MAF Biosecurity New Zealand
and ERMA New Zealand Standard

Facilities for Microorganisms and Cell Cultures: 2007

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

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ERMA New Zealand

The Environmental Risk Management Authority (ERMA), in accordance with section 11(1)(fb) of the Hazardous and Substances and New Organisms Act 1996, approves this standard – **Facilities for Microorganisms and Cell Cultures: 2007** as a standard for containment facilities.

Rob Forlong **Date**

Chief Executive
ERMA New Zealand
(for the Environmental Risk Management Authority)

MAF BIOSECURITY NEW ZEALAND

MAF, in accordance with section 39 of the Biosecurity Act 1993, approves this standard – **Facilities for Microorganisms and Cell Cultures: 2007** as a standard for transitional facilities.

Clive Gower-Collins **Date**

Manager, Import Standards
MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry

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Foreword

The Environmental Risk Management Authority (ERMA) is responsible for making decisions under the Hazardous Substances and New Organisms (HSNO) Act 1996 on applications to introduce and/or develop new organisms (including genetically modified organisms) in New Zealand.

MAF Biosecurity New Zealand (MAFBNZ), a division of the Ministry of Agriculture and Forestry (MAF), is the lead agency in New Zealand's biosecurity system. It is responsible for preventing the importation of unwanted pests and diseases, and for controlling, managing or eradicating them should they arrive.

MAFBNZ is also the agency responsible for enforcing the new organism provisions of the HSNO Act, including HSNO Act Approvals and associated containment controls.

The Import Standards Group of MAFBNZ develops import health standards and operational standards in order to exercise those enforcement responsibilities.

This standard – *Facilities for Microorganisms and Cell Cultures: 2007*, is a joint ERMA - MAF standard prepared by MAFBNZ (Import Standards Group) in collaboration with ERMA New Zealand.

This version cancels and replaces the previous version (standard *154.03.02: 2002 - Containment Facilities for Microorganisms*) and those parts of the MAF Regulatory Authority (Animal Health and Welfare) standard *154.02.17 – Transitional Facilities for Biological Products*[1] that currently provide for viable microorganisms and animal cell cultures.

Significant amendments from the previous version are:

- expanding the scope of the standard to include animal cell cultures
- expanding the scope of the standard to encompass transitional facilities for:
  - unwanted microorganisms
  - animal cell cultures
  - any other microorganism considered by a chief technical officer to be a risk good
- clarification of registers
- provision of an audit escalation pathway and audit dispensation guidelines

[1] This standard will be amended during the first half of the 2007/08 financial year.

Review and Amendment

This standard is subject to review and amendment at any time, to ensure that it continues to meet current needs.

Reviews and amendments, in the form of new versions, will be notified to Operators of facilities approved under this standard.

Operators are responsible for ensuring that the most recent version of this standard is being used.

This standard is accessible on:

www.biosecurity.govt.nz/commercial-transport-and-border-management/standards/forest-products
www.biosecurity.govt.nz/commercial-transport-and-border-management/standards/animal-and-animal-products

The MAF Unwanted Organisms Register is accessible by the following link:

mafuwsp6.maf.govt.nz/uor/searchframe.htm

Contact Persons

For all operational issues, please contact the MAF Inspector responsible for your facility.

The person responsible for all matters relating to the review and amendment of this standard is a senior adviser within the Operations Team of MAFBNZ. This person can be contacted through the office below:

Operations Team
MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry
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1 Introduction

1.1 Purpose

Microorganisms and animal cell cultures included in the scope of this standard (section 2.1) have been identified as risk goods under the Biosecurity Act 1993. Work with these organisms, which include genetically modified organisms, unwanted organisms, risk species and restricted organisms, is subject to compliance with statutory regulations specified in the Biosecurity Act 1993 and the Hazardous Substances and New Organisms (HSNO) Act 1996. This standard was developed to meet the requirements of these Acts, in regard to setting minimum specifications for:

- holding microorganisms and animal cell cultures, that are new to New Zealand, in a containment facility,
- inspection, storage, treatment, quarantine, holding, or destruction of microorganisms and animal cell cultures in a transitional facility.

1.2 General

This standard should be read in conjunction with AS/NZS 2243.3: 2002 - *Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities*. This joint Australian/New Zealand Standard sets out the requirements, responsibilities and general guidelines relating to safety in laboratories where microorganisms are handled, including minimum physical containment specifications for working with various risk groups of microorganisms. The standard is also incorporated in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

Before any microorganisms and cell cultures can be imported into New Zealand, a permit to import is required from MAFBNZ. The permit may require further conditions to be met in addition to the requirements of an import health standard (IHS) and any relevant HSNO Act Approval.

All facilities approved to this standard are subject to regular audits by MAFBNZ.

1.3 Microorganisms and Cell Cultures held in Containment Facilities

Microorganisms and cell cultures that are **new** organisms (including genetically modified organisms) must be held in containment facilities and are not approved for release into New Zealand.

Approval for these organisms to be imported into, and/or developed in, containment facilities, is given subject to containment controls specified by ERMA or, in regard to low risk genetically modified organisms[1], by Institutional Biological Safety Committees (IBSCs) or the Chief Executive of ERMA New Zealand under delegation from ERMA.

New organisms must meet the biosecurity requirements of the transitional facility prior to being held in a containment facility.

[1] HSNO (Low-Risk Genetic Modification) Regulations 2003

1.4 Microorganisms and Cell Cultures held in Transitional Facilities

Microorganisms and cell cultures that are considered by a CTO to be risk goods are required to be held in transitional facilities for the purposes specified in section 1.1. Risk goods are those for which it is reasonable to suspect constitute, contain or harbour an organism that may:

- cause unwanted harm to natural and physical resources or human health in New Zealand, or
- interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

Microorganisms and cell cultures that are risk goods are those organisms listed in the scope of this standard in section 2.1. Permission to import such organisms is given through a permit to import and an import health standard and may be subject to conditions specified by MAF.

New organisms held in a containment facility must meet the biosecurity requirements of the transitional facility prior to work being carried out in the containment facility.

In order to hold and propagate unwanted organisms[1] the permission of a CTO is required (sections 52 and 53, Biosecurity Act 1993). Operators should contact the Operations Team of MAFBNZ in the first instance to make arrangements to obtain CTO permission.

2 Scope

2.1 Included in Scope

The scope of this standard includes the minimum requirements that must be met for the containment of the following categories of organisms in transitional or containment facilities for the purposes specified in section 1.1.

- Microorganisms and animal cell cultures (including genetically modified organisms) that are new organisms and/or risk species under the HSNO Act.
- Microorganisms that are unwanted organisms or restricted organisms.
- Plants, including plant tissue cultures, that are new organisms under the HSNO Act, and which have been directed to be held under this standard in a HSNO Act Approval.
- Any other microorganism and/or animal cell culture considered by a CTO to be a risk good, e.g., live animal cells, which may contain viruses.
- Unidentified microorganisms from border interceptions, post-entry quarantine, or incursion investigations.

The scope also includes:

- the minimum requirements of a Quality Management System (QMS),
- the minimum structural and operating requirements of facilities,

[1] http://www.biosecurity.govt.nz/commercial-imports/unwanted-organisms-register-

- how facilities and Operators may be approved,
- the audit regime and the management of non-compliance.

2.2 Excluded from Scope

The scope of this standard does **not** include the requirements that must be met for the containment of:

- non-viable products (biological products) derived from living organisms,[1]
- human cell cultures (non genetically modified),[2]
- plant tissue cultures[3], other than those directed to be held under this standard in a containment facility by a HSNO Act Approval.

2.3 Development of Plants that are New Organisms

Some HSNO Act Approvals provide for the development of plants, derived from plant tissue cultures, in facilities approved to the previous MAF/ERMA New Zealand Standard *154.03.02: 2002 - Containment Facilities for Microorganisms*. This allows for manipulations leading to the development of the new plant to be carried out under suitable containment conditions. Whereas the importation of plant tissue cultures is outside the scope of this revised standard *(Facilities for Microorganisms and Cell Cultures: 2007)*, existing and future HSNO Act Approvals for development or importation of plants may be carried out under this standard if specified in an Approval.

It is expected that once a new plant has been developed and removed from the tissue culture environment, further manipulations will need to meet the requirements of the MAF Standard *155.04.09 - Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species.* However, this will be specified in the respective HSNO Act Approval.

In some cases, work involving plants which incorporate the use of new microorganisms may need to be carried out in a facility approved to both the plant and microorganism standards cited above. However, this will also be specified in the respective HSNO Act Approval.

[1] These requirements are specified in MAF Regulatory Authority (Animal Health and Welfare) Standard *154.02.17 – Transitional Facilities for Biological Products*

[2] MAF does not consider human cell cultures to be risk goods under the Biosecurity Act 1993

[3] The requirements for plants and plant cell cultures which are new organisms are specified in MAF Biosecurity Authority Standard *155.04.09 – Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*.

3 References

3.1 Normative References

The following normative documents contain provisions which, through reference in this text, constitute requirements of this standard. For dated references, the latest version of these publications applies.

- Australian/New Zealand Standard *2243.3: 2002 – Part 3: Safety in Laboratories: Microbiological Aspects and Containment Facilities*
- Australian/New Zealand Standard *2982.1:1997 - Laboratory Design and Construction – Part I: General Requirements*
- Biosecurity Act 1993
- Cartagena Protocol on Biosafety 2000
- Hazardous Substances and New Organisms (HSNO) Act 1996
- Hazardous Substances and New Organisms (organisms not genetically modified) Regulations 1998
- Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003
- Import and Exports (living modified organisms) Prohibition Regulations 2005
- International Air Transport Association (IATA) Dangerous Goods Regulations (2005)

3.2 Informative References

The following informative documents are provided for information and guidance purposes only and do not constitute requirements of this standard.

- Australian/New Zealand Standard *ISO 9001: 2000 Quality Management Systems – Requirements*
- Biosecurity New Zealand Standard *155.04.03: 2005 – A Standard for Diagnostic Facilities which undertake the Identification of New Organisms, excluding Animal Pathogens*
- Biosecurity (Costs) Regulations 2006
- MAF Biosecurity Authority Standard *155.04.09 – Containment Facilities for new Organisms (including genetically modified organisms) of Plant Species*
- MAF Regulatory Authority (Animal Health and Welfare) Standard *154.02.17 – Transitional Facilities for Biological Products*
- NZS/ISO/IEC *17025: 2005 - General Requirements for the Competence of Testing and Calibration Laboratories*
- Privacy Act 1993
- Relevant Import Health Standards www.biosecurity.govt.nz/commercial-imports/plant-imports/relevant-import-health-standards-and-application

4 Terms and Definitions

For the purposes of this standard the following terms and definitions apply.

audit
A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which specific criteria are fulfilled.

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

NOTE: Goods given biosecurity clearance by an Inspector are released to the importer without restrictions.

biosecurity direction
Written authority from an Inspector, given under section 25 of the Biosecurity Act 1993, to move uncleared goods from a transitional facility or biosecurity control area to another transitional facility, containment facility or biosecurity control area, or to export those goods from New Zealand.

cell culture
Growth of animal or plant cells *in vitro*.

chief technical officer (CTO)
The persons appointed by the Director-General as chief technical officers under section 101 of the Biosecurity Act 1993.

containment facility
A place approved in accordance with section 39 of the Biosecurity Act 1993, for holding organisms that should not, whether for the time being or ever, become established in New Zealand.

controls (HSNO Act 1996)
Any obligations or restrictions imposed on any hazardous substance or new organism, or on any person in relation to any hazardous substance or new organism, by this or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of this or any other Act for the purposes of controlling the adverse effects of that substance or organism on people or the environment.

corrective action request (CAR)
A request for a corrective action to remedy a non-compliance.

develop
Under section 2 of the HSNO Act 1996 develop, in relation to new organisms,
(a) means:
  (i) genetic modification;
  (ii) regeneration of a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism;
  (iii) fermentation of a microorganism that is a new organism;

(b) does not include field testing.

Director-General
The chief executive of the Ministry of Agriculture and Forestry.

enforcement officer
Means an enforcement officer appointed under section 98 or section 99(3) of this [HSNO] Act.

ERMA New Zealand
Is made up of the following three components:

(a) Environmental Risk Management Authority (ERMA) - a quasi-judicial decision-making body (and also the Governing Board of ERMA New Zealand), who make decisions on applications to import hazardous substances and new organisms (including genetically modified organisms) into New Zealand.

(b) Ngā Kaihautū Tikanga Taiao - a committee to advise and assist the Authority from a Māori perspective.

(c) ERMA New Zealand - the Agency that is the administrative support organisation for the Authority, including advising applicants and evaluating and reviewing applications to assist the Authority.

fermentation vessel
A container for liquid culturing or 'bulking up' of microorganisms, typically greater than 10L. The fermentation vessel must be so designed as to prevent the release of the organism into the surrounding environment.

genetically modified organism (GMO)
Unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material:

(a) have been modified by *in vitro* techniques; or

(b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques.

import health standard (IHS)
A document issued under section 22 of the Biosecurity Act 1993, which specifies the requirements to be met for the effective management of risks associated with 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.

Inspector
A person appointed under section 103 of the Biosecurity Act 1993 to undertake administering and enforcing the provisions of the Biosecurity Act.

Institutional Biological Safety Committee (IBSC)
Committees with delegated authority from ERMA New Zealand, under sections 19, 40 and 42 of the HSNO Act 1996, to assess applications for the:

(a) development of low-risk genetically modified organisms in containment; and

(b) importation of low-risk genetically modified organisms into containment.

IBSCs also assign containment levels for organisms as prescribed in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

in vitro
The experimental reproduction of biological processes in artificial environments, usually outside living organisms.

Living Modified Organism (LMO)
Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. This includes organisms produced by the fusion of cells from different taxonomic families, which overcomes natural physiological reproductive or recombination barriers, and which are not techniques used in traditional breeding and selection.

low-risk genetic modification
Refers to modifications as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

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

new organism
Under section 2 of the HSNO Act 1996, new organism means (with some qualifications):

(a) an organism belonging to a species that was not present in New Zealand before 29 July 1998:

(b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

(c) an organism for which a containment approval has been given under this Act:

(ca) an organism for which a conditional release approval has been given:

(cb) a qualifying organism approved for release with controls:

(d) a genetically modified organism:

(e) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

Operator
The person or organisation, approved by the Director-General, who has overall responsibility for a facility, under section 40 of the Biosecurity Act 1993.

organism
Under section 2 of the HSNO Act 1996, an organism:

(a) does not include a human being:

(ab) includes a human cell:

(b) includes a micro-organism:

(c) includes a genetic structure, [other than a human cell], 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 to be an organism for the purposes of the Biosecurity Act 1993:

(e) includes a reproductive cell or developmental stage of an organism.

permit to import
A written order issued by the Director-General authorising the importation of risk goods to a specified facility.

pest
An organism specified as a pest in a pest management strategy.

Quality Management System
The term "quality management system" in this standard means the quality, administrative and technical systems that govern the operations of a facility.

restricted organism
Any organism for which a containment approval has been granted in accordance with the Hazardous Substances and New Organisms Act 1996 (including any approval deemed to have been granted under sections 254(1), 25493), 254(80(a), 25591), 255(2), 256, 258(1), and 258(3)).

risk good
Any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) may constitute, harbour, or contain 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.

risk species (HSNO Act 1996)
Any species, subspecies, infrasubspecies, variety, strain or cultivar prescribed as a risk species under section 140.

NOTE: *Section 140(1)(h) enables regulations that prescribe that a risk species may have adverse effects on the health and safety of people or the environment.*

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.

unwanted organism
Any organism that a chief technical officer believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health (Biosecurity Act 1993).

vermin
Organisms that are to be excluded from the facility, e.g. rodents, birds, invertebrates etc.

5 Acronyms

BACC	Biosecurity Authority Clearance Certificate
BCH	Biosafety Clearing House
CAR	corrective action request
CTO	chief technical officer
ERMA	Environmental Risk Management Authority
GMC	GMO for importation into containment
GMD	GMO for development in containment
GMO	genetically modified organism
HSNO	Hazardous Substances and New Organisms
IATA	International Air Transport Association
IHS	import health standard
IBSC	Institutional Biological Safety Committee
LMO	living modified organism
MAF	Ministry of Agriculture and Forestry
MAFBNZ	Ministry of Agriculture and Forestry Biosecurity New Zealand
NOC	new organism into containment
OIE	[World] Organisation for Animal Health
PC	physical containment
QMS	Quality Management System

6 Approval

6.1 Approval of a Facility

6.1.1 General Provisions and Requirements

Containment and transitional facilities must be approved in accordance with section 39 of the Biosecurity Act 1993. They must have an Operator and be constructed and operated in accordance with this standard (section 8).

The facilities must comply with:

- the purpose of, and controls specified in, a HSNO Act Approval for new organisms to be held in the respective facility
- conditions specified by MAF on a permit to import and in an import health standard, where applicable
- conditions related to a pest or unwanted organism, specified by a CTO on a permission, issued pursuant to sections 52 and 53 of the Biosecurity Act 1993, where applicable

6.1.2 Procedure for Approval

Any person wishing to have a facility approved should follow the procedure below:

1. Establish contact with the Inspector responsible for supervision of facilities in the applicable geographical area.
2. Prior to construction or establishment of the facility, discuss the general provisions and requirements of approval with the Inspector, to ensure compliance with this standard.
3. Document the Quality Management System in the containment manual (section 7).
4. When the [prospective] Operator considers the requirements of this standard have been met, request the Inspector to inspect the facility and review the containment manual.

The Inspector must be satisfied that:

- the Operator has met the requirements of this standard (sections 6.1.1 and 8)
- the Quality Management System meets the requirements of this standard (section 7)
- the facility and Operator application forms, and consent to disclosure form, have been completed by the [prospective] Operator (see Appendices and the MAFBNZ website[1])

Following this, the Inspector will send the application forms and a copy of the containment manual to the contact person at MAFBNZ, together with their written recommendation for approval.

Approval of a containment or transitional facility will be provided in writing.

A facility may be approved for an unspecified time, a specified time or until a specified event.

NOTE: *The Inspector will provide documentation outlining the approval process and the anticipated timeline and cost.*

6.1.3 Modifications to an Approved Facility

Subsequent to approval, any major modifications to the facility or changes in containment procedures must be notified to the Inspector. Major modifications will require inspection by the Inspector and approval by MAFBNZ to ensure the facility continues to comply with this standard.

Major modifications are those that potentially affect the integrity of containment, such as construction or removal of walls, or significant changes in the description of work to be carried out.

An Operator considering major modifications to a facility should follow the procedure below:

1. Prior to modification of the facility, contact the Inspector to discuss the modifications and determine whether continued compliance with this standard is likely.
2. After modifications have been completed, arrange for an on-site inspection with the Inspector to ensure that any existing HSNO Act Approvals or permits to import etc, can be complied with. A new floor and/or site plan may be required.

Minor modifications are those not affecting the integrity of containment, such as changes in procedure or Quality Management System updates. Minor modifications should be recorded and checked by the Inspector at the next visit.

[1] http://www.biosecurity.govt.nz/commercial-transport-and-border-management/registration/operators-and-inspectors

6.2 Approval of the Operator

6.2.1 General Provisions and Requirements

The Operator is ultimately responsible for ensuring that organisms are held in containment and that the respective facility is used for the purposes specified in section 1.1.

The Operator of a facility is a person, normally an individual (e.g., business owner, director or manager), but may be the Crown, a corporation sole, or a body of persons (whether corporate or un-incorporate). If the Operator is the Crown, corporation sole, or a body of persons, then an individual must be nominated who has delegated and written authority for the resourcing and operation of the facility, as per the provisions under section 6.1. This individual will nominally be the Operator.

The Operator is responsible for the operation of the facility, ensuring mechanisms are in place for resourcing the facility to operate to this standard (section 6.1.1) and ensuring that the requirements of the Quality Management System (section 7) can be met.

An Operator must be approved by the Director-General in accordance with section 40 of the Biosecurity Act 1993, if the Director-General is satisfied that the applicant:

- is a fit and proper person to operate the facility
- has the authority to resource and operate the facility
- has the technical and financial resourcing mechanisms in place to maintain that facility

6.2.2 Procedure for Approval

Any person wishing to be approved as an Operator of a facility should follow the procedure below:

1. Contact the Inspector responsible for supervision of facilities in the applicable geographical area to discuss the general provisions and requirements of approval.
2. Complete the application form and consent to disclosure forms and send to the Inspector, with any attachments.

The Inspector must be satisfied that the requirements of section 6.2.1 of this standard can be met.

Following this, the Inspector will forward the application to the contact person at MAFBNZ, together with their written recommendation for approval.

Approval of an Operator will be provided in writing.

An Operator may be approved for an unspecified time, a specified time or until a specified event.

NOTE: *The Inspector will provide documentation outlining the approval process and the anticipated timeline and cost.*

6.2.3 Leased Facilities

If a facility, or part of a facility is leased, the lease contract (or non-gratia arrangement) with the owner must clearly identify the Operator and the operational arrangements contracted with the owner for meeting the requirements of this standard.

Lease contracts must be made available to the Inspector who must be satisfied that no part of the contract is inconsistent with the requirements of this standard for the operation of the facility.

6.2.4 Changes to Operator

The Inspector must be notified of any proposed changes to the Operator, or individuals nominally appointed as Operator. Prospective new Operators must complete an application according to the requirements of section 6.2.2 (see Appendix 2).

NOTE: *It is illegal for a facility to operate without an approved Operator (Section 40 (6) of the Biosecurity Act 1993).*

6.3 Cancellation of Approval of a Facility or Operator

A facility's approval may be cancelled in accordance with section 39 of the Biosecurity Act 1993 if:

- the facility no longer complies with the requirements of this standard
- the Director-General is satisfied the facility is no longer used for the purpose specified in the approval

An Operator's approval may be cancelled in accordance with section 40 of the Biosecurity Act 1993 if the Director-General is satisfied that:

- the Operator is no longer operating the facility in compliance with this standard
- the Operator is no longer a fit and proper person to operate the facility
- the Operator has ceased to act as Operator of the facility

Notice of cancellation will be given in writing to the operator.

7 Quality Management System

7.1 General Provisions and Requirements

The Operator must document and implement a Quality Management System (QMS) for the facility based on the **principles** of, but not requiring accreditation to, AS/NZS ISO 9001: 2000, NZS/ISO/IEC 17025: 2005, or similar recognised quality management system.

This means that the QMS must demonstrate the adoption of systems, policies and procedures to:

- address how the requirements of this standard are to be met,
- measure and monitor the effectiveness of containment systems and procedures and demonstrate how this process is used to continually improve the QMS.

The QMS should be documented as a "containment manual" or in an alternative format that clearly documents requirements and enables ready access for practical use and inspection. Facilities accredited to AS/NZS ISO 9001:2000, for example, do not need a separate manual, provided that the requirements of this standard are covered in their quality system and can be readily accessed.

The Inspector must approve the QMS and have access to a current copy of the containment manual, or a copy of the documents describing the approved QMS

The items included in section 7.2 describe the minimum requirements of the containment manual.

7.2 Specific Requirements

7.2.1 Containment

Describe the main functions of the organisation and the reason(s) for holding or working with the microorganisms and/or cell cultures. The functions specific to the purpose of the type of facility (transitional or containment) must be described.

Document procedures describing how the facility will be operated to:

- comply with the specific requirements of the transitional facility and/or the containment facility
- comply with the structural and operational requirements of this standard (section 8)
- comply with the purpose of any HSNO Act Approvals and associated containment controls, and/or conditions specified by permit(s) to import, import health standard(s), and CTO permissions
- ensure that work practices will meet the requirements of the above
- meet the requirement to monitor and evaluate the effectiveness of such practices and incorporate improvements into the QMS

Provide a floor plan showing:

- the general layout of the facility
- the location and identity of laboratories/rooms within the facility, identifying areas of physical containment (PC)
- the storage location of microorganisms and/or animal cell cultures that are subject to the requirements of this standard

7.2.2 Management

Identify the Operator and the individual nominally appointed as the Operator, if applicable, and specify the responsibilities of the Operator in relation to complying with the requirements of this standard.

Specify how the Operator will:

- review containment and management policies and procedures and implementation strategies to ensure they are effective
- communicate the importance of complying with the regulatory requirements and the escalation implications of non-compliance
- take full account of the advice of delegated managers, including biological safety officers and IBSCs, where applicable

- implement initial and continued training programmes commensurate with the level of containment and purpose of the facility
- ensure that containment procedures are documented and put into practice
- implement a safety programme which is consistent with biosecurity requirements, such as those specified in AS/NZS 2243.3: 2002, or any additional HSNO Act controls or MAF conditions
- prepare, implement, evaluate and improve emergency and contingency plans and procedures

Identify all other individuals with management responsibility and specific delegations and specify their responsibilities. This includes delegated managers, project leaders, curators and other approved users.

7.2.3 Training Programme

All people working in the facility must have appropriate working knowledge commensurate with their responsibilities. The QMS must include a training programme that describes how people working in the facility will be made aware of, and understand:

- the requirements of this standard
- the purpose of the facility
- the statutory and regulatory requirements which relate to work with microorganisms and animal cell cultures being held in containment and transitional facilities (refer to section 3.1 – Normative References)
- the principles and practices of containment, as established in AS/NZS *2243.3: 2002, Part 3: Safety in Laboratories - Microbiological Aspects and Containment Facilities*
- the procedures used in the facility to maintain containment and fulfil the purpose of the type of facility
- the purpose of, and controls specified by, any HSNO Act Approval in the development or import of new microorganisms and animal cell cultures contained in the facility
- the purpose of and controls specified by any HSNO Act Approval for new organisms transferred from another facility
- the conditions specified by MAF in any permit(s) to import, import health standard(s) and/or CTO permission(s) relating to any unwanted microorganism, animal cell culture or other microorganism determined by a CTO to be a risk good
- any amendments to this standard

The QMS must also specify how the training programme is to be implemented, evaluated and improved and must stipulate the frequency of refresher courses.

Records of training must be documented for all people working in the facility.

7.2.4 Internal Audit

The Operator must ensure that an internal audit is carried out to assess the effectiveness of containment policies, risk management, and operational procedures. Section 7.11.2 describes the requirements in more detail.

7.2.5 Amendments

The Operator must update the QMS to incorporate:

- the purpose of and controls specified by any subsequent HSNO Act Approvals
- the purpose and controls accompanying any transfers from another facility
- conditions required by any subsequent permits to import
- permission requirements granted by a CTO
- any subsequent amendments made to this standard, any relevant import health standard or operational standard and/or normative reference (section 3.1)

A copy of the amended QMS must be notified to the Inspector.

The Operator must review the QMS at least once a year to ensure that it is appropriate and effective, and to introduce any identified changes or improvements.

7.2.6 Document Control

The Operator must have a document control system to record any amendments to the QMS.

The version number and issue date of the documented QMS must be recorded on each page. The nature of amendments, and the person responsible, must be recorded.

8 Structural and Operational Requirements

8.1 General

Facilities must be constructed and operated in a manner consistent with the purpose of the type of facility and to ensure that microorganisms and animal cell cultures are securely contained and held only within the facility.

The requirements of this standard may be supplemented by:

- additional controls specified by any HSNO Act Approvals, when approving a new microorganism or cell culture in a containment facility
- additional conditions specified by MAF in a permit to import or import health standard
- permissions granted by a CTO

8.2 Physical Containment

8.2.1 General Provisions and Requirements

AS/NZS 2243.3: 2002 specifies the minimum requirements of physical containment (PC) and includes all the requirements of AS/NZS *2982.1: 1997 - Laboratory Design and Construction – Part I: General Requirements*. Appendix B of AS/NZS 2982.1: 1997 specifies additional PC requirements for microbiological laboratories.

8.2.2 PC1 and PC2 Requirements

The minimum requirements for PC1 and PC2 will be those identified in AS/NZS 2243.3: 2002 with the following exceptions described below.

1. The specifications of section 4.8.3(a) relating to ceilings is not required. However, ceilings must, at a minimum, be constructed of a semi-rigid material[1]. Operators of facilities not currently meeting the ceiling requirements of AS/NZS 2243.3:2002 should seek advice on whether to instigate a work programme to reach compliance. It is highly recommended that new facilities endeavour to meet the ceiling specifications of AS/NZS 2243.3: 2002.
2. Emergency drench showers (section 4.8.3(e)) and non-slip floors (section 4.8.3(a)) are not required.
3. Fly screens are not required on opening windows (Appendix B 4(d) of AS/NZS 2982.1:1997) unless specified by a HSNO Act Approval or MAFBNZ.
4. Ventilation in PC2 laboratories – where a risk assessment shows that it is required[2], specific types of work must be conducted in a laboratory with either:
   - a ventilation system that establishes a negative pressure in the laboratory so that there is a directional airflow into the laboratory (refer to AS/NZS 2982.1:1997, Appendix B4 (b)), or
   - a class II biological safety cabinet (refer to AS/NZS 2243.3: 2002, section 6.7)

8.2.3 PC3 and PC4 Requirements

The minimum requirements for PC3 and PC4 will be those identified in AS/NZS 2243.3: 2002.

8.2.4 Physical Containment of Unidentified Microorganisms

This section relates to the physical containment of unidentified microorganisms in facilities, primarily those isolated from border interceptions or found within New Zealand, and are suspected of being risk species or organisms that are risk goods.

Facilities working with unidentified microorganisms must have documented procedures for determining the risk category of organisms, with reference to OIE or AS/NZS 2243.3: 2002 risk grouping determinations, and must assign the appropriate level of physical containment commensurate with risk.

Facilities contracted to hold microorganisms in these categories must be approved to this standard.

The minimum physical containment level for a laboratory working with unidentified microorganisms isolated from **animals** is PC2. For investigations into suspected unwanted or new organisms, the level of containment required for diagnostic samples will be determined by MAFBNZ. Exotic disease organisms, which may be risk group 3 or above (as defined by OIE or AS/NZS 2243.3: 2002 risk groupings), may be required to be held at PC3 or above.

[1] This allows laboratories constructed using a suspended tiling system to comply.
[2] Either by ERMA New Zealand (for new organism approvals), by MAF in a permit to import, or by a CTO.

Unidentified microorganisms found on **plants** intercepted at the border, held in transitional facilities (post-entry quarantine), or discovered as part of incursion investigations, must be held at PC2 with the following additional requirements:

1. External windows must be closed and sealed.
2. Areas used as offices by laboratory personnel must be separated from the laboratory.
3. A pressure steam steriliser for decontamination of laboratory wastes must be available, preferably located in the laboratory where the waste is generated. Where the steriliser is outside the laboratory, the wastes must be bagged and placed in an unbreakable container with a secure lid for transport to the steriliser. Unsterilised wastes must not be stored outside the facility. Transport containers must have provision for penetration of steam during sterilising.
4. To reduce the risk of escape of viable airborne microorganisms or propagules, the movement of potentially contaminated air must be controlled by either:
   a. Provision of a ventilation system that establishes a negative pressure in the facility so that there is a directional airflow into the working area.

      The pressure differential must be achieved by means of an independent room exhaust fan discharging to the outside atmosphere through a HEPA filter (section 4.8.3; AS/NZS 2243.3: 2002). Additionally, all fume hoods that discharge to the outside atmosphere must be fitted with HEPA filters.

      OR

   b. conducting all work in a Class II biological safety cabinet (section 6.7; AS/NZS 2243.3: 2002)

      Only preparations in which the organism is killed or contained (e.g. slides, sealed tubes, etc.) may be handled outside the cabinet.

8.3 Operational Containment

8.3.1 Storage

Microorganisms and animal cell cultures held in a containment or transitional facility, are often not in active use for the purposes for which they are held, such as those under inactive HSNO Act Approvals or held under a CTO permission. Under such circumstances and while they are permanently stored within a culture collection, they do not necessarily need to be stored at the PC level set out in the relevant HSNO Act Approval. However, they must be adequately labelled and stored securely to prevent unauthorised access, either within or adjacent to a transitional or containment facility.

8.3.2 Access

In addition to the access requirements for each PC level described in AS/NZS 2243.3: 2002:

- each facility or building within a facility, must have signage indicating restricted access and a sign indicating where visitors must report
- effective procedures must be established to prevent unauthorised access to the facility
- entrances to the facility must be kept locked, except when in active use.

Access to the facility should be limited to trained personnel authorised to work in the facility. However, visitors may be permitted entry provided they are accompanied by such personnel. Visits must be recorded in a visitors log book for security purposes, and visitors must adhere to access procedures.

Entry and exit procedures must be made available at the entrance to the facility, specifying essential requirements such as laboratory coats and protective clothing, signing access log books, and hand washing.

8.3.3 Treatment and Disposal of Biological Waste

The requirements for treatment and disposal of biological waste (including viable microorganisms and animal cell cultures) are described in AS/NZS 2243.3: 2002. Sterilisation and disposal procedures of biological waste must be scientifically validated and shown to be effectively used in the facility to devitalise the waste being treated.

Laboratories containing fermentation vessels must have a spill management system in place that is able to contain the full volume of any potential spills. The system must include scientifically validated methods for sterilisation and procedures for the subsequent disposal of the waste.

No viable microorganisms or animal cell cultures may be removed from a facility, except with the approval from the Inspector responsible for that facility. New organisms are subject to treatment and disposal in accordance with controls specified in the HSNO Act Approval, which may be additional to the requirements of this standard. Procedures must be established to ensure that no accidental or unintended removal occurs.

8.3.4 Exposure of Plants or Animals to Microorganisms

Research involving the exposure of plants or animals to microorganisms may require a HSNO Act Approval (for new organisms and/or the development of new plants) or permission from a CTO. Such activities must be carried out in accordance with the requirements of this standard and any approval or permissions granted.

NOTE: *Any work involving the manipulation of animals, as defined in the Animal Welfare Act 1999, must be in accordance with the code of recommendations and minimum standards for the welfare of animals. This requirement is independent of this standard.*

8.4 Registers

8.4.1 Records of Microorganisms and Cell Cultures

Records must be kept listing, and being able to distinguish between, the microorganisms and cell cultures held in the facility for the following categories:

- imported microorganisms and cell cultures, including those imported through transfer from another facility
- unwanted microorganisms
- other microorganisms and cell cultures which are risk goods but not on MAF's Unwanted Organism Register.

8.4.2 Register of HSNO Act Approvals, New Microorganisms and New Cell Cultures

The Operator must maintain a register of all HSNO Act Approvals and containment controls[1] for new microorganisms and/or new cell cultures.

The register must be able to clearly link each new organism to a HSNO Act Approval and the project leader and curator, and identify whether the new organism:

- is in active use
- is not in active use, e.g., in storage
- has been destroyed.

In addition, for GMOs, the register must:

- identify the name of the project(s)
- provide a description of the:
  - species and strain of host
  - vector and insert DNA
  - donor species DNA.

For some HSNO Act Approvals it is not practical to identify and describe all GMOs developed as intermediaries within a project. Where development leads to a GMO, or a collection of GMOs (such as cDNA libraries) that will be held and stored, that GMO or collection must be recorded in the register. For every GMO developed (including intermediaries) however, whether or not they will be stored, it must be possible to track these to the appropriate HSNO Act Approval.

The register must be updated within 10 days of receipt of a HSNO Act Approval, or transfer of new organisms to the facility.

The register need not be independent of a larger and wider organism register or culture collection. It is suggested that one list be established and maintained for all organisms held within the facility, and provision made for the ability to access and retrieve specific categories of organism information required by this or any other standard.

8.5 Identification of New Organisms

Under sections 44 and 46 of the Biosecurity Act 1993, every person has a duty to inform MAFBNZ, as soon as practicable, of the suspected or identified presence of a new organism, or a notifiable organism not normally seen or otherwise detected in New Zealand. If an Operator is made aware of such presence, the contact persons for this standard should be contacted.

If an unidentified organism is subsequently identified as a new organism **and** is to be stored and/or propagated for further work (including development under the HSNO Act 1996), application for a HSNO Act Approval must be lodged with ERMA New Zealand.

[1] Containment controls include this MAF/ERMA standard as well as those additional controls set by the Authority.

If an unidentified organism is subsequently identified as an unwanted organism, CTO permission under section 53 of the Biosecurity Act 1993 is required (section 8.6). In some instances, CTO permission and a HSNO Act Approval will be required since some unwanted organisms will be new organisms, and vice-versa.

8.6 Unwanted Organisms

Under sections 52 and 53 of the Biosecurity Act 1993, work involving an unwanted organism, including sale, propagation, spread, release or cause to be released, requires the permission of a CTO. A CTO may specify the PC level and any additional conditions if permission is granted.

Application forms for seeking permission from a CTO to work with an unwanted organism are available at:

http://www.biosecurity.govt.nz/commercial-imports/unwanted-organisms-register-

The Operator must hold documented evidence of CTO permissions for activities involving unwanted organisms.

8.7 HSNO Act Approvals

8.7.1 General

The Operator must hold documented evidence of HSNO Act Approvals and containment controls for all microorganisms and animal cell cultures that are new organisms held within a containment facility. For GMOs, the category[1] to which the modification belongs and the PC level must be specified.

8.7.2 Fermentation

While fermentations involving volumes less than 10L do not require a HSNO Act Approval in addition to existing GMD, GMC or NOC Approvals for the organism, Operators must ensure that they have an additional HSNO Act Approval if the fermentation involves volumes greater than 10L.

8.7.3 Organisation and Site Restrictions on Use of HSNO Act Approvals

8.7.3.1 Background

All development of GMOs (GMD) Approvals are organisation-specific.

All import of a new organism into containment (NOC) Approvals are organisation non-specific, unless otherwise stated in the Approval. However, import of a GMO into containment (GMC) Approvals are organisation-specific when made under delegated authority by IBSCs and the Chief Executive of ERMA New Zealand.

Where an organisation is located on more than one site, organisation-specific Approvals can be used across sites, unless otherwise stated in an Approval. Organisms under these Approvals may also be transferred to other containment facilities as long as agreement is sought from the respective

[1] Category A developments require a minimum of PC1 containment.
Category B developments require a minimum of PC2 containment.

Operators and these facilities are able to comply with the Approval requirements. Transferred GMOs however, cannot be developed further without an additional HSNO Act Approval.

8.7.3.2 Requirements

HSNO Act Approval holders must be aware of the restrictions placed on where Approvals can be exercised, in terms of the organisation and site, particularly those made under delegated authority by IBSCs and the Chief Executive of ERMA New Zealand.

Operators must ensure that they comply with the organisation and site restrictions of HSNO Act Approvals and that this information is easily available and communicated to Approval users. In addition, measures must be put in place to ensure that specific microorganisms and cell cultures are not transferred from facilities if the Approval does not allow it.

NOTE: *MAF approval is required prior to any transfers occurring.*

8.8 Transfer (Import and Export) of Microorganisms and Cell Cultures between Facilities

8.8.1 General Requirements

Microorganisms and animal cell cultures imported and exported (transferred) between facilities or overseas require MAF approval and must be packaged and labelled appropriately. A transfer approval, which is essentially a written authorisation for biosecurity direction, is required for transfers between containment facilities and between transitional facilities, but need not necessarily be required from a transitional to a containment facility (section 8.8.3).

Transfer request forms are available from the facility Inspector, who will advise applicants of the approval process. Prior to sending the completed request form to the Inspector for approval, applicants must ensure that:

- the importing facility is approved to this standard and can comply with any additional controls or conditions associated with the organism(s) being transferred
- authorisation has been received from authorised signatories (section 8.8.2) of both the exporting and importing facilities

Transfer approval for any microorganisms or cell cultures having a containment requirement of PC3 or above can only be made by a CTO.

Operators are responsible for ensuring that copies of transfer requests and records of transfers are kept and that the facility registers are updated accordingly.

Operators are also responsible for tracking the consignment and ensuring that the importing facility has received it. Operators of the importing facility must notify the Inspector upon receipt of the consignment.

8.8.2 Authorised Transfer Request Signatories

Only an Operator, or their approved signatories, can authorise transfer requests on behalf of a facility. Signatories are approved by MAF through the Operator making written request to an Inspector. In general, a facility will have a maximum of one approved signatory per site, in addition

to the Operator, unless the Operator is not an individual or is not regularly available to sign the requests. An approved signatory will normally be an individual who holds a senior and responsible position within the organisation, is very familiar with the requirements of this standard, will ensure that compliance requirements are met and would act nominally as the Operator (section 6.2.1).

8.8.3 Transfer from a Transitional Facility to a Containment Facility

Microorganisms and animal cell cultures included in the scope of this standard must be held in either a transitional or containment facility approved to this standard. Since these facilities are often co-located on the same site, the transfer of microorganisms and animal cell cultures from a transitional to a containment facility does not require a formal transfer approval and the intervention of an Inspector. However, Operators are responsible for ensuring that the purpose(s) of holding the organisms in the transitional facility is met and that authorisation for transfer to the containment facility has been obtained from the Operator or an approved signatory prior to transfer. In particular, the Operator must ensure that, to the best of their knowledge and prior to transfer:

- the consignment contains only the organism(s) specified in the permit to import
- the organisms are packaged appropriately and the primary package is intact upon receipt
- the primary package is opened in an area at the specified PC level, by suitably trained and authorised personnel

The Operator must document that the transitional facility requirements have been met. The QMS must also specify the actions that will be taken when the requirements are not met.

8.8.4 Transport Requirements

Transport of microorganisms and animal cell cultures must comply with the International Air Transport Association (IATA) Dangerous Goods Regulations, according to the level of risk. These regulations define the requirements for certification, the maximum quantities that can be transported by cargo or passenger aircraft, the external labelling requirements (including the identifying United Nations number) and the details to be included in the attached Shippers Declaration for Dangerous Goods, where applicable. Although the IATA Dangerous Goods Regulations are written specifically for air transport, the packaging and labelling requirements must be applied to all transport to final facility destinations in New Zealand.

Operators must ensure, to the best of their ability, that goods being imported into, and within, New Zealand are packaged as per the IATA Dangerous Goods Regulations, according to the minimum requirements specified below but concordant with the level of risk.

The minimum requirement for microorganisms and cell cultures is to be packaged according to Packing Instruction No. 650 of the IATA Dangerous Goods Regulations.

All products that are infectious or potentially infectious for humans or animals must be packaged according to Packaging Instruction No. 602 of the IATA Dangerous Goods Regulations.

While AS/NZS 2243.3: 2002 provides some detail on the packaging and transport requirements for microorganisms, the IATA Dangerous Goods Regulations should be consulted since they are updated annually.

8.8.5 Multiple Transfers

Facilities regularly transferring microorganisms and/or animal cell cultures, particularly where these organisms are the same type each time, may seek authorisation for multiple transfers, removing the need for an Inspector to authorise each individual transfer. Before authorisation is given however, MAF must be confident that the requirements of sections 8.8.1 and 8.8.4 will be met and accurate records of all multiple transfers will be kept. The QMS of the exporting and importing facilities must clearly document the process to be followed.

Operators must apply to an Inspector for multiple transfer authorisations. These may be issued for a specific time or event and can be cancelled at any time if an Inspector determines that the transfer requirements are not being complied with.

8.8.6 Overseas Export

8.8.6.1 General

Microorganisms and/or animal cell cultures may be exported overseas from transitional and containment facilities in New Zealand. A transfer approval is required from an Inspector, who will advise Operators of the process to be followed, depending on the nature and risk of the organism to be exported.

8.8.6.2 Export of Organisms that are Not Living Modified Organisms

The overseas export of organisms that are **not** Living Modified Organisms[1] (LMOs) does not require any special considerations other than those relating to the nature and risk of the organism being exported. Operators should refer to any permit to import, HSNO Act Approval, CTO permission or other such document, for any special requirements or restrictions on export.

8.8.6.3 Export of Living Modified Organisms

The export of LMOs is governed internationally by the Cartagena Biosafety Protocol. In New Zealand, the administration of the protocol is legislated by the Import and Exports (living modified organisms) Prohibition Regulations 2005 which must be complied with by all persons exporting LMOs internationally. All LMOs exported overseas must have an approved Biosafety Clearing House (BCH) Reference Number. If the LMO is not being exported for contained use (for example the LMO is to be exported for release into the environment), Specific Consent from the Minister for the Environment is required. Exporters should contact the Ministry for the Environment in the first instance. The transfer of LMOs for export must be approved by MAF.

ERMA New Zealand is the national competent authority in New Zealand that administers BCH numbers for LMOs listed in HSNO Act Approvals. For Approvals that pre-date May 2005, Operators must contact ERMA New Zealand to obtain a BCH number. For Approvals granted after May 2005, the BCH number(s) are included in the Approval documentation.

MAF requires that exporters complete a Transfer Request form (the correct form is available from an Inspector) which must include the BCH number, to verify the export has been approved, as well as listing the exporting and importing organisations and contacts and information of the organism being exported. No additional documentation is required, other than what would routinely accompany the export.

[1] LMOs include GMOs – see definition.

8.9 Contingency Plans

The Operator must ensure that contingency plans are in place for:

- the accidental spillage of microorganisms or cell cultures within the facility (see AS/NZS 2243.3: 2002)
- breaches of containment caused by the release of microorganisms or cell cultures outside the facility through accident, deliberate action, natural disaster, fire, sabotage, theft, or any other event

Contingency plans must ensure that resources are identified and made available for the contingency.

In the event of any spillage or breach of containment of an organism, the contingency plan must be implemented immediately.

Breaches of containment constitute a non-compliance and must be notified to an Inspector as soon as practicable and at least within 24 hours.

8.10 Vermin Control Programme

A vermin control programme must be implemented within the facility. The programme must describe how pest animals, such as rodents, birds and invertebrates are to be excluded from the facility, how surveillance for their presence is to be maintained and what control activities will be undertaken if detected.

8.11 Audits

8.11.1 External Audits

Facilities approved to this standard will be audited every 6 months by MAF, by an Inspector or an Enforcement Officer. Operators can expect to be notified of the 6-monthly audits and every attempt will be made to arrange a time convenient for both parties. MAF reserves the right to audit at any time however, and audits may be unscheduled, especially if non-compliances have previously been found.

The audit will be a compliance audit, where the facilities' defined systems are compared against those required by this standard. It will necessarily include a process audit, which will validate the processes and procedures in place.

The Operator must provide Inspectors, or any other representative of a CTO, access to the facility, records and documents for inspection and audit or to investigate non-compliances with this standard. The Operator, facility manager, or any delegated technical representative, must be available to assist and ensure that all relevant procedures, documents and records are made available.

8.11.2 Internal Audits

The Operator must ensure that an internal compliance audit is carried out every 6 months. The objectives of this audit are to:

- ensure that systems, procedures and processes are in place to meet the requirements of this standard
- ensure that those systems, procedures and processes are being complied with
- evaluate the effectiveness of systems, procedures and processes
- identify how the QMS can be improved
- identify areas of risk in the facility and its operations
- establish the adequacy of risk management measures and review their adequacy
- make recommendations where weaknesses or inefficiencies are observed

During the internal audit, particular emphasis must be placed on verifying that the registers (section 8.7) are accurate and up to date, the training programme is being implemented and is effective, and any corrective actions have been resolved in a timely manner.

To perform their role effectively, internal auditors should have as much organizational independence from management, to enable unrestricted evaluation of management activities and personnel. Although this is often difficult in smaller facilities, it should be considered by all facility management as a matter of course.

Operators must maintain records of internal audits, corrective actions, completed actions and closeout and ensure that the QMS has been modified where improvements have been identified. The process for translating the results of internal audits into improvements in the QMS must be documented.

8.11.3 Audit Frequency Dispensation

MAF may grant audit dispensation from 6-month to annual audits to facilities that continually perform well in their external audits. Criteria that will be taken into account for dispensation to be granted include:

- the compliance history over the previous two years - facilities must have no critical non-compliances or major non-compliances, and fewer than two minor non-compliances (promptly resolved) over the previous two years
- confidence of the Inspector in the Operator and key personnel to comply with the requirements of this standard
- the ability of the Operator to monitor, evaluate and improve the QMS

Requests for dispensation must be made in writing by the Operator to the Inspector. Inspectors will forward the request to a Manager, Facility Approvals Group, along with their recommendation for approval.

Dispensations will be notified in writing and may be granted for a specified or unspecified time.

If a critical non-compliance, major non-compliance or greater than two minor non-compliances are identified in any subsequent audit, the dispensation will be cancelled and the original audit frequency will be resumed.

8.12 Non-Compliance

8.12.1 General

Non-compliances are failures to comply with the requirements of this standard. They are generally identified during the course of audits but may be notified to an Inspector at any time by the Operator. Non-compliances are managed by MAF through an escalation pathway (section 8.12.6) based on the level and frequency of non-compliance. The principles of natural justice will be followed however, such that any non-compliance found during an audit or inspection may be appealed by the Operator to the Inspector.

All non-compliances must be reported to the Operator and MAFBNZ. Internal and external audit reports must list all non-compliances, corrective action requests (CARs) and the timeframe for these to be completed.

Non-compliances are classified as follows.

8.12.2 Critical Non-Compliance

A critical non-compliance is defined as a major failure in an operation or system that caused, or could have caused, a serious risk to biosecurity, the environment, or the health and safety of people and communities. It can lead to cancellation of the facility and/or Operator approval. Examples of critical non-compliances include, but are not limited to:

- releasing organisms from a transitional facility without biosecurity clearance
- releasing organisms from a containment facility without a HSNO Act Approval
- breaches in containment
- a significant failure in the structural containment provisions of a facility
- operating a facility without an Operator
- Operator allowing uncleared good to be transferred to non-approved premises
- making major modifications to buildings or facility services (e.g. air handling systems) without MAF approval
- using a HSNO Act Approval specific to another facility

In the event of a critical non-compliance, the Operator must:

- notify the Inspector as soon as practicable and within 24 hours
- discontinue any activity related to the critical non-compliance that presents a biosecurity risk
- take immediate corrective action to safeguard the environment, the health and safety of people and communities and restore compliance[1]

[1] This should be done in consultation with the Inspector

If the critical non-compliance involves a new organism, the Inspector must notify ERMA New Zealand as soon as practicable. Such events are reported in ERMA New Zealand's' Quarterly Report to the Minister for the Environment.

In the event of a critical non-compliance, the Inspector:

- must investigate the critical non-compliance and lodge an investigation report with MAFBNZ as soon as practicable
- may direct that all work using microorganisms or cell cultures cease immediately until the non-compliance is rectified

Critical non-compliances may require further investigation and possibly lead to prosecution, depending on the nature and circumstances of the event. It is expected that at least one revisit audit will be required to ensure that the critical non-compliance has been effectively resolved and measures have been to taken to prevent its recurrence.

8.12.3 Major Non-Compliance

A major non-compliance is defined as a major failure in an operation or system that may cause, or lead to, a biosecurity risk. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Major non-compliances may be created by escalation of outstanding issues from previous audits and include, but are not limited to:

- failure of the Operator to detect significant and obvious non-compliances
- failure of the Operator to action CARs from previous audits
- activities conducted outside the scope of a HSNO Act Approval
- failure to operate the facility to meet the requirements of this standard
- imports not recorded in register
- restricted material not stored in appropriately identified area

In the event of a major non-compliance, the Operator must:

- notify the Inspector as soon as practicable and within 24 hours
- take immediate corrective action to restore the facility and/or operations to a compliant condition
- discontinue any activity related to the major non-compliance that presents a biosecurity risk

If the major non-compliance involves a new organism, the Inspector must notify ERMA New Zealand as soon as practicable.

8.12.4 Minor Non-Compliance

A minor non-compliance is defined as a situation that does not represent a major failure of an operation or system but results in a decrease in confidence in the management of the facility that may not immediately cause or lead to a biosecurity risk. Minor non-compliances include, but are not limited to:

- QMS not up to date
- transfers and inventory not accurate

- boxes on the floor
- failure to maintain staff training records
- missing signage
- lab coats not being worn.

In the event of a minor non-compliance, the Operator must:

- take corrective action to rectify the non-compliance within an acceptable time frame
- record the non-compliance and notify the Inspector on the next audit or visit.

Minor non-compliances involving new organisms are notified to ERMA New Zealand by MAFBNZ through its regular reporting procedures.

8.12.5 Recommendations

Recommendations are defined as advice given to highlight areas of an operation or system that require improvement even though a non-compliance has not occurred. Recommendations must be considered by audit parties when formulating post-audit actions, particularly if there are indications that failure to give attention to these items may lead to a future non-compliance. Recommendations are not subject to CARs.

8.12.6 Non-Compliance Audit Escalation Pathway

A non-compliance audit escalation pathway will operate to manage situations where:

- Operators have failed to identify, notify or action obvious non-compliances
- an Inspector has detected obvious non-compliances that should have been identified, notified and actioned by a competent Operator
- an Inspector repeatedly identifies the same non-compliances
- an Inspector believes the Operator is negligent in their responsibilities

Appropriate, timely and competent management of non-compliances will **not** usually result in non-compliance escalation. The escalation pathway will generally incorporate an increased number of audits or inspections until the Inspector can be confident that the facility is fully compliant with this standard. The audit escalation pathway will operate as follows:

1. Operators that receive a critical non-compliance will have their facilities audited as frequently as required, as determined by MAFBNZ, for the Inspector to gain confidence that the non-compliances will not recur.
   - If a second critical non-compliance occurs within 12 months of the first, the Inspector may recommend cancellation of the Operator and/or the facility approval.
2. Operators that receive a major non-compliance may be subject to two extra unscheduled facility audits in the following 12 months.
   - If a second major non-compliance occurs within 6 months of the first, the Inspector may recommend cancellation of the Operator and/or the facility approval.

3. Operators that receive five minor non-compliances, or a second major non-compliance, within 12 months of the first, will be subject to extra facility audits at the discretion of the Inspector, in consultation with management of MAFBNZ.

8.13 Records

The Operator must keep appropriate records of operation as required for the QMS. Records must be kept for a minimum of seven years from receipt, preparation or amendment and must include, as a minimum:

- facility plans, specifications, structural drawings etc
- facility and Operator approvals
- copies of permits to import and conditions, biosecurity clearances and directions (BACCs) and authorisations for transfer from MAF
- records of inspections of uncleared goods, especially those moving from a transitional facility to a containment facility
- copies of HSNO Act Approvals and associated controls
- records of internal and external audits and corrective actions
- staff training records
- copies of any CTO exemptions for working with unwanted organisms
- records relating to new microorganisms and animal cell cultures itself must be kept for a minimum of seven years after any organism is destroyed
- copies of any lease agreements or contracts with other users of the facility
- copies of any audit dispensations
- records of major and minor modifications to facilities

8.14 Costs

Costs associated with the approval of facilities and Operators, audit and inspection are cost-recovered by MAFBNZ in accord with the Biosecurity Act 1993 and the Biosecurity (Costs) Regulations 2006. The Operator is required to pay all reasonable costs and is entitled to a breakdown of these costs and explanation if required.

9 Appendices

Appendix 1 Application for Approval of a Facility for Microorganisms and Cell Cultures

Appendix 2 Application for Approval of an Operator of a Containment/Transitional Facility

Appendix 3 Consent to Disclosure of Information

Appendix 1 Application for Approval of a Facility for Microoganisms and Cell Cultures

Application for Approval of a Transitional or Containment Facility

(pursuant to section 39 of the Biosecurity Act 1993)

An application for approval of a transitional or containment facility must be made to the Director-General, using this form. This application form is an approved form in accordance with section 39(2) of the Biosecurity Act 1993.

Send the completed form and other documentation to the Inspector responsible for supervision of the transitional or containment facility (contact details are listed in the relevant standard).

If there is any change to the contact details provided in this application, you must inform MAF Biosecurity New Zealand, PO Box 2526, Wellington, in writing.

Type of Facility (transitional or containment): .....

Name of Facility: .....

.....

Purpose of Facility: .....

.....

.....

Physical Location (attach a site plan)[1]: .....

.....

Postal Address: .....

.....

Telephone No: ..... Facsimile: .....

E-mail: .....

Nature of the Goods to be held in the Facility: .....

.....

.....

Proposed Physical Containment level(s): .....

Full Name of Operator: .....

Full Name of Facility Manager[2]: .....

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[1] The site plan must show the relationship of the facility to other rooms or buildings

[2] If the operator is the Crown, corporation sole, or a body of persons.

Applicant Declaration:

I, ...
(full legal name)

being the applicant for the approval of the above transitional/containment (delete one) facility and declaring that the above facility meets the requirements of:

.....
(*MAFBNZ or MAFBNZ/ERMA NZ standards*)

apply to have it approved by the Director-General as a transitional/containment (delete one) facility for the purpose stated above.

I include with this application:

- a copy of the approved Containment Manual (describing the Quality Management System)
- a site plan of the facility showing the relationship of the facility to other rooms or buildings

Full Name of Applicant: .....

Signature of Applicant: .....

Date:.....

Appendix 2 Application for Approval of an Operator of a Facility

Application for Approval as an Operator of a Transitional or Containment Facility

(pursuant to section 40 of the Biosecurity Act 1993)

An application for approval as an operator of a transitional or containment facility must be made to the Director-General, using this form. This application form is an approved form in accordance with section 40(1) of the Biosecurity Act 1993.

Send the completed application form and other documentation to the Inspector responsible for supervision of the transitional or containment facility (contact details are listed in the relevant standard).

If there is any change to the contact details provided in this application, you must inform MAF Biosecurity New Zealand, PO Box 2526, Wellington, in writing.

Type of Facility (transitional or containment): .....

Name of Facility: .....

.....

Purpose of Facility: .....

.....

.....

Physical Location: .....

.....

Postal Address: .....

.....

Telephone No: ..... Facsimile: .....

E-mail: .....

Full Legal Name of Proposed Operator: .....

.....

Designation: .....

Full Legal Name of Facility Manager[1]: .....

.....

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[1] If the operator is the Crown, corporation sole, or a body of persons.

Applicant Declaration:

I, ...
(full legal name)

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

(a) I am able to comply with the MAF Biosecurity New Zealand/ERMA New Zealand standards: .....

.....
(MAFBNZ or MAFBNZ/ERMA NZ standards)

(b) I will ensure that the operation of the facility is in accordance with this/these standard(s).

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

I include with this application:

- evidence showing that I meet the requirements to be an Operator
- a signed copy of the consent to disclosure of information by the New Zealand Police

Signature of Applicant/Facility Manager:.....

Date:.....

Appendix 3 Consent to Disclosure of Information

Consent to Disclosure of Information

Licensing & Vetting Service Centre
Officer of the Commissioner
PO Box 3017
WELLINGTON

I,.....
[Surname] [Fore Names]

.....
[Maiden or any other names used]

Sex: [M/F] Date and Place of Birth: .....

Nationality: .....

Residential Address: .....

Suburb: .....

City: .....

New Zealand Drivers Licence Number: .....

hereby consent to the disclosure by the New Zealand Police of any information they may have pursuant to this application to be registered as an operator of a transitional or containment facility, to the Ministry of Agriculture and Forestry.

Signed: ..... Date: .....

COMMENTS OF THE NEW ZEALAND POLICE

Collection of Personal Information on Individuals

In regard to any personal information being collected on this application for approval of an Operator of a transitional or containment facility under the Biosecurity Act 1993 (that is personal information about an identifiable individual), notification is hereby provided in accordance with Principle 3 of the Privacy Act 1993, to individuals of the following matters:

1. This information is being collected for purposes relating to approval of a transitional or containment facility and administration of the Biosecurity Act 1993.

2. The recipient of this information, which is also the agency that will collect and hold the information, is Biosecurity New Zealand, PO Box 2526, Wellington.

3. The collection of information is authorized under section 40 of the Biosecurity Act 1993. The provision of this information is necessary in order to process this application. Failure to provide information is likely to result in the return of this application form to the applicant and ultimately may result in a refusal by the Director-General, to approve the facility as a transitional or containment facility.

4. You are reminded that under Principles 6 and 7 of the Privacy Act 1993, you have the right of access to, and correction of, any personal information, which has been provided.