Ministry for Primary Industries
Manatū Ahu Matua

Facility Standard

Standard for Transitional Facilities for the Identification of Organisms

155.04.03

19 December 2018

Issued under the Biosecurity Act 1993

New Zealand Government

TITLE

Facility Standard: Standard for Transitional Facilities for the Identification of Organisms

COMMENCEMENT

This Facility Standard comes into force on 19 December 2018

REVOCATION

This Facility Standard revokes and replaces:

Ministry for Primary Industries Standard 155.04.03: A standard for diagnostic facilities which undertake the identification of new organisms, excluding animal pathogens, issued August 2006.

ISSUING AUTHORITY

This Facility Standard is issued under section 39 of the Biosecurity Act 1993.

Dated at Wellington, 19 December 2018

Director, Plants and Pathways
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the Facility Standard, but is intended to indicate its general effect.

Purpose

This Facility Standard sets out the general requirements for the approval of transitional facilities in New Zealand which undertake the identification of organisms, including organisms which may be new organisms, excluding animal pathogens.

Background

Organism identification or diagnosis, especially of organisms not known to occur in New Zealand, requires recognised expertise in various scientific disciplines (bacteriology, entomology, mycology, nematology, virology etc.) and specialised laboratory equipment is generally required.

Such work must be undertaken in a transitional facility approved as such by the Ministry for Primary Industries (MPI) for the identification or diagnosis of organisms.

The key elements of a well-functioning transitional facility approved to this standard are the effective implementation of a quality management system and the ability of the facility to demonstrate technical competence and generate technically valid results.

Who should read this Facility Standard?

This Facility Standard should be read by Operators or prospective Operators of transitional facilities which undertake the identification of organisms, including new organisms, but excluding animal pathogens.

Why is this important?

If a place does not comply with the building, operation and maintenance requirements of this Facility Standard, it will not be approved as a transitional facility and, if already approved, the approval may be suspended or cancelled.

If an Operator does not comply with the operating requirements of this Facility Standard, the Operator's approval may be suspended or cancelled.

It is an offence to operate a place as a transitional facility if it is not approved as a transitional facility or if the person operating the place is not an approved Operator of that facility, or if those approvals are suspended. It is also an offence if a person who operates a transitional facility does not comply with the operating standards for the facility.

Document History

This Standard is subject to periodic review.

Version Date	Section Changed	Change(s) Description
August 2006	7.3, Police Form.	Removed: Step 7.3 & form (requirement for quarterly reports) as covered in ISO standard 174-025 and by the other MPI requirements in this standard. Police form updated.

Version Date	Section Changed	Change(s) Description
20 December 2018	Throughout	Updated to RG format. Title change to reflect it is a transitional facility standard and to better describe its purpose. Clarified application to new organism identification. Removed processes relating to approval of facilities and Operators and associated application forms. Amended definitions to remove those already defined in legislation. Removed Schedule 2 list and included link to other operational standards Reorganised layout more clearly into structure and operations

Other information

Guidance information

The information contained within a border throughout this document is for guidance and is not part of the statutory requirements.

Costs

Applicants for a facility approval, and for approval to be an Operator, must pay an application fee.

MPI will charge for ongoing monitoring and inspection for compliance with this standard and any conditions of an approval. Fees are at the rates set out in the Biosecurity (Costs) Regulations 2010.

Part 1: Requirements

1.1 Application

(1) This Facility Standard applies to transitional facilities (TF) which undertake identification of organisms.

(2) Examples of organisms include:

a) dead organisms or parts thereof;
b) invertebrates, including molluscs, insects, spiders, nematodes and mites;
c) microorganisms from, or associated with, plants, including bacteria, fungi, viruses, viroids and phytoplasmas;
d) plants, including higher plants, mosses and aquatic weeds; and
e) vertebrates, including reptiles and amphibians.

(3) If the identification results in a new organism (or potentially a new organism) the organism must be directed to a containment facility or requires CTO direction under the Act.

Guidance

- Unidentified pure cultures or specimens or in/on substrates (e.g. leaves, soil, water) or mixed cultures, imported for propagation must be imported under a HSNO Act approval and research undertaken in an approved facility (Facility Standards).
- Identification of animal pathogens is excluded from the scope of this standard and must be undertaken under EPA and MPI Standard: Facilities for microorganisms and cell cultures, 2007a.
- Identification of human pathogens is excluded from the scope of this standard, except for those that may be isolated from plant tissues.
- Facility operators (Operators) should be aware of other requirements of the Act and HSNO that may apply to the operation of a TF and to unwanted organisms and new organisms.

1.2 Incorporation by reference

(1) Relevant parts of the current versions of the following documents are incorporated by reference in this Facility Standard under section 142M(1)(a) of the Biosecurity Act 1993 (the Act):

a) Australia Standards/New Zealand Standard*, AS/NZS 2243.3: 2002 Safety in Laboratories - Part 3: Microbiological aspects and containment facilities*;
b) *General requirements for the competence of testing and calibration laboratories* NZS/ISO/IEC17025: 2017.
c) *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes* ILAC-G13:08/2007.
d) ISO/IEC Guide 43-1:1997 (E) *Proficiency testing by inter-laboratory comparisons – Part 1: Development and operation of proficiency testing schemes*.

(2) Under section 142O(3) of the Act it is declared that section 142O(1) does not apply, that is, a notice under section 142O(2) of the Act is not required to be published before material that amends or replaces the above listed standards, guideline or lists has legal effect as part of these documents.

1.3 Definitions

(1) Definitions are found in Schedule 1.

Part 2: Approval

2.1 Approval of a place as a transitional facility

(1) A place where activities within the scope of this standard are being undertaken must be approved as a transitional facility by the Director-General in accordance with section 39 of the Act.

(2) A quality manual must be submitted to MPI for approval prior to the place being approved as a transitional facility.

2.2 Approval of a person as an operator of a transitional facility

(1) A transitional facility must have an operator approved as such by the Director-General in accordance with section 40 of the Act.

Guidance

- Before applying for a place to be approved as a facility, or for a person to be approved as an Operator, a person or company should be familiar with this standard and should:
  - Refer to the local MPI office or MPI inspector for transitional facility information, Operator and facility application forms. This information may also be found on the MPI website at: https://www.mpi.govt.nz/importing/border-clearance/transitional-and-containment-facilities/ ;
  - Contact the local MPI office or MPI inspector to discuss the general provisions and requirements for approval, including operator training and preparation of the operating manual. This may require an on-site visit by the MPI inspector.
  - Arrange for an on-site meeting with the MPI inspector after establishment of the facility (and before the approval is granted) to ensure that approval requirements can be met.
- It is unlawful to operate a facility without an Operator.
- A main role of the Operator is to ensure that processes described in the operating manual are being followed, and hence the requirements of this standard and any other requirements are being met. As such, the Operator must have the required authority from the owner of the facility to ensure that the requirements of this standard will be met.
- Operators are responsible for all activities relating to the operation of the facility and must identify and provide the resources needed to meet the requirements of this standard.

Part 3: Physical and Structural Requirements

3.1 Transitional facility location

(1) A site plan of the property must be included in the quality manual showing the location of the diagnostic TF on the site and identifying all facility entrances and access points.

(2) Boundaries of neighbouring properties must be shown.

(3) The physical location of the property must be clearly shown in relation to roads in the area.

3.2 Containment requirements

(1) In addition to the requirements of clause 5.3 of ISO/IEC 17025:2017, the Operator must ensure that the facility is able to contain the organisms that are being tested/identified and that the facility complies with the following requirements:

a) windows in the facility are closed and locked or sealed;
b) a pressure steam steriliser for decontamination of laboratory wastes is available, preferably located within the facility;
c) where a pressure steam steriliser is not available within the facility, laboratory wastes are to be bagged and placed in an unbreakable container with a secured lid for transport to the pressure steam steriliser;
d) wastes are not stored outside the facility before they are sterilised;
e) transport containers used for waste and for protective clothing have provisions for the penetration of steam during sterilising;
f) HEPA filters are used in the facility for the outflow of air (and for fumehoods) (if appropriate, e.g. work involving culturing of fungi);
g) the facility door is kept locked when the room is unoccupied;
h) protective clothing is not worn outside the facility and is transported in closed bags or boxes for sterilisation before laundering;
i) outer clothing and personal effects are kept in storage facilities situated adjacent to the facility area and are not taken into the facility;
j) personnel wash their hands with liquid soap and warm water after handling regulated/quarantine material, and before leaving the facility;
k) a high level of cleanliness is maintained in the facility and measures are taken to ensure good housekeeping in the facility at all times;
l) the area where inspections/ tests are to be conducted on live organisms capable of escaping/spreading is within an enclosed area and effectively sealed to prevent organism escape of all life stages;
m) the area(s) where potentially new or unwanted organisms are to be handled, inspected or tested has a prominent sign labelled as follows:

DIAGNOSTIC FACILITY

MPI Registration Number:

QUARANTINE AREA

UNAUTHORISED ENTRY PROHIBITED

Name of Facility Operator:

n) the sign is permanently affixed, clearly visible and professionally made. The sign has a yellow background with black lettering and a minimum fit to A4 size;
o) the facility is sealable to permit decontamination with gases or disinfectants; and
p) the general accommodation and working environment comply with the procedures for Physical Containment Level 2 facilities specified in the *Australian Standard/New Zealand Standard - Safety in Laboratories Part 3: Microbiological aspects and containment facilities AS/NZS 2243.3 2002*.

Guidance

- The requirements above (a-i) are taken directly from AS/NZS 2243.3:2002, PC3 requirements.

Part 4: Operational Requirements

4.1 Quality system and quality manual

(1) A quality system must be developed and maintained for the facility in accordance with the requirements of ISO/IEC 17025:2017, unless specific exceptions are approved by MPI (on a case-by-case basis; e.g. small laboratories using a very small number of tests), and this standard.

(2) The quality manual, which is a requirement of the quality system:

a) must include procedures and work instructions that clearly show how the facility will deliver the services required by MPI;
b) must clearly specify the scope of the activities for which the facility is approved to undertake (e.g. virology testing for *Vitis* species, entomology identifications for cut flowers);
c) (to facilitate amendments) must be prepared in loose-leaf form, have a number and date on each page and include a table of contents;
d) must describe the communication pathways with the MPI inspector(s) or approved person(s) responsible for granting or recommending the granting of biosecurity clearance for the consignment (if applicable);
e) must describe the procedure for determining if an organism is a new organism or not.

(3) The procedures specified in the quality manual must be subject to document control. MPI must be notified of any amendments to the procedures.

4.2 Organisation and management

(1) Facilities must be externally accredited to ISO/IEC 17025:2017 by an accreditation body which is internationally recognised for the accreditation of testing laboratories (e.g. a member of the Mutual Recognition Arrangement within an international or regional co-operation of accreditation bodies).

(2) Operators must ensure that the laboratory is organised and operated in such a way that all the requirements of this standard are met.

(3) Facilities must be legally identifiable and the owner of the facility must be identified in the quality manual.

4.3 Work with unwanted, suspected unwanted or new organisms

4.3.1 Unwanted/suspected unwanted organisms

(1) Propagation, breeding, or multiplication of an unwanted organism, an organism that is strongly suspected to be an unwanted organism, or an act that is likely to result in propagation, breeding, or multiplication, must not be undertaken unless permitted by a chief technical officer (CTO) under section 53 of the Act.

Guidance

- Application forms for a permission under section 53 of the Act can be obtained by contacting the MPI inspector.
- Propagation or multiplication could include the following: culturing a fungal or bacterial unwanted organism or suspected unwanted organism on media for identification purposes, or inoculating herbaceous indicator plants with a virus that is an unwanted or suspected unwanted organism.

4.3.2 New organisms

(1) Development of a new organism must NOT be undertaken within the facility unless the relevant requirements of the HSNO Act are complied with.

(2) All identified new organisms must be destroyed unless the relevant requirements of the HSNO Act are complied with.

Guidance

- Approval from MPI may also be required if the new organism is also an unwanted organism.

(3) In addition to sections 44 and 46 of the Act, should facility staff strongly suspect the presence of, or identify, a new organism in post-entry quarantine or from the border, then the contact person at the front of this standard must be alerted.

(4) If a new organism is detected (i.e. general surveillance) or an unusual occurrence of an organism known to be present in New Zealand is suspected or identified, then the exotic disease and pest emergency hotline 0800 809 966 must be alerted.

a) The appropriate contacts must be alerted on the same day that the organism is identified or suspected. The following information must be provided to the contact person:

i) suspected disease/results of tests (including method of diagnosis/identification);
ii) species and number of organisms affected; and
iii) import permit number (if applicable, e.g. post entry quarantine).

4.4 Personnel

(1) In addition to requirements stated in clause 5.2 of ISO/IEC 17025:2017, Operators must ensure that:

a) facilities have sufficient personnel with appropriate education, training, technical knowledge and experience for organism sampling and identification;
b) when facilities are in operation that an experienced diagnostician is on duty;
c) facility scientists maintain training and keep an awareness of significant high impact pests;
d) key personnel have access to appropriate journals and up-to-date reference textbooks in their field of expertise;
e) quality manuals describe the training programmes for new or inexperienced staff; and
f) facility management and technical staff do NOT knowingly have a conflict of interest.

4.5 Facility waste

(1) Operators must ensure that all material (including biosecurity risk material, e.g. packaging) that does not receive biosecurity clearance is destroyed, unless approval is obtained from an inspector to retain or store the material or organisms. Records of destruction must be kept.

(2) Prior to disposal, facility waste, which may contain organisms, must be effectively decontaminated by pressure steam sterilisation, incineration, appropriate chemical treatment (refer to AS/NZS 2243.3:2002), by freezing (see definition of frozen) or by another approved method.

(3) Disposal procedures must comply with the procedures for Physical Containment Level 2 facilities specified in the *Australian Standard/New Zealand Standard - Safety in Laboratories Part 3 Microbiological aspects and containment facilities AS/NZS 2243.3 2002*.

(4) Autoclave indicator tests must be used at regular intervals to monitor the microbiological killing power of the sterilisation process. They shall be placed in appropriate positions in the load, including those least likely to attain sterilisation conditions.

Guidance

- Standard autoclave indicator tapes should be used routinely when autoclaving.

4.6 Movement of unwanted or suspected unwanted organisms and quarantine material between facilities

(1) In addition to the requirements of clause 5.8 of ISO/IEC 17025:2017, Operators must ensure that extreme care is taken in transporting quarantine material and unwanted or suspected unwanted organisms within and between facilities. Approval from the MPI inspector must be obtained before movement between facilities can occur.

(2) A person who moves an organism that is known to be an unwanted organism must ensure that the requirements of sections 52 and 53 of the Act are complied with.

4.7 Equipment and reference materials

(1) The requirements of clause 5.5 of ISO/IEC 17025:2017 must be complied with.

4.8 Records

(1) In addition to the requirements of clause 4.12 of ISO/IEC 17025: 2017, Operators must, on a consignment basis, maintain copies/records of:

a) relevant biosecurity/quarantine directives (e.g. the relevant MPI Standards);
b) arrival date of the consignment and/or specimen(s) in the diagnostic facility;
c) any treatment undertaken on arrival at the diagnostic facility; and
d) results of diagnostic tests or pest identification.

(2) All the records listed above must be retained for a period of at least 7 years and be available to the CTO or his or her authorised representative on request.

4.9 Security and access

(1) Operators must ensure that there are adequate procedures for controlling access to the facility and the movement of all specimens associated with imported material.

a) access to the facility must be limited to personnel who are authorised users;
b) visitors to the facility must be accompanied by an authorised user and sign a visitors register.

(2) Operators must at any reasonable time provide access to MPI, or an authorised representative of MPI, for inspection/audit purposes.

(3) MPI inspectors must be informed immediately of any incidents which could significantly compromise containment and the quarantine security of the facility.

(4) Operators must ensure that there are adequate procedures for inspecting facilities after significant natural events that may have affected structural integrity of a facility (e.g., earthquake, flood, wind).

4.10 Reporting escape of a new organism

(1) If a new organism escapes, Operator must notify the MPI inspector as soon as practically possible.

(2) As part of the quality system, the Operator must prepare a contingency plan to contain or, if directed by an inspector, authorised person or CTO, destroy any new organism that may be suspected or confirmed to be in the facility.

4.11 Audit and review

(1) In addition to the requirements of clause 4.13 and 4.14 of ISO/IEC 17025:2017, Operators must ensure that:

a) an internal audit of the facility's activities is carried out at least once every six months to verify that the operations continue to comply with the requirements of the quality system;

i) where the audit findings cast doubt on the correctness or validity of the facility's test results, the Operator must take immediate corrective actions and notify MPI in writing (the contact person).

b) the quality system is reviewed at least once a year to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements;

i) written records of this review shall be maintained by the quality manager and made available to MPI on request.

c) The facility maintains accreditation to ISO/IEC 17025:2017.

Guidance

- MPI may also carry out unannounced inspections and/or audits of the facility to check for compliance with the requirements of this standard.
- A quality manager is described in clause 4.1.5 i, of ISO/IEC 17025:2017).

4.12 Costs

(1) MPI costs involved associated with compliance auditing/inspection of the facility will be recovered in accordance with the Biosecurity (Costs) Regulations 2010.

Part 5: Inter-laboratory comparison testing

5.1 Participation in inter-laboratory comparison testing

(1) All facilities approved to this standard must participate in inter-laboratory comparisons (unless agreed otherwise by MPI) to verify the integrity of the laboratory results produced.

Guidance

- Access to inter-laboratory comparisons can be achieved through the following mechanisms:
  - Participation in a formal proficiency testing scheme operated in accordance with ISO/IEC Guide 43-1:1997 – *Proficiency testing by inter-laboratory comparisons – Part 1: Development and operation of proficiency testing schemes*; or
  - Participation in a formal proficiency testing scheme operated by a recognised provider; or
  - Participation in less formal inter-laboratory comparisons with one or more other laboratories organised by one of the participating laboratories.
- Preference should be given to the option(s) in the order listed above.
- Prior to approval as a diagnostic facility, a proficiency testing plan should be agreed upon between MPI and the proposed Operator as to the suitability of the option(s) chosen. Where the last option above is proposed, the plan needs to state the other laboratories intended as participants in the scheme.

(2) Laboratories chosen for inter-laboratory comparison testing must be selected on the basis of their ability to meet the testing requirements in terms of technical competence and any specific requirements relevant to the testing. The facility being approved must state whether the chosen facility is accredited to NZS/ISO/IEC 17025 or any other quality standard.

(3) Where a diagnostic facility is preparing its own samples for inter-laboratory testing, it needs to have the appropriate resources and documented procedures for the overall process of preparation and distribution of test materials, and for the analysis of the results, including:

a) material preparation, and a description of the type of material that will be sent to the testing facility (e.g. budwood or fresh leaves or freeze dried tissue);
b) compliance with national and international regulations applicable to test item transport;
c) ensuring adequate packaging and labelling;
d) ensuring appropriate transport and distribution arrangements;
e) ensuring adequate reporting to MPI;
f) controlling packaging processes to ensure conformity with relevant transport requirements and to prevent deterioration of the sample in transit;
g) ensuring that material labels are securely attached to the material packaging of individual units and remain legible and intact within the period of use;
h) how results from participating laboratories will be analysed and the criteria for judging the performance of participants as satisfactory or otherwise.

Guidance

- Validation of identification by an independent party for post-clearance (post biosecurity clearance, i.e. general surveillance) samples may also serve as an inter-laboratory comparison.
- It is very important that fresh leaf samples are kept cool at all times, but not frozen, during transportation.
- Positive controls should be sent with the samples.

(4) Where a conflict of interest may exist (e.g. for facilities testing their own material), an inspector must, after consultation with the contact person, select the number and type of samples used in the inter-

laboratory comparison and the tests to be performed, and collect and send these samples to the laboratories.

5.2 Inter-laboratory comparison testing reports

(1) Results of inter-laboratory comparison testing by each diagnostic facility must be sent to the MPI contact person for review following compilation of the results.

(2) If the diagnostic facility participates in a proficiency scheme of an external provider, the following information must be provided:

a) Name and address of the testing facility;
b) Copy of the proficiency testing report provided from the external provider;
c) Clear indication of the facility's results and performance (proficiency testing reports normally code facility identifiers for anonymity); and
d) Relevant specific permit numbers associated with the test results.

(3) If the facility arranges its own inter-laboratory comparisons, the following information must be provided:

a) name and address of the testing facility;
b) a compilation of the results from each participating facility, clearly showing the test(s) conducted;
c) clear indication of the facility's results and performance;
d) relevant specific permit numbers associated with the test results.

(4) Where the results of an inter-laboratory comparison show an unsatisfactory performance on the part of the facility being approved, the MPI inspector must be notified in writing as soon as practicable and an investigation taken into the reasons for the non-conformance. Corrective action must be taken to prevent a reoccurrence.

Schedule 1 – Definitions

The following terms and definitions apply to this Standard. Other terms and definitions used are as per the Biosecurity Act 1993 and any regulations made under this Act.

Animal - Any member of the animal kingdom, excluding humans.

Decontamination - Removal and/or sterilisation of contaminants.

EPA - Environmental Protection Authority

Frozen -

a) For Fruit Fly Host Material: The product must have been subject to freezing until the core temperature has been held at (or below) minus 18°C for a minimum of 7 days.
b) For Non-Fruit Fly Host Material: The product must have been subject to freezing until the core temperature is held at (or below) minus 10°C for a minimum of 7 days.

ISO - International Standardisation Organisation.

MPI - Ministry for Primary Industries.

Microorganism - A microscopic organism, including protozoa, fungi, archaea, bacteria, viruses and unicellular algae.

New organism – As defined in the Hazardous Substances and New Organisms Act 1996.

Nursery stock - Whole plants or parts of plants imported as propagation material, excluding seeds (e.g., cuttings, scions, budwood, root divisions, bulbs, corms, tubers and rhizomes).

Packaging - Product used in supporting, protecting or carrying a commodity (ISPM, 2003).

Pathogen – A microorganism causing disease (ISPM Pub. No. 3, 1996).

Plant - Living plants and parts thereof, including seeds and germplasm (FAO, 1990; revised IPPC, 1997).

Post-entry quarantine (PEQ) - Quarantine applied to a consignment after entry (FAO, 1995).

Procedure - An activity that is carried out for a specific purpose and which includes what shall be done and by whom; when, where, and how it shall be done; what materials, equipment, and documentation shall be used; and how it shall be controlled.

Propagation material - Whole plants or parts of plants intended for growing purposes, excluding seeds.

Quality Manual- defined in ISO/IEC 17000

Quality System - defined in ISO/IEC 17000

Unit - A single undivided plant or plant product entity, often used in sampling procedures.

a) for fresh fruit and vegetables: a unit is an individual piece of produce, e.g. for bananas, a unit is one hand, for grapes, a unit is one bunch.
b) for nursery stock: e.g. a unit is one plant, one bulb or one cutting. For tissue cultures it is the vessel containing the cultures.
c) for fresh cut flowers and foliage: e.g. a unit is an individual fresh flower, a single piece of foliage or a stem, as appropriate.