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 organization with a mandate from its 172 Member Countries and Territories to improve animal health worldwide. In its capacity as the global reference organization 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.

2.2 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.*
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>November 2010</td>
<td>Removed reference to NAHLN.</td>
</tr>
<tr>
<td>March 2009</td>
<td>Updates OIE organizational descriptions; includes reference to NAHLN.</td>
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<tr>
<td>September 2008</td>
<td>Incorporation of the <em>OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008</em>.</td>
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