Subcommittee on Plant Health Diagnostics

SPHD Reference Standard No. 3
(SPHD RS No. 3)

Guidelines for the Development and Approval Processes of National Diagnostic Protocols

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AUTHOR	DSWG

Contents

1. INTRODUCTION

1.1 Scope

The *Guidelines for the Development and Approval Processes of National Diagnostic Protocols* (SPHD RS No.3) is a SPHD Reference Standard providing guidelines on the development and approval of diagnostic procedures/protocols (refer to SPHD RS No.1 for definitions). In this document the term "diagnostic protocol" will refer to either a diagnostic procedure or a diagnostic protocol. The Reference Standard has been developed to standardise and incorporate relevant information in diagnostic protocols for the identification of emergency plant pests in Australia.

An overview of protocol development and assessment is provided in Appendix 1 & 2.

1.2 Purpose

The purpose of this Reference Standard is to provide guidelines to SPHD for the development and approval processes that diagnostic protocols undergo in order to be regarded as National Diagnostic Protocols (NDPs). Once developed, the diagnostic protocol will be evaluated and approved using the forms and guidelines laid out in this Reference Standard. Following approval and endorsement by SPHD, the document will be recognised as a NDP.

1.3 Review

The SPHD RS No.3 will be reviewed every five years or earlier if required. Changes to the Reference Standard are subject to the approval and endorsement of SPHD members.

1.4 Reference Standards

All SPHD Reference Standards can be found on the NPBDN website (https://www.plantbiosecuritydiagnostics.net.au/resources/#). On the Resource page search for the term 'Reference Standard'.

1.5 References

- IPPC. 1997. ISPM No. 6 *Guidelines for Surveillance*. Food and Agriculture Organisation for the United Nations, Rome.
- IPPC. 2001. ISPM No. 13 *Guidelines for the Notification of Non-compliance and Emergency Action*. Food and Agriculture Organisation for the United Nations, Rome.
- IPPC. 2006. ISPM No. 27 *Diagnostic Protocols for Regulated Pests*. Food and Agriculture Organisation for the United Nations, Rome.
- IPPC. 2011. *Procedural Manual.* Food and Agriculture Organisation for the United Nations, Rome. September 2011.
- IPPC. 2012. ISPM No. 5 Glossary of Phytosanitary Terms. FAO, Rome.

2. SPHD PROCEDURES FOR THE DEVELOPMENT AND APPROVAL OF NDPs

2.1 Introduction

The SPHD procedure for the development of NDPs has been adapted from the IPPC Procedural Manual, Section 3.6.3. *Technical Panel to Develop Diagnostic Protocols for Specific Pests* (IPPC 2011).

Definitions of terms, acronyms and abbreviations used are contained in the SPHD RS No.1: Glossary of terms and *ISPM No. 5 Glossary of Phytosanitary Terms* (IPPC 2012).

2.2 Annual Work Programme

SPHD annually identifies priorities for the development of diagnostic protocols. Guidance from Plant Health Australia and any other requests for reviews and amendments to a diagnostic protocol that have been received by SPHD/Plant Health Committee members should be taken into account when submitting a work program to the SPHD Executive Officer (EO).

2.3 Nominations of Experts

The EO calls for nominations of Experts for development or review of a diagnostic protocol.

The list of nominated Experts is submitted to SPHD for acceptance.

The chosen Experts are invited to participate in the development or review of the diagnostic protocol(s) by open process.

2.4 Development and Approval of Diagnostic Protocols

This process is used where a NDP, or IPPC Protocol published under ISPM 27, does not exist.

The EO will keep the author of the protocol informed of the protocol progression through these stages.

2.4.1 New NDP

An NDP or IPPC protocol does not exist.

A suitable expert/author will lead the development of a diagnostic protocol either by adapting an international diagnostic protocol, if it exists, or by developing a new diagnostic protocol. The author uses the *Instructions to Authors* for *NDPs* for guidance (SPHD RS No. 2 Section 3) and if needed additional instructions may also be given.

The draft protocol is submitted to SPHD for approval.

An Assessment Panel nominated by SPHD will evaluate the protocol for style and content using the checklist in Appendix 3 and approve for peer review and verification, or return to the author or person nominated by SPHD with comments for further work required before resubmission.

All protocols will be Peer Reviewed by a Plant Health Expert approved by SPHD (in accordance with SPHD RS No. 4).

The Assessment Panel will determine during the evaluation whether there are procedures in the protocol which need verification. If required, verification of the diagnostic protocol is

undertaken by an Independent Laboratory approved by SPHD (in accordance with SPHD RS No. 4).

The diagnostic protocol and the associated reports are assessed by DSWG or a nominated Assessment Panel following the procedures outline in Appendix 4 – 6.1).

- The diagnostic protocol is accepted if it conforms to SPHD RS No.2, is shown by the verification report to be reproducible and the peer review report confirms the information included is accurate and current. Following recommendations of the reviewers, editing is undertaken by a SPHD nominated Expert and those aspects of the protocol needing clarification are negotiated with the author.
- Following editing the protocols are returned to authors and reviewers for comment before approval.
- If the diagnostic protocol is not accepted by the assessment panel it is either returned to the author for review and resubmission, or after negotiation with the author, forwarded to another author to undertake the revision.

The Assessment Panel makes the recommendation that SPHD approve the Diagnostic Protocol as a NDP. The SPHD EO should include the reviewer(s) and verifying laboratory in the acknowledgements and include version information on the front page. The diagnostic protocol will be submitted to SPHD for endorsement as a NDP in accordance with 2.5.

The endorsed diagnostic protocol is published on the SPHD website.

2.4.2 International protocols

A NDP or IPPC Protocol does not exist, but an international peer reviewed diagnostic protocol (e.g. EPPO, QUADS) is published.

A person or organisation can request that a published international diagnostic protocol should be assessed as suitable for a Provisional NDP until such time that it is validated in Australia.

The submitter should provide evidence that the protocol has the capability to diagnose the named plant pest, in terms of reliability, reproducibility and performance, in Australia.

The diagnostic protocol and any associated reports are assessed by an Assessment Panel nominated by SPHD (Appendix 4 - 6.2). If approved, the Assessment Panel makes the recommendation that SPHD accept the diagnostic protocol as a Provisional NDP.

For subsequent endorsement as a NDP the Provisional NDP must submitted to SPHD as a new protocol under 2.4.1.

2.4.3 Emergency diagnostic protocols

A new diagnostic protocol is developed in an emergency response when:

- No diagnostic protocol exists and a new diagnostic protocol is developed in an Australian laboratory;
- An international protocol exists but is not considered suitable by plant health experts in Australia; or
- A NDP exists but an alternative protocol has since been developed which is considered more appropriate for diagnosing an emergency pest.

An interested party (author/applicant) may submit the new diagnostic protocol developed in an emergency response for SPHD approval. The new protocol is referred to as the Emergency Diagnostic Protocol (EDP). EDPs will only be considered if shown to perform equal to or better than existing endorsed provisional diagnostic protocols or NDPs.

When an EDP is submitted to SPHD for approval, the author/applicant must provide appropriate validation data (e.g. accuracy, precision, specificity, detection limits) and/or peer reviewed published documents. The documents may be subject to technical review by an expert approved by SPHD.

The Submission must also indicate the intended use of the EDP.

The Assessment Panel reviews the documents (Appendix 4 – 6.3) and when approved provides recommendations to SPHD for the EDP to be accepted for the emergency response event.

SPHD should assess the EDP for an emergency response event within 14 days or less from submission.

SPHD shall inform the Consultative Committee on Emergency Plant Pests (CCEPP) of its decision and advise PHC.

At the conclusion of the emergency response event, for subsequent endorsement as a NDP the Emergency Diagnostic Protocol must be submitted to SPHD as a new protocol under 2.4.1 or as a reviewed protocol under 2.5.

2.4.4 Adding a procedure to an existing NDP

A NDP exists. As a result of developments in diagnostic procedures and/or techniques, a new diagnostic procedure should be added to improve the NDP.

In all cases, when a NDP is amended with a new method/procedure, a verification report from an Independent Laboratory must be provided for the new method/procedure, preferably at the same time, as per SPHD RS No. 4. This report can be organised by the author/applicant after approval by SPHD, or can be organised by SPHD.

The new procedure/technique is adopted into the NDP if it is shown to improve the diagnosis of the named categorised plant pest in terms of reliability, reproducibility, performance and test costs, and proven reproducible by the verification report.

If approved, (Appendix 4 – 6.4), the Assessment Panel recommends that SPHD approves the inclusion/replacement of the new procedure/technique into the NDP.

2.5 Endorsement of NDPs

A draft protocol or reviewed protocol has been submitted to SPHD with a recommendation by the Assessment Panel that it is suitable for approval as an NDP.

The protocol will be sent by the state and territory representatives of SPHD to their respective Chief Plant Health Managers with a letter requesting their acceptance of the protocol as an NDP and an undertaking that it will be used by them to identify suspect incursions of the pest (Appendix 5).

If approved and accepted PHC is notified of the new NDP.

2.6 Review of NDPs

All NDPs are to be peer reviewed for currency by the Assessment Panel every five years or earlier if required, using the procedures and checklist included in *SPHD RS No. 4*.

The Assessment Panel may choose to engage other Plant Health Experts to assist with the process.

If updates are required, the Assessment Panel engages an Expert to develop an updated draft of the diagnostic protocol. If the changes are substantial, and include new procedures, the approval process will be undertaken as if this were a new protocol, including Verification and/or peer review.

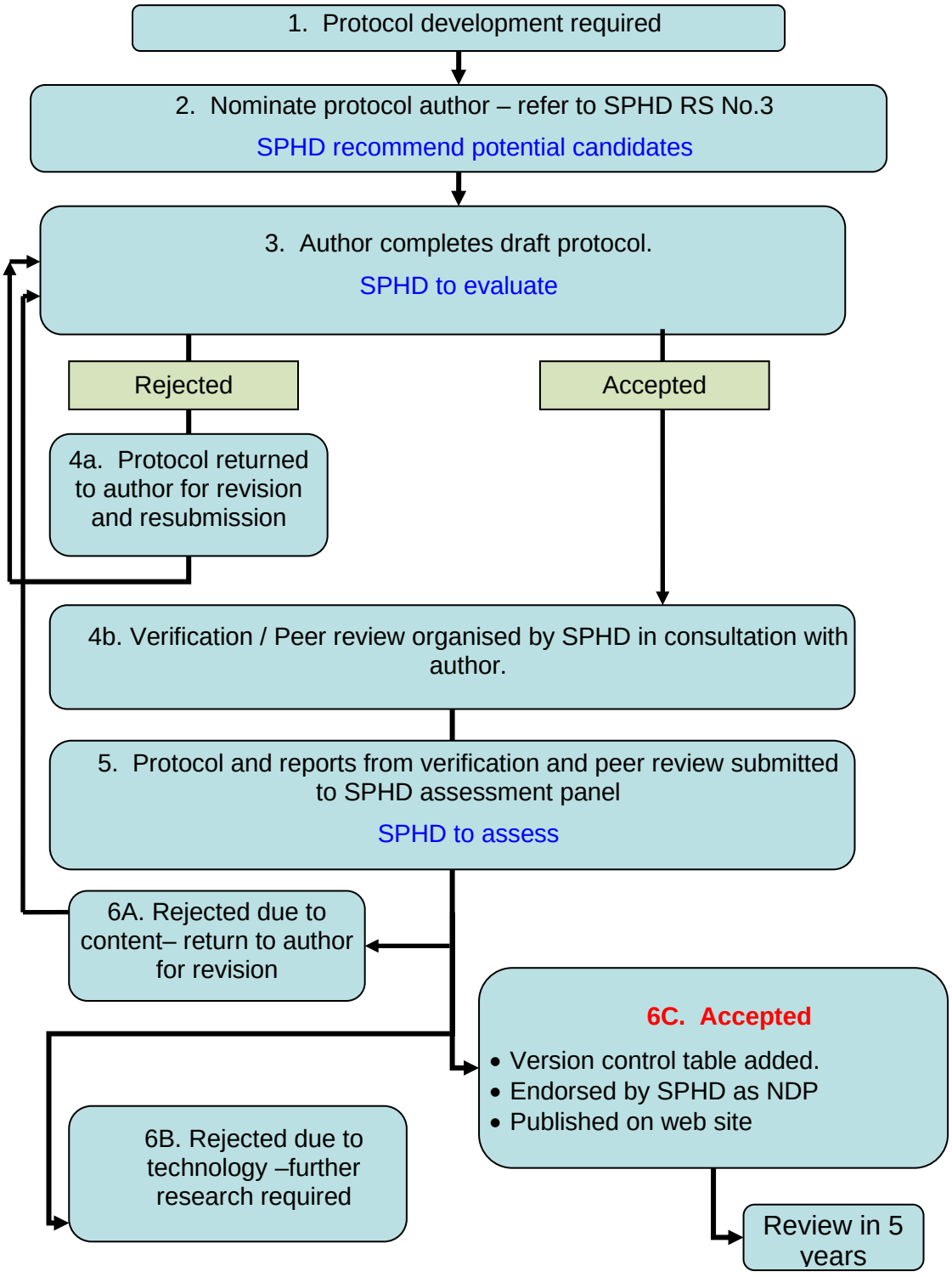
The revised draft is submitted to SPHD for approval.

If approved and the protocol contains new procedures, the protocol is submitted to SPHD for re-endorsement.

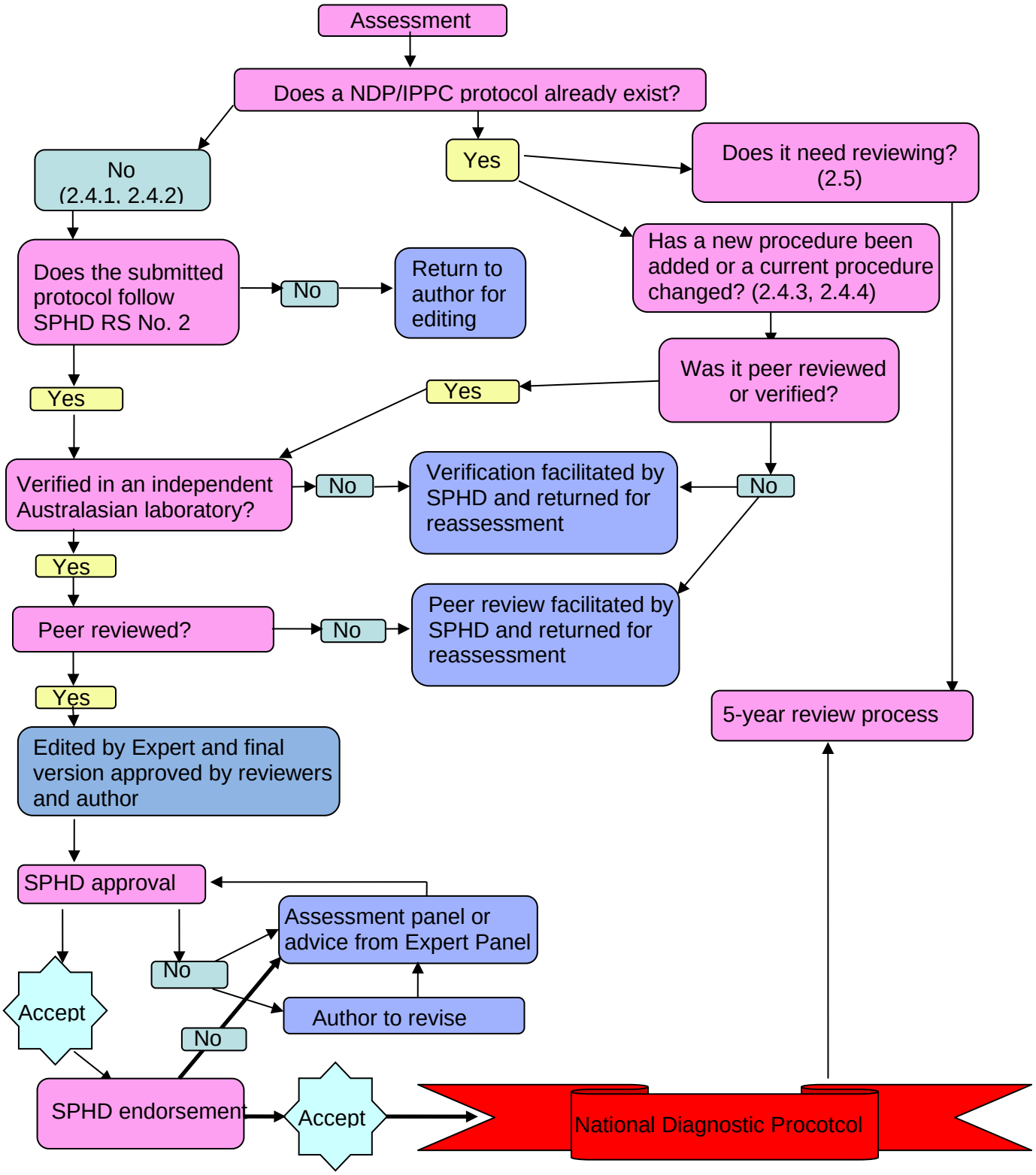
If approved and the protocol does not contain new procedures, PHC is notified of the review and the updated document is placed on the web site with a new version number.

Note: once a pest is established within Australia, the NDP will remain on the National Plant Biosecurity Diagnostic Network portal with a note on the front page explaining that the pest is established in Australia and that the protocol will no longer be subject to update or review.

3. APPENDIX 1. PROTOCOL DEVELOPMENT FLOWCHART



4. APPENDIX 2. PROTOCOL ASSESSMENT FLOWCHART.



5. APPENDIX 3: EVALUATION CHECKLIST FOR DRAFT DIAGNOSTIC PROTOCOLS.

Protocol Name.....

Section	Query	Y, N or N/A	Comments
Overall	Style guide followed?		
	Contents page?		
	Pages numbered?		
Introduction	Length <400 words?		
	Risk or geographic information omitted?		
	Host range included?		
Taxonomy	Adequate?		
Detection/ Identification	Symptom/Pest description included?		
	Images OK?		
	Detection methods included?		
	Information on confusion with other species included?		
	More than one method of ID included?		
	If not, is that OK?		
	Are there procedures which need verification?		

Section	Query	Y, N or N/A	Comments
Contacts	Expert details included with sufficient detail? (who and where)		
Acknowledgements	Adequate?		
References	Included?		
	Consistent and correct style?		
General comments	Any sections not mentioned above should be removed?		
	Any sections not mentioned above should be included?		
	Any recommendations to the reviewers?		

Recommendations (delete those not applicable)

1. Editing required then review
2. Need more work before review
3. Need verification and peer review
4. Need only peer review

Evaluated by:

Name:.....Signature.....

Name:.....Signature.....

Name:.....Signature.....

Name:.....Signature.....

Date: / /

6. APPENDIX 4: ASSESSMENT CHECKLISTS

6.1 New NDP

Date		
Title of Diagnostic Protocol		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

a	Does a NDP/IPPC already exist?	yes	no
b	Does the protocol follow the SPHD RS No. 2 guidelines?	yes	no
c	Has a verification report been provided by an approved Independent Laboratory?	yes	no
d	Was the report of sufficient quality and follow SPHD RS No. 4 guidelines?	yes	no
e	Were all relevant methods in the protocol included in the verification?	yes	no
f	Were the protocol(s) reproducible?	yes	no
g	Has a peer review report on the appropriate sections been provided by an approved Plant Health Expert?	yes	no
h	Were the relevant sections approved?	yes	no
I	Has the final edited document been accepted by reviewers and authors	yes	no

Assessment Panel Evaluation

a	Accept for endorsement	yes	no
b	Clarification by Expert Panel / Peer Reviewer / Verification Laboratory required	yes	no
c	Author to revise and resubmit – additional assessment only required	yes	no
d	Author to revise and resubmit - Peer Review and Verification required	yes	no

Appendix 6.1 New NDP (Continued)

Assessment Panel Recommendations

Initials:
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6.2 International Protocol

Date	
Title	
Author/Applicant	
Members of Assessment Panel	Name: Signature Name: Signature Name: Signature Name: Signature Name: Signature Name: Signature

a	Does a diagnostic protocol already exist?	yes	no
b	Is the protocol an approved international diagnostic protocol?	yes	no
c	Are accepted taxonomic references or keys given in the diagnostic protocol?	yes	no
d	Are critical characteristics of the plant pest adequately described in the diagnostic protocol?	yes	no
e	Are symptom descriptions/images available in the diagnostic protocol?	yes	no
f	Are any reagents required readily available in Australia?	yes	no
g	If no, are equivalent reagents available?	yes	no
h	Are reference specimens or controls readily available (DNA, invertebrates or herbaria)?	yes	no
i	If not in the protocol, are the diagnostic characteristics illustrated on a network database (e.g. PaDIL)?	yes	no
j	Does the diagnostic protocol provide a list of laboratories and Experts capable of performing the techniques in the international protocol?	yes	no
k	Does the diagnostic protocol include a list of international experts able to verify results?	yes	no
l	Has the protocol been reviewed and approved by an Expert Panel?	yes	no

Assessment Panel Evaluation

a	Accept	yes	no
b	Clarification by Expert Panel required	yes	no
c	Supplementary assessment required before resubmission	yes	no
d	Rejection	yes	no

Appendix 6.2 International Protocol (Continued)

Assessment Panel Recommendations

Initials:
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6.3 Emergency Diagnostic Protocols

Date		
Title of Diagnostic Protocol		
Author/Applicant		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

a	Does a NDP/IPPC already exist?	yes	no
b	Does a provisional diagnostic protocol already exist?	yes	no
c	Is the EDP an international diagnostic protocol?	yes	no
d	Does it follow the SPHD RS No. 2 guidelines?	yes	no
e	Does the EDP adequately meet the accuracy, precision, specificity and detection limit requirements for diagnosing the EDP?	yes	no
f	Has the EDP been verified by an Independent Laboratory?	yes	no
g	Has the EDP been reviewed and approved by the Expert Panel?	yes	no
i	Are critical characteristics of the plant pest adequately described in the EDP?	yes	no
j	Are accepted taxonomic references or keys given in the EDP?	yes	no
k	Are symptom descriptions/images available in the EDP?	yes	no

Assessment Panel Evaluation

a	Accept	yes	no
b	Author to revise and resubmit	yes	no
c	Clarification by Expert Panel / Verification Laboratory required	yes	no
d	Reject	yes	no

Appendix 6.3 Emergency Diagnostic Protocol (Continued)

Assessment Panel Recommendations

Initials:
……

6.4 Adding a procedure to an existing NDP

Date		
Title of Diagnostic Protocol		
Author / Applicant		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

a	Does a NDP already exist?	yes	no
b	Does the new method/technique follow the SPHD RS No. 2 guidelines?	yes	no
c	Does the new method/technique improve the diagnosis?	yes	no
d	Has a verification report been provided by an approved Independent Laboratory?	yes	no
e	Was the report of sufficient quality and follow SPHD RS No. 4 guidelines?	yes	no
f	Were all relevant methods in the protocol included in the verification?	yes	no
g	Were the protocol(s) reproducible?	yes	no

Assessment Panel Evaluation

a	Accept	yes	no
b	Author to revise and resubmit	yes	no
c	Clarification by Expert Panel / Verification Laboratory required	yes	no
d	Reassess after verification	yes	no
e	Reject	yes	no

Appendix 6.4 Adding a procedure to an existing NDP (Continued)

Assessment Panel Recommendations

Initials:
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7. APPENDIX 5: Example of email requesting endorsement to CPHM via SPHD rep

Attached is a protocol for xxxxxxxxxxxxxxxxxxxxxxxxxxx which has been assessed as suitable for endorsement by a SPHD assessment panel.

It has undergone the process of development and approval outlined in SPHD reference standard RS No 3. This includes:

- Peer review by a scientist approved by SPHD as a suitable reviewer
- Verification of the procedures in the protocol (unless otherwise indicated) undertaken in a laboratory approved by SPHD
- Editing of the protocol as suggested by peer reviewer and verification laboratory
- Approval of the final protocol by author and reviewers
- Approval of the protocol by SPHD

SPHD requests that you respond via email to indicate that:

- you agree that the protocol is suitable for the purpose
- you agree to use the endorsed NDP as the preferred method to taxonomically identify the pest in case of an incursion

If no response is received by xxxxxxx your approval is taken by default.

If you have any concerns or queries please contact SPHD EO on sphd@agriculture.gov.au