Specific Accreditation Criteria
Life Sciences ISO/IEC 17025 Annex

Plant Health Diagnostic Testing

January 2018

© Copyright National Association of Testing Authorities, Australia 2013

This publication is protected by copyright under the Commonwealth of Australia Copyright Act 1968.

NATA's accredited facilities or facilities seeking accreditation may use or copy this publication or print or email this publication internally for accreditation purposes.

Individuals may store a copy of this publication for private non-commercial use or copy a reasonable portion of this publication in accordance with the fair dealing provisions in Part III Division 3 of the Copyright Act 1968.

You must include this copyright notice in its complete form if you make a copy of this publication.

Apart from these permitted uses, you must not modify, copy, reproduce, republish, frame, upload to a third party, store in a retrieval system, post, transmit or distribute this content in any way or any form or by any means without express written authority from NATA.

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 also comply with ISO/IEC 17025, the NATA ISO/IEC 17025 Standard Application Document (SAD) and the Life Sciences ISO/IEC 17025 Appendix. 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 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 (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 does not represent requirements for accreditation. However such use should be considered to be part of good laboratory practice and contribute to harmonisation with procedures for emergency plant pest responses.

4 Management requirements

4.5 Subcontracting of tests and calibrations

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 effect 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.

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. International Air Transport Associational) 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.

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 industry peers.

'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).

Plant Heath Diagnostic facilities must have at least one 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 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 Heath 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.

5.3 Accommodation and environmental conditions

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.

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 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.

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.

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 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.

5.4.4 Non-standard methods

This category includes modified standard methods, rapid method techniques (instrumental or biochemical), kit methods 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 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 *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 to laboratory staff and 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 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.

5.7 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

In general, specimen containers should not be pre-labelled. Labelling 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 organisms suspected to be of biosecurity concern (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 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.

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 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.

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 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.

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 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.

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 results.

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

Proficiency testing

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

However 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:

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 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.

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 (including levels of competency attained) for a period of six months in the respective disciplines of their facility prior to issuing test reports in isolation. During training they should and 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.

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

The suitability of these arrangements will be evaluated at assessment.

5.10.2 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).

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.* www.saiglobal.com.

IPPC International Standard for Phytosanitary Measures No.27 *Diagnostic Protocols for Regulated Pests*. www.ippc.int/core-activities/standards-setting/ispms

SPHDS Reference Standard No. 2 Development of National Diagnostic Protocols- Procedures for Authors *http://plantbiosecuritydiagnostics.net.au/wordpress/wp-content/uploads/2013/03/RS2-Development-of-NPDs-procedures-for-authors-V4-0.pdf*

Other references

PaDIL. Pest and Disease Image Library www.padil.gov.au

PLANTPLAN: Australian Emergency Plant Pest Response Plan Plant Health Australia.

www.planthealthaustralia.com.au/biosecurity/incursion-management/plantplan

NATA Procedures for Accreditation

Amendment Table

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

Section or Clause	Amendment
New document	This document represents a direct adoption of the former Biological Testing Annex F. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.