PM 7/98 Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity

EPPO Online Training Workshop on ISO Standard 17025 (2017) and PM 7/98 (4) Introductory Session
2020-12-10

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Laboratory analysis are performed in the framework of inspection programmes to detect and identify pests

on consignments (imported or exported)

for the surveillance of their territory (in fields, nurseries glasshouses….), in the framework of eradication programmes

A positive test may result in official measures being taken by an NPPO (eradication, destruction or rejection of consignments)

Need for a harmonized approach and of reliable tests

Background - EPPO Diagnostics programme started in 1998

- Work conducted by Panels (groups of experts)
- Panels are composed of specialists from EPPO member countries

Horizontal Diagnostic Panel

Diagnostics and Quality Assurance

Specialized Diagnostic Panels

Diagnostics in Bacteriology
Diagnostics in Entomology
Diagnostics in Nematology
Diagnostics in Mycology
Diagnostics in Virology and Phytoplasmology

EPPO Diagnostics – overview of objectives and achievements

Objectives:

- to achieve a harmonized approach to detection and identification for regulated pests and for validation of tests.

Achievements

- Over 140 Diagnostic Standards approved
- Workshops and conferences organized
- Involvement in projects and other activities
- Collaboration with other organizations (IPPC Technical Panel on Diagnostic Protocols, European Cooperation for Accreditation, Euphresco, European Association of Phytobacteriologists, European Mycology Network)

A little bit of history – Quality assurance and accreditation

1999

- First discussions on the potential role for EPPO to assist diagnostic laboratories in obtaining accreditation.
- Should EPPO develop a quality assurance Standard for diagnostic laboratories?

- Decision: wait for the ISO/IEC Standard 17025 *General requirements for the competence of testing and calibration laboratories* (2002 version)

2003

- Decision: Need for harmonization for interpretation of ISO/IEC 17025 for plant pest diagnostic laboratories

2004/ 2007

- Development of PM 7/84 *Basic requirements for quality management in plant pest diagnosis laboratories* approved

2007/ 2009

- Development of PM 7/98 *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* on the interpretation of ISO 17025 for plant pest diagnosis activities

2007+

- EPPO Database on Diagnostic Expertise – http://dc.eppo.int

2012

- Online questionnaire on the use of these Standards in 2012

2014

- First revision of PM 7/98 approved in 2014

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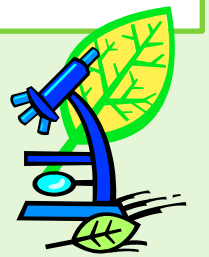
A laboratory preparing for accreditation should only use validated tests

Validated test = test with the following performance criteria

Analytical sensitivity
Analytical specificity
Reproducibility
Repeatability
Depending on the scope of the test selectivity may also need to be determined.



Validated tests providing performance criteria are considered as “standard tests” (equivalent to "standard methods" in ISO 17025).

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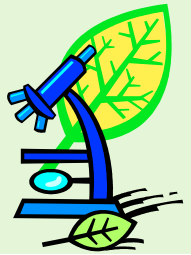
Laboratory performing a test

Test with validation data

Laboratory performs a verification (to confirm its competence in performing the test).

Test with no or incomplete validation data

Laboratory should produce the missing validation data



Validation tables per discipline: how to perform validation?

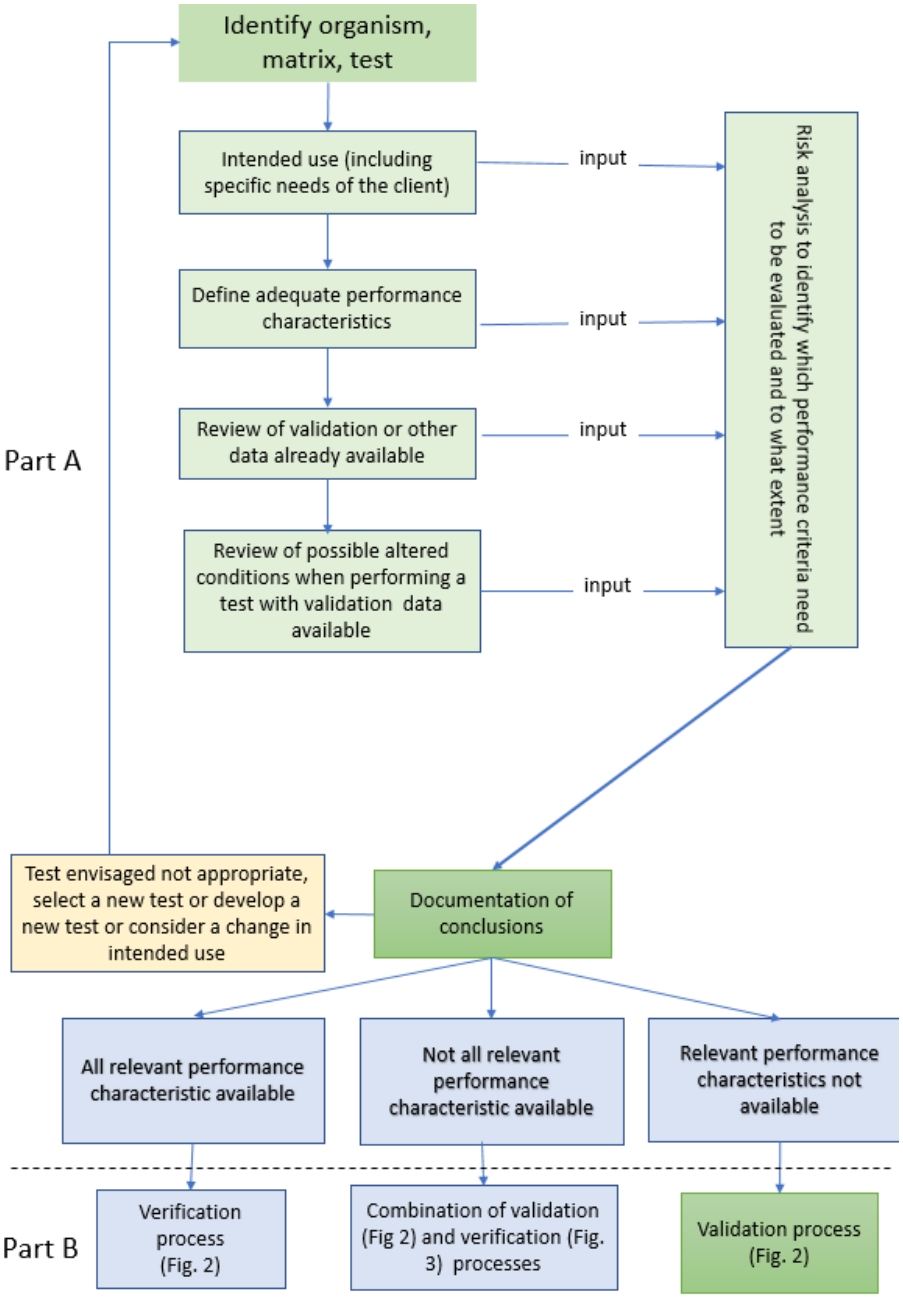
Molecular methods, e.g. PCR , real time PCR, LAMP **Remark. This step also includes methods for isolation of DNA from the sample material.**	
Analytical sensitivity	Analyse at least 3 series of spiked sample extracts with a range of 10^1 - 10^6 cells of the target organism/mL. Preferentially this is done by making decimal diluted cell suspensions of the target bacterium in the sample extracts. Determine the lowest cell density giving a positive test result. If consistent results are not obtained after 3 series, then additional series should be prepared and tested. Analytical sensitivity refers to a specific set of test parameters which should be stringently defined and standardised, e.g. brand of PCR reagents (in particular DNA polymerase) and PCR cycle conditions.
Analytical specificity	Analyse (i) strains of the target bacterium covering genetic diversity, different geographic origin and hosts and (ii) a set of non-target bacteria, in particular those associated with the sample material. Use cell suspensions of pure cultures at approximately 10^6 cells/mL. In addition, the test results can be supported by 'in silico' comparison of probe/primer sequences to sequences in genomic libraries.
Selectivity	Determine the relative insensitivity of the test to variations of the sample material, e.g. by using different hosts of the same family, different cultivars of the host plant.
Repeatability	Analyse at least 3 replicates of spiked sample extracts with a low concentration. If consistent results are not obtained additional replicates should be prepared and tested.
Reproducibility	As for repeatability but with different operator(s) if possible, on different days and with different equipment when relevant.

2017

- EPPO Workshop on Flexible Scope, Wageningen (NL), 2017-06-26/28, 46 participants from 24 countries. Including Laboratory managers, Quality Managers, and representatives from Accreditation bodies.

2018

- First major revision of PM 7/84 and PM 7/98 (approved 2018)
- Inclusion of flexible scope in plant health
- Inclusion of the risk analysis concept in PM 7/98 (3)



2017

- A new ISO 17025 Standard *General requirements for the competence of testing and calibration laboratories* was approved on 2017-12-13 and its **implementation was to be required by 2020-12-01 (date delayed due to COVID-19)**

2019

- EPPO Workshop on the revision of PM 7/98, ANSES Maisons-Alfort (FR), 2019-02-11/13, 40 participants from 19 EPPO countries, exchanges between laboratories on their experience with the implementation of the 2017 version of ISO 17025 for accreditation

Panel on Diagnostics and Quality Assurance Maisons-Alfort (FR) 2019-02-13/15

Feb 2019

May 2019

Sep 2019

- Careful check of the 2017 ISO Standard to consider what modifications are needed in PM 7/98 to provide guidance to plant health laboratories applying for accreditation according to the new ISO Standard.
- Subgroups to work on different parts of the Standard. It was agreed to finalise the new version in a subsequent Expert Working Group (EWG)
- Workshop for Heads of Laboratories

New version of PM 7/98 (4) What is new? And what has stayed the same?

- **General structure** – kept as for PM 7/98 (3) but cross references added to sections in ISO 17025 (which was restructured)
- PM 7/98 (4) and PM 7/84 (2) now made **standalone documents** rather than including cross references
- Tables giving detailed guidance for the validation process by field (Bacteriology, Botany, Entomology, Mycology, Nematology, Virology & Phytoplasmology) reviewed
- **Less prescriptive – more risk based** – than previous version in line with ISO 17025 (2017)

New version of PM 7/98 (4)
What is new? And what has stayed the same?

- Section on management requirements expanded into subsections:
  - General requirements,
  - Structural requirements,
  - Resource requirements,
  - Process requirements,
  - Management systems requirements,
  - Risk management

  2 management systems (Option A and B in ISO) - PM 7/98 (4) addressing **Option A**.
- Information systems – added requirement that they are validated

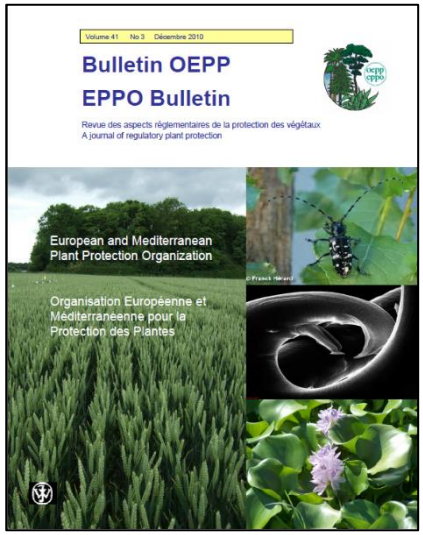
New factors introduced into PM 7/98 in line with ISO 17025 (2017)

- **Impartiality** (identification of risk and management of laboratory activities to safeguard impartiality)
- **Confidentiality** (of results and of customer's information is guaranteed - requirements for reporting to the NPPO for regulated pests or new pests explained).
- **Nonconforming work** (previously partly covered under deviations) now evaluated with risk analysis to assess impact and actions needed
- More comprehensive guidance on **risk management at operational and strategic levels** (previously had risk assessment for validation and verification only). Examples of possible tools given.

Where we are now?

PM 7/98 (4) *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity*

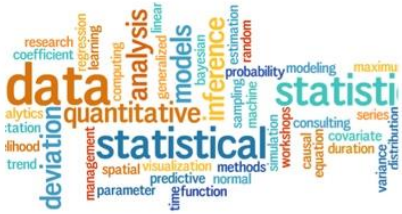
- Sent for country consultation summer 2019
- Country comments reviewed by EWG in teleconference
- Final version prepared and circulated to Panel on Diagnostics and QA
- Received final approval in September 2019 at Council
- Published in the EPPO Bulletin

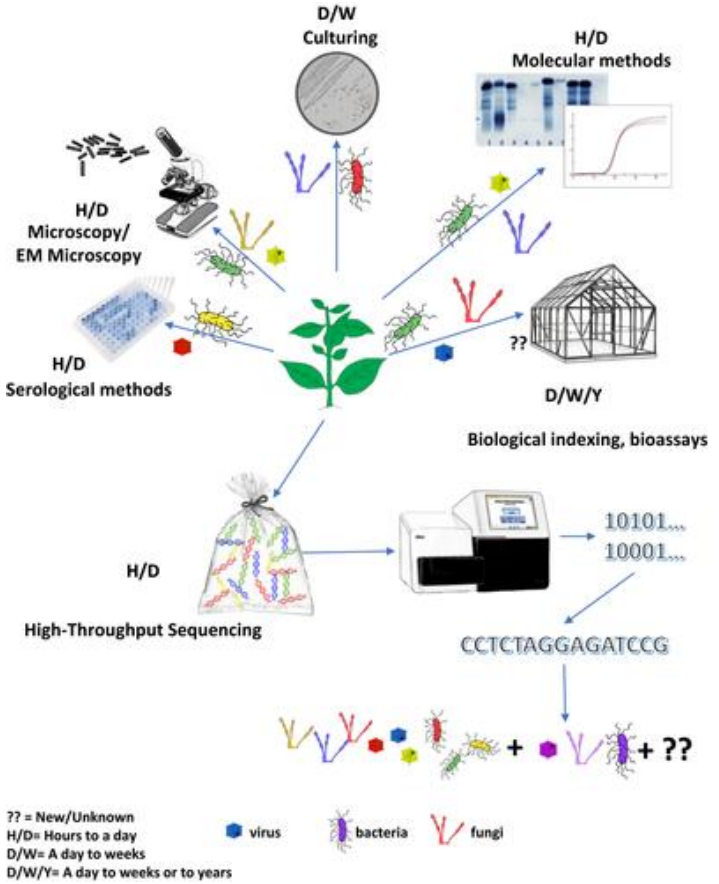


Current and future activities

- Training Workshop: Plenary Session and Group Activity sessions
- NEXT WEEK!

- Future revisions of PM 7/98 to include
  - ➢More guidance on Statistical analysis
  - ➢Improve **harmonization** of the tables by discipline
  - ➢ Include **High Throughput Sequencing**





EPPO's achievements are based on contributions from and collaboration between EPPO and also non-EPPO experts

- Thank you to all the experts who have contributed to our work, through Panel meetings, EWG, Workshops and sending comments
- We welcome the collaboration with the National Accreditation bodies and the EA

EUROPEAN ACCREDITATION

Joint revised EA EPPO communique October 2018

Paris, 10 October 2018

EA and EPPO continue their cooperation for accreditation of plant pest diagnostic laboratories