The Bulletin

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OIE STANDARDS – VETERINARY LABORATORIES

By LEBOGANG MOTSOENENG

The OIE (World Organisation for Animal Health) is an intergovernmental organization coordinating, supporting and promoting animal disease control. The OIE is the WTO (World Trade Organisation) reference organisation for standards relating to animal health and zoonoses. The OIE publishes 2 codes (Terrestrial and Aquatic) and 2 manuals (Terrestrial and Aquatic) as the principle reference for WTO members. The Terrestrial Animal Health Code and Aquatic Animal Health Code respectively aim to assure the sanitary safety of international trade in terrestrial animals and aquatic animals, and their products. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and the Manual of Diagnostic Tests for Aquatic Animals provide a harmonised approach to disease diagnosis by describing internationally agreed laboratory diagnostic techniques.

The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) aims to facilitate international trade in animals and animal products and to contribute to the improvement of animal health services world-wide. The principal target readership is laboratories carrying out veterinary diagnostic tests and surveillance, plus vaccine manufacturers and regulatory authorities in Member Countries. The objective is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products.

South Africa as one of the 181 OIE member countries has to adhere to the requirements and standards set by the OIE. This is ensured by SANAS accreditation and DAFF (Department of Agriculture, Forestry and Fisheries) approval.

The OIE Validation Guidelines include the following: Section 3.6 of the Terrestrial Manual

Chapter 3.6.1. Development and optimisation of antibody detection assays
Chapter 3.6.2. Development and optimisation of antigen detection assays
Chapter 3.6.3. Development and optimisation of nucleic acid detection assays
Chapter 3.6.4. Measurement uncertainty
Chapter 3.6.5. Statistical approach to validation
Chapter 3.6.6. Selection and use of reference samples and panels
Chapter 3.6.7. Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife
Chapter 3.6.8. Comparability of assays after changes in a validated test method

MATRIX IN LINE WITH VALIDATION DATA

BY LEBOGANG MOTSOENENG

In the past facilities were accredited using the blanket approach on the matrix for specific scopes e.g. food or water samples, however that created problems because facilities would use the method for any type of sample not taking into consideration the matrix which the facility has validated on the method. Accreditation is specific not general; accordingly, whatever information gets put on the schedule of accreditation must be a true reflection of what the laboratory is capable of. Additionally, this will assist in levelling the playing field for all accredited laboratories – enables laboratories to compete on an equal footing.

Dr Ludwig Hieber states that method validation is the process used to confirm that the specific analytical procedure employed for a specific test against a specific matrix is suitable for its intended use.

Most facilities will validate a method only using one type of food product and then will require a blanket approach on the matrix accredited. SANAS has made a decision to specify the matrix covered by the laboratory in their validations, this ensures that the laboratory fully validates/verifies their methods against the intended uses. This gives SANAS the assurity that if the laboratory ever test for a different sample e.g. Isotonic samples, the facility will be fully aware of the interferences that the sample can cause to affect results.

In conclusion validation/verifications are an important aspect of ISO 17025 requirements and SANAS assessors shall ensure that requirements has been fully implemented and that only validated matrix are specified on the schedule of accreditation.

REMINDER:
ANNUAL ACCREDITATION FEE FOR 2018/2019 FINANCIAL YEAR

Prior to the commencement of each financial year, an invoice for annual accreditation fees gets issued, the invoice covers the period from April until the end of March of the following year. The quotations and invoices for the 2017/18 financial year annual fees will be issued from February to April 2018.

In instances where the accredited facilities' supply chain management (SCM) processes requires that a purchase order be generated first, we urge those facilities to advise us by **Wednesday 31 January 2018**.

As per the SANAS Fees document (P14), payment is due by **31 May 2018** unless a payment arrangement has been made and approved. It is of the utmost importance that the payment arrangement request is done in writing and send to the relevant finance staff indicated below. The cut-off date for the submission of payment arrangement requests is on 31 May 2018. The request must be e-mailed to SANAS Business Manager on: angeliqueb@sanas.co.za.

If payment nor arrangement is not in place by the 01st of June 2018, suspension due to non-payment will be enforced. Suspension for non-payment will be valid for 3 months. Should the facility not be reinstated by the end of suspension period, a 10% administrative fee will be added to the total annual fees invoiced amount.

Should you have any queries or concerns, please contact the following Finance personnel:

- Debtors Administrator: Elwina Daniels – 012 394-3521, elwinad@sanas.co.za
- Business Manager: Angelique Brits – 012 394-3773, angeliqueb@sanas.co.za

CONTACT INFORMATION

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