

**MAF BIOSECURITY AUTHORITY
STANDARD
PBC-NZ-TRA-PQCON**

**Specification for the Registration
of a Plant Quarantine or
Containment Facility,
and Operator**

MAF Biosecurity Authority
Ministry of Agriculture and Forestry
P O Box 2526
Wellington
New Zealand

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Application for Approval as a Transitional Facility Operator
Application for Approval as a Transitional Facility

VERSION CONTROL

This MAF Biosecurity Authority standard replaces all versions of MAF Regulatory Authority standard 155.04.01: Specification for the Registration of a Plant Quarantine or Containment Facility, and Operator.

REVIEW

This MAF Biosecurity Authority Standard is subject to periodic review. The next review date is 1 August 2000. Amendments will be issued to holders of controlled copies to ensure the standard continues to meet current needs.

ENDORSEMENT

This MAF Biosecurity Authority Standard is hereby approved.

Director, Plants Biosecurity

Date:

AMENDMENT RECORD

Amendments to this Standard will be given a consecutive number and will be dated.

Please ensure that all amendments are inserted, obsolete pages removed, and the record below is completed.

Amendment No:	Entered by:	Date:
1	MAF Biosecurity Authority	10 Nov 1999
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1. INTRODUCTION

1.1 SCOPE

This Standard describes the requirements for the registration of plant quarantine and containment facilities and operators of these facilities, as required under the Biosecurity Act 1993.

1.2 REFERENCES

The following documents are referred to in this Standard:

- Biosecurity Act (1993) (as amended by the Biosecurity Amendment Act (1997))
- Biosecurity (Costs) Regulations 1993
- Commodity Specific MAF Biosecurity Authority Import Health Standards
- MAF Regulatory Authority Standard 155.02.06: Importation of Nursery Stock.
- MAF Regulatory Authority Standard 155.02.05: Importation of Seed for Sowing
- MAF Regulatory Authority Standard 154.03.02: Containment Facilities for Micro-organisms
- MAF Regulatory Authority Standard 155.04.03: Specification for the Registration of a Plant Pest Diagnostic Facility, and Operator.
- NZS 5602 1987 (ISO 9002), Quality Systems - Model for Quality Assurance in Production and Installation, Standards Association of N.Z.
- Australia/New Zealand Standard, Part 3, Safety in Laboratories, AS/NZS 2243.3: 1995
- International Standards for Phytosanitary Measures 5; Glossary of Phytosanitary Terms, FAO, Rome, June 1996

1.3 DEFINITIONS

Approved

Having received written approval from the Director General of the Ministry of Agriculture and Forestry.

Audit

An evaluation to determine the degree of conformity with prescribed criteria and provides a basis for ongoing improvement.

Authorised Person

A person for the time being appointed as an authorised person by a Chief Technical Officer under section 103 of the Biosecurity Act (1993).

Biosecurity Clearance

A clearance under section 26 of the Biosecurity Act 1993 for the entry of goods into New Zealand.

Biosecurity/Quarantine Direction

A direction given by an inspector (Supervisor).

Chief Technical Officer

A person appointed a chief technical officer under section 101 of the Biosecurity Act (1993).

Containment Facility

A facility registered by the Director General of the Ministry of Agriculture and Forestry as a containment facility under section 39 of the Biosecurity Act 1993.

Containment Operator

Person registered by the Director General of the Ministry of Agriculture and Forestry to operate a containment facility under section 40 of the Biosecurity Act 1993 and in accordance with this standard.

Diagnostic Facility (Plants)

A transitional facility registered by the Director General of the Ministry of Agriculture and Forestry as a plant diagnostic facility under section 39 of the Biosecurity Act 1993, for diagnosing (identifying) plants or plant pests.

Diagnostic Operator (Plants)

A person registered by the Director General of the Ministry of Agriculture and Forestry, under section 40 of the Biosecurity Act 1993, to operate a diagnostic facility in accordance with MAF Biosecurity Authority Standard PBC-NZ-TRA-DIAGN.

Director, Forests Biosecurity

A person appointed by the Director General of the Ministry of Agriculture and Forestry as having responsibility for managing the Forests Group within MAF Biosecurity Authority. The Director, Forests Biosecurity is also a chief technical officer.

Director General

Director General of the Ministry of Agriculture and Forestry.

Director, Plants Biosecurity

A person appointed by the Director General of the Ministry of Agriculture and Forestry as having responsibility for managing the Plants Group within MAF Biosecurity Authority. The Director, Plants Biosecurity is also a chief technical officer.

Germplasm

Plants intended for use in breeding or conservation programmes.

Import Health Standard

A document issued under section 22 of the Biosecurity Act 1993 by a chief technical officer, specifying the requirements to be met for the effective management of risks associated with the importation of risk goods before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance.

Organism

An organism:

- (a) Does not include a human being or a genetic structure derived from a human being;
- (b) Includes a micro-organism;
- (c) Subject to paragraph (a) of this definition, includes a genetic structure that is capable of replicating itself (whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity);
- (d) Includes an entity (other than a human being) declared by the Governor-General by Order in Council to be an organism for the purposes of this Act;
- (e) Includes a reproductive cell or developmental stage of an organism;
- (f) Includes any particle that is a prion.

Pest

Any species, strain or biotype of plant, animal or pathogenic agent, injurious to plants or plant products.

Plant

Living plants and parts thereof, including seeds.

Propagative Material

Plants intended to remain planted, to be planted or replanted.

Procedure

Means a document that specifies, as applicable, the purpose and scope of an activity; 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.

Quarantine

Confinement of organisms or organic material that may be harbouring pests or unwanted organisms.

Quarantine Facility

A transitional facility registered by the Director General of the Ministry of Agriculture and Forestry as a quarantine facility under section 39 of the Biosecurity Act 1993 for holding plants or plant products, which may be harbouring pests or unwanted organisms, until a biosecurity clearance is granted by an authorised person.

Quarantine Operator

A person registered by the Director General of the Ministry of Agriculture and Forestry, under section 40 of the Biosecurity Act 1993, to operate a quarantine facility in accordance with this standard.

Quarantine Pest (including weeds)

A pest of potential economic importance to New Zealand and not yet present in New Zealand, or present but not widely distributed and is being officially controlled.

The New Zealand Ministry of Agriculture and Forestry has classified quarantine pests into the following groups, depending on their potential to have economic/environmental impacts to plant, animal or human health:

(a) Risk Group 1 Pest

A quarantine pest which, if introduced into New Zealand, has the potential to cause unacceptable economic impacts on the production of a commodity/commodities and/or on the environment.

(b) Risk Group 2 Pest

A quarantine pest which, if introduced into New Zealand, would cause a major disruption to market access and/or significant economic impacts on the production of a particular commodity/commodities, and for which some other importing countries require specific pre-export phytosanitary treatments.

(c) Risk Group 3 Pest

A quarantine pest which, if introduced into New Zealand, would cause major disruption to market access for a wide range of New Zealand commodities and/or significant economic effects on their production and for which some other importing countries impose stringent phytosanitary measures, including prohibiting the entry of the host commodity.

Regulated non-quarantine pest

A pest whose presence in a consignment of plants for planting affects the intended use of those plants with an economically unacceptable impact. Such a pest would be controlled under a New Zealand Government operated or audited certification scheme.

Regulated non plant pests/unwanted organisms

A pest (including a parasite or predator) which is not a pest of plants, but may be associated with plants or plant products and is of concern to human or animal health.

Risk goods

Any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:

- (a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or
- (b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

Supervisor

A person appointed as an Inspector by a Chief Technical Officer under section 103 of the Biosecurity Act 1993.

Supplier

The party responsible for the performance of the inspection and audit work under a contract with the Ministry of Agriculture and Forestry Biosecurity Authority.

Transitional facility

- (a) Any place approved as a transitional facility in accordance with section 39 of the Biosecurity Act (1993) for the purpose of inspection, storage, treatment, quarantine, holding, or destruction of uncleared goods; or
- (b) A part of a port declared to be a transitional facility in accordance with section 39 of the Biosecurity Act (1993).

PART ONE: REQUIREMENTS FOR THE FACILITY AND OPERATOR

2.0 APPROVAL OF A FACILITY AND AN OPERATOR

2.1 REGISTRATION

2.1.1 Registration of Plant Quarantine or Containment Facilities

Plant quarantine or containment facilities in New Zealand shall be registered by the Director General in accordance with section 39 of the Biosecurity Act 1993. An application for registration of any facility as a quarantine facility or a containment facility shall be made to the Director General on an approved form (see Appendices) to be obtained from a Chief Technical Officer, MAF Biosecurity Authority, Box 2526, Wellington.

The type of quarantine or containment facility to be used shall be determined by the type of pests or unwanted organisms (quarantine pests) that may be imported or associated with the imported product. Pest risk is determined by the Ministry of Agriculture and Forestry by considering the risk of introduction (entry and establishment) of a pest via an import pathway and the consequence of the establishment of the pest.

2.1.2 Registration of Plant Quarantine or Containment Operators

Plant Quarantine or Containment operators in New Zealand shall be registered by the Director General in accordance with section 40 of the Biosecurity Act 1993. An application for registration of any person as a quarantine or containment operator shall be made to the Director General on an approved form (see Appendices) to be obtained from a Chief Technical Officer, MAF Biosecurity Authority, Box 2526, Wellington.

2.1.3 Levels of Registration of Quarantine/Containment Facilities

Registration shall be classified into one of the following four levels:

(i) Level 1 Quarantine Facility:

For plant propagating material which may be infected/infested with risk group 1 pests which cannot be detected by visual inspections at the point of entry and are highly unlikely to be spread by wind, water, insects or other vectors.

(ii) Level 2 Quarantine Facility:

For plant propagating material that may be infected/infested with risk group 1 pests which cannot be detected by visual inspections at the point of entry and can be spread by wind, water, insects or other vectors/means.

(iii) Level 3 Quarantine Facility:

For plant propagating material which may be infected/infested with:

- risk group 1 pests which require specific tests for detection
- risk group 2 pests.

(iv) Level 4 Containment Facility:

For plant quarantine pests which are being bred or cultured in host plants (e.g. viruses) for diagnostic or research purposes or for plant material which is known to be infested/infected with quarantine pests in risk groups 1 or 2.

2.1.4 Post Entry Quarantine Requirements

The country:commodity specific import health standard (IHS) or the relevant MAF Biosecurity Authority Standard (MAF Regulatory Authority Standard 155.02.06: Importation of Nursery Stock; and MAF Regulatory Authority Standard 155.02.05: Importation of Seed for Sowing) will state the minimum post entry quarantine requirements.

A Level 3 quarantine facility and a Level 4 containment facility may be audited every six months by a Chief Technical Officer or authorised representative to ensure requirements specified in the standard are being met. If the requirements are not met, the facility and/or the operator may be de-registered in accordance with the Biosecurity Act (1993).

2.2 MANAGEMENT

The quarantine or containment operator shall be responsible for the operation of the facility including:

- care of material,
- checking of material,
- notifying the Supervisor of any detected disease symptoms,
- undertaking any required treatment,
- destruction of infected/infested material (in consultation with a Chief Technical Officer or authorised representative),
- meeting all security requirements,
- keeping and maintaining all required records,
- ensuring all personnel entering the facility understand and abide by the quarantine or containment requirements.

All costs involved in the registration and inspection of the quarantine or containment facility, shall be recovered in accordance with section 135 of the Biosecurity Act 1993 and/or the Biosecurity (Costs) Regulations 1993.

The quarantine or containment operator shall be responsible for making arrangements for the supply of diagnostic services from a Ministry of Agriculture and Forestry registered Plant Diagnostic Facility (see standard 155.04.03). The scope of the contract or agreement for diagnostic supply shall include pest identification services for all the required categories of pests (see section 3 of this standard).

2.3 RECORDS

During the quarantine or containment period, the quarantine or containment operator shall, on a consignment basis, maintain an activity register, which shall contain copies/records of:

- the phytosanitary certificate (photocopy acceptable)
- relevant biosecurity/quarantine direction
- import health standard/permit
- arrival date in the quarantine or containment facility
- any treatment undertaken on arrival
- dates of planting or potting quarantine material
- room or bench location of material during quarantine
- MAF approved routine pest control operations/programmes
- records and results of required tests
- pest detection's and any associated control action(s)
- date of biosecurity clearance or destruction of the consignment

Subsequent to biosecurity clearance or destruction of the consignment, all records listed above shall be retained for a period of twelve months and shall be available to a Chief Technical Officer, an authorised representative or the Supervisor on request.

2.4 ACCESS TO A QUARANTINE/CONTAINMENT FACILITY

The quarantine or containment operator shall provide access to a Chief Technical Officer or authorised representative for inspection/audit purposes.

2.5 AUDIT OF OPERATIONS

Unless otherwise specified in the import health standard/permit to import, or directed by a Chief Technical Officer or authorised representative, unannounced audits may be undertaken by a Chief Technical Officer, an authorised representative, or the Supervisor during the quarantine or containment period to confirm compliance with this standard in accordance with the Biosecurity Act (1993).

2.6 SECURITY OF QUARANTINE/CONTAINMENT FACILITY

The quarantine or containment facility must be secured during the quarantine or containment period so that material cannot be removed without the prior approval of a Chief Technical Officer, an authorised representative or the Supervisor. The quarantine or containment operator must have adequate procedures for controlling access to the quarantine or containment facility.

In the case of Level 1 or Level 2 quarantine facilities, the facility shall only be used for the purpose of screening imported plant propagative material under quarantine. Should another consignment of imported plant propagating material be added to the quarantine facility, the quarantine period for the first consignment shall be extended to coincide with the release of the second import, unless it can be shown that there can be no cross infection/infestation by all pests common to both consignments.

In the case of Level 3 quarantine facilities mixing of consignments may occur, however regard shall be taken for the consequences of cross contamination, and plant movement within facilities should not occur. These facilities may also be used for the purpose of holding indicator plants for tests being completed on plants within the facility. Indicator plants used as positive controls for quarantine pests shall be held in a Level 4 Containment facility only.

2.7 REPORTING OF PESTS

The quarantine operator shall report the detection of any pests or disease symptoms found in the quarantine facility to a Chief Technical Officer or the Supervisor within 48 hours of observing the pest(s).

A containment operator shall report any quarantine pest or disease symptoms detected other than those already notified, within 48 hours of observing the pest(s).

2.8 TREATMENTS APPLIED TO PLANTS IN QUARANTINE

All forms or types of treatment applied to plants in quarantine shall be approved by a Supervisor or Chief Technical Officer prior to application or use. Records shall be kept of all treatments applied to plants during quarantine. Treatments specifically targeting regulated pests shall only be applied to plants in quarantine after written approval has been granted by a Chief Technical Officer or the Supervisor.

Waste material shall be collected in a robust container (plastic bag) that can be sealed. Waste containers are to be kept in the quarantine or containment facility until examined by a Supervisor and cleared for disposal by an approved method.

2.9 IMPORT HEALTH STANDARDS

An import health standard (IHS) is required for all plants and plant products entering New Zealand in accordance with section 22 of the Biosecurity Act 1993. All plant propagating material imported shall comply with the relevant IHS before quarantine direction can be granted by the inspector in accordance with section 125 of the Biosecurity Act 1993. Prior to granting quarantine direction the inspector shall:

- check for compliance with the requirements of the IHS;
- ensure that the material is being directed to a facility registered in accordance with section 39 of the Biosecurity Act 1993;

- ensure that the operator of the facility is registered in accordance with section 40 of the Biosecurity Act 1993;
- be satisfied that the facility is ready and able to accommodate the quantity of material to be imported.

3.0 SPECIFICATIONS FOR A QUARANTINE OR CONTAINMENT FACILITY

3.1 LEVEL 1 QUARANTINE FACILITY (OPEN GROUND SITES)

Some plant species that only have risk group 1 pests which are not likely to be transmitted by wind, water, insects or other vectors may be grown in an open ground quarantine facility. Open ground facilities are subject to the isolation requirements below, and those prescribed in the relevant import health standard or Permit to Import. All open ground quarantine sites shall:

- have ready access for quarantine inspections,
- provide good growing conditions for the imported plant material,
- not be subject to flooding.

The following minimum isolation requirements must be met unless otherwise stated in the relevant import health standard or Permit to Import.

For herbaceous plants in quarantine:

- 50 metre distance from plants of the same genus;
- 20 metre distance from all other herbaceous plants (excluding lawn);
- 5 metre distance from woody plants.

For woody plants in quarantine:

- 50 metre distance from plants of the same genus;
- 20 metre distance from all other woody plants;
- 5 metre distance from herbaceous plants (excluding lawn).

Barriers such as a waterway, sealed road, or solid fence may allow for reduced isolation distances.

“Buffer zones” may be established around quarantine crops under the following conditions:

- the plants within the “buffer zones” (buffer plants) are included in the quarantine facility and are therefore subject to quarantine requirements regarding treatment or destruction;

- the isolation requirements from other plants outside the quarantine area shall apply to the quarantine plants only, as specified above (i.e. the area within the 50 metre isolation from plants of the same genus may be occupied by buffer plants);
- intensive (sampling) inspections of the plants within the quarantine facility by the Supervisor shall be restricted to the quarantine plants only;
- the quarantine area (including buffer zone) shall be clearly delineated on all sides.

Operators' of Level 1 quarantine facilities shall make arrangements for the supply of diagnostic services for the following pest categories:

- Plants (weeds), Fungal, bacterial, viral/phytoplasma.

3.2 LEVEL 2 QUARANTINE FACILITY:

Plant species with risk group 1 pests which are likely to be transmitted by wind, water, insects or other vectors shall be grown under conditions which minimises the risk of these quarantine pests becoming established in New Zealand. There are three types of Level 2 Quarantine Facilities, that is, Quarantine Aquarium for aquatic plants, Greenhouse/Screenhouse for terrestrial plants, and tissue culture facilities for *in-vitro* plants or plant material.

Operators of Level 2 Quarantine Facilities shall make arrangements for the supply of diagnostic services for all pest categories (see MAF standard 155.04.03).

3.2.1 Quarantine Aquarium for aquatic plants.

The critical structural requirements are:

- each aquarium shall be clear sided and clearly labelled as follows:

<p>QUARANTINE AQUARIUM</p> <p>Ministry of Agriculture and Forestry Registration Number: </p> <p>Name of Quarantine Operator:</p>

- each aquarium shall be placed in a watertight tray, the bottom of which shall contain a dilute solution of copper sulphate (5 parts per million or a small grain of a copper sulphate crystal in a litre of water);
- each aquarium shall be inside a building which can be secured;
- each aquarium shall be at least 5m away from a non-quarantine aquarium.

3.2.2 Level 2 Quarantine Greenhouse/Screenhouse

The critical service and structural requirements/specifications are as follows:

- the quarantine facility shall be constructed and operated in a manner that shall contain, in isolation, the plant material and any associated pests;
- the structure shall be completely enclosed in glass, polythene, or other continuous material except for the entry/exit and ventilation requirements. The requirement for plastic film cladding is a minimum of 200 microns thick (heavy duty) polyfilm;
- all windows, louvres or vents shall be effectively screened with insect-proof mesh with a maximum aperture of 0.6mm or a 30 X 30 (per sq. inch) mesh;
- the vents and doors shall be tight fitting and constructed of material which shall maintain rigidity at all times;
- the structure shall have a concrete floor, be strong enough to withstand the normal range of weather conditions and not be subject to flooding;
- the structure shall have an insect-proof anteroom or porch with a double door for entrance/exit. There must be sufficient space to permit the entry of people and planting material with one door being closed at all times;
- a gully or soil trap connected to sewage, septic tank or a suitable rubble drain shall be used. The quarantine operator shall ensure that all material released into the sewage or waste water system is in compliance with local or regional by-laws/regulations;
- a foot bath utilising an effective disinfectant shall be used;
- appropriate plant hygiene measures (e.g. disinfection of cutting tools) shall be maintained at all times;
- the facility shall be maintained free of weeds, lichen and moss;
- yellow sticky insect traps shall be appropriately installed in each quarantine house at a minimum rate of one per 15 square metres of planted area and replaced for every new consignment after inspection by the Supervisor;
- all plants must be grown in sterilised or inert media and be easily accessible for inspection by the Supervisor;
- during the quarantine period the quarantine facility shall only be used for the registered purpose;

- The quarantine facility shall have a prominent sign labelled as follows:

<p>LEVEL 2 QUARANTINE FACILITY</p> <p>MAF Registration Number: _____</p> <p>ACCESS RESTRICTED TO AUTHORISED PERSONNEL ONLY</p> <p>Name of Quarantine Operator: _____</p>
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3.2.3 Level 2 Quarantine Tissue Culture Laboratory

In addition to the critical service and structural requirements/specifications for a level 2 Quarantine Greenhouse/Screenhouse, the following conditions are required:

- plantlets in tissue culture shall be handled and grown under secure conditions;
- all plantlets in tissue culture must be clearly labelled as quarantine material and separated from containers with non-quarantine plantlets;
- operating procedures to NZS 5602 or ISO 9002 Standard shall be developed by the quarantine operator to prevent cross contamination of material not in quarantine with material in quarantine;
- a loose-leaf controlled copy of the quality manual shall be made available to a Chief Technical Officer or authorised representative for approval prior to registration.

3.3 LEVEL 3 QUARANTINE FACILITY

Plant material which may be infected/infested with risk group 1 quarantine pests, the identity of which can only be determined by conducting specific tests, and risk group 2 quarantine pests shall be inspected and tested in a Level 3 Quarantine Facility.

Operators of Level 3 quarantine facilities shall make arrangements for the supply of diagnostic services for all pest categories.

3.3.1 Level 3 Quarantine Greenhouse

The critical service and structural requirements/specifications for a Level 3 Quarantine Greenhouse are as follows:

- the quarantine facility shall be constructed and operated in a manner that shall contain, in isolation, the plant material and any associated pests;

- the structure shall be completely enclosed in glass, polythene, or other impact-resistant material except for entry/exit and ventilation requirements;
- all windows, louvres or vents shall be effectively screened with insect-proof mesh with a maximum aperture of 0.6mm or 30 X 30 (per sq. inch) mesh;
- the vents and doors shall be tight fitting and constructed of material which shall maintain rigidity at all times;
- the structure shall have concrete floor, be strong enough to withstand the normal range of weather conditions and not be subject to flooding;
- the structure shall have an insect-proof anteroom or porch with a double door for entrance/exit. There must be sufficient space to permit the entry of people and planting material with one door being closed at all times;
- a gully or soil trap connected to sewage, a septic tank or a suitable rubble drain shall be used. The quarantine operator shall ensure that all material released into the sewage or waste water system is in compliance with local or regional by-laws/regulations;
- a foot bath utilising an effective disinfectant shall be used;
- appropriate phytosanitary measures (e.g. disinfection of cutting tools) should be maintained at all times;
- the facility shall be maintained free of weeds, lichen and moss;
- all plants shall be grown in sterilised or inert media;
- all plants shall be grown on raised benches and be easily accessible for inspection by the Supervisor;
- yellow sticky insect traps shall be appropriately installed in each quarantine house at a minimum rate of one per 15 square metres of planted area and replaced for every new consignment after inspection by the Supervisor;
- during the quarantine period the quarantine facility shall only be used for the registered purpose;
- the quarantine facility shall have a prominent sign labelled as follows:

LEVEL 3 QUARANTINE FACILITY

MAF Registration Number: _____

ACCESS RESTRICTED TO AUTHORISED PERSONNEL ONLY

Name of Quarantine Operator: _____

- the operator shall provide evidence that all testing for quarantine pests can be conducted in accordance with the requirements stipulated in the import health standard. Tests may be undertaken, on the quarantine operator's behalf, by a testing laboratory approved by a Chief Technical Officer;
- the operator shall provide a monthly report summary to the Supervisor listing the plants in the facility (number and type) and their current status (e.g. under treatment, awaiting disposal). The report shall also detail what plants have been given biosecurity clearance, destroyed, transferred, or otherwise removed from the facility since the last report.
- the operator shall establish and maintain procedures and instructions for the following NZS 5602 or ISO 9002 quality system requirements:
 - management responsibility (the qualifications, experience and responsibilities of all persons involved in pest diagnosis shall be included in this)
 - quality system
 - document control system
 - process control
 - inspection and testing
 - control of non-conforming product
 - corrective action
 - handling, storage, packaging and delivery
 - quality records
 - internal audits
 - training
- a loose-leaf controlled copy of the quality manual shall be made available to a Chief Technical Officer or authorised representative for approval prior to registration.

3.3.2 Level 3 Quarantine Tissue Culture Laboratory

In addition to the critical service and structural requirements/specifications for a Level 3 Quarantine facility, the following conditions are required:

- plantlets in tissue culture shall be handled and grown under secure conditions;

- All plantlets in tissue culture must be clearly labelled as quarantine material and separated from containers with non-quarantine plantlets;
- Operating procedures to NZS 5602 or ISO 9002 Standard shall be developed by the quarantine operator to prevent cross contamination of material not in quarantine with material in quarantine;

3.4 LEVEL 4 CONTAINMENT FACILITY

The Level 4 Containment Facility is for the storage or breeding/culturing of risk group 1 and 2 quarantine pests in plant material. Such organisms may need to be imported for storage in reference collections or bred/cultured for identification as a result of an exotic pest outbreak or interception at the border.

Operators of Level 4 containment facilities shall make arrangements for the supply of diagnostic services for all pest categories.

3.4.1 Level 4 Containment Greenhouse

The critical service and structural requirements for a Level 4 Containment Greenhouse are as follows:

- the containment facility shall be constructed and operated in a manner that shall contain the pests and host plants in isolation;
- the structure shall be completely enclosed in glass, polythene, or other impact-resistant material;
- the structure shall have an insect-proof anteroom or porch with a double door for entrance/exit. There shall be sufficient space to permit the entry of people and planting material with one door being closed at all times;
- the vents and doors shall be tight fitting and constructed of material which shall maintain rigidity at all times;
- the doors and facility vents shall be sealable to permit decontamination with gases such as formaldehyde. The doors shall be fitted with automatic closers and locks;
- the structure shall have concrete floor with a non-slip finish, be strong enough to withstand the normal range of weather conditions and not be subject to flooding, and have smooth surfaces, including bench tops and cupboards, to permit wipe down access for decontamination;
- all plants shall be grown on raised benches, in sterilised or inert media, and be easily accessible for inspection by the Supervisor;

- a gully or soil trap connected to sewage, a septic tank or a suitable rubble drain shall be used. The quarantine operator shall ensure that all material released into the sewage or waste water system is in compliance with local or regional by-laws/regulations;
- a foot bath utilising an effective disinfectant shall be used;
- appropriate phytosanitary measures (e.g. disinfection of cutting tools) should be maintained at all times;
- the facility shall be maintained free of weeds, lichen and moss;
- the containment facility shall only be accessible to persons authorised by the containment operator;
- yellow sticky insect traps shall be appropriately installed in each quarantine house at a minimum rate of one per 15 square metres of planted area and replaced for every new consignment after inspection by the Supervisor;
- the outer door must have a clearly visible sign stating:

<p>LEVEL 4 CONTAINMENT FACILITY</p> <p>MAF Registration Number: _____</p> <p>ACCESS RESTRICTED TO AUTHORISED PERSONNEL ONLY</p> <p>Name of Quarantine Operator: _____</p>

- if required have access to a micro-organism containment facility (see Ministry of Agriculture and Forestry standard 154.03.02);
- if required the intake and exhaust air from any ventilation system be fitted with HEPA filters and prefilters in accordance with the specifications for Physical Containment (PC) Level 3 facilities in Australia/New Zealand Standard (AS/NZS) 2243.3:1995, Safety in Laboratories, Part 3, Microbiology;
- all freezers, refrigerators or other storage cabinets for quarantine organisms shall be kept locked, except when samples are being taken or returned;
- during the containment period the containment facility shall only be used for the registered purpose;
- the containment operator shall provide evidence that all activities associated with the handling of quarantine pests can be conducted in accordance with the requirements stipulated in the import health standard or as directed by a Chief Technical Officer

or authorised representative. The operator shall establish and maintain procedures and instructions for the following NZS 5602 or ISO 9002 quality system requirements:

- management responsibility (the qualifications, experience and responsibilities of all persons working in the containment facility shall be included under management responsibility)
 - quality system
 - document control system
 - process control
 - inspection and testing
 - control of non-conforming product
 - corrective action
 - handling, storage, packaging and delivery
 - quality records
 - internal quality audits
 - training
- a loose-leaf controlled copy of the quality manual shall be made available to a Chief Technical Officer or authorised representative for approval prior to registration.

3.4.2 Level 4 Containment Tissue Culture Laboratory

In addition to the critical service and structural requirements/specifications for a level 4 containment facility, the following conditions are required:

- Plantlets in tissue culture shall be handled and grown under secure conditions;
- All plantlets in tissue culture shall be clearly labelled as containment material and separated from containers with non-quarantine plantlets;
- Operating procedures to NZS 5602 or ISO 9002 Standard shall be developed by the quarantine operator to prevent cross contamination of material not in containment with material in containment.

4.0 BIOSECURITY CLEARANCE

For Level 1, 2 and 3 Quarantine Facilities, if a Chief Technical Officer or authorised representative is satisfied that during the specified quarantine period, no quarantine pests were detected, or if found, successfully treated, biosecurity clearance shall be given in writing by a Supervisor.

5.0 DESTRUCTION OF PLANT MATERIAL OR PESTS

A Chief Technical Officer shall direct the quarantine or containment operator to destroy all plant material or pests for which biosecurity clearance has not been granted unless approval has been given to maintain or store the plant material or pests.

6.0 DE-REGISTRATION OF THE QUARANTINE/CONTAINMENT FACILITIES OR OPERATORS

If the Director General is no longer satisfied that the quarantine or containment operator is operating and/or maintaining the quarantine or containment facility in accordance with this standard, or the facility no longer meets the requirements of this standard, registration of the operator/facility will be cancelled in accordance with sections 39 and 40 of the Biosecurity Act 1993.

PART TWO: REQUIREMENTS OF THE SUPERVISOR

SCOPE OF PART TWO

Part Two of this standard specifies the requirements for the supplier of supervision of Plant-Quarantine or Containment facilities in New Zealand to ensure that these facilities are operating in compliance with Part One of this standard.

SERVICE OUTLINE

The supplier shall provide the Chief Technical Officer with a service to supervise the activities of operators who are required to operate facilities according to Part One of this standard.

7.0 SERVICE REQUIREMENTS

7.1 GENERAL REQUIREMENTS

Supervision shall be administered in accordance with standard EN45004, this standard, a national quality system based on ISO 9001 and any relevant legislation.

The supplier shall provide quarterly reports to the appropriate Chief Technical Officer giving an update on the supplier's management structure and key personnel (refer section 5.2), and results of internal audits and corrective actions.

The supplier and employees shall have no financial interest in the quarantine or plant containment facilities or any other affiliations that could be construed as a conflict of interest.

A Chief Technical Officer may audit the Supervisor at each plant quarantine or containment facility.

7.2 KEY PERSONNEL

Within one month of receipt of this standard, the supplier shall make formal arrangements for provision of the key personnel listed below. A Chief Technical Officer shall be notified in writing of these arrangements.

7.2.1 Management representative

The management representative (reporting to senior management) shall have defined authority and responsibility for ensuring that there are systems in place to meet the requirements of this standard and that these systems are implemented and maintained.

7.2.2 Supervisors of Plant Quarantine or Containment Facilities

A Chief Technical Officer shall approve Supervisors before they are appointed.

Qualifications: The Supervisor shall be an inspector as defined by the Biosecurity Act 1993 who has a science degree or similar training. The Supervisor shall be able to demonstrate the s/he has an understanding of the principles of quarantine, quality systems and auditing, import health standards, the requirements of this Standard, the relevant legislation and some appreciation of the business and objectives of the operator. For **Level 1 Plant Quarantine Facilities only** the Supervisor shall be able to identify, on site, common local (non-regulated and MAF approved) diseases infecting the plants in the facilities they are supervising.

The supplier shall ensure that a person appointed to be a supervisor of a Plant-Quarantine or Containment facility is able to describe in a way that can be clearly understood by the operator of these facilities:

- the commonly used means for meeting the requirements of this Standard including the controls specified by the Authority for the quarantine of imported plants;
- the circumstances in which such means can fail to comply;
- what steps should be taken to re-establish compliance.

The supplier shall be responsible for the training of Supervisors, so that they know their responsibilities for this Standard.

7.2.3 Access to expertise

The supplier shall provide Supervisors with access to a person who has demonstrable expertise relating to plant pathology and has containment experience or training in the principles of quarantine and containment. This person shall be able to provide practical advice on the technical aspects of this Standard.

The supplier shall be responsible for the training of Supervisors, so that they know their responsibilities for this Standard.

8. TECHNICAL REQUIREMENTS

8.1 REGISTRATION OF THE FACILITY

The requirements for registration are described in Part One of this Standard and the Supervisor shall inspect the facility before making a recommendation on registration.

The location of the quarantine or containment facility shall be clearly identified by the operator both on site and on maps and/or diagrams provided to the Supervisor.

Note: For Level 1 quarantine facilities only:

An area larger than the quarantine site (i.e. the entire farm) may on inspection be “site approved” by the Supervisor. This may allow the registration of additional quarantine sites within the approved area without the need for re-inspection by the Supervisor but subject to the area being substantially unchanged from the time of the approval.

If the quality system is accredited by an external agency as described in Part One, the Supervisor shall satisfy him/herself that the requirements of this Standard are addressed in the quality assurance programme.

8.2 REGISTRATION OF AN OPERATOR

Requirements for registration are described in Part One.

Where the facility is leased, the Supervisor shall examine the contract and be satisfied that the contract does not override the requirements of the Standard.

The Supervisor shall make a recommendation to a Chief Technical Officer taking the requirements of this Standard into consideration.

8.3 CANCELLATION OF REGISTRATION

Expiry of registration will occur at a time specified in the certificate of registration or upon the occurrence of an event specified in the registration.

Also, if the Supervisor is satisfied that the Plant Quarantine or Containment facility:

- no longer complies with this Standard including controls specified by the Authority, or
- is no longer being used for the purpose or one or more of the purposes specified in the approval,

he/she shall discuss the issue with the operator. Then, if necessary, and after informing the operator of his/her intention in writing, the Supervisor shall make a recommendation to a Chief Technical Officer that registration of the facility should be cancelled.

If the Supervisor is satisfied that the operator;

- is not operating the facility according to this Standard including controls specified by the Authority, or
- is no longer a fit and proper person, or
- ceases to act as the operator or requests cancellation

he/she shall discuss the issue with the operator. Then, if necessary, and after informing the operator of his/her intention in writing, the Supervisor shall make a recommendation to a Chief Technical Officer that registration of the operator should be cancelled. If an alternative operator cannot be registered then the registration of the facility shall also be cancelled.

8.4 SUPERVISION OF A FACILITY

8.4.1 Minimum requirements for inspection

The Supervisor shall complete crop inspections of quarantine facilities at least three times in the first three months of quarantine, and then at least once every three months thereafter unless otherwise specified in the import health standard, permit to import, or by a Chief Technical Officer or authorised representative. An audit of the operation shall be completed at least once every six months during a crop inspection (if possible). Crop inspections and audits of containment facilities shall be completed once every 6 months. If the facility is left unoccupied for more than 6 months the Supervisor shall audit the facility either prior to or within one week of arrival of a new consignment.

During the crop inspection the Supervisor shall assess that:

- the identity of the plants in the facility correlates with the species specified on the permit(s) to import, the export certification is in order and any post-arrival requirements of the import health standard have been, or are being complied with;
- the plants in the facility correlate with the register;
- activities listed in the activity register comply with the quarantine or containment manual;
- the plants are free of pests (see section 8.4.2 below).

During the audit the Supervisor shall assess that:

- the procedures as required in the quarantine or containment manual are practised;
- the structural requirements as set out in this Standard (see section 3) are being maintained.

8.4.2 Sampling for pests or disease symptoms

On each crop inspection, the Supervisor shall inspect all plants pertaining to the particular consignment for evidence of pest or disease symptoms. The Supervisor shall select samples of plants (see table 1 below) for a more intensive inspection using a 10x hand lens or similar examination tool. For all inspections the Supervisor shall complete as far as possible a Ministry of Agriculture and Forestry approved Quarantine Inspection Report form.

Note for Level 1 Quarantine Facilities only: damage or symptoms of insect pests shall not be sampled or identified unless specified for general surveillance requirements. The Supervisor shall identify on site any common non-regulated pests when detected.

Should a pest be found or pest symptom be detected:

- An appropriate tissue sample shall be taken;
- The sample shall be packaged in Ministry of Agriculture and Forestry approved sample container;
- A quarantine specimen identification form shall be completed;
- The sample shall be sent for identification to a Ministry of Agriculture and Forestry registered Plant Pest Diagnostic Facility (see standard 155.04.03).

Note: All plant quarantine or containment facilities shall have prior arrangements made for diagnostic supply as specified in section 3 of this standard. If the operator has arrangements for more than one diagnostic supplier to complete diagnostics the Supervisor shall decide which supplier receives the sample based on the likely pest of concern.

Table 1: Sampling requirements

Consignment (homogenous) size	Sample size
1-50	all
51-100	30
101 upwards	60

8.4.3 Non-compliance

Incidents of non-compliance will be dealt with by issuing:

- A **critical situation report** (CAR) (or Quarantine Report) for situations that may present a serious risk to biosecurity, e.g. plants being moved out of the quarantine or containment facility without approval; quarantine pest identified.

A Chief Technical Officer shall be advised immediately and the action taken shall be in accordance with section 126 or 127 of the Biosecurity Act.

The Supervisor shall give a direction in writing to the operator of the facility specifying the suspected failure to comply or unsatisfactory circumstances, stating what the operator is required to do to remedy the situation and specifying the time within which the direction must be complied with.

A Chief Technical Officer may direct that all planting within the facility is to cease immediately and may not be permitted to recommence until the non-conformity is rectified.

If a Chief Technical Officer considers it necessary s/he may intervene in the management and operation of the facility in order to ensure compliance with the standards for that facility; or terms upon which the organism is confined in the facility.

- A **corrective action request** (CAR) for a non-compliance that is not a serious risk to biosecurity, e.g. plants not maintained properly.

Work will be permitted to continue but the facility will be given a specified period of time to rectify the non-conformity.

The issuance of corrective action requests during any of the above audits/visits will necessitate that follow up audits be performed which specifically address compliance to the subject of the request.

8.4.4 Transfer of plants between quarantine facilities

The Supervisor may authorise the transfer of plants between facilities of equal level or to facilities of greater level (e.g. Level 1 to Level 2) when satisfied that:

- the receiving facility is an approved quarantine or containment facility which meets the quarantine or containment requirements (including any controls specified by the Authority) for the species as specified by the Permit to Import,
- the method of transfer shall ensure that the plants or any possible contaminant cannot escape,
- the Supervisor of the receiving facility confirms that the receiving facility can accommodate the plants and approves the transfer,
- a Chief Technical Officer approves the transfer for plants requiring Level 3 quarantine or containment.

The written authority may be for single or multiple transfers within a specified time.

At the time of the transfer the Supervisors shall be satisfied that:

- the transfer can be monitored so that both Supervisors know when the transfer is to occur and when it has occurred,
- a record of the transfer is noted in the registers of both facilities.

8.4.5 Cost recovery

The Supervisor shall recover the costs associated with approval of the facility and supervision of the facility in accordance with the Biosecurity (Costs) Regulations, 1993.

8.4.6 Reporting requirements

The Supervisor shall provide, to the appropriate Chief Technical Officer, every six months, for Level 1 and 2 quarantine facilities and Level 4 containment facilities, and every 2 months, for Level 3 quarantine facilities, a written report that identifies the plant species being held in each facility and a brief report on inspections and audits. It shall include notes on any major non-conformities encountered during that period and the outcome of the associated CARs.

8.4.7 Biosecurity clearance of quarantine plants

On completion of the final inspection, and subject to the absence of any regulated pests, the Supervisor shall forward a completed Quarantine Report form to a Chief Technical Officer recommending the consignment is given Biosecurity Clearance. Biosecurity Clearance shall be given in writing to the Operator subject to confirmation by a Chief Technical Officer or authorised representative.

8.4.8 Records

The Supervisor is required to keep records of visits and audits of the facility for a period of five years. These records shall include copies of authorisations, audit findings and reports of critical situations, CARs and the results of follow-up visits.

APPENDICES: APPLICATION FORMS

APPLICATION FOR APPROVAL AS A TRANSITIONAL FACILITY OPERATOR
PURSUANT TO SECTION 40 OF THE BIOSECURITY ACT, 1993.

The application for approval as operator of a transitional facility shall be made to the Director General by the person responsible for the facility and its operation. Qualifications and experience of the operator (and the manager, if the manager is to be appointed as well as the operator) to be detailed on a separate page.

Applicants name:.....

Designation:

Organisation:.....

Postal Address:.....

Telephone No:..... Facsimile:..... E-mail:

Name of facility:.....

Purpose of facility: [inspection] [storage] [treatment] [quarantine]
(delete those that do not apply) [holding] [destruction of uncleared goods]

I,
being the person (the proposed operator) responsible for the facility named above, declare that:

- I have technical and financial resourcing mechanisms in place to maintain that facility;
- I have read and understand MAF Standard (enter full date and title of standard)

.....
and I will ensure that the operation of the facility is in accordance with this Standard.

I hereby apply for approval as the operator of the above facility.

.....
Signature of Applicant

.....
Date

APPLICATION FOR APPROVAL OF A TRANSITIONAL FACILITY

PURSUANT TO SECTION 39 OF THE BIOSECURITY ACT, 1993.

Name of facility:.....

Purpose of facility: [inspection] [storage] [treatment] [quarantine]
(delete those that do not apply) [holding] [destruction of uncleared goods]

Location Address:.....

Operator's Name:.....

Organisation:.....

Postal Address:.....

Telephone No:..... Facsimile:..... E-Mail:.....

Uncleared goods which will be held in the facility:.....

.....

Capacity of transitional facility: e.g. number of organisms accommodated, net volume of holding space

.....

I,
being the applicant declare that the above facility meets the requirements of MAF Standard (enter full title and date of standard)

.....
and apply to have it approved by the Director General as transitional for the purpose stated above.

.....
Signature of Applicant Date