



# **Specific Accreditation Criteria**

**ISO/IEC 17025 Application Document  
Life Sciences - Annex**

**Plant Health Diagnostic Testing**

**July 2018**

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# Plant Health Diagnostic Testing

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.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Agribusiness (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.

## Introduction

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 Health Diagnostic Testing relates to plant pests and plant pathogens. Pests are defined by the International Plant Protection Convention (IPPC) as any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

The additional accreditation criteria in this annex are applicable to all Plant Health Diagnostic Testing facilities including field or screening facilities.

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 does not represent requirements for accreditation, but should be considered to be part of good laboratory practice and contribute to harmonisation with procedures for emergency plant pest responses.

## 5 Structural requirements

**5.5** Plant Health Diagnostic facilities must have at least one Plant Health Diagnostic Professional who will usually be present during normal working hours. This person shall provide technical control over tests 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 would normally be expected to be either a Senior Plant Health Diagnostic Professional or a Plant Health Diagnostic Professional. Where the scope of testing is limited this requirement may be waived. Where this circumstance arises, a decision will be made on a case by case basis.

The person in charge 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 at all times 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 Health Diagnostic Facility

Where screening/field plant health diagnostic facilities are established they must be under the direction of a designated plant health diagnostic professional from the accredited diagnostic facility.

## **6 Resource requirements**

### **6.2 Personnel**

#### **6.2.2**

#### Senior Plant Health Diagnostic Professional

Is a person who possesses the following qualifications:

- a Doctorate of Philosophy in a relevant biological discipline, and
- who has not less than 5 years full time experience in identification of plant pests, or
- expertise that is deemed to be equivalent of a) or b) as assessed by industry peers.

#### Plant Health Diagnostic Professional

Is a person who possesses one of the following qualifications:

- a degree in a relevant biological discipline, at a university or other tertiary institutions recognised in Australia, or
- a qualification that is deemed to be the equivalent of a).

**6.2.5** Individuals in training would be expected to undertake and have documented training (including levels of competency attained) for a period of six months in the respective disciplines prior to issuing test reports in isolation. During training they should have appropriate supervision until relevant qualifications and competencies 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.

### **6.3 Facilities and environmental conditions**

**6.3.1** Accommodation must be appropriate for the work that is undertaken. Consideration must be given to providing dedicated work areas including where:

- activities may pose a hazard to other staff (e.g. agricultural chemicals, human pathogenic microorganisms);
- activities may be affected or influenced by not being segregated (e.g. tissue culture, PCR tests);

- biosecurity containment is required.

Where possible, office areas should be separate from areas used to undertake testing.

## **6.4 Equipment**

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

## **6.5 Metrological traceability**

**6.5.1** 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.

**6.5.3** Where appropriate to the nature of the plant health 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 Disease Herbarium (VPRI), Bundoora (WDCM851);
- Western Australian Department of Agriculture and Food, Western, Australian Plant Pathogen Collection (WDCM77);
- Queensland Department of Agriculture, Fisheries and Forestry, Plant Pathology Herbarium Indooroopilly (WDCM27);
- New South Wales Department of Primary Industries, 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 specimen from which the cultures were sourced.

As reference cultures of exotic microorganisms are generally not available in Australia, nucleic acid is acceptable for use as a control (see below).

### Nucleic Acid

Nucleic acid control material must be traceable to a verified collection or culture. A specimen, culture or 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.

### Lyophilised positive controls

Lyophilised (freeze-dried) controls are available from ELISA (Enzyme Linked ImmunoSorbent Assay) kit manufacturers and are suitable for this purpose. Results

from these tests can only be validated when the control material reacts appropriately, although other material can be substituted if it reacts similarly.

### Morphology

Vouchered specimens from a suitable host should be validated by a recognised expert. Diagnostic image libraries that are prepared in collaboration with recognised experts should be used, such as the Pest and Disease Image Library (PaDIL).

### Reference collection management

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

The facility must demonstrate a system to maintain separation of reference and specimen material.

Virtual reference material (textbooks, image libraries, published DNA sequences) must be from a validated source.

## **7 Process Requirements**

### **7.1 Review of request, tenders and contracts**

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

### **7.2 Selection, verification and validation of methods**

#### **7.2.1 Selection and verification of methods**

**7.2.1.1** 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.

**7.2.1.2** 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 archived in an accessible manner.

Some manufacturers provide method documentation (kit inserts) with their product and these may be included or referred to in methods manuals. These documents must, however, be included in the document control process in operation. 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.

**7.2.1.5** The guidelines stated in the former SPHDS Reference Standard No. 2 Development of National Diagnostic Protocols - Procedures for Authors, should be

followed in the drafting of a diagnostic procedure/protocol for a specific pest or pest group although the format may need to meet institutional requirements for templates and governance.

## **7.2.2 Validation of methods**

**7.2.2.1** Validation of methods, where required, must be in accordance with AS/NZS 4659 *Guide to determining the equivalence of food microbiology test methods*.

### 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. optical density for ELISA), by statistically valid means.

The source of thresholds must be documented.

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 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.

**7.2.2.4** Refer to *General Accreditation Guidance: Validation and verification of quantitative and qualitative test methods* for details of the method validation decision process.

## **7.3 Sampling**

### Specimen collection

If collection of specimens is outside the control of the facility, the collector(s) should be informed of the facility's collection requirements. These requirements must be documented and accessible to the external persons who may submit specimens. For example:

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

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

## **7.4 Handling of test or calibration items**

**7.4.1** Facilities must comply with relevant packaging regulations (e.g. International Air Transport Association) when referring samples to other facilities, including

those within the same organisation. However, where interstate facilities are involved, compliance with interstate biosecurity 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. The referring facility must follow up on any delayed results.

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

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.

Unless indicated otherwise by the submitter, specimens should be stored under appropriate conditions for a minimum of two weeks after the issue of the final test report. It is assumed that these timelines will be sufficient for the submitter to review the test report and, if necessary, confirm the identity of the specimen with the testing facility or request further testing.

**7.4.2** In general, specimen containers should not be pre-labelled. Labelling of lids only is not acceptable.

Each specimen container must be labelled with a unique identification (in accordance with PLANTPLAN). Where confusion with another specimen from the same plant or source 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 labelling must be on the slide itself. The request form received with each specimen (or batch) is required to provide additional information not included on the specimen container itself. For specimens labelled with bar codes, QR codes or RFID chips, the laboratory must have access to the associated information.

Additional information should include:

- the host name or source of the specimen or other unique identification;
- the name of owner (or representative);
- the date of collection;
- number of specimens or specimen containers.
- 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).
- An indication of the type of testing, or specific tests required.

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

**7.4.3** 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 submission of further specimens is 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 of the specimen for testing must be included on test reports.

## **7.7 Ensuring the validity of results**

**7.7.1** 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 protocol material must cover the range of biological testing classes included in the laboratory's scope of accreditation. Reference material (e.g. images, textbooks or vouched specimens) suitable to perform the morphological identification of pests, must be available.

Acceptable ranges must be defined for internal quality control results.

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

### 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).

**7.7.2** The availability of formal proficiency testing programs in Australia is limited.

As proficiency testing programs become available, each facility must participate in a suitable program that covers the appropriate 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 suitable 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 undertaken in accordance with the providers' schedules, irrespective of whether the timing coincides with the testing of other plant diagnostic submissions.

On receipt of results of a proficiency testing program, the following actions must be taken:

- proficiency testing performance is reviewed and discussed by the Plant Health Diagnostic Professional providing technical control, and all relevant scientific/technical staff;
- records are kept to demonstrate that the review of results has occurred;
- unsatisfactory results and other deficiencies identified by the program provider(s) are addressed and records kept; and

- 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 or review of reports previously issued for species that gave unsatisfactory results in the proficiency tests).

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

#### Infrequently performed tests/techniques

Staff should participate in proficiency testing programs and other supplementary activities to maintain operator skills.

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

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.

## **7.8 Reporting of results**

### **7.8.1 General**

**7.8.1.1** Any person providing diagnoses shall be a recognised Plant Health Diagnostic Professional in the relevant discipline, as defined under 6.2.2 and in the State or Territory in which the facility operates.

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

The suitability of these arrangements will be evaluated at assessment.

**7.8.1.2** Preliminary test results may be reported verbally. The facility must have a documented protocol for issuing results verbally.

A record must be kept of the time and date of such verbal 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 or face to face enquiries, taking into account the information being requested (e.g. test results, interpretation of results).

### **7.8.2 Common requirements for reports (test, calibration or sampling)**

**7.8.2.1** The referring facility is responsible for ensuring that final 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 testing facility, without alterations that could affect its interpretation.

The referring facility may wish to issue the testing facility's report in full. In such cases a copy of this report must be retained.

## 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

- ISO/IEC 17025      General requirements for the competence of testing and calibration laboratories
- AS/NZS 4659      Guide to determining the equivalence of food microbiology test methods

### NATA Publications

NATA Accreditation Criteria (NAC) package for Agribusiness

General Accreditation Guidance      Validation and verification of quantitative and qualitative test methods

### Other Publications

IPPC International Standard for Phytosanitary Measures No.27 *Diagnostic Protocols for Regulated Pests* (<https://www.ippc.int/en/core-activities/standards-setting/ispms/#publications>)

Former SPHDS Reference Standard No. 2 Development of National Diagnostic Protocols - Procedures for Authors (<http://plantbiosecuritydiagnostics.net.au>)

Pest and Disease Image Library (PaDIL) ([www.padil.gov.au](http://www.padil.gov.au))

PLANTPLAN: Australian Emergency Plant Pest Response Plan, Plant Health Australia ([www.planthealthaustralia.com.au/biosecurity/incursion-management/plantplan](http://www.planthealthaustralia.com.au/biosecurity/incursion-management/plantplan))

## Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Whole document	<p>Clauses have been aligned with ISO/IEC 17025:2017.</p> <p>Any criteria included in the previous issue that are now covered by ISO/IEC 17025:2017 have been removed.</p> <p>No new interpretative criteria or recommendations have been included other than editorial changes.</p>