Biological Testing ISO/IEC 17025 Application Document

Annex F: Plant Health Diagnostic Testing

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This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting Plant Health Diagnostic Testing under the field of Biological Testing.

Applicant and accredited facilities must also comply with the ISO/IEC 17025 standard and the Biological Testing field application document and any field annexes, policies and/or technical circulars (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO/IEC 17025 but since not all clauses require interpretation the numbering may not be consecutive.

The establishment of criteria for the accreditation of plant health diagnostic testing in this annex was a joint project between the Subcommittee on Plant Health Diagnostic Standards (SPHDS) and NATA.

Plant Heath Diagnostic Testing relates to Plant Pests and Diseases, described by the International Plant Protection Convention as any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products (IPPC).

The additional accreditation criteria in this annex are applicable to all Plant Health Diagnostic Testing facilities, irrespective of size, range of testing or number of personnel. These criteria are however potentially applicable to all plant health diagnostic testing facilities including field or screening facilities. It should however be noted that it is not possible to set rigid requirements for all aspects of a facility's operation. Some flexibility is necessary so that each facility's unique situation can be considered. The acceptability (or otherwise) of certain practices can therefore only be determined by assessment.

This annex also refers to a number of national guidelines and standards e.g. PLANTPLAN written by Plant Health Australia. The mandatory application of certain sections of these documents has been included in this annex. The use of other sections of these documents do not represent requirements for accreditation, however should be considered as part of good laboratory practice and harmonised procedures in emergency plant pest response.

Tests covering plant health diagnostic testing are listed under the following classes:

8.40 Plant health diagnostics – Bacteriology

8.41 Plant health diagnostics – Virology

8.42 Plant health diagnostics – Mycology

8.43 Plant health diagnostics – Other microorganisms (incorporating phytoplasmas)

8.44 Plant health diagnostics – Nematodes

8.45 Plant health diagnostics – Molluscs

8.46 Plant health diagnostics – Insecta

8.47 Plant health diagnostics – Acarina

8.48 Plant health diagnostics – Other invertebrates

8.61 Plant biology

4 Management requirements

4.5 Subcontracting of tests and calibrations

The referring facility and not the referral facility is responsible for ensuring that referral facility examination results and findings are provided to the person making the request. If the referring facility prepares the report, it must include all essential elements of the results reported by the referral facility, without alterations that could effect its interpretation.

The referring facility may wish to issue the referral facility's report in full. In such case it must be ensured that a copy of this report is maintained.

4.5.2 Collection instructions, facility handbooks, etc would normally be considered sufficient notification to customers of the referral arrangements.

4.5.3 Specimen referral

Facilities must comply with relevant packaging regulations (e.g. IATA) when referring samples to other facilities, including those within the same organisation. However, where interstate facilities are involved, compliance with interstate quarantine regulations must be ensured. If an emergency plant pest is suspected the requirements of PLANTPLAN must also be applied.

A record must be kept of specimens referred for testing to other facilities. A record must also be kept of the return of results. There must be a procedure for following-up results which have not been received.

5 Technical requirements

5.2 Personnel

5.2.1

'Senior Plant Heath Diagnostic Professional' means a person who possesses the following qualifications:

a) a Doctorate of Philosophy in a relevant biological discipline, and

b) who has not less than 5 years full time experience in identification of plant pests, or

c) expertise that is deemed to be equivalent of a) or b) as assessed by peer review.

'Plant Heath Diagnostic Professional' means a person who possesses one of the following qualifications:

a) a degree in a relevant biological discipline, at a university or other tertiary institutions recognised in Australia, or

b) a qualification that is deemed to be the equivalent of a).

For ***Plant Heath Diagnostic facilities*** there shall be at least the equivalent of one full time Plant Heath Diagnostic Professional who will usually be present during normal working hours. This person shall provide technical control over

tests for which the facility is accredited and shall have demonstrable experience in those tests.

For Diagnostic facilities, the designated person(s) in charge under whose direction and control the facility operates shall:

- approve and be responsible for operational practices and staffing;
- determine the range of tests provided and the methods and procedures used;
- ensure appropriate consultation on plant diagnostic and scientific issues;
- ensure regular review of the facility's management system, internal quality control and proficiency testing/external quality assurance data and the methods used, and discuss all aspects of the facility's performance with the scientific/technical staff;
- ensure that all staff participate in continuing education;
- ensure the continuity of overall supervision in situations where the supervision is provided by more than one person; and
- ensure that work performed at the facility outside normal working hours is carried out by scientific or technical staff approved to do so by the designated supervisor, having regard to their training and experience.

Screening/Field Plant Heath Diagnostic Facility

A facility that is an integral part of a Diagnostic Plant Heath facility apart from its geographical location. In either circumstance the Screening/Field facility will have a documented agreement with the Diagnostic facility to ensure that the range of testing provided and the standard of work is under the direction and control of a designated Plant Heath Diagnostic Professional from the accredited from the Diagnostic facility.

5.3 Accommodation and environmental conditions

Consideration must be given to separating procedures from the main work area where:

- these procedures may pose a hazard to other staff (e.g. agricultural chemicals, human pathogenic microorganisms);
- these procedures may be affected or influenced by not being segregated (e.g. tissue culture, PCR tests);
- where a quiet and uninterrupted work environment is required (e.g. microscopy).

5.4 Test and calibration methods and method validation

5.4.1 General

Methods manuals

Method documentation should be reviewed on a regular basis and a record of method review must be kept. Where there are no changes, a date and acknowledgement of review will be sufficient.

Methods no longer in use must be clearly identified and preferably be archived.

Some manufacturers provide method documentation (kit inserts) with their product and these may be included in methods manuals. These must, however, be authorised e.g. signed and dated by the responsible staff member. Where this information is not sufficiently detailed to cover all required information to perform the test by facility staff, it must be supplemented with the additional information.

Inserts for new batches received must be checked for changes in procedure and a copy of the new insert placed in the manual.

Thresholds:.Use can be made of published thresholds. These should, however, be validated for use with the facility's own test methods. It may be necessary for facilities to establish their own thresholds (e.g. OD for ELISA), by statistically valid means.

The source of thresholds must be documented.

5.4.2 Selection of methods

Facilities must use endorsed *National Diagnostic Procedures/Protocols for Plant Pests* where available. Facilities may be required to use other standard methods in the absence of National Diagnostic Procedures/Protocols. For example, the International Plant Protection Convention (IPPC) or other protocols for Diagnostic Tests approved by the Consultative Committee on Emergency Plant Pests for diagnosis in Australia may be specified.

5.4.3 Laboratory-developed methods

The guidelines stated in the SPHDS Reference Standard No. 2 *Development of Diagnostic Procedures – Technical Procedures*, should be followed in the drafting of a diagnostic procedure/protocol.

5.4.4 Non-standard methods

This category includes modified standard methods, rapid method techniques (instrumental or biochemical) and in-house methods. Any variation of a standard test that could affect the outcome of the test result, (e.g. change to time or temperature of incubation or the use of alternative growth media) must be validated in accordance with AS/NZS 4659 *Guide to determining the equivalence of food microbiology test methods*.

Rapid test systems may not require further validation if:

- Validation data can be referenced to a published method and is applicable to the facility's scope of work;
- Validation has been undertaken by the manufacturer and is available and applicable.

The facility, however, must be able to demonstrate that it can reproduce the method specifications of the rapid test systems. Records of performance of the rapid test method and its applicability to the facility's scope of testing need to be kept by the facility.

5.4.5 Validation of methods

Refer to Technical Note 17: Guidelines for the validation and verification of quantitative and qualitative test methods for details of the method validation decision process.

Validation data must be retained and be available for review at assessment.

5.6 Measurement traceability

5.6.3 Reference standards and reference materials

Where appropriate to the nature of the Plant Heath Diagnostic Testing performed, the facility must hold and maintain collections of pests for the purposes of quality control and reference when conducting identifications.

Microbiology

Reference collections should be sourced from collections registered with the World Federation for Culture Collections. Where reference material is not sourced from recognised collections, the facility must demonstrate the validity of the material used. The following collections are recommended;

World Data Centre for Microorganisms (WDCM)

- Victorian Plant Pathology Herbarium, Knoxfield (WDCM851)
- WA DAF Western Australian Plant Pathogen Collection (WDCM77)
- QDPI Plant Pathology Herbarium Indooroopilly (WDCM27)
- NSW DPI Plant Pathology Herbarium Orange (WDCM365)

All cultures held by the facility must be uniquely identified. The system of identification must maintain traceability to the recognised culture collection or sample from which the cultures were sourced.

Nucleic Acid

Nucleic acid control material must be traceable to a verified collection or culture. A part of the material from which the nucleic acid was derived should be lodged in a recognised culture collection, herbarium or insect collection. Where diagnosis depends on DNA sequence similarity, the reference sequence should be derived from a vouchered specimen or culture.

Morphology

Vouchered specimens from a suitable host should be validated by a recognised expert. Diagnostic image libraries e.g. Pest and Diseases Image Library (PaDIL), prepared in collaboration with recognised experts should be used.

Reference collection management

Facilities must hold and maintain or have ready access to a physical collection of appropriately curated and definitively identified material required to perform positive verification checks on methods.

The facility must demonstrate a system to maintain separation of Reference and Sample material.

Where virtual reference material (textbooks, image libraries, published DNA sequences) is relied upon, this must be from a validated source.

5.7 Sampling

Specimen collection

Where specimen collection is outside the control of the facility, the collectors must be informed of the facility's collection requirements. These requirements must be documented. For example:

- containers/tubes required for each test
- amount of specimen required
- labeling requirements
- specimen storage requirements (e.g. room temperature vs. refrigeration)
- specimen transport requirements
- requirements with respect to request forms

In general, specimen containers should not be pre-labeled. Labeling of lids only is not acceptable

Consumables provided by the facility for collection or used in the facility, in particular tubes containing additives, must be monitored for expiry dates.

Where an Emergency Plant Pest is suspected the requirements of PLANTPLAN in relation to sample handling must be followed.

5.8 Handling of test and calibration items

5.8.1 Specimen reception

Procedures for handling suspect quarantinable organisms (including procedures for transport, according to PLANTPLAN) and for notification of appropriate authorities must be documented.

5.8.2 Specimen labelling requirements

Each specimen container must be labeled with a unique identification (in accordance with PLANTPLAN). Where confusion with another specimen from the same plant is possible, the container must also be labelled with sufficient detail to distinguish the two.

For survey testing, each specimen container must be individually labelled, but need not identify an individual plant.

Note: It is recommended that the date of collection be recorded on the specimen container.

For specimens submitted on glass slides (e.g. thrips or mites) the required identification must be on the slide itself. This can be achieved with the use of frosted slides or adhesive labels.

The request form received with each specimen (or batch) is required to provide additional information not included on the specimen container itself

The required details are:

- host name or other unique identification;
- name of owner (or representative);
- date of collection;
- type of specimen.
- the location where the specimens were collected must be provided (e.g. property name or geographical region and a GPS record to be provided where possible).

Where an emergency plant pest is suspected, chain of evidence procedures in compliance with PLANTPLAN must be followed.

5.8.3 Where inadequately labelled specimens are received, the facility must assure itself of the identity of the specimen. Where the identity of the specimen cannot be assured and a recollection would be possible, testing should not proceed on the initial specimen.

If specimens that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of the problem and any subsequent action taken. A comment on the unsuitability for testing of the specimen must be included on test reports.

5.8.4 Sample preparation

In testing situations where the pooling of samples is considered acceptable practice, the facility must follow a predefined and documented protocol. Any changes to the protocol must be validated and records of the validation kept.

Specimen retention

Unless indicated otherwise, samples should be stored under appropriate conditions until tests are completed and stored for a minimum of two weeks after the issue of the test report. It is assumed that these timelines will be sufficient for the referring customer to review the test report and, if necessary, confirm the identity of the sample with the testing facility or request further testing.

5.9 Assuring the quality of test and calibration results

General

Many factors will influence the frequency with which quality control is performed. The quality control (QC) protocol must take into account these factors and be such that the facility has confidence in the results issued. The adequacy of quality control procedures will be reviewed at assessment.

The QC material used must cover the range of hosts and pests encountered.

Reference material (e.g. images, textbooks or vouched specimens) suitable to perform the morphological identification of pests, must be available.

Low/normal/high, positive/negative controls must be included as appropriate for the test.

Where appropriate, the use of control material that has a value close to the serological assay cut off should be considered.

Where calibration of an assay is required, appropriate material must be used as a calibrator. If the material selected is not intended for use as a calibrator, ascribed calibration values must be substantiated.

Acceptable ranges must be defined for internal quality control material.

Internal quality control results must be recorded and primary quality control data (e.g. instrument printouts, original work notes) must be retained.

A protocol for action to be taken where QC results fall outside acceptable ranges must be documented.

Unless otherwise specified in the manufacturer's instructions, QC material must be analysed for each test on each day of testing.

The facility must have a system of long-term monitoring of quality control results to assess method performance.

Graphical presentation of numerical quality control results is recommended as this may assist the early detection of trends.

Infrequently performed tests/techniques

The facility's program to review its ongoing competence to perform such tests should include participation by all relevant staff in scheduled internal replicate testing activities (e.g. once every three months), satisfactory participation in available proficiency testing programs and other supplementary activities to maintain operator skills.

Proficiency testing

It is acknowledged that the availability of formal proficiency testing programs is currently limited.

As proficiency testing programs become available, each facility must participate in those programs which cover the range of tests performed and species examined. Where proficiency testing programs are not available, alternative measures (e.g. exchange of samples with other facilities) must be considered.

Participation in a proficiency testing program is mandatory when the program is local (i.e. in Australia), is Plant Diagnostic based and is relevant to the work undertaken by the facility.

Proficiency testing samples must be tested and the results submitted to the program providers in accordance with the providers' schedules, irrespective of whether the timing coincides with the testing of Plant Diagnostic submissions.

On receipt of results from the program providers, it must be ensured that:

a) proficiency testing performance is reviewed and discussed by the Plant Heath Diagnostic Professional providing technical control, and all relevant scientific/technical staff;

b) records are kept to demonstrate that the review of results has occurred;

c) unsatisfactory results and other deficiencies identified by the program provider(s) are addressed and records kept; and

d) the implication of unsatisfactory proficiency testing performance on diagnostic test results must be considered and a record of the

considerations and action taken kept (e.g. withdrawal of reports issued for results affected).

As far as practicable, proficiency testing samples must be treated in the same way as diagnostic test samples. Additionally, consideration should be given to ensuring that all staff (including part-time and evening staff) participate in proficiency testing.

5.10 Reporting the results

Persons authorising test reports

Any person providing diagnoses shall be a recognised Plant Heath Diagnostic Professional in the relevant discipline, as defined under 5.2.1 and in the State or Territory in which the facility operates.

Individuals in training would be expected to undertake and document training for a period of six months in the respective disciplines of their facility prior to issuing test reports in isolation and use an appropriate title and have appropriate supervision until relevant qualifications are obtained.

The use of discipline terms in titles is optional, however, each facility shall ensure that the 'function or role' of the reporting staff member is evident on test reports.

Suitable members of staff, other than recognised Plant Heath Diagnostic Professionals, may issue test reports for specific classes of test. A list shall be maintained of such members of staff and the classes of test for which they may issue test reports.

The suitability of these arrangements will be evaluated at assessment.

5.10.2 Preliminary test reports may take the form of telephoned results. The facility must have a documented protocol for issuing telephoned results.

A record must be kept of the time and date of such results, who received the results and the reporting staff member. It must be clear what results have been reported. Following the issue of such results, a hardcopy, or electronic, report must be issued.

The facility must also have a documented protocol for the handling of telephone enquiries, taking into account the information being requested (e.g. test results, interpretation of results).

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

AS/NZS 4659 (Parts 1-4) – *Guide to determining the equivalence of food microbiology test methods.*

IPPC International Standard for Phytosanitary Measures No.27 *Diagnostic Protocols for Regulated Pests*.

SPHDS Reference Standard No. 2 *Development of Diagnostic Procedures: Technical Procedures*

Other references

PLANTPLAN: Australian Emergency Plant Pest Response Plan Plant Health Australia. Available on Plant Health Australia website.