

LABORATORY ACCREDITATION ENHANCES INTERNATIONAL CREDIBILITY

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The Plant Health and Environment Laboratory (PHEL) supports MAF Biosecurity New Zealand's (MAFBNZ) activities by identifying and/or validating all suspected exotic, new and emerging pests and diseases affecting plants and the environment. The credibility of test results is critical to our laboratory since significant biosecurity decisions such as the initiation of incursion responses or the treatment, destruction or reshipment of consignments at the border are based on our identifications. One of the ways of ensuring the credibility of results in a laboratory environment is to demonstrate their consistent quality.

In 2007, PHEL obtained accreditation to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* (www.ianz.govt.nz). This accreditation formally recognises that PHEL meets internationally accepted standards of quality, performance, technical expertise and competence. It gives an additional level of assurance to our clients of the performance, competency and quality of our results.

In recent years, there has been a push internationally for plant diagnostic laboratories to become accredited to ISO/IEC 17025. Many veterinary laboratories are already accredited. For example, the MAFBNZ Animal Health Laboratory, in Wallaceville, was accredited in 2000 for a range of microbiological and serological tests.

Accreditation mandatory

The challenge of pursuing ISO/IEC 17025 accreditation for PHEL emerged in late 2003, when a review of the *MAF Standard for Plant Pest Diagnostic Laboratories and Operators* made ISO/IEC 17025 accreditation a mandatory requirement for approval. The revised standard requires all laboratories providing identifications of new organisms which support MAFBNZ functions to be ISO/IEC 17025 accredited.

The scope of PHEL's accreditation covers tests (e.g., PCR, RT-PCR or ELISA) for bacteria, phytoplasmas and viruses, and morphological identifications of fungi and invertebrates. Non-accredited ELISA and PCR tests conducted at PHEL follow the same quality requirements and methodology as the accredited tests. Currently, PHEL has 14 signatories to cover the scope of accreditation. These signatories are referred to as key technical persons (KTP) in the IANZ accreditation programme.

Accreditation has yielded many benefits for PHEL, including improved effectiveness and productivity of testing and increased credibility of test results nationally and internationally. Staff are proud of the achievement of accreditation. Advantages include having documented systems in place for testing, recording, traceability and training new staff. It also provides staff with an easy system for improvement and change, e.g. raising quality improvements, continuous monitoring through internal audits and document review.

Issues and challenges

Two key challenges identified by IANZ for any laboratory working towards ISO/IEC 17025 accreditation are proficiency testing and traceability.

Proficiency testing is an essential and effective means of assessing a laboratory's ability to competently perform tests, identifications or measurements. It is a continuous assessment by an external third party of technical competence to perform a particular test or identification. Proficiency testing schemes are firmly established for human and animal health laboratories in New Zealand and other parts of the world, e.g. Australian National Quality Assurance Program, but until recently there were no formal proficiency testing schemes for plant health laboratories.

FAPAS[®] (Food Analysis Performance Assessment Scheme, www.fapas.com) launched the first of its proficiency testing programmes for plant health in 2005. In the absence of formal proficiency testing schemes, and in order to satisfy ISO/IEC 17025, PHEL has established local plant health schemes with various laboratories in Australia and Canada, e.g. informal laboratory-to-laboratory arrangements. Internal proficiency programmes have also been developed to verify staff competence.

A laboratory also needs to ensure there is traceability of samples from specimen reception through to reporting. PHEL has found that it is important to have a good laboratory information system/database for data capture, reporting and reissuing reports. Traceability also covers reagents (e.g. recording batch numbers of reagents), equipment (e.g. calibration records available and traceable back to standard reference points) and reference material.

Quality improvements are ongoing, e.g. refining standard operating procedures (SOP) to ensure they are in line with recent scientific advances.

European quality assurance workshop

Brett Alexander, Team Manager (Mycology and Bacteriology) at PHEL, Auckland, attended the European and Mediterranean Plant Protection Organisation (EPPO) Workshop on Quality Assurance held in Holte, Denmark in December 2007. This was the first official EPPO workshop on quality assurance and was jointly organised with the Danish Plant Directorate. The workshop included general

presentations on the existing standards on quality assurance for laboratories as well as presentations showing experiences with the implementation of quality assurance in plant health laboratories, EPPO initiatives on quality assurance, proficiency testing and objective evidence of competence.

Brett provided a New Zealand perspective on accreditation of plant diagnostic laboratories. Delegates were impressed by the simplicity and practical nature of the PHEL approach to accreditation. The second part of the workshop consisted of practical sessions on method validation and preparation of reference materials, how to write quality assurance documents, metrology and how to conduct an internal audit.

In the last five to ten years, 19 out of 109 labs in the European Union have become accredited to ISO/IEC 17025 and many more have started down the accreditation path. It is important that laboratories take advantage of the expertise that has been developed to date since it may avoid duplication of effort and prevent laboratories from repeating the same mistakes. Quality assurance provides many opportunities for collaboration, e.g. sharing of SOPs and diagnostic protocols and establishing proficiency testing programmes with other laboratories. Areas where PHEL plans to investigate further include the possibility of a flexible scope for our PCR test method and using FAPAS[®] for external proficiency testing.