

# Subcommittee on Plant Health Diagnostic Standards

## SPHDS Reference Standard No.3 (SPHDS RS No. 3)

### *Guidelines to the Approval Process of National Diagnostic Protocols*

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## INTRODUCTION

### Scope

The Subcommittee on Plant Health Diagnostic Standards (SPHDS) document *Guidelines to the Approval Process of National Diagnostic Protocols* (SPHDS RS No. 3) is a SPHDS Reference Standard providing guidelines on the approval process of diagnostic protocols (refer to SPHDS RS No. 1 for definitions) that should be developed and written in accordance with the SPHDS RS No. 2. In this document the term “diagnostic protocol” will infer reference to either a diagnostic procedure or a diagnostic protocol. The Reference Standard has been developed to standardise and incorporate relevant information in a process of verifying and reviewing diagnostic protocols for the identification of emergency plant pests in Australia.

### Purpose

The purpose of this Reference Standard is to provide guidelines to independent plant health professionals and/or Independent Laboratories for the approval process that diagnostic protocols undergo in order to be regarded as National Diagnostic Protocols (NDP). Once developed, the diagnostic protocol will be submitted to SPHDS for approval, using the forms and guidelines laid out in this Reference Standard, and Plant Health Committee endorsement, and when approved and endorsed, the document will be recognised as a NDP.

### Review

The SPHDS RS No. 3 will be reviewed every three years. The review will be implemented by the Diagnostic Standards Working Group (in consultation with the Subcommittee) for expert input. Changes to the Standard are subject to the approval of SPHDS members for adoption, and endorsement by the Plant Health Committee.

### Reference Standards

All of the SPHDS Reference Standards can be found on the SPHDS website [www.daff.gov.au/sphds](http://www.daff.gov.au/sphds)

### References

## APPROVAL PROCESS FOR NATIONAL DIAGNOSTIC PROTOCOLS

There are four scenarios:

### SCENARIO 1 *Approval of a newly developed Protocol as a National Diagnostic Protocol*

**Situation:** An NDP does not exist. A new diagnostic protocol is developed. The protocol has not been approved by SPHDS. The new diagnostic protocol is referred to as the *Diagnostic Protocol* when submitted for approval.

An interested party (Author/Applicant) may submit a new diagnostic protocol for SPHDS approval. *Diagnostic Protocols* that are submitted are subject to an assessment by the Assessment Panel (refer to *SPHDS RS No. 1: Glossary of Terms*). The *Diagnostic Protocol* will follow the *SPHDS RS No. 2: Development of Diagnostic Protocols - Technical Procedures*.

In all cases, a Verification Report from an Independent Laboratory and a Peer Review report from a Plant Health Expert must also be submitted, preferably at the same time, as per the *SPHDS Reference Standard No. 4: Guidelines for Verification and Peer Review Reports*. These reports can be organised by the author/applicant after approval by SPHDS, or can be organised by SPHDS.

**Objective:** To assess the *Diagnostic Protocol* for recommendation to be endorsed as a NDP.

**Result:** The *Diagnostic Protocol* is accepted if shown by the Verification Report to be reproducible and the Peer Review report confirms the information included is accurate and current. The Assessment Panel makes the recommendation that SPHDS approve the *Diagnostic Protocol* as a NDP. The Plant Health Committee (PHC) will then be approached to endorse and recognise the *Diagnostic Protocol* as a NDP.

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.

**Record Document:** *Form 1: Diagnostic Protocol Assessment - Scenario 1*

**SCENARIO 2** *Approval of a draft or approved IPPC or other international diagnostic protocol as a Provisional National Diagnostic Protocol until validated in Australia*

**Situation:** A NDP does not exist, but a draft or approved IPPC or other international diagnostic protocol (e.g. EPPO, QUADS) is available. The protocol has not been approved by SPHDS. The draft or approved IPPC or international diagnostic protocol is referred to as the *Diagnostic Protocol*.

An interested party (Author/Applicant) may submit a new diagnostic protocol for SPHDS approval. *Diagnostic Protocols* that are submitted are subject to review by the Assessment Panel, with assistance from an Expert Panel if required. The *Diagnostic Protocol* will follow the *SPHDS RS No. 2: Development of Diagnostic Protocols - Technical Procedures*.

**Objective:** To adopt a draft or approved international diagnostic protocol as a *Provisional National Diagnostic Protocol* until such time that it is validated in Australia.

**Result:** The *Diagnostic Protocol* is accepted if there is reasonable evidence that the protocol has the capability to diagnose the named categorised plant pest, in terms of reliability, reproducibility and performance, in Australia. This evidence may include a Verification Report and Peer Review report if deemed appropriate by the Assessment Panel. The Assessment Panel makes the recommendation that SPHDS approve the *Diagnostic Protocol* as a Provisional National Diagnostic Protocol until it is validated in Australia. When validated, the Provisional National Diagnostic Protocol will be resubmitted to SPHDS under Scenario 1. PHC will then be approached to endorse and recognise the *Diagnostic Protocol* as a NDP.

**Record Document:** *Form 2: Diagnostic Protocol Assessment - Scenario 2*

**SCENARIO 3** *Approval of an Emergency National Diagnostic Protocol for a plant pest) during an emergency response*

**Situation:** In the absence of a NDP:

- (a) An international diagnostic protocol (draft or approved) does not exist.

A new diagnostic protocol (equivalent to working diagnostic protocol) is developed in Australia for an emergency plant pest in an emergency response event. The diagnostic protocol has not been approved by SPHDS.

An interested party (Author/Applicant) may submit the new diagnostic protocol for SPHDS approval. The new protocol is referred to as the *Emergency Diagnostic Protocol*.

- (b) An international diagnostic protocol (draft or approved) does exist, but a Plant Health Expert/s does not consider it appropriate for diagnosing an emergency plant pest in Australia in an emergency response event.

A new diagnostic protocol is developed in an Australian laboratory and is considered more appropriate for diagnosing an emergency pest than an international diagnostic protocol in an emergency response event. The protocol has not been approved by SPHDS.

An interested party (Author/Applicant) may submit the new diagnostic protocol developed in an emergency response for SPHDS approval. The new protocol is referred to as the *Emergency Diagnostic Protocol*. *Emergency Diagnostic Protocols* will only be considered if shown to perform equal to or better than the IPPC or other international diagnostic protocol.

- (c) An international diagnostic protocol (draft or approved) does exist, and a Plant Health Expert/s considers it appropriate for diagnosing an emergency plant pest in Australia in an emergency response event. The protocol has not been approved by SPHDS.

An interested party (Author/Applicant) may submit the international diagnostic protocol for SPHDS approval. The new protocol is referred to as the *Emergency Diagnostic Protocol*.

*Emergency Diagnostic Protocols* that are submitted are subject to technical review by an Expert Panel approved by SPHDS.

When an *Emergency Diagnostic Protocol* is submitted to SPHDS for approval, the Author/Applicant must provide validation data (accuracy, precision, specificity, detection limits) and/or peer reviewed published documents. The *Emergency Diagnostic Protocol* will follow the *SPHDS RS No. 2 Development of Diagnostic Protocols - Technical Procedures*, if appropriate in an emergency response event.

**Objective:** To approve the *Emergency Diagnostic Protocol* for an emergency response event within 14 days or less.

**Result:** The *Emergency Diagnostic Protocol* is accepted if shown to diagnose the emergency plant pest in terms of reliability, reproducibility and performance or to perform equal to or better than the IPPC or other international diagnostic protocol. The Assessment Panel makes recommendations to SPHDS to approve the *Emergency Diagnostic Protocol* as an Emergency National Diagnostic Protocol for the emergency response event. SPHDS shall inform the Consultative Committee on Emergency Plant Pests (CCEPP) of its decision and the CCEPP will determine its endorsement in an emergency response event.

At the conclusion of the emergency response event, the Author/Applicant will re-submit the *Emergency Diagnostic Protocol* to SPHDS for approval under Scenario 1.

**Record Document:** *Form 3: Diagnostic Protocol Assessment - Scenario 3*

**SCENARIO 4** *Approval of a new method/technique for inclusion/replacement in an existing National Diagnostic Protocol*

**Situation:** A NDP exists. As a result of new developments in diagnostic procedures and/or techniques, the diagnostic procedure or elements of the diagnostic protocol should be amended 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, preferably at the same time, as per *SPHDS RS No. 4*. This report can be organised by the author/applicant after approval by SPHDS, or can be organised by SPHDS.

**Objective:** To approve a new procedure/technique for inclusion/replacement in an existing NDP.

**Result:** 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. The Assessment Panel makes recommendations that SPHDS approves the inclusion/replacement of the new procedure/technique into the NDP.

**Record Document:** *Form 1: Diagnostic Protocol Assessment - Scenario 4.*



## ASSESSMENT PROCESS

### SCENARIO 1 *Developing a National Diagnostic Protocol*

#### Mandatory Assessment:

The Assessment Panel confirms that:

- A nationally approved diagnostic protocol does not already exist for the named emergency plant pest;
- The diagnostic protocol is written in accordance with *SPHDS RS No. 2 Development of Diagnostic Protocols - Technical Procedures*;
- A verification report has been supplied by an Independent Laboratory previously approved by SPHDS;
- The author(s) of the verification report have sufficient technical expertise recognised by SPHDS;
- The verification report is in the appropriate format (SPHDS RS No. 4) and is of a quality found to be acceptable by the panel;
- The peer reviewer has appropriate scientific expertise recognised by SPHDS;
- The peer review report is in the appropriate format (SPHDS RS No. 4) and is of a quality found to be acceptable by the panel.

The Assessment Panel then:

- a. Accepts the Diagnostic protocol for approval by SPHDS, or
- b. Requests that the author(s)/applicant(s) revises the protocol and resubmit, or
- c. Requests further clarification from the verifying laboratory, peer reviewer and/or Expert Panel before the protocol is reconsidered for approval by SPHDS or
- d. Reassesses the Diagnostic protocol after Peer Review and verification completed.

**Form 1: Diagnostic Protocol Assessment - Scenario 1** ☐  
Newly Developed Protocol

Date			
Title of Diagnostic Protocol			
Author(s)			
Applicant(s)			
Recommended Reference Laboratory(s)			
Members of Assessment Panel	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	

**1. Mandatory Assessment**

a	Does a NDP already exist?	yes	no
b	Does the Protocol follow the SPHDS RS No. 2 guidelines?	yes	no
c	Has a verification report been provided by an approved Independent Laboratory?	yes	no
d	Were the author(s) of the verification report of appropriate technical competency?	yes	no
e	Was the report of sufficient quality and follow SPHDS 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
h	Has a peer review report on the appropriate sections been provided by an approved Plant Health Expert?	yes	no
i	Were the relevant sections approved?	yes	no

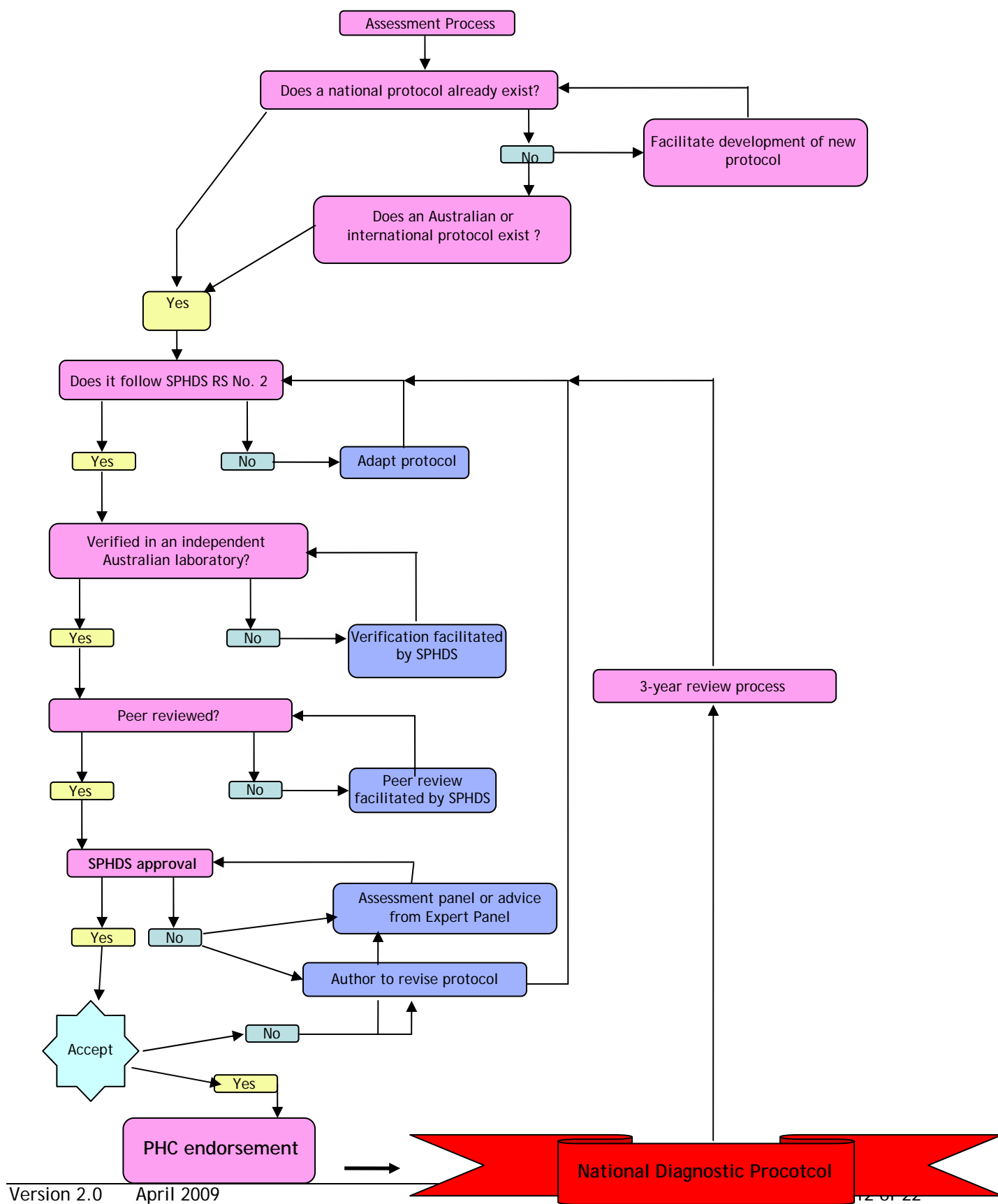
**Assessment Panel Evaluation**

a	Accept	yes	no
b	Author to revise and resubmit	yes	no
c	Clarification by Expert Panel / Peer Reviewer / Verification Laboratory required	yes	no
d	Reassess after peer review and verification	yes	no

Assessment Panel Recommendations	

Initials: .....

## Approval Process of National Diagnostic Protocols Flow Chart



**SCENARIO 2** *Approval of a draft or approved IPPC or other international diagnostic protocol as a Provisional National Diagnostic Protocol until validated in Australia*

**Mandatory Assessment:**

The Assessment Panel confirms that:

- A nationally approved diagnostic protocol does not already exist:
- That the protocol is a draft or approved IPPC or other international diagnostic protocol.
- That critical information is included:
  - a. Taxonomic keys or references
  - b. Characteristics of the plant pest
  - c. Symptoms descriptions or images
- An Expert Panel has reviewed and approved the international diagnostic protocol.
- That the supplementary assessment was accepted.

**Supplementary Assessment:**

The Assessment Panel confirms that:

- Reagents are available
- References specimens and/or controls are available
- Diagnostic characteristics available in protocol or alternative source
- Laboratories and Experts capable of identifying or verifying identification are listed.

The Assessment Panel then:

- a. Accepts the Diagnostic protocol for approval by SPHDS, or
- b. Requests further clarification from the Expert Panel before the protocol is reconsidered for approval by SPHDS, or
- c. Requests that the author(s)/applicant(s) provide additional information and resubmit, or
- d. Rejects the application as not suitable.

**Form 2A: Diagnostic Protocol Assessment - Scenario 2**

Draft or approved IPPC or other international diagnostic protocol

Date		
Title of Diagnostic Protocol		
Author(s)		
Applicant(s)		
Recommended Reference Laboratory(s)		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

**1. Mandatory Assessment**

a	Does a Diagnostic Protocol already exist?	yes	no
b	Is the Protocol a draft or approved IPPC or other 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	Has the Protocol been reviewed and approved by an Expert Panel?	yes	no
g	Have the criteria in the Supplementary Assessment been met?	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

**Form 2B: Supplementary Diagnostic Protocol Assessment**  
 Scenario 2 - Draft or approved IPPC or other international diagnostic protocol

Date		
Title of Diagnostic Protocol		
Author(s)		
Applicant(s)		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

## 2. Supplementary Assessment

Undertaken in consultation with the Expert panel.

a	Are the reagents readily available in Australia?	yes	no
b	If no, are equivalent reagents available?	yes	no
c	Are reference specimens or controls readily available (DNA, invertebrates or herbaria)?	yes	no
d	If not in the protocol, are the diagnostic characteristics illustrated on a network database (e.g. PaDIL)?	yes	no
e	Does the Diagnostic Protocol provide a list of laboratories and Experts capable of performing the techniques in the international protocol?	yes	no
f	Does the Diagnostic Protocol include a list of international Experts able to verify results?	yes	no

### Assessment Panel Evaluation of Supplementary assessment

a	Accept	yes	no
b	Request further information before resubmission	yes	no

Assessment Panel Recommendations	

Initials: .....



**SCENARIO 3** *Approval of an Emergency National Diagnostic Protocol for a plant pest during an emergency response*

**Mandatory Assessment:**

The Assessment Panel confirms that:

- An Approved NDP or a Provisional National Diagnostic Protocol does not already exist;
- The Emergency Diagnostic Protocol (EDP) is written in accordance with *SPHDS RS No. 2 Development of Diagnostic Protocols - Technical Procedures*;
- The EDP is shown to diagnose the emergency plant pest in terms of reliability, reproducibility and performance or to perform equal to or better than any other international diagnostic protocol;
- A verification report has been supplied by an Independent Laboratory approved by SPHDS;
- The author(s) of the verification report have sufficient technical expertise recognised by SPHDS;

The Assessment Panel then:

- a. Accepts the Emergency Diagnostic Protocol for approval by SPHDS, or
- b. Requests that the author(s)/applicant(s) revises the protocol and resubmit, or
- c. Requests further clarification from the verifying laboratory and/or Expert Panel before the Emergency Protocol is reconsidered for approval by SPHDS, or
- d. Rejects the application.

**Form 3: Diagnostic Protocol Assessment - Scenario 3**  
Approval for an EDP during an emergency pest response

Date		
Title of Diagnostic Protocol		
Author/Applicant		
Recommended Reference Laboratory(s)		
Members of Assessment Panel	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature
	Name:	Signature

**1. Mandatory Assessment**

a	Does an NDP already exist?	yes	no
b	Does an Provisional Diagnostic Protocol already exist?	yes	no
c	Is the EDP an approved or draft IPPC or other international diagnostic protocol?	yes	no
d	Does it follow the SPHDS 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 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

Assessment Panel Recommendations	

Initials: .....

**SCENARIO 4** *Approval of a new method/technique for inclusion/replacement in an existing National Diagnostic Protocol*

**Mandatory Assessment:**

1. Assessment Panel confirms that:

- An Approved NDP exists for the named emergency plant pest;
- The new method/technique for inclusion/replacement is written in accordance with *SPHDS RS No. 2 Development of Diagnostic Protocols – Technical Procedures*;
- The new method/technique for inclusion/replacement has been shown to be to improve the diagnosis of the named categorised plant pest in terms of reliability, reproducibility, performance and test costs.
- The new method/technique for inclusion/replacement has been verified by an Independent Laboratory previously approved by SPHDS;
- The author(s) of the verification report have sufficient technical expertise recognised by SPHDS;
- The verification report is in the appropriate format (SPHDS RS No. 4) and is of a quality found to be acceptable by the assessment panel;

2. The Assessment Panel then:

- a. Accepts the new method/technique for approval by SPHDS, or
- b. Requests that the author(s)/applicant(s) revises the new method/technique and resubmit, or
- c. Requests further clarification from the verifying Laboratory and/or an Expert Panel before the new method/technique is reconsidered for approval by SPHDS, or
- d. Rejects the application.

3. On approval, the NDP is amended by SPHDS and submitted to PHC for approval.

- With the original author/applicants approval, the new method/technique is incorporated into the NDP in the appropriate section.
- Alternatively the new method/technique may be included as an appendix.

**Form 4: Diagnostic Protocol Assessment - Scenario 4** ☐  
 New method/technique for inclusion/replacement in existing NDP

Date			
Title of Diagnostic Protocol			
Author(s)			
Applicant(s)			
Recommended Reference Laboratory(s)			
Members of Assessment Panel	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	
	Name:	Signature	

**2. Mandatory Assessment**

a	Does a NDP already exist?	yes	no
b	Does the new method/technique follow the SPHDS 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	Were the author(s) of the verification report of appropriate technical competency?	yes	no
f	Was the report of sufficient quality and follow SPHDS RS No. 4 guidelines?	yes	no
g	Were all relevant methods in the protocol included in the verification?	yes	no
h	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

***Form 4: Diagnostic Protocol Assessment - Scenario 4 (continued)***

Assessment Panel Recommendations

Initials: .....