
	<i>The American Association for Laboratory Accreditation</i>	
	R216 – Specific Requirements: Veterinary Laboratory Accreditation Program	Document Revised: November 9, 2010
		Page 1 of 4

**R216 – SPECIFIC REQUIREMENTS: VETERINARY LABORATORY
ACCREDITATION PROGRAM**

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	<i>The American Association for Laboratory Accreditation</i>	
	R216 – Specific Requirements: Veterinary Laboratory Accreditation Program	Document Revised: November 9, 2010
	Page 2 of 4	

1. Introduction


The World Organization for Animal Health (OIE) formed in 1924 as the Office International des Epizooties and is still known by the initials of the original organization's name. It is an intergovernmental organisation with a mandate from its 172 Member Countries and Territories to improve animal health worldwide. In its capacity as the global reference organisation for animal health and zoonoses, the OIE elaborates standards that ensure the safety of world trade in animals and animal products within the framework of the WTO SPS Agreement. The OIE also provides standards for animal disease surveillance, prevention and control methods, including laboratory diagnostic and vaccine quality. The OIE works closely with other international organizations such as the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Bank. The following pages introduce a criteria alignment between *ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories* and the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*.

These additional requirements supplement *ISO/IEC 17025:2005* to evaluate diagnostic and clinical veterinary laboratories that conduct commercial, government, academic, and international veterinary testing in the following areas: infectious disease diagnostics, disease surveillance, virology, pathology, microbiology, immunology, screening for growth promoters and drug/chemical residue that includes antibiotics, antihelmethetics, pesticides, metals, organics, DNA/RNA, and GMO. As part of the requirements for this Program, laboratories are required to own an original copy of *ISO/IEC 17025:2005* and the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*. The OIE Standard may be purchased from the OIE at the following website: <http://www.oie.int>. The 17025 Standard may be purchased from <http://www.iso.org>.

2. Normative References, Terms, and Definitions

This section is included to assist interpretation of the requirements from the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008* and *ISO/IEC 17025:2005*.

2.1 Normative references include the relevant definitions given in *ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles*, *ISO 9000:2005, Quality management systems – Fundamentals and vocabulary*; the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008*; *OIML D 23*, and *ILAC-G24 / OIML D 10*.

	<i>The American Association for Laboratory Accreditation</i>	
	R216 – Specific Requirements: Veterinary Laboratory Accreditation Program	Document Revised: November 9, 2010
	Page 3 of 4	

2.2 Terms and Definitions

2.2.1 Terms from the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*

2.2.1.1 Sample: The material that is derived from a specimen and is used for testing purposes.

2.2.1.2 Specimen: The material, exclusively of animal origin, submitted for testing.

2.2.1.3 Validation: The process through which a test method is confirmed to be fit for the intended purpose.

2.2.2 Term relationships clarified between *ISO/IEC 17025:2005* and the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*

2.2.2.1 Sample (of animal origin) = Specimen

2.2.2.2 Sampling = Collection

2.2.2.3 Sampler = Collector

2.2.2.4 Sample location = Collection location


2.2.2.5 Testing = Infectious animal disease diagnostic testing = Disease diagnostic testing = Diagnostic testing = Diagnostic services = Diagnostics

2.2.2.6 Opinions and interpretations = Opinions and diagnostic interpretations

2.2.2.7 Processing = Handling

3. Accreditation Criteria

The general criteria for accreditation of laboratories and/or field testing organizations are contained within *ISO/IEC 17025:2005*.

	<i>The American Association for Laboratory Accreditation</i>	
	R216 – Specific Requirements: Veterinary Laboratory Accreditation Program	Document Revised: November 9, 2010
	Page 4 of 4	

Specific criteria are used to augment the general criteria applicable to a certain field of testing, testing technology, or specific test. The specific criteria for accreditation of veterinary laboratories are stated in the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*.

Veterinary testing laboratories seeking accreditation for mobile or field testing must also meet the additional criteria outlined in *R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories*.

These specific requirements also are designed to complement any applicable regulatory requirements that may affect government veterinary laboratories (state, regional, national, and international.) Please note: *ISO/IEC 17025:2005* clause 4.1.2 requires that each laboratory meet applicable regulatory requirements.

Document Revision History

Date	Description
November 2010	Removed reference to NAHLN.
March 2009	Updates OIE organizational descriptions; includes reference to NAHLN.
September 2008	Incorporation of the <i>OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008</i> .
November 2005	Initial distribution.