

# Subcommittee on Plant Health Diagnostic Standards

## SPHDS Reference Standard No. 4 (SPHDS RS No. 4)

### *Guidelines for Peer Review and Verification Reports*

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## INTRODUCTION

### Scope

The Subcommittee on Plant Health Diagnostic Standards (SPHDS) document *Guidelines for Verification and Peer Review Reports* (SPHDS RS No. 4) is a SPHDS Reference Standard providing guidelines on the verification process of diagnostic procedures/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 plant pests.

### Purpose

The purpose of this Reference Standard is to provide guidelines and instructions to an Independent Expert and/or Independent Laboratory for conducting a verification process on relevant diagnostic procedures specified by SPHDS, and undertaking a peer review of the scientific information provided in the introduction and taxonomic sections on the diagnostic protocol. Once developed, the diagnostic protocol will be submitted to SPHDS for approval and Plant Health Committee endorsement, and when approved and endorsed, the document will be recognised as a National Diagnostic Protocol.

### Review

The SPHDS RS No.4 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 SPDHS 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

IPPC. 2006. ISPM No. 27 *Diagnostic Protocols for Regulated Pests*. Food and Agriculture Organisation for the United Nations, Rome.

## PART A

# SPHDS PROCESS FOR PEER REVIEW AND VERIFICATION OF DIAGNOSTIC PROTOCOLS/PROCEDURES BY AN INDEPENDENT LABORATORY AND EXPERT

## Introduction

This refers to the verification and review process of a diagnostic protocol that has been prepared in accordance with SPHDS RS No. 2, Parts A & B, and is submitted to SPHDS for approval to be recognised as a NDP.

Each protocol submitted to SPHDS for approval should contain the methods and guidance necessary for the named pest(s) to be detected and positively identified as described in SPHDS RS No. 2, Part B.

## Peer Review

### 1. Definition

Peer Review is a process by which a Plant Health Expert and/or Expert approved by SPHDS, reviews the currency and accuracy of the Procedures/Protocols.

### 2. General considerations

The original author of the protocol may recommend the Expert to Peer Review the protocol to be approved by SPHDS.

### 3. The Process

Peer review of the Diagnostic Protocol must be undertaken by an Plant Health Expert and/or Expert approved by SPHDS according to the following requirements:

- Peer review. The Expert shall review the relevant sections of the protocol requested by SPHDS for currency and accuracy of detail, including the introduction, taxonomic information (sections 4.2 and 4.3 from SPHDS RS No.2), citations, applicability of the procedures and any other information specified by SPHDS. The Expert is also required to determine that all text and images are appropriately and correctly acknowledged.
- The Expert shall prepare a brief written report of the Peer Review process including a completed peer review checklist at Part B.

Report. Contents must include where relevant, but not be limited to:

- The Procedure/Protocol being reviewed, author and date.
- Is the information provided accurate and current?
- Recommendations for improvements if required.

Peer review checklist. Reporting should include the completion of the peer review checklist at PartB.

## Verification

### 1. Definitions

Verification is a process by which an Independent Laboratory demonstrates that the diagnostic procedures can be followed and gives reproducible results and if necessary, identifies critical improvements in the methods described.

Independent Laboratory. The Independent Laboratory can be public, private, or part of the Author's/Applicant's organization as long as the personnel used to conduct the verification undertake the procedure/protocol independently of the author and do not use the same equipment (if possible) or supplies. The laboratory should be one where the type of assay in question is done on a routine basis.

### 2. General considerations

Relevant diagnostic procedure(s) described in the protocols need to be verified by an Independent Laboratory in order to prove reproducibility of the procedure(s).

The purpose of the Independent Laboratory is to verify the reproducibility of procedures within the protocol specified by SPHDS but not to duplicate all the data generated by the original author(s).

Where appropriate, sample/s should be provided to the verification laboratory by the Author/Applicant and should preferably be tested simultaneously by both the Author/Applicant and the verification laboratories.

The original author of the protocol may recommend an Independent Laboratory for approval by SPHDS to undertake the verification.

### 3. The process

- 3.1 SPHDS will specify which procedures within the protocol require verification.
- 3.2 The Author(s) must prepare any necessary samples and send them together with the protocol to the Independent Laboratory under the appropriate approvals.
- 3.3 The Independent Laboratory shall conduct the diagnostic procedure(s) step-by-step according to the protocol submitted in the application addressing the following issues:
  - 3.3.1 Clarity and completeness of the documented diagnostic procedure(s); and
  - 3.3.2 Reproducibility of the diagnostic procedure(s).
- 3.4 The Independent Laboratory submits a verification report including verification checklist to SPHDS.

Report. The Independent Laboratory shall prepare a succinct written report of the verification process and forward to the Executive Officer of SPHDS. Contents must include where relevant, but not be limited to:

- Title page - included protocol being verified, author and date.
- Methodology.
  - What procedures are being verified?
  - If procedures cannot be verified an explanation should be provided.
  - What samples were used.
- Results.
  - Were the methods comprehensive and clear?
  - Were the methods reproducible (show data)?

- Where used, are data from International sequence databases (eg GenBank) derived from appropriately validated specimens?
- Recommendations for improvements.
- References if required.

Completed verification checklist. The Independent Laboratory shall complete the verification checklist at Part C.

- 3.5 The Assessment panel of SPHDS accepts the Verification Report or invites the authors to resubmit after revision.

## PART B

# **Peer review report checklist**

Protocol:

Date of review:

### **Notes**

Please answer the questions listed below to complete the table. **Yes** or **No** answers are sufficient for most questions. However, for some questions, we also ask that you fill out the “comments” column. The “Issues to be considered” column is intended as a guide to consider when recording comments and to assist in identifying possible improvements.

Please summarise your review of the protocol in a separate letter or report. General comments may be made at the end of this document or in your report. If there is some problem with the protocol that is not addressed in the questions provided, please note the problem at the end of the document or in the report. Suggested changes should be made as track changes to the protocol. Alternatively they can be presented as comments in this document or in the report.

For more information on the requirements of a protocol and the peer review and verification process please refer to SPHDS RS 2 Technical Procedures V3.0 (Section Part B) and SPHDS RS 4 Verification and Peer Review V1.0 (relevant sections included).

### **1. Overall quality**

Question		Issues to be considered	Y/N	Comments
1.1	<b>Will the protocol allow a taxonomically accurate identification of the organism?</b> <i>You may wish to answer this question in conjunction with the specific questions on identification listed below.</i>	If not, then please note the elements of the protocol that could hinder taxonomic identification. Please note how an ambiguity could arise.		
1.2	<b>Is the entire document concise?</b>	Please briefly identify sentences, paragraphs or sections that are unnecessary for detection or identification or that could be shorter.		



Question		Issues to be considered	Y/N	Comments
1.3	Is every section of the document clear?	Please briefly note any section that may be confusing. Identify inconsistencies and contradictions.		
1.4	Does the document include information about the presence or distribution of the pest in Australia? <i>No such information should be included.</i>	If so, please identify the section where this information is given.		

## 2. Introduction

Question		Issues to be considered	Y/N	Comments
2.1	Are the pest species causing the damage or disease clearly described and referenced?			
2.2	Is the information directly relevant to diagnostic identification and also accurate and up to date?	Please identify any sentences or paragraphs unnecessary for identification of the species or that could be replaced by an appropriate reference.		
2.3	Does it contain information that would be better placed in another section of the protocol, such as information on detection, identification or taxonomy?	Please identify any such sentences or paragraphs and indicate where they should be placed.		
2.4	Is the introduction less than 400 words?			

Question		Issues to be considered	Y/N	Comments
2.5	Is the host range properly described, taking account of taxonomic revisions, and using primary reference sources?			
2.6	Is the host range listed necessary for diagnosis?			

### 3. Taxonomy

Question		Issues to be considered	Y/N	Comments
3.1	Has a complete taxonomic classification been provided and properly referenced with all recognised taxonomic levels and the correct authority?	If not, then please indicate what is missing.		
3.2	Is the taxonomy accurate and up to date and does it take into account the most recent revisions?	If not, please note the reference for the current accepted taxonomy.		
3.3	Is some taxonomic uncertainty indicated in the document?			

### 4. Detection

This covers the information needed to detect the pest in the host material. Different procedures are often used for detection and identification. However for some pests, particularly insects, there may be significant overlap between detection and identification. In the following questions please limit comments to those dealing with detection.

Question		Issues to be considered	Y/N	Comments
4.1	Does the protocol provide adequate information for detection of the organism?			
4.2	Is there information in this section that would be better placed in the identification section? <i>For some insects there may be significant overlap of the information.</i>	Is so, please identify the sentences, paragraphs or and sections and specify where they would be best placed.		
4.3	Are detection methods described in sufficient detail to be followed without referring to other literature?	If not, then please identify the methods or elements requiring more details.		
4.4	Are signs or symptoms associated with the pest adequately described?	If not, please indicate which signs or symptoms require further explanation		
4.5	Are the life stages that are likely to be encountered adequately described?	If not, please indicate which life stages require further description and explanation.		
4.6	Is there sufficient information on organisms or symptoms that may be confused with the pest?	If not, please indicate possible areas of confusion		
4.7	Is a sampling procedure required, and if so, is the procedure adequately described?			
4.8	Does the sampling procedure identify aspects of the sample that may impact on detection and diagnosis?			

Question		Issues to be considered	Y/N	Comments
4.9	Is there any point of contention, uncertainty or ambiguity in the detection information?	Please briefly note these potential problems.		
4.10	Is the most up-to-date information on detection provided?	If not, please note the sources of more up-to-date information.		
4.11	Is information for detection of the pest from asymptomatic plants or plant products provided?			

## 5. Identification

Question		Issues to be considered	Y/N	Comments
5.1	Where there are multiple procedures, is a flow diagram identifying the processes for identification included?			
5.2	Are the suggested steps sufficient for accurate identification, and are the steps in a suitable order?			
5.3	Are the minimum requirements for a positive identification included?			

For each identification method, please answer each of the following questions. Where there is more than one identification method, please duplicate the table below, label the table as per the detection method, and answer the questions specific to that particular identification method. Later tables contain additional questions that relate to morphological and molecular identification.

## Method 1

Name of method:

Question		Issues to be considered	Y/N	Comments
5.4	Has the author selected the most useful and accurate diagnosis method(s)?	If not, then please briefly comment on the deficiency in terms of utility.		
5.5	Is the most up-to-date identification method(s) used?	If not, please note the more up-to-date method(s) not used.		
5.6	Is there any point of contention or uncertainty in the method?	Please briefly note any point of contention or uncertainty in the method.		
5.7	Is the method described in sufficient detail to be followed without referring to other literature?	If not, then please note the elements that require more detail.		
5.8	Are the results and observations required for identification clearly stated?	Please note where any lack of clarity occurs.		
5.9	Does the method require a specific control and if it does, is the control properly described	Please note the kind of information that is lacking.		
5.10	If reference material (a positive control) is required, is a source of the reference material noted in the document?			
5.11	Are unambiguous criteria provided for positive and negative results?			

Question		Issues to be considered	Y/N	Comments
5.12	Is guidance provided on distinguishing the pest organism from related species or taxa?			

## 6. Morphological identification

If morphological identification is included, then please answer the following questions in addition to those above.

Question		Issues to be considered	Y/N	Comments
6.1	Are methods for preparing, mounting and examining the pest provided?			
6.2	If culturing or isolation is necessary, are sufficient details provided so that this may be done without referring to other literature?			
6.3	Is an identification key provided?			
6.4	If provided, could the key be followed by a diagnostician who is not an expert on the family of organisms?	If not, then please note the part of the key that would present difficulty.		

Question		Issues to be considered	Y/N	Comments
6.5	<b>Does the morphological description include all necessary information and indications of difficulties? <i>For example, descriptions of each gender, illustrations of diagnostic features, morphometric data, taxonomic description of organism, culture characteristics.</i></b>	If not, then please indicate what is missing and the significance, if any, of the deficiency.		

## 7. Molecular and serological tests

Question		Issues to be considered	Y/N	Comments
7.1	<b>If a nucleic acid test is described, does the protocol identify a reference sequence (including accession number) in a publicly available database, such as GenBank, from an isolate or specimen that has been sufficiently described (validated) in a collection, publication or database?</b>			
7.2	<b>If a commercial kit is used, is it readily available?</b>			
7.3	<b>If a commercial kit is available but is not used, are adequate reasons given for using an alternative?</b>			

Please complete the following table. If no (N) is indicated please briefly state in the comments column why the criterion was not met.

Is adequate information provided on the following for each identification method:	Method 1 Y/N N/A	Method 2 Y/N N/A	Method 3 Y/N N/A	Comments
Accuracy				
Specificity				
Reproducibility				
Sensitivity				
Positive control				
Negative control				
Reference material				
Sources of test reagents				
Specifications of test reagents				
Equipment				
Specifications of equipment				

## 8. References, copyright, contacts and acknowledgements

Question		Issues to be considered	Y/N	Comments
8.1	Is all information appropriately referenced?	Please identify significant information used in the document that is not referenced.		
8.2	Is the reference list complete?	Identify references that have been used but not entered in the reference list or vice versa.		
8.3	Are the most important references used?	Identify important papers and other sources that have been missed.		



Question		Issues to be considered	Y/N	Comments
8.4	Are you aware of any material in the protocol very similar or identical to material published elsewhere? <i>This may be significant for copyright reasons.</i>	If so, please identify the material.		
8.5	Does the document include photographs, and if so, is the region or country identified where the photograph was taken and is the photographer acknowledged?	If not, then please note the elements that require more detail.		
8.6	Are the names and addresses of the authors of the protocol provided?			
8.7	Have the major contributors been appropriately acknowledged?			
8.8	Are the details of a contact person or laboratory with expertise on the organism provided?			

## 9. General comments

Please comment on the suitability of the protocol for definitive diagnosis and suggest improvements if appropriate.

Reviewer:

Signature:

## PART C

# **Verification report checklist**

Protocol:

Date of verification:

### **Notes**

Please provide a report on the verification of the protocol and complete the table below. In your report, please describe the results of testing the protocol and include a brief description of the samples that were used. Please comment on the usefulness of the protocol for diagnosing the described species, and if you consider the protocol could be improved, briefly describe the desired improvements and outline possible amendments. If preferred, improvements may be included as track changes to the protocol.

To complete the table, **Yes** or **No** answers are sufficient for most questions. However, we also ask that for some questions you fill out the “comments” column. The “Issues to be considered” column is intended as a guide to consider when recording comments and to assist in identifying possible improvements. Please note that not all questions may be applicable to the protocol you are testing. If an answer is negative or critical, please provide some explanation and include any information requested. These comments can be included in the table or in the report, but need not be duplicated. If included in the report, please reference the number of the question.

General comments may be made at the end of this document or in your report. If there is some problem with the protocol that is not addressed in the questions provided, please note the problem at the end of the document or in your report.

For more information on the requirements of a protocol and the peer review and verification process please refer to SPHDS RS 2 Technical Procedures (Section Part B) and SPHDS RS 4 Peer Review and Verification (relevant sections included).

**1. Verification and reproducibility**

Question		Issues to be considered	Y/N	Comments
1.1	Were all procedures in the protocol tested?	Identify any procedures not tested and briefly note reasons. If you were only requested to verify some procedures, just answer for those procedures.		
1.2	What procedures and parts of the protocol were verified?	If there is some uncertainty about verification of some part of the protocol, please note it and provide some explanation. If a procedure or part of a procedure failed please provide details on that failure.		
1.3	Were all procedures in the protocol reproduced and done without technical difficulty?	If a procedure was not reproduced or was difficult to reproduce, please note it and provide some detail of what occurred.		
1.4	Was the protocol verified without a positive control?	If no positive control was used, please comment on the value of a positive control to verification.		

**2. Diagnosis**

Question		Issues to be considered	Y/N	Comments
2.1	Will the protocol allow reliable detection?			

Question		Issues to be considered	Y/N	Comments
2.2	Will the protocol allow identification of the organism?			
2.3	Does the protocol clearly state what results are required for identification?			

### 3. Clarity and comprehensiveness

For each method described in the protocol, please answer each of the following questions. Where there is more than one method, please duplicate the table below, label the table as per the method, and answer the questions specific to that particular method.

Method 1

Name of method:

Question		Issues to be considered	Y/N	Comments
3.1	Is the description of the procedure comprehensive and clear?			
3.2	Was there any problem following the procedure?	If yes, please provide some details.		
3.3	If a commercial kit is used is it readily available?			

Question		Issues to be considered	Y/N	Comments
3.4	Are sufficient details provided so that the procedure could be done without referring to other literature? <i>If a commercial kit is used as per manufacturer's instructions, these do not need to be repeated.</i>			
3.5	Is there any point of contention, uncertainty or ambiguity in the procedure?	Please briefly note any point of contention, uncertainty or ambiguity.		
3.6	Are the procedure parameters clearly described?			
3.7	Is the source of each reagent adequately described?			
3.8	Is there a sufficient description of equipment used?			
3.9	Does the procedure require any specialised equipment that would not be available in all laboratories?	If so, please comment on whether this is a barrier to detection or diagnosis.		
3.10	Does the procedure state what positive and negative controls are to be used?			
3.11	If a specific control is required, is it properly described?	Please note the kind of information that is lacking		
3.12	Does the procedure clearly state what the expected results should be?			

Question		Issues to be considered	Y/N	Comments
3.13	Are unambiguous criteria provided for positive and negative results?			
3.14	If a specific sampling method is required, is it adequately described?			

#### 4. Results of verification tests

Duplicate this section for each procedure described in the protocol.

Method 1

Name of method:

Question		Issues to be considered	Y/N	Comments
4.1	What samples were used for verification?			
4.2	Was a positive control available for testing?			
4.3	Did you test the sensitivity of the procedure (if relevant)?	If not, then please provide a reason for not testing sensitivity		
4.4	Was the procedure sufficiently sensitive (if tested)?	Please indicate the maximum level of dilution or minimum concentration of pathogen that was detected.		
4.5	Did your results agree with those supplied with the procedure (if any)?	Please provide data from the experiments and address any discrepancy.		

Question		Issues to be considered	Y/N	Comments
4.6	Were there any false positive or false negative results?			
4.7	Did you test the specificity of the procedure?	If yes, then please supply details?		
4.8	Did you vary the procedure in any way? (perhaps use a different extraction method for DNA)	If so, then please provide evidence that your method was as sensitive and specific as the supplied procedure		

## 5. Sequencing

Where sequencing is included in the protocol, please answer the following.

Question		Issues to be considered	Y/N	Comments
5.1	Is sequencing required for diagnosis?	If not, please briefly describe why not.		
5.2	Is an accession number for a reference sequence noted in the procedure?			
5.3	Are all reference sequences in a publicly available database, such as GenBank?			
5.4	Is the reference sequence from an isolate or specimen that has been sufficiently described (validated) in a collection, publication or database?			



**6. General comments**

Please comment on the suitability of the protocol for definitive diagnosis and suggest improvements if appropriate.

Verified by:

Signature:

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