

Subcommittee on Plant Health Diagnostics

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

Guidelines for the Development, Approval and Endorsement Processes of National Diagnostic Protocols

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1. INTRODUCTION

1.1 Scope

The *Guidelines for the Development, Approval, and Endorsement Processes of National Diagnostic Protocols* (SPHD RS No. 3) is a SPHD Reference Standard providing guidelines for DPWG on the development and approval of diagnostic procedures/protocols (refer to SPHD RS No. 1 for definitions). The Reference Standard has been developed to standardise and incorporate relevant information in diagnostic protocols for the identification of emergency plant pests in Australia.

The workflow for protocol development and assessment is provided in Appendix 1 & 2.

1.2 Purpose

The purpose of this Reference Standard is to provide guidelines to DPWG for the development, approval and endorsement processes that diagnostic protocols undergo to be regarded as National Diagnostic Protocols (NDPs). Once developed, the diagnostic protocol will be evaluated and approved by DPWG, using the forms and guidelines laid out in SPHD RS No. 3. Following DPWG approval and subsequent endorsement by SPHD, the document will be recognised as an 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 DPWG review and approval, followed by endorsement of SPHD members.

1.4 Reference Standards

All SPHD Reference Standards can be found on the NPBDN website (<https://www.plantbiosecuritydiagnostics.net.au/>). Click on the “Resources” tab, and then on the “[National Diagnostic Protocols](#)”.

1.5 References

- IPPC. 2021. ISPM No. 6 *Surveillance*. Food and Agriculture Organisation for the United Nations, Rome.
- IPPC. 2021. ISPM No. 13 *Guidelines for the Notification of Non-compliance and Emergency Action*. Food and Agriculture Organisation for the United Nations, Rome.
- IPPC. 2021. 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. 2024. ISPM No. 5 Glossary of Phytosanitary Terms. FAO, Rome.

2. SPHD PROCEDURES FOR THE DEVELOPMENT, APPROVAL AND ENDORSEMENT 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 2024).

2.2 Annual Work Programme

SPHD annually identifies priorities for the development of diagnostic protocols, this includes the NDP Project Plan developed by PHA in consultation with the DAFF, DPWG and SPHD. Guidance from PHA and any other requests for reviews and amendments to a diagnostic protocol that have been received by SPHD members should be taken into account when submitting a work program to the NDP Coordinator.

2.3 Nominations of Experts

The NDP Coordinator calls for nominations of SMEs for development or review of a diagnostic protocol.

The list of nominated SMEs is submitted to DPWG for selection.

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

2.4 Development, Approval and Endorsement of National Diagnostic Protocols

This process is used where an NDP, or IPPC Protocol published under ISPM 27, does not exist or is not fit for purpose.

The NDP Coordinator 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 an NDP 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); additional instructions may be given, if needed.

The draft protocol is submitted to DPWG for approval via the NDP Coordinator, and to SPHD for endorsement.

An Assessment Panel, consisting of DPWG members or their delegates, 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 DPWG with comments for further work required before resubmission.

All protocols will be peer reviewed by a SME approved by DPWG (in accordance with SPHD RS No. 4).

The Assessment Panel will determine during the evaluation whether there are procedures in the protocol that need verification. If required, verification of the diagnostic protocol is undertaken by an Independent Laboratory approved by DPWG (in accordance with SPHD RS No. 4).

The diagnostic protocol and the associated reports are assessed by the Assessment Panel following the procedures outlined in Appendix 4 – 6.1 via the NDP Coordinator.

- 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 DPWG nominated SME 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 endorse the Diagnostic Protocol as an NDP. The NDP Coordinator should include the reviewer(s) and verifying laboratory in the acknowledgements and version information on the front page. The diagnostic protocol will be submitted to SPHD for endorsement as an NDP in accordance with 2.5.

The endorsed diagnostic protocol is published on the SPHD website (<https://www.plantbiosecuritydiagnostics.net.au/resources/>).

2.4.2 International protocols

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

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

The protocol should be submitted to the NDP Coordinator together with 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 DPWG (Appendix 4). The Assessment Panel recommends that SPHD accept the diagnostic protocol as a Provisional NDP, if appropriate.

For subsequent endorsement as an NDP, the Provisional NDP must be 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 considered unsuitable by SME in Australia; or
- An NDP exists but an alternative protocol has since been developed which is considered more appropriate for diagnosing an emergency plant pest.

An interested party (author/applicant) may submit the new diagnostic protocol developed in an emergency response to the NDP Coordinator for DPWG approval and SPHD endorsement. 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 DPWG 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 SME approved by DPWG.

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 or rejected for the emergency response event.

EDPs should be reviewed by SME's post-response.

At the conclusion of the emergency response event, for subsequent endorsement as an NDP the EDP 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

An 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 an NDP is amended with a new method/procedure, a verification report from an Independent Laboratory must be provided to the NDP Coordinator 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 DPWG, or can be organised by DPWG.

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 endorses 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 via the NDP coordinator with a recommendation by the Assessment Panel that it is suitable for approval as an NDP.

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 SME to assist with the process.

If updates are required, the Assessment Panel engages an Independent 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.

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

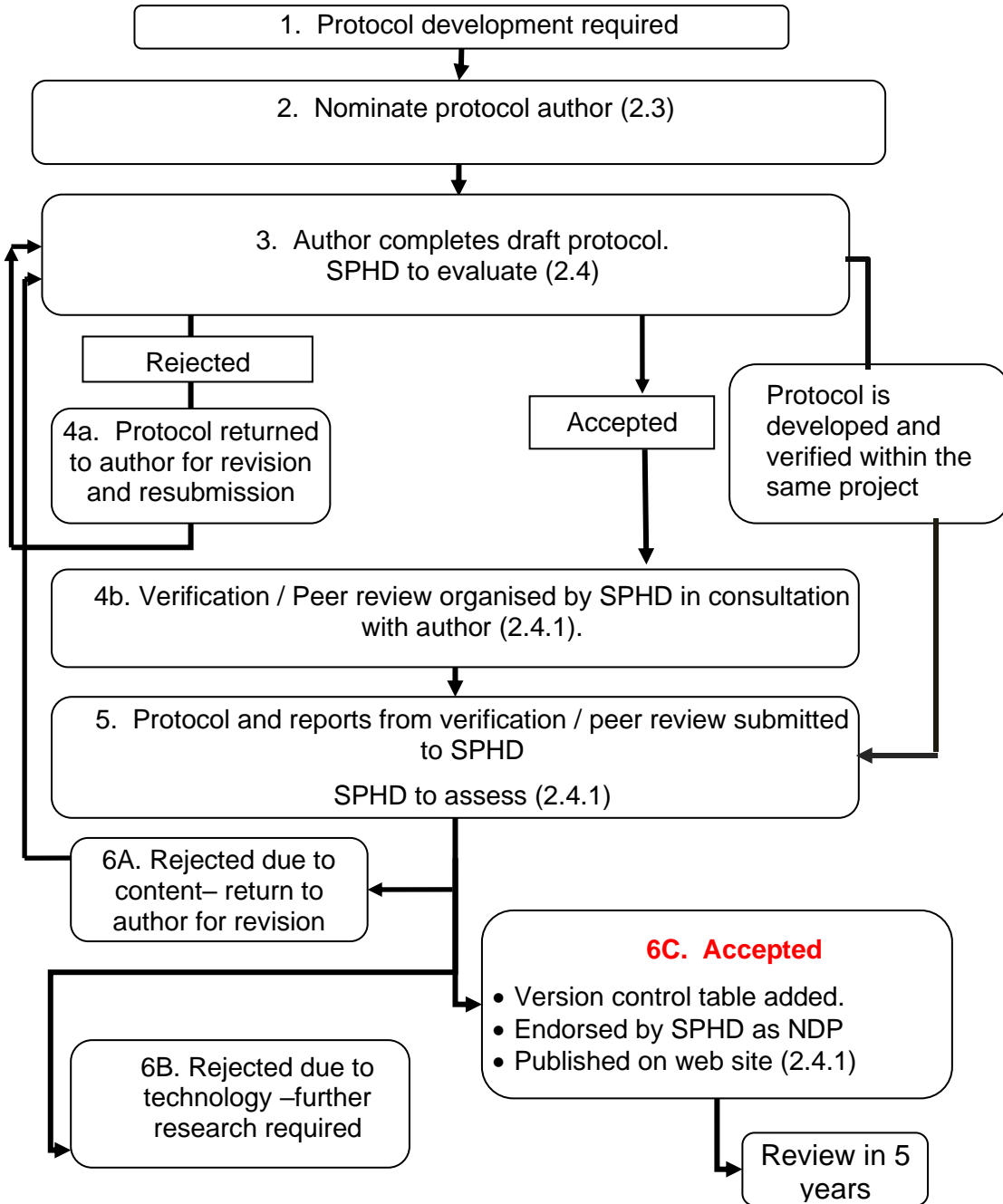
Note: once a pest is established within Australia, the NDP will remain on the [National Plant Biosecurity Diagnostic Network \(NPBDN\) \(plantbiosecuritydiagnostics.net.au\)](https://plantbiosecuritydiagnostics.net.au) with a note on the front page explaining that the pest is established in Australia and that the protocol will no longer be subject to update or review.

2.7 Non-NDP diagnostic resources

Validated non-NDP diagnostic resources will be included on [National Plant Biosecurity Diagnostic Network \(NPBDN\) \(plantbiosecuritydiagnostics.net.au\)](https://plantbiosecuritydiagnostics.net.au) with the additional explanation.

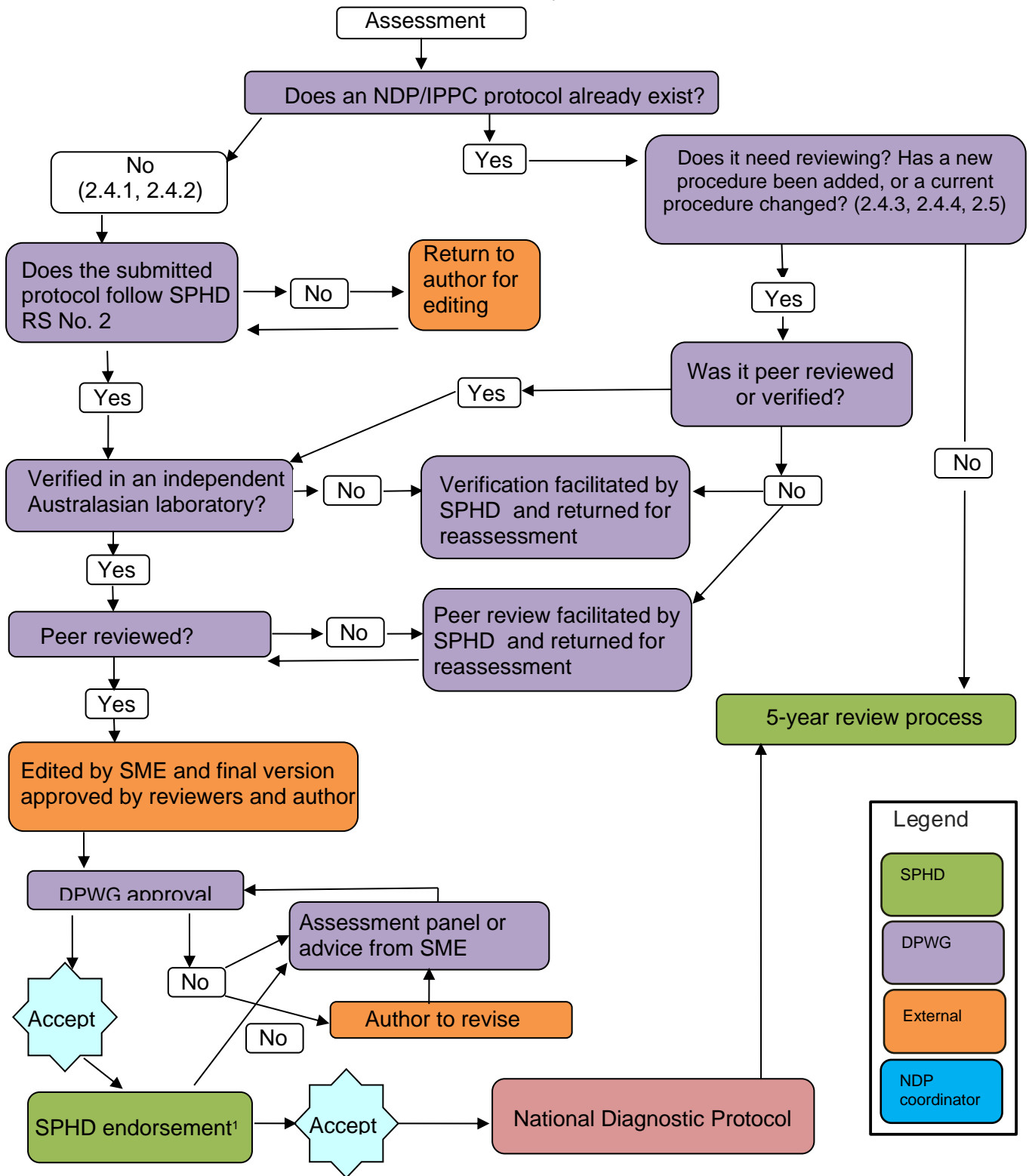
“The following non-NDP diagnostic resources have been developed but may not have been verified or validated to the level of endorsement required for an NDP, but are included as they can be used for detection and/or identification of priority pests where an NDP does not exist or can be used for priority and established pests. The diagnostic resources may also include protocols that support plant health certification for domestic market access and industry distribution of plant materials. Protocols may also include those used for detection and identification of established pests or for detection of exotic pests that are screened during Post entry quarantine.”

APPENDIX 1. PROTOCOL DEVELOPMENT FLOWCHART



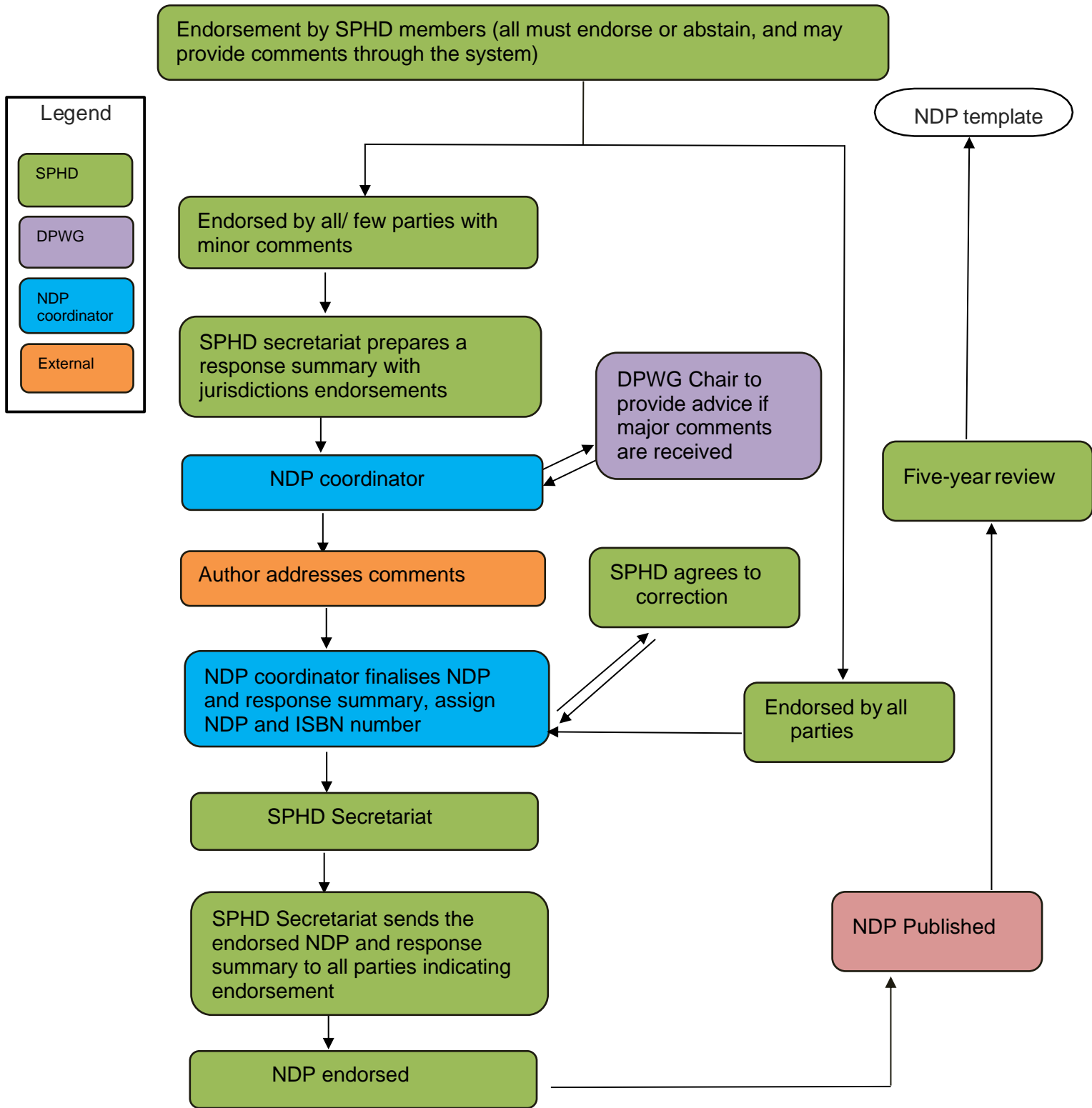
APPENDIX 2. PROTOCOL ASSESSMENT FLOWCHART.

Section 1 Protocol assessment overview as facilitated by the NDP Coordinator



¹See appendix 2 section 2 for the detailed SPHD endorsement workflow

Section 2 Detailed SPHD endorsement process



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?		
	Are the tables and figures in the main text in sequential order?		
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? Where triage is needed, what are symptoms associated with biotic and abiotic causes?		
	More than one method of ID included?		

Section	Query	Y, N or N/A	Comments
	If not, is that OK?		
	Are there procedures which need verification?		
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)

Evaluated by:

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

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

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

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

4. Need only peer review

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

Date: / /

APPENDIX 4: ASSESSMENT CHECKLISTS

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 an 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 Subject Matter 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 4 section 1 New NDP (Continued)

Assessment Panel Recommendations

Initials:

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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 4 section 2 International Protocol (Continued)

Assessment Panel Recommendations

Initials:

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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 an 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
	Is there an alternative NDPDN resource that can be used?	yes	no
d	Does it follow the SPHD RS No. 2 guidelines?	yes	no
e	Does the EDP adequately/reasonably meet the accuracy, precision, specificity and detection limit requirements for diagnosing the EDP?	yes	no
f	Are critical characteristics of the plant pest adequately described in the EDP?	yes	no
g	Are accepted taxonomic references or keys given in the EDP?	yes	no
h	Are symptom descriptions/images available in the EDP?	yes	no
k	Should it be developed into an NDP following the outbreak?	yes	no

4. Adding a procedure to an existing NDP

Date													
Title of Diagnostic Protocol													
Author / Applicant													
Members of Assessment Panel	<table> <tr> <td>Name:</td> <td>Signature</td> </tr> <tr> <td>Name:</td> <td>Signature</td> </tr> <tr> <td>Name:</td> <td>Signature</td> </tr> <tr> <td>Name:</td> <td>Signature</td> </tr> <tr> <td>Name:</td> <td>Signature</td> </tr> <tr> <td>Name:</td> <td>Signature</td> </tr> </table>	Name:	Signature	Name:	Signature	Name:	Signature	Name:	Signature	Name:	Signature	Name:	Signature
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a	Does an 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 4 section 4 Adding a procedure to an existing NDP (Continued)

Assessment Panel Recommendations

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Initials:

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