality control activities, resources and staff training.	ISO and AAVLD requirements are similar. AAVLD discusses documenting improvements in section 4.12.4.
4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5 Technical requirements	**5. TECHNICAL REQUIREMENTS**	
5.1 General	**5.1 General**	
5.1.1 Many factors determine-the correctness and reliability of the-tests and/or calibrations performed by a laboratory. These factors include contributions from: - human factors (5.2); - accommodation and environmental conditions (5·3); - test and calibration methods and method validation (5.4); - equipment (5.5); - measurement traceability (5.6); - sampling (5.7); - the handling of test and calibration items (5.8). The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. 5.1.2 The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.	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.	ISO and AAVLD requirements are similar.
5.2 Personnel	**5.2 Personnel**	
5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.	5.2.1 The laboratory shall ensure the initial and ongoing competence of all laboratory personnel to do their assigned work using objective criteria.	ISO and AAVLD requirements are similar.
5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.	5.2.3. The laboratory shall have a system which ensures the establishment and maintenance of a training program relevant to the	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.	present and anticipated needs of the laboratory.	
5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.	5.2.1 The laboratory shall ensure the initial and ongoing competence of all laboratory personnel to do their assigned work using objective criteria.	ISO and AAVLD requirements are similar.
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. 5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	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 that is documented as qualified and competent to do testing and related work.	ISO and AAVLD requirements are similar.
5.3 Accommodation and environmental conditions	**5.3 Accommodation and environmental conditions**	
5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be	5.3.1 Laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, shall be	ISO and AAVLD requirements are similar. ISO does have an additional statement

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.	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.	that this information shall be recorded but in section 5.3.2. in both ISO and AAVLD it is stated that the lab shall record environmental conditions.
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.	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.	ISO 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.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.	5.3.4 Access to and use of areas affecting test results shall be controlled.	ISO and AAVLD requirements are similar.
5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	5.3. All aspects of the physical facilities must provide an appropriate environment for the conduct of the activities of all disciplines required for laboratory accreditation. Laboratories, offices, storage space and animal holding rooms shall be clean, maintained in good repair and be adequate in number and size for the intended function of the laboratory.	ISO and AAVLD requirements are similar.
Not Applicable	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.	AAVLD addresses safety, biosafety, biocontainment and biosecurity because of the nature of the infectious and highly infectious agents the labs handle. This is not covered in ISO but is a critical element of the AAVLD requirements.
5.4 Test and calibration methods and method validation	**5.4 Test methods**	
5.4.1 General	5.4.1 General	

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data. The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	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. 5.4.1.2 Test methods shall be approved for use by qualified, authorized personnel, according to established procedures. 5.4.1.3 Tests shall be appropriately controlled. 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. 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 other information sources. 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).	AAVLD requirements are similar but AAVLD adds specific information with respect to method validation.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.4.2 Selection of methods	**5.4.2. Selection of Methods**	
The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application. When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been 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. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated. The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.	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. 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. 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).	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.4.3 Laboratory-developed methods	**5.4.3. Validation of Test Methods**	
The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured. **5.4.4 Non-standard methods** When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use. **5.4.5 Validation of methods** 5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. 5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. 5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the	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 has been validated, where possible according to the principles outlined in the OIE Manual of Standards for Diagnostic Tests and Vaccines and other related OIE references. While it is preferred that all test methods, developed in-house or drawn from reputable collections of standard methods, undergo an in-house validation using an appropriate number of samples from the population of interest, the user is not required to re-validate international or national standard methods, but shall 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 shall provide documented evidence of data on and statistically valid assessment of comparative performance for those assays that are harmonized by inter-laboratory comparison to an accepted and validated standard method. 5.4.3.1. Note: Test methods may be classified as "validated for use" by meeting the following criteria. 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:	ISO and AAVLD requirements are similar. AAVLD has a note which gives specific information on criteria on how to classify as "validated for use" and more specifics on record retention in regards to method validation. Due to the nature of their work with new and emerging pathogens, method development and validation are critical aspects of veterinary diagnostic laboratories and the AAVLD Requirements. These details are not addressed in ISO standards.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.	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); 3)Published in a peer-reviewed journal with sufficient documentation to establish diagnostic performance and interpretation of results; 4) Documentation of internal or inter-laboratory comparison to an accepted methodology or protocol. 5.4.3.2. Validation data, including all original observations, calculations, equipment monitoring and calibration records and archived procedures used to formulate performance characteristics, 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. 5.4.3.2. 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.	

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.4.6 Estimation of uncertainty of measurement		
5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. 5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. 5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	Not Applicable	AAVLD Requirements do include measurement uncertainty at this time.
5.4.7 Control of data	**5.4.4. Control of data**	
Not Applicable	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.	AAVLD has a a section on control of data giving specific details on what types of data shall be secured, retrieved and approved by qualified personnel. ISO does not.
5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	5.4.4.2 Manual calculations and data transfers shall be subject to appropriate checks in a systematic manner.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:	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:	ISO and AAVLD requirements are similar.
a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;	a) 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;	ISO and AAVLD requirements are similar.
b) procedures are established and implemented for protecting the 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;	b) 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 and AAVLD requirements are similar.
c) 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 and calibration data.	c) 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.	ISO and AAVLD requirements are similar.
5.5 Equipment	**5.5 Equipment**	
5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).	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 established for key equipment where those properties have a significant effect on the results. 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.	ISO and AAVLD requirements are similar. ISO and AAVLD requirements are similar. Note: AAVLD does not specifically use the term “new” equipment however section 5.5.2 requires “equipment and software be capable of achieving the required accuracy…” and section 5.5.10. requires that if equipment is out of direct control of the laboratory it shall be checked before placing into use.
5.5.3 Equipment shall be operated by authorized 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.	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.	ISO and AAVLD requirements are similar.
5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.	5.5.4 Each item of equipment used for test activities significant to a test result shall be uniquely identified.	ISO and AAVLD requirements are similar.
5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:	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:	ISO and AAVLD requirements are similar.
a) the identity of the item of equipment and its software;	a) identity of the item of equipment;	ISO and AAVLD requirements are similar.
b) the manufacturer's name, type identification, and serial number or other unique identification;	b) manufacturer’s name, type identification, and serial number or other unique identification;	ISO and AAVLD requirements are similar.
c) checks that equipment complies	c) verification that equipment	ISO and AAVLD

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
with the specification (see 5.5.2);	complies with the specification;	requirements are similar.
d) the current location, where appropriate;	d) the current location, where appropriate;	ISO and AAVLD requirements are similar.
e) the manufacturer's instructions, if available, or reference to their location;	e) the manufacturer's instructions, if available, or reference to their location;	ISO and AAVLD requirements are similar.
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;	ISO and AAVLD requirements are similar.
g) the maintenance plan, where appropriate, and maintenance carried out to date;	g) maintenance carried out to date and the maintenance plan;	ISO and AAVLD requirements are similar.
h) any damage, malfunction, modification or repair to the equipment.	h) damage, malfunction, modification or repair to the equipment.	ISO and AAVLD requirements are similar.
5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.	5.5.6 Maintenance procedures shall be established.	ISO and AAVLD requirements are similar.
5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).	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).	ISO and AAVLD requirements are similar.
5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration	5.5.9 Whenever practical, all equipment under the control of the laboratory and requiring calibration	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.	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.	
5.5.9 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.	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.	ISO and AAVLD requirements are similar.
5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.	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.	ISO and AAVLD requirements are similar.
5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.	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: 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	Are ISO and AAVLD requirements are similar.
5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	5.5.11 Test equipment, including both hardware and software, shall be safeguarded from adjustments which could invalidate the test results.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.6 Measurement traceability		
5.6.1 General		
All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.	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 established for key equipment where those properties have a significant effect on the results.	ISO and AAVLD requirements are similar.
5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités). A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).		
5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: - the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; - the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. Participation in a suitable program of interlaboratory comparisons is required where possible.	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.	ISO and AAVLD requirements are similar.
5.6.2.2 Testing		
5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. 5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials,	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).		
5.6.3 Reference standards and reference materials	**5.6. Measurement traceability**	
5.6.3.1 Reference standards		
5.6.3.2 Reference materials Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.	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).	ISO and AAVLD requirements are similar.
5.6.3.3 Intermediate checks Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.	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.	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.6.3.4 Transport and storage 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.	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. 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.	ISO and AAVLD requirements are similar.
5.7 Sampling	**5.7 Specimens**	
5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.	5.7.1 The laboratory shall have procedures for the collection of specimens to ensure that they are both appropriate to the test being undertaken and suitable for testing. 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. 5.7.1.3 When sampling from populations, as appropriate, the laboratory shall have a statistically defined plan for sample collection.	ISO and AAVLD requirements are similar.
5.7.2 Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.	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).	ISO and AAVLD are similar. AAVLD uses the term "sampling" to refer to collection of test specimens (e.g. from the animal, from a population of animals) and uses the term specimen to cover the same intent of ISO 5.7.2 (e.g. Pooling or "sub-sampling" of specimens), AAVLD requires test

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
		procedures to specify the intended analyte (5.4.2.3c), source of the specimen (5.10.3b) and use of a validated test (5.4.2.4) plus (4.4.1 Review of Contract) notification of a client when using a non-validated approach (deviation, addition, exclusion from the documented procedure).
5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.	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.	ISO and AAVLD requirements are similar.
5.8 Handling of test and calibration items	**5.8 Handling of Specimens**	
5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/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.	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.	ISO and AAVLD requirements are similar.
5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification	5.8.2 The laboratory shall have a system for identifying specimens that ensure no confusion between	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.	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).	
5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion. 5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.	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. 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.	ISO and AAVLD requirements are similar.
5.9 Assuring the quality of test and calibration results	**5.9 Ensuring the quality of test results**	
5.9.1 The laboratory shall have quality control procedures for monitoring the	5.9.1 The laboratory shall have quality control procedures for	ISO and AAVLD requirements are

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
validity of tests and calibrations undertaken.	monitoring the validity of test results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	similar.
The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.	a) internal quality control schemes using statistical techniques (e.g. control charts);	ISO and AAVLD requirements are similar.
This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	Second part of 5.9.1.: This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	ISO and AAVLD requirements are similar.
a) regular use of certified reference materials and/or internal quality control using secondary reference materials;	b) where applicable, use of international reference reagents for preparation of national and/or working standards for internal quality control;	ISO and AAVLD requirements are similar.
b) participation in interlaboratory comparison or proficiency-testing programs;	f) participation in interlaboratory comparison or proficiency testing programs.	ISO and AAVLD requirements are similar.
c) replicate tests or calibrations using the same or different methods;	c) when practical, replicate tests using the same or different methods;	ISO and AAVLD requirements are similar.
d) retesting or recalibration of retained items;	e) re-testing of retained specimens or samples;	ISO and AAVLD requirements are similar.
e) correlation of results for different characteristics of an item.	d) correlation of results for different characteristics of a specimen or sample;	ISO and AAVLD requirements are similar.
5.9.2 Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.	5.9. 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.	ISO and AAVLD requirements are similar.
5.10 Reporting the results	**5.10 Reporting test results**	
5.10.1 General The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and	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	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
objectively, and in accordance with any specific instructions in the test or calibration methods. The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4 In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations. 5.10.2 Test reports and calibration certificates. Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so: (See ISO 17025 Standards, Version 2005 for details). **5.10.3 Test reports** 5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following: (See ISO 17025 Standards, Version 2005 for details). 5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: (See ISO 17025 Standards, Version 2005 for details).	instructions in the test method or contract. 5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information: (See AAVLD Requirements, Version 6.2 for details). 5.10.3 Where applicable, the test report shall also include: (See AAVLD Requirements, Version 6.2 for details).	

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
5.10.4 Calibration Certificates 5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: (See ISO 17025 Standards, Version 2005 for details). 5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. When statements of compliance are made, the uncertainty of measurement shall be taken into account. 5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported. 5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.	This is not applicable to testing laboratories.	This is not applicable to testing laboratories and therefore not included in AALVD Requirements.
5.10.5 Opinions and interpretations When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.	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.	ISO and AAVLD requirements are similar.
5.10.6 Testing and calibration results	5.10.5 When the test report	ISO and AAVLD

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
obtained from subcontractors When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.	contains results of tests performed by subcontractors, these results shall be clearly identified.	requirements are similar.
5.10.7 Electronic transmission of results In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).	5.10.6 In the case of transmission of test results and/or interpretations by telex, facsimile or other electronic or electromagnetic means, the requirements of the AAVLD Standard shall be met.	ISO and AAVLD requirements are similar.
5.10.8 Format of reports and certificates The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.	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.	ISO and AAVLD requirements are similar.
Not Applicable	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.	ISO requirements do not address preliminary reports. These reports are valuable and critical to AAVLD clients.
5.10.9 Amendments to test reports and calibration certificates Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:	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	ISO and AAVLD requirements are similar.

Table 1 Cross-reference between ISO-17025 and AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

ISO 17025 REQUIREMENTS	AAVLD REQUIREMENTS	COMMENTS
"Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard. When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	contain a reference to the original test report and shall meet all the requirements of the AAVLD Standard. 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.	

Table 2 Comparison of AAVLD accreditation 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 bodies	AAVLD Accreditation Committee	National ISO 17025 accrediting bodies, e.g., American Association for Laboratory Accreditation (A2LA, in USA), Standards Council of Canada (SCC)
Authority	The AAVLD 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 as the international standard for laboratory accreditation
Standard	AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 6.2	ISO/IEC 17025:2008**, 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.

Table 2 Comparison of AAVLD accreditation and ISO 17025 accreditation bodies

Feature	AAVLD accreditation	ISO 17025 accreditation
Format of audit	Sampling audit of all services, site visit team of 2-4 trained auditors	Restricted to specific methods or declared scope of testing. Procedural audit, site visit team of 1 or more trained auditors
Cost	Annual Lab dues - $800/year Audit year - $1,300 for single lab plus $500/branch lab. Local transportation and hotel expenses may be provided by labs during site visits.	Biennial full audit - $10,000 – $20,000* Intervening year audit fees - ~$5,000* *including on-site expenses
Outcomes	a. Report with non-conformances, Requirements and Recommendations to lab director with timeline for responses b. Documentary evidence of correction of non-conformances required c. Accredited labs posted on AAVLD website, certificate issued	a. Report of non-conformances, Requirements and Recommendations to lab director with timeline for responses b. Documentary evidence of correction of non-conformances required c. Scope of testing of accredited labs posted on A2LA/SCC website, certificate issued