DOI: 10.1111/epp.12779

EPPO STANDARD - DIAGNOSTICS

PM 7/84 (3) Basic requirements for quality management in plant pest diagnostic laboratories

Specific scope: This Standard specifies the general quality management requirements needed to perform diagnostic tests for plant pests in a laboratory. Another Standard, PM 7/98, includes specific quality management requirements for laboratories preparing for accreditation according to the ISO/IEC Standard 17025 *General requirements for the competence of testing and calibration laboratories* (references to relevant parts of ISO/IEC Standard 17025 are included).

Specific approval and amendment: This Standard was first approved in 200-09.

First revision approved in 2018-09. This first revision was prepared to incorporate the conclusions and recommendations of the Workshop on Flexible Scope 2017-06-26/28.

Second revision approved in 2021-09. This second revision was prepared to align different sections with PM7/98 (5).

Authors and contributors are given in the Acknowledgements section.

1 | INTRODUCTION

Development of management systems (also referred to as quality management systems or quality systems) and accreditation have become a concern for many laboratories in the EPPO region. This document describes requirements to support laboratories conducting plant pest diagnostic activities in designing their management system. In the context of a plant pest diagnostic activity, results of one or more tests can be combined to contribute to a diagnosis. Quality management consists of activities that ensure the quality and confidence of the results provided by a laboratory. It is based on management requirements and technical requirements (see below). Laboratories applying for accreditation should base their systems on the ISO/IEC Standard 17025 *General requirements for the competence of testing and calibration laboratories*.

This document does not deal with health and safety matters. Laboratory practices should conform to national health and safety regulations.

This document was prepared on the basis of the following standards:

- ISO17025: 2017 *General requirements for the competence of testing and calibration laboratories*
- EPPO Standard PM 3/64 *Intentional import of organisms that are plant pests or potential plant pests*
- EPPO Standard PM 7/76 *Use of EPPO diagnostic protocols*
- EPPO Standard PM 7/77 *Documentation and reporting on a diagnosis*.

2 | TERMS AND DEFINITIONS

For terms and definitions see EPPO Standard PM 7/76 *Use of EPPO diagnostic protocols*.

3 | MANAGEMENT REQUIREMENTS

The laboratory should establish, implement and maintain a management system covering all facilities and activities of the laboratory.

The management system should describe the facilities and activities covered (including the customers and pests for which tests are carried out). An annual quality control plan should be defined (see Section 4.2). The management system should be documented.

The management system of the laboratory should ensure that:

- Appropriate resources are available to conduct the plant pest diagnostic activity, for example personnel, facilities and equipment (see also Section 4, Technical requirements)
- Purchased supplies (e.g. equipment, reagents) and services (calibration services, proficiency testing services, testing services, e.g. sequencing) are appropriate for the intended use
- The responsibilities and tasks of personnel are clearly defined (e.g. by organizational flow charts) and appropriately assigned
- Possible conflicts of interest between personnel and activities performed are identified and prevented
- Training is documented and assessed (see also Section 4, Technical requirements)

- Procedures and instructions are available to and implemented by the personnel, including standard operating procedures (SOPs)
- The customer is informed on request of the relevant data regarding the testing of its sample
- Any subcontracted work should be authorized in accordance with EPPO Standard PM 7/130 *Guidelines on the authorization of laboratories to perform diagnostic activities for regulated pests*
- Confidentiality of results to the customer is guaranteed, although a procedure should be in place to ensure that findings of regulated pests or new pests are reported to the NPPO (including a requirement for customers from other countries to report such findings to the NPPO of their country)
- A mechanism is in place to deal with complaints
- Mechanisms are in place to record, analyse and correct any deviation from procedures or the requirements of the customer
- Internal audits are conducted to verify that all operations continue to comply with the requirements of the managements system and ISO/IEC Standard 17025
- Documentation is maintained and archived.

The management system should be reviewed periodically by the top management. This implies a periodical assessment of all the components of the system and routine recording of deviations in the system and subsequent corrective actions that have been taken.

4 | TECHNICAL REQUIREMENTS

4.1 | General

Many factors determine the reliability of the test results. These factors include:

- Personnel
- Facilities and environmental conditions
- Diagnostic tests
- Equipment (except reference material and data)
- Reference materials and reference data
- Sampling
- Sample handling.

4.1.1 | Personnel

The laboratory management should define and ensure the competence and expertise of those who perform each specific stage of the plant pest diagnostic activity and their competence to use the equipment. The laboratory management should also ensure that the laboratory personnel, whatever their status (e.g. students, staff seconded from another organization), carry out their work in an impartial manner and respect confidentially requirements.

Personnel performing specific tasks should be qualified on the basis of appropriate education, training, experience and/or demonstrated skills (see examples in Appendix 1). Staff undergoing training should be appropriately supervised and authorized. Staff records should be maintained, including records concerning the date on which authorization and/or competence to perform a specific task is confirmed and training records. A procedure should be put into place to review, ensure and monitor competence; this is especially critical after long absences.

4.1.2 | Facilities and environmental conditions

Laboratory facilities should enable correct performance of the plant pest diagnostic activities. Depending on the type of testing being performed, different steps of plant pest diagnostic activities may be combined in a working area, provided that necessary precautions are taken to avoid cross-contamination resulting from samples, reference materials and facilities (see Appendix 1). Specific guidance on handling quarantine organisms has been developed (see Table 1 in EPPO Standard PM 3/64 *Intentional import of live organisms that are plant pests or potential plant pests*) and specific regulations may apply in countries, e.g. Regulation (EU) 2016/2031[1] (EU, 2016).

A laboratory usually comprises testing facilities and ancillary facilities (entrances, corridors, storage rooms, toilets, archives, etc.). Separate locations or clearly separated/designated working areas are recommended for the following:

- Reception of samples
- Preparation of samples (segregate location for samples likely to be highly contaminated or powdery, e.g. soil samples, plants infected by fungi, insects or mites, tubers with soil)
- Testing of samples
- Storage of samples
- Appropriate disposal of material and waste
- Maintenance of reference materials/cultures
- Preparation and storage of media, buffers and reagents.

Different activities can be separated by time. The work area should be appropriately disinfected between different samples and/or activities. Specific requirements are mentioned in Appendix 2.[1]

The laboratory should be appropriately equipped to ensure proper storage, testing and containment of samples.

[1]Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. The relevant articles in this Regulation are 60 to 64.

Access to the laboratory should be restricted to authorized personnel, who should be aware of the intended use of a particular area and restrictions imposed on working in such areas.

The laboratory should monitor, control and record environmental conditions where they may influence the quality and reliability of the test results. Failures resulting from deviating environmental conditions should be documented and corrective actions recorded (see Appendix 2).

Measures should be taken to ensure good housekeeping in the laboratory. Space should be sufficient to allow work areas to be kept clean and tidy. Clothing appropriate to the testing being performed should be worn, especially when working in microbiological and molecular laboratories.

4.1.3 | Diagnostic tests

4.1.3.1 General

The laboratory should use appropriate tests and procedures for all analyses performed within its scope. These include sampling, handling, transport, where relevant, storage, preparation and testing of samples. It is expected that plant pest diagnostic laboratories will have an understanding of the biology of organisms and take this into account when subsampling and/or when preparing the sample for testing. Equipment, reagents and consumable materials should be appropriate for the intended use.

All instructions, standards, technical manuals and reference data relevant to the work of the laboratory should be kept up to date and made readily available to personnel. Deviation from tests should occur only if documented, technically justified, authorized by an appropriate person and accepted by the customer.

4.1.3.2 Selection of tests

The laboratory should select tests that are suitable according to the circumstances of use (see EPPO Standard PM 7/76 *Use of EPPO diagnostic protocols*). Tests described in the legislation (e.g. European Union or national legislation) are mandatory for the countries concerned. If no test is mandatory, tests published as international, regional or national standards should preferably be used. Whenever such tests are not available, or whenever performance could be improved, laboratory-developed or adapted tests could be considered.

The laboratory should ensure that it selects the latest valid edition of a test unless it is not appropriate or possible to do so. When necessary, the test description should be supplemented with additional details to ensure consistent application in the laboratory. Requirements for tests used under accreditation are provided in PM 7/98 (EPPO, 2019).

4.1.3.3 Performance of the laboratory

The laboratory should confirm that it can properly carry out the selected tests (see Section 4.2). This confirmation should be repeated when the test changes or equipment has changed.

4.1.4 | Equipment (except reference material and data)

The laboratory should have access to the equipment required for testing and this should be operated by competent personnel. Equipment, whether under the laboratory's permanent control or not, should be listed and a programme should be documented and implemented for the handling, storage, transport, maintenance, verification, calibration and corrective action of key equipment which significantly affects the results.

Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits should be taken out of service, clearly labelled or marked, and appropriately stored until it has been repaired and shown to perform correctly when appropriate or disposed of (e.g. for reagents, consumables). The laboratory should examine the effect of such deviation and initiate the management of non-conforming work procedures.

4.1.4.1 Calibration and verification programmes

Frequency of calibration and verification should be planned and reviewed when necessary. This can be based on risk analysis (examples and recommendations can be found in Appendix 3). Calibrations may be performed in-house by using certified or appropriate reference material provided by a competent producer. Calibrations should have traceability to International System of Units (SI) whenever possible. Only qualified personnel should perform calibration and verification programmes, using procedures appropriate to the intended use. Calibration and verification may also be performed externally by specialized, competent companies.

Documents on external and internal calibration and verification of performance (including when the next calibration is due) should be maintained and made available within the laboratory. Equipment should be appropriately labelled (see Appendix 4).

4.1.4.2 Maintenance of equipment

Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer) should be readily available for use by the appropriate laboratory personnel. Maintenance of

essential equipment should be carried out at specified intervals, preferably based on risk analysis as determined by factors such as the rate of use and age/complexity of the equipment, and this maintenance documented (see Appendix 5 for guidance on maintenance of equipment).

4.1.4.3 Records

Records should be maintained for equipment significant to the tests performed. Depending on the type and sensitivity of equipment, and the conditions required by the manufacturer to ensure failure-free running, the records should include:

- The identity of the item of equipment, including software and firmware versions
- The current location
- The manufacturer's name and type identification
- The manufacturer's instructions
- Dates, results and copies of reports and certificates of all calibrations or verifications, adjustments, date of next calibration or verification where appropriate
- Maintenance carried out to date and the maintenance plan, where appropriate
- Damage, malfunction and repair to the equipment.

4.1.5 | Reference material and reference data

Reference material provides essential traceability and is used, for example:

- To monitor performance of detection and identification tests
- To demonstrate the accuracy of results
- To calibrate or verify equipment
- To monitor laboratory performance
- To validate or verify tests
- To enable comparison of tests.

4.1.5.1 Biological reference material

If possible, certified biological reference material should be used, from which biological reference material, and subsequently working material, can be produced. Laboratories may also produce their own biological reference material from which working material is derived. To maintain confidence in the status of biological reference material, verification of identity and purity should be carried out according to defined procedures and schedules (including, as applicable, morphology, pathogenicity, virulence, antigenic properties, molecular properties, etc.). The laboratory should have procedures for safe handling, transport, storage and use of biological reference material to prevent contamination or deterioration and to protect their integrity.

Working material derived from biological reference material (e.g. reference cultures) from an international collection should be kept separate from the original material.

4.1.5.2 Other sources, including reference data

These include books, pictures, slides collections, morphological identification keys, scientific literature and sequence databases that can be used to support diagnosis. Reference data should be kept up to date and readily available.

4.1.6 | Sampling

Sampling is a procedure in which material is collected outside a laboratory to perform a test. A sample should be representative of the material under test and should be selected based on knowledge of the distribution of the pest to be detected. Such a representative sample may not always be available, if so, this should be documented. Sampling usually involves targeting symptomatic plants or plant parts.

Correct sampling is an operation that requires careful attention. Not all laboratories are involved in sampling. Laboratories involved in sampling should have a sampling process (both plan and procedure) for collecting samples to be followed whenever practicable. This process should address the factors to be controlled and be based on appropriate statistical tests.

The laboratory should have procedures for recording relevant data relating to sampling whether the process is performed by the laboratory staff or by the customer.

4.1.6.1 Records of sampling

Details of sampling should be recorded and communicated to the appropriate personnel. Records should include the following:

- Sampling procedure
- Date and time of sampling
- Data to identify and describe the sample (e.g. matrix, plant species, batch number, suspected pest)
- The name of the person who performed the sampling
- The equipment used
- Environmental or transport conditions
- Sampling location
- Deviations, additions or exclusions from the documented sampling procedure.

4.1.7 | Sample handling

The laboratory should have procedures for safe transportation, receipt, handling, protection, storage, retention and/or disposal of samples, including all provisions necessary to protect the integrity of the sample and to protect the interest of the laboratory and the customer.

Subsampling by the laboratory prior to testing is considered to be part of the test. Subsampling should be designed taking into account uneven distribution of pests.

The laboratory should have a system for uniquely identifying samples. The system should be designed and operated to ensure that samples cannot be confused

physically or when referred to in records or other documents. The system should, if appropriate, accommodate a subdivision of groups of samples and the transfer of samples within and from the laboratory. The identifier of a sample should be retained as long as this sample is retained by the laboratory. Suggested content for a form to identify a sample is presented in Appendix 6.

Plant pests may be sensitive to factors such as temperature or duration of storage and transport, so it is important to check and record the condition of the sample on receipt by the laboratory. If there is insufficient material in the sample or the sample is in poor condition due to physical deterioration, incorrect temperature, torn packaging or deficient labelling, or when a sample does not conform to the description provided, or if the test required is not described in sufficient detail, the laboratory should consult with the customer before deciding whether to test or refuse the sample. In any case, the facts and the results of discussions should be recorded.

Samples awaiting testing should be stored under suitable conditions to minimize changes to any pest populations present and to protect them from cross-contamination. Storage conditions should be defined and recorded when necessary. Where samples have to be returned to the customer, care is required to ensure that they are not damaged.

A procedure for the retention and disposal of samples should be written. Samples should be stored until the test results are obtained, or longer if required (e.g. for potential complementary analysis).

A laboratory should have procedures in place to treat samples after testing to conform to national or international regulations for quarantine and other plant pests. The procedures should also be designed to minimize the possibility of contaminating the test environment or materials. Further details on confinement conditions may be found in EPPO Standard PM 3/64 *Intentional import of live organisms that are plant pests or potential plant pests*.

4.2 | Ensuring the validity of test results

The validity of test results should be ensured at different levels, i.e. for each test and diagnostic process, as well as for global quality control of the laboratory.

Internal quality management consists of compliance with all the procedures undertaken by a laboratory for the continuous evaluation of its work. The main objective is to ensure the consistency of results day to day and their conformity with defined criteria. If analysis of data is found to deviate from the defined criteria, then appropriate action should be taken to prevent incorrect results from being reported. The interval between internal quality checks (defined in Table 1) will be influenced by the number of actual tests performed. Monitoring of test validity should be planned, reviewed and registered. Wherever possible positive/negative controls should be used: this should be the minimum level for quality control. A quality control programme may also consist of different checks, as described in Table 1.

TABLE 1 Internal and external quality checks

Elements of quality control programme	Level of control[a]
The use of reference material (e.g. target organism, closely related organisms, non-target organisms which might be naturally present in a composite material), see Section 4.1.5.	First
Internal/endogenous control (e.g. COX, NAD5, 18S)	First
The use of artificially contaminated samples	First or second
Replicate testing using the same test (technical replicates or repeated testing)	First or second
Comparative testing of the same sample by different operators	First or second
Vertical audit[b] of records for a specific sample/analysis	Second or third
Blind testing by processing samples with known levels of pests between routine samples	Second
Comparison of results of different tests based on different biological principles	Second
Retesting of retained plant material or extracts thereof, water or soil samples and insect traps (within a predetermined suitable storage time and condition of the material before retesting)	Second
Trend analysis on first-, second- and third- line controls (e.g. positive controls, Shewhart chart or results from proficiency tests), including quantitative data	Second or third
Intra- or interlaboratory evaluation of documentation of the specific determinants on which diagnoses are based (in particular for visual determination of insects, nematodes and fungi)	Third
Interlaboratory comparisons (in particular, proficiency tests)	Third
Supporting data (e.g. contra-expertise)	Third
Use of alternative instrumentation that has been calibrated to provide traceable results	First or third
Functional and intermediate check(s) of measuring and testing equipment	First or third

[a]First-line controls are used to monitor the actual performance of the test, second-line controls are used for the performance of a single operator within a laboratory and third-line controls evaluate the performance of the laboratory.

[b]Checking all steps of the diagnostic process for a particular sample.

A procedure should be in place for managing infrequently used tests. Operators' transferable skills may provide evidence of competence in tests based on the same method. Whenever possible, an external quality assessment (such as an external proficiency programme or proficiency tests) should be used to demonstrate competence. The validity of test results is influenced by both technical performance of personnel and test performance characteristics. If the validity of test results is called into question, it is important to be able to distinguish between these two. A test may demonstrate appropriate process control but poor diagnostic performance or vice versa.

4.3 | Reporting the results

See EPPO Standard PM 7/77 *Documentation and reporting on a diagnosis*.

5 | FEEDBACK ON THIS STANDARD

If you have any feedback concerning this Diagnostic Standard, please contact diagnostics@eppo.int.

6 | PROTOCOL REVISION

An annual review process is in place to identify the need for revision of Diagnostic Standards. Standards identified as needing revision are marked as such on the EPPO website. When errata and corrigenda are in press, this will also be marked on the website.

APPENDIX 1 - EXPERTISE AND COMPETENCE

An expert will have a combination of deep knowledge in a specific field, longstanding experience and particular cognitive skills.

A competent person will be able to demonstrate that he/she can perform a particular task successfully.

For example, for the selection of morphological or morphometrical methods expertise is required. For the use of the selected tests, the laboratory should confirm that its staff is competent to carry out the morphological and/or morphometrical identification.

Examples of factors to consider when evaluating expertise or competence can be found in Table A1.

TABLE A1 Examples of factors to consider when evaluating expertise or competence

Expertise (in a specific field)	Competence (for a particular task)
Education/training: diplomas/certificates	Education/training: diplomas/certificates
Peer evaluation	Interlaboratory comparison (in particular, proficiency testing)
Proven track record: successful outcomes	Blind samples
Measure of esteem, e.g. member of international Working Group or Panels, journal editor, reviewer, technical expert, keynote speaker, invited expert, technical assessor	Internal controls (including data trending where possible): validation data
Publications: relevant to the area of work	Contra-expertise inside or outside the laboratory
Annual review/validation	Audit (both internal and external)
Continued professional development (CPD) leading to a professional qualification (e.g. in the UK Royal Society of Biology, chartered biologists/plant health professional)	CPD

APPENDIX 2 - ENVIRONMENTAL MONITORING AND AVOIDANCE OF CONTAMINATION

The laboratory should ensure that environmental conditions, laboratory arrangements and working procedures are such as to minimize the risk of cross-contamination through air, surfaces, equipment, personnel, etc. Contaminations can be minimized or avoided in the following ways:

- Laboratory equipment should not routinely be moved between different areas inside the laboratory.
- Where relevant a documented vector control programme should be in place.
- Reference materials/cultures should be stored in a separate location in the laboratory.
- Housekeeping and cleaning procedures should be defined, implemented and documented, for both equipment and facilities.
- Hygienic working procedures (e.g. use of "sticky" mats when appropriate, use of gloves, disinfectants, filter tips for pipettes, disposable plastic ware) should be defined and implemented.
- Careful handling of samples.

The laboratory should monitor the quality of laboratory air and surfaces of relevant areas at regular intervals. The monitoring can be done by using air settlement plates (e.g. plate count agar or other appropriate non-selective plates), contact plates (for even surfaces) or swabbing (for other surfaces and equipment), and insect traps. Buffers exposed to air or surfaces can also be tested.

For laboratories working on nematodes, the normal hygienic procedures ensure that contamination is avoided.

Specific additional requirements for molecular laboratories

- Dedicated molecular work areas should be organized for (a) nucleic acid extraction and purification, (b) preparation of mastermix, (c) addition of sample to the mastermix, (d) nucleic acid amplification and (e) analysis of amplification products. It is highly recommended to have at least three distinct rooms. Preparation of mastermix, nucleic acid extraction and/or analysis of amplification products should not be performed in the same room.
- Dedicated equipment (including pipettes) should be used in each work area. Dedicated laboratory coats should preferably be used in each work area (at least a specific coat for mastermix preparation) and gloves should be worn.
- Tubes containing amplification reaction products should not be opened within work areas used for nucleic acid extraction or mastermix/reaction mixture preparation.
- UV PCR workstation are decontaminated at each use using UV light.

Specific guidelines for monitoring contamination with bacteria and fungi

To monitor for airborne and surface contamination air samplers, settle plates, contact plates or swabbing (see below) can be used weekly.

Air settlement plates, preferably three in each area to be monitored, should be exposed to air contaminants for a definite time (30 min recommended), closed and incubated for 3 days (at approximately 30°C) or 5 days (at room temperature). Contact plates should be exposed on the surfaces to be monitored for 15 s (recommended), closed and incubated as above. The acceptable level of cfu/plate/area (background counts) for bacteria or fungal colonies should be defined by the laboratory according to the testing being carried out and according to the special requirements of the environment (e.g. clean rooms). Environmental monitoring should be documented, and corrective actions described and performed if needed and recorded. Cleaning should be intensified if needed and new samples taken after corrective actions have been performed.

Specific guidelines for monitoring contamination with insects

Pests should be monitored using sticky plates.

APPENDIX 3 - CALIBRATION OF EQUIPMENT AND VERIFICATION OF PERFORMANCE OF EQUIPMENT

Calibration

The information in Table A2 is provided for guidance purposes and the frequency will be based on the need, use, type and previous performance of the equipment (in particular in relation to the drift observed between calibrations).

TABLE A2 Recommendations and suggested frequencies for calibration of equipment

Type of equipment	Recommendation	Suggested frequency
Reference thermometers and reference thermocouples	(a) Full traceable re-calibration (b) Single point (at working temperature)	(a) Every 7 years (b) Annually
Spectrophotometric equipment	Calibration	Annually
Calibration weight(s)	Full traceable calibration	Every 7 years
Microscopes	Traceable calibration of stage micrometer	Initially
Pipettes	Calibration	Annually
Autoclaves (for media preparation)	Calibration	Annually

TABLE A3 Guidance on verification of performance of equipment

Type of equipment	Recommendation	Suggested frequency
Temperature-controlled equipment (incubators, baths, refrigerators, freezers, Berlese funnels, slide drying benches, etc.)	(a) Establish stability and uniformity of temperature	(a) Initially, and after repair, modification
	(b) Monitor temperature	(b) Daily/each use
Thermocyclers	Verification of efficiency	Annually
Spectrophotometer	Certified plate	Annually
Working thermometers, working Thermocouples and data loggers	Check against reference thermometer at ice-point and/or working temperature range	Annually
Sterilizing ovens	(a) Establish stability and uniformity of temperature	(a) Initially, and after repair/modification
	(b) Monitor sterilization	(b) Each use
Autoclaves (for destruction)	(a) Establish characteristics for typical loads/cycles	(a) Initially, and after repair/modification
	(b) Establish stability and uniformity of temperature (c) Monitor sterilization	(b) Annually (c) Each use
Chemical fume hood	(a) Establish performance	(a) Initially, and after repair/modification
	(b) Filters and air flow monitoring	(c) Yearly
Laminar air flow cabinets and biosafety cabinets (microbiology)	(a) Establish performance	(a) Initially, and after repair/modification
	(b) Check with sterility plates or swabbing	(b) Monthly
	(c) Filters and air flow monitoring	(c) Yearly
Growth chambers	(a) Monitor temperature, humidity and light	
(b) Monitor for pests using sticky traps	(a) Each use (b) Monthly	
pH meters	Adjust check using at least two buffers	Daily/first use
Balances	Check zero and reading against check weight	Daily/first use
Check weight(s)	Check against calibrated weight or check on balance immediately following traceable calibration	Annually
Stills, de-ionizers and reverse osmosis units	(a) Check conductivity (b) Check for microbial contamination	(a) Before use (b) Monthly if the treated water or the end-use product containing the treated water are not sterilized by autoclaving or filtration before use
Gravimetric diluters	(a) Check weight volume (weight) dispensed	(a) Daily
	(b) Check dilution ratio	(b) Monthly
Automatic media preparators	Check sterility using chemical and biological indicators	As recommended by manufacturer
Pipettors/pipettes	Check accuracy, fidelity and precision of volume dispensed	Regularly (to be defined by taking account of the frequency and nature of use, and depending on the drift observed)
Spiral platers	(a) Establish performance against conventional method	(a) Initially and annually
	(b) Check stylus condition and the start and end points	(b) Daily/each use
	(c) Check volume dispensed	(c) Monthly
Colony counters	Check against number counted manually	Annually
Anaerobic jars/incubators	Check with anaerobic indicator	Each use

Verification of performance

The information in Table A3 is provided for guidance purposes and the frequency will be based on the need, type, use and previous performance of the equipment. Monitoring frequency should be adapted to the conditions of the laboratory with frequency being higher at the beginning and adapted later based on identified risk.

APPENDIX 4 - EQUIPMENT: IDENTIFICATION AND LABELLING PROCEDURES

This example document suggests the information sufficient to clearly identify equipment.

Identification procedure

Each piece of equipment should be identified by a unique code, all of which should be recorded in a specific register. Different methods and codes can be used, and they will depend on the system implemented by the quality assurance department of each laboratory. The two following methods may be used:

- The identification code is, for example, composed of five alphanumeric characters: three letters referring to the equipment type and two numbers indicating the number in a series. Example: BAL02 represents the second (02) balance (BAL) in the laboratory. The main advantage of this coding method is that the code indicates the type of equipment to which it refers.

- The equipment is identified by a unique specific serial number. Example: material n°250, whatever it may be, is the 250th piece of equipment registered and identified in the laboratory. Although this system is very easy to apply, it is not possible to have an idea of the type of equipment concerned from its number.

Labelling procedure

Each piece of equipment should be permanently labelled with its unique code. This label should not be modified or removed. It is therefore often suggested that the equipment is etched with its unique code. The code should be positioned to be easily read without needing to handle the equipment. Care should be taken when etching equipment to avoid damaging it.

A temporary label may also mention the date when the next calibration, verification or maintenance is due.

APPENDIX 5 - GUIDANCE ON MAINTENANCE OF EQUIPMENT AND ENVIRONMENT

Table A4 is provided for guidance purposes and the frequency will be based on the need, use, type and previous performance of the equipment.

TABLE A4 Guidance on maintenance of equipment and environment

Type of equipment	Recommendation	Suggested frequency
Incubators (for microbiological purposes)	Clean and disinfect internal surfaces	Monthly
Incubators (for other than microbiological purposes)	Clean and disinfect internal surfaces	Every 3 months
Refrigerators, freezers, ovens	Clean and disinfect internal surfaces	Annually
Centrifuges	(a) Service	(a) Annually
	(b) Clean and disinfect	(b) After each use
Autoclaves	(a) Make visual checks of gasket, clean/drain chamber	(a) Regularly as recommended by the manufacturer
	(b) Full service	(b) Annually
	(c) Safety check of pressure vessel	(c) Annually
Safety cabinets	Full service and mechanical check	Annually
Laminar flow cabinets	Service and mechanical check	As recommended by the manufacturer
Microscopes	(a) Clean and full maintenance service	(a) Annually
	(b) Check eye-piece graticule	(b) Every 6 months
pH meters	Clean electrode	After and before each use
Balances, gravimetric diluters	(a) Clean	(a) After each use
	(b) Service	(b) Annually
Stills	Clean and de-scale	as required (e.g. every 3 months)
De-ionizers, reverse osmosis units	Replace cartridge/membrane	As recommended by the manufacturer
Anaerobic jars	Clean/disinfect	After each use
Media dispensers, volumetric equipment, pipettes and general service equipment	Decontaminate, clean and sterilize as appropriate	After each use
Spiral platers	(a) Service	(a) Annually
	(b) Decontaminate, clean and sterilize	(b) After each use
Mixers/blenders	Clean	After each use
Thermocyclers	General service	Annually
Growth chamber	Clean	After each use
Berlese funnels	Clean	After each use
Slide drying benches	Clean	Weekly
Laboratory	(a) Clean and disinfect working surfaces	(a) Daily and during use
	(b) Clean and disinfect floors, sinks and basins	(b) Weekly
	(c) Clean and disinfect other surfaces	(c) Every 3 months

APPENDIX 6 - SUGGESTED FORM FOR SAMPLE IDENTIFICATION (LABORATORY SHEET)

Sample record form

The example sample record form shown below enables anonymous tracing of samples or batches of samples within a laboratory. A group of samples may be recorded as one batch when they arrive from the same client, are all of the same plant species or plant part and the same analysis is required.

Batch identification code (if appropriate):	
Plant species:	Purpose of sampling (e.g. import, control of outbreak, survey):
Analysis requested by the client:	Nature of the submitted material to analyse (e.g. plant part, isolated pest):
Name of the person receiving/recording the sample:	Date and if relevant time of sampling:
	Date of reception/recording:
	Suitability of the sample for testing:

Comments (e.g. urgent, type and name of applied pesticides, etc.):

Sample identification codes	
Laboratory identification code *(code given by the laboratory, unique to each sample)*	Client's identification code *(identification code given by the client, unique to each sample)*

Analysis undertaken	
Analysis protocols *(used by the laboratory)*	Date and signature *(of the operator responsible for choosing the relevant analysis protocol)*

Report of the analysis sent	
Report number	Date and signature *(of the operator responsible for sending the report)*