Ministry for Primary Industries
Manatū Ahu Matua

Facility Standard

Draft IHS Biological Products

MPI-STD-BIOLOGICAL

[Document Date]

Issued under the Biosecurity Act 1993

New Zealand Government

TITLE

Facility Standard: Biological Products

COMMENCEMENT

This Facility Standard comes into force on [Effective Date]

REVOCATION

This Facility Standard revokes and replaces the following:

a) *MPI Standard 154.02.17: Transitional Facilities for Biological Products, 14 February 2014*.

ISSUING AUTHORITY

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

Dated at Wellington, [Document Date]

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Introduction

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

Purpose

This facility standard relates to transitional facilities for uncleared biological products that are imported under one of the following import health standards (or any import health standard which replaces them):

a) *Import Health Standard for Biological Products (including samples), BIOPRODIC.ALL*
b) *Import Health Standard: Soil, Rock, Gravel, Sand, Clay and Water, MPI.STD.SOWTR*
c) *Import Health Standard: Dried and Preserved Plant Material, and Fresh Plant Material for Testing, Analysis or Research, MPI.STD.PLANTMATERIAL*

The purpose of this facility standard is to:

a) Set out the requirements relating to building, maintaining and operating this kind of facility.

This facility standard does not apply to intentional biological amplification (*in-vivo* and/or *in-vitro*) of microorganisms within, or in material derived from, uncleared biological products. In order to undertake such work, the facility must be approved to the current version of the *Standard for Facilities for Microorganisms and Cell Cultures, 154.03.02,* which also allows for;

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

Any work involving the manipulation of animals must be in accordance with Part 6 of the Animal Welfare Act 1999. This requirement is independent of this facility standard.

Background

The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms that may cause harm to natural and physical resources and human health. Imported risk goods have the potential to introduce pests and unwanted organisms into New Zealand. For that reason, imported risk goods must obtain biosecurity clearance before they are allowed to enter New Zealand.

Uncleared biological products that this facility standard relates to must go to a transitional facility on arrival in New Zealand. They must remain there until they are:

a) given biosecurity clearance, or
b) moved to another appropriately approved facility (via a movement authorisation), or
c) exported (via a movement authorisation), or
d) destroyed.

A place cannot operate as a transitional facility unless it is approved by the Director-General under section 39 of the Act. In order to be approved, the place must comply with the Act and the requirements in this standard. Details about how to apply for facility approval can be found at the following MPI website (http://www.mpi.govt.nz/importing/border-clearance/transitional-and-containment-facilities/forms-and-templates/). Facility approvals may be subject to conditions.

A transitional facility must be operated by an operator approved by the Director-General under section 40 of the Act. The MPI website (http://www.mpi.govt.nz/importing/border-clearance/transitional-and-containment-facilities/forms-and-templates/) explains how to become an approved operator. Operator approvals are

subject to the condition that the operator will comply with this standard and with any other conditions imposed by the Director-General.

Who should read this Facility Standard?

Operators and prospective operators of transitional facilities for uncleared biological products approved by MPI should read and be familiar with this facility standard.

Why is this important?

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

If an operator does not comply with the operating requirements of this facility standard, the operator's approval may be suspended or cancelled.

It is an offence to operate a place as a transitional facility if the place is not approved as a transitional facility or the person operating the place has not been approved as an operator under the Act, or if those approvals are suspended.

It is also an offence for a person who operates a transitional facility not to comply with this facility standard.

Document History

Refer to Schedule 1.

Other information

Guidance

Guidance has been prepared to accompany this facility standard and has been presented as guidance boxes within the standard. The guidance sets out the ways in which the requirements of this facility standard can be met and contains other useful information. Operators and applicants for approval should read and be familiar with the guidance information.

Costs

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

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

Part 1: Requirements

1.1 Application

(1) This facility standard applies to transitional facilities holding uncleared biological products that have been directed to a transitional facility upon arrival in New Zealand, and/or transitional facilities in which such uncleared biological products are being used.

Guidance 1.1

- For the purposes of this facility standard, a biological product is defined as a non-viable (not capable of living, replicating, reproducing or developing) product derived from a living organism other than from a human being, and includes a sample of animal origin. It does not include viable microorganisms or viable cell cultures.

1.2 Definitions

(1) Definitions of terms used in this facility standard are set out in Schedule 2.

(2) Terms used in this facility standard that are defined in the Act have the meanings set out in the Act, unless a different meaning is given in Schedule 2. The Act is available at http://www.legislation.govt.nz/

1.3 Implementation arrangements

(1) The following implementation arrangements apply to transitional facilities already approved under *Transitional Facilities for Biological Products, 154.02.17*.

a) Transitional facilities that are already approved under section 39 of the Act at the date of issue of this facility standard must meet the facility standard requirements within 12 months of issue.

b) The operator must ensure that all applications in relation to the transitional facility's approval are submitted to the MPI Inspector no later than nine months from the date of issue of this facility standard.

(2) All new transitional facility applications made after the date of commencement of this facility standard must comply with this facility standard.

Part 2: Physical and Structural Requirements

2.1 Transitional facility premises and location

(1) The transitional facility, including all transitional areas, must be constructed, operated and maintained in a manner that ensures uncleared biological products are securely contained at all times, taking into account all reasonably foreseeable circumstances.

Guidance 2.1(1)

- A transitional facility may be a building or a room within a building. It may also be made up of a combination of connected or separate buildings, laboratories and associated rooms within a defined place.

(2) The transitional facility must be located in a place that is provided with suitable services and systems in order to meet the requirements of this facility standard and to manage the biosecurity risks associated with the activities undertaken with the uncleared biological products being held within the transitional facility.

Guidance 2.1(2)

- The location, construction and operation of a transitional facility and the activities undertaken within it using uncleared biological products should take into account any environmental or infrastructure risks, such as flooding, level of seismic activity, high winds, power disruptions and availability of appropriate waste management systems.
- Such risks should be considered in the context of potential effects on the ability to effectively manage the risks of the uncleared goods and may result in changes to location, structure, and operation as a result.
- Suitable services could include continuous power supply, waste disposal, and accessibility to/for emergency services.

(3) The transitional facility must be constructed and managed to ensure that uncleared biological products can be segregated from all domestic products and products that have received biosecurity clearance.

(4) All surfaces within buildings, laboratories, rooms and other structures of the transitional facility must be sealed and able to be readily cleaned to ensure decontamination is easily achieved.

Guidance 2.1(4)

- Surfaces include, but are not limited to, floors, ceilings and benches.

(5) Buildings and other structures that comprise the transitional facility, or are parts thereof, and are intended to be constructed and managed to securely contain uncleared biological products, must be fully enclosed with lockable entry and exit points.

2.2 Transitional facility owner, operator and user arrangements

(1) If a transitional facility (or parts thereof), or land on which the facility is sited, is leased, the lease contract (or other arrangement) with the owner must clearly identify the operator and the operational arrangements established with the owner for meeting the requirements of this facility standard.

(2) If the transitional facility (or parts thereof) is used by any party not contractually associated with the operator or owner, there must be a documented contract/arrangement that clearly demonstrates that the legal responsibilities of the operator are not compromised.

Guidance 2.2(1) and (2)

- A transitional facility and/or the land on which it is located might not be owned by the person(s)/organisation(s) operating or using it. Occasionally, the land and structures within the facility may have separate owners and these could be distinct from the facility users.
- Additionally, there may be multiple organisations using a transitional facility, even though the transitional facility is operated by only one of those organisations.
- Any lease or other arrangements between owners, users and the operator need to be understood in order to ensure these do not compromise the ability to comply with the requirements of this facility standard.
- The operator has ultimate discretion to permit or decline the use of the transitional facility by other parties and/or the activities such parties may wish to undertake in it and does not need MPI's permission to make such decisions.

(3) Lease contracts/arrangements must be documented and made available to the MPI Inspector (on request) who must be satisfied that no part of the contract/arrangement is inconsistent with the requirements of this facility standard for the operation of the facility.

2.3 Activities using uncleared biological products

(1) All activities using uncleared biological products within the transitional facility must be undertaken and managed in a manner that ensures the uncleared biological products remain securely contained at all times.

(2) The transitional facility (or parts thereof) may be used for purposes not involving uncleared biological products. Any such use must not compromise the ability to comply with the requirements of this facility standard when the facility is being used for purposes involving uncleared biological products.

Guidance 2.3(2)

- Purposes not involving uncleared biological products could include the processing of domestically-sourced goods.

(3) In order to determine if the requirements of this facility standard can be complied with for all activities using uncleared biological products, a biosecurity risk assessment must be undertaken for these activities, except for:

a) Sensory analysis of food products that have been commercially produced or produced in a test kitchen, for human consumption (with the appropriate official documentation certifying the production of food products for human consumption); and
b) Non-genetically modified cell lines where the cell media contains a risk good (such as foetal calf serum or bovine serum albumin) and the cell line is derived from humans; and
c) Samples for interlaboratory proficiency testing.

(4) The biosecurity risk assessment must take into account any factors that potentially increase the likelihood that any microorganisms associated with the uncleared biological product are not able to be effectively managed under the requirements of this facility standard.

(5) The biosecurity risk assessment must be documented and must include consideration of the following:

a) The animal or plant species the uncleared biological product derives from
b) The country the uncleared biological product derives from and the presence or absence of risk organisms in that country that may present a biosecurity risk to New Zealand
c) The type of uncleared biological product
d) The type of processing that may have been applied to the uncleared biological product that may mitigate the presence of microorganisms
e) Intentional or unintentional exposure to animals, humans, and the environment

f) Why and how the uncleared biological product is proposed to be used and the potential exposure route(s)
g) How often the biological agents or hazards are being used
h) Frequency of exposure to people, animals and/or plants
i) Specific procedures relating to assay types, receipt of uncleared biological product and tracking of uncleared biological product
j) Scale of work the biological products are being used for
k) Suitable training for all staff working with the uncleared biological product
l) Details of any human, animal or plant diseases or environmental damage (biosecurity and biosafety factors) that may be associated with exposure to, or release of, biological agents or hazards
m) How to mitigate each risk to the lowest level that is reasonably practicable (necessary control measure(s))
n) Any other relevant matters.

Guidance 2.3(5)

- The range of risk goods that are included within the definition of uncleared biological products is wide and diverse, as are the activities that may be undertaken with them in a transitional facility under this facility standard. This means it is not possible to prescribe in this facility standard how the biosecurity risks that may be associated with all such activities should be managed.
- The essential part of undertaking any activities using uncleared biological products is to ensure that any biosecurity risks that such activities may present are identified, can be effectively managed within the transitional facility and do not compromise the ability to maintain compliance with this facility standard. This is to ensure animal, human and environmental elements are not exposed to risk organisms which may be contained within biological products.

Guidance 2.3(5)(b)

- Uncleared biological products can originate from countries with animal/plant diseases not present in New Zealand.

Guidance 2.3(5)(f)

- The use of the uncleared biological product may involve further processing, analysis (including destructive analysis), media preparation, assays, component extraction (for example, nucleic acids, proteins) and other *in-vitro* work, as well as *in-vivo* activities involving plants or animals.
- The routes of exposure may be unknown. Certain activities may increase the likelihood of microorganisms present within the uncleared biological products to multiply, spread (for example, if aerosols are created), cause infection (for example, if *in-vivo* activities are being undertaken or if plants/animals may be unintentionally exposed), and/or be exposed to the wider environment.

Guidance 2.3(5)(k)

- Staff working with the uncleared biological product may include those involved with product receipt, laboratory staff, and contractors.

Guidance 2.3(5)(m)

- Mitigating risk to the lowest level that is reasonably practicable could include personal protective equipment required, controlled entry and exit to the laboratory area(s) being used, how spills will be contained and the suitable disinfectant(s) for the uncleared biological product.

(6) Uncleared biological products must not be removed from the facility unless they have been:

a) Authorised by an MPI Inspector under section 25 of the Act to be moved to another transitional facility or biosecurity control area or a containment facility; or
b) Given a biosecurity clearance by an MPI Inspector under section 26 of the Act; or

c) Approved by an MPI Inspector to be exported; or
d) Destroyed in accordance with section 3.6(1) of this facility standard.

(7) The following requirements must be complied with if activities involving *in-vitro* use of uncleared biological products are being undertaken in the transitional facility.

a) The minimum biosafety level of the transitional facility is determined by the biosecurity risk level of the material imported. The biosafety level must be suitable for the category of work carried out.
b) The transitional facility must implement one of the waste disposal methods described in clause 3.6 of this facility standard.

(8) The following requirements must be complied with if the transitional facility is undertaking *in-vivo* experimentation using biological products:

a) A written application must be submitted to the Chief Technical Officer (CTO) for permission to undertake *in-vivo* use of biological products, which must include:

i) An experimental work plan that outlines:

1) why the experiment is taking place
2) how the trial will run
3) how the results will be assessed and/or analysed
4) for *in-vivo* work in animals, whether or not the animal manipulations have been approved by an animal ethics committee (or similar)

ii) A description of the transitional facility measures that outlines:

1) how the uncleared biological product use will be tracked
2) where the uncleared biological product will be stored
3) how the uncleared biological product will be used
4) where the *in-vivo* work will be carried out
5) how the experimental animals/plants will be tracked
6) how the waste (including, but not limited to, animal carcases, plants and associated material, and remaining uncleared biological product) will be treated on completion of the trial work

b) *In-vivo* use of biological products must not commence until the CTO has granted permission in respect of such use.

2.4 Signage

(1) Prominent signs must be displayed at all entrances to the transitional facility and areas within building(s) or premises, or parts thereof, which are designated as the transitional facility under the Act. Signs must specify:

a) That the premises are a “Transitional Facility as Approved by the Ministry for Primary Industries”.
b) That entry is restricted to persons authorised by the [named] operator or their delegate.
c) The emergency (or after hours) contact details of the operator and/or person(s) managing the facility, or parts thereof.

(2) A copy of the transitional facility sign must be included in the operating manual as set out in clause 3.1(4)(i).

Guidance 2.4

- Signs are not permitted to display the MPI logos, as per the Flags, Emblems, and Names Protection Act 1981.

Part 3: Operational Requirements

3.1 Operating manual

(1) Each transitional facility must prepare an operating manual and that operating manual must be approved by the Director-General (or their delegate). The manual must set out how the facility will be managed, operated and maintained to continually meet the requirements of this facility standard and the relevant requirements of any applicable IHS.

Guidance 3.1 (1)

- The approval of the facility will be limited to the purpose and scope of activities identified in the operating manual relating to uncleared biological products.
- The operating manual becomes the main means by which compliance against this facility standard is assessed, primarily because it identifies the specific measures to be used in the transitional facility to meet the requirements of the standard.

(2) The policies, procedures and requirements associated with the operating manual must be complied with.

(3) The operating manual must be in English and have the following structure:

a) A table of contents.
b) Sequentially numbered pages.
c) A version number and date on each page.
d) All sections numbered.

Guidance 3.1(3)

- Sequentially numbered pages can be in the format of 'Page X of Y'

(4) The operating manual must include:

a) The scope of what is included in the operating manual, including:
   i) The purpose of the transitional facility, as set out in the facility approval,
   ii) Management structure, including roles and responsibilities.
   iii) A list of the relevant IHS(s) applicable to the uncleared biological products.
   iv) A description of the uncleared biological products being imported and a description of the nature of the activities being undertaken with them.
   v) A site map of the transitional facility (see clause 3.1(4)(b) below).
   vi) A description of the design and construction of the facility relevant to the management of biosecurity risks.
   vii) Policies, processes and procedures relating to all activities using uncleared biological products.
   viii) An overview of the quality assurance system used to ensure that all structural, operational and maintenance aspects of the transitional facility and this facility standard are complied with.

Guidance 3.1(4)

- If a facility is approved in accordance with more than one transitional facility standard (for example, this facility standard and *Transitional Facilities for General Uncleared Risk Goods, TFGEN* , the operating manuals for each may be combined into the one manual, provided that the requirements of each standard are clearly laid out to ensure there is no confusion or

ambiguity as to the nature of the risk goods being held in the facility, or parts thereof, and the activities using those risk goods and where these can be undertaken.

Guidance 3.1(4)(a)(v)

- The site map should include the organisation's entire premises with particular emphasis on areas designated as a transitional facility. *Note* where a facility is approved under different transitional facility standards (for example, this facility standard and TFGEN), all transitional facility areas (for example, devanning area and processing areas for biological products) should be identified or labelled on the map such that the MPI Inspector can correctly identify the boundaries and transitional facility approval as set out in the operating manual.

Guidance 3.1(4)(a)(vii)

- The operating manual may refer to other documents, on the proviso the operating manual lists where those documents can be found.

b) A site plan or map for the facility (see clause 2.1) showing (as applicable):

i) The location of the facility and proximity to major geographical features.
ii) Buildings, parts of buildings and other structures that comprise the facility.
iii) All entry and exit points.
iv) Location of uncleared biological product storage areas
v) Any transitional areas.
vi) Areas where specific activities involving uncleared biological products will be undertaken

Guidance 3.1(4)(b)

- Examples of major geographical features include, but are not limited to, roads, rivers, lakes, and built up areas.
- The site plan/map should include the organisation's entire premises, ensuring that all areas designated as the transitional facility are identified.
- Examples of specific activities involving uncleared biological products include waste disposal, processing, and decontamination.
- If a facility is approved in accordance with more than one transitional facility standard (for example, this facility standard and TFGEN), the site plan/map should identify those parts of the facility that relate to each standard, including those parts which may relate to more than one standard (for example, devanning area and processing areas for biological products).
- This will assist the MPI Inspector in identifying the boundaries covered by the scope of each transitional facility approval, as well as making it clear to facility users what areas relate to specific risk goods and the activities using them.

c) A description of the management structure of the transitional facility that outlines:

i) The name and contact details of the transitional facility owner.
ii) The name and contact details of the operator (and operator delegate, if applicable) and their responsibilities.
iii) All personnel with key roles and responsibilities relating to the requirements of this facility standard and what those responsibilities are.
iv) Any other relevant information.

Guidance 3.1(4)(c)

- While the operator has overall responsibility (accountability) for ensuring that the transitional facility is compliant with the requirements of this facility standard, they are not expected to do all the work. While the accountability cannot be delegated, various responsibilities can be delegated to persons with the appropriate knowledge, expertise, and competence to ensure those

responsibilities are met. Identifying the personnel with these responsibilities in the operating manual informs all users where those responsibilities sit and the extent of them. It also reinforces the onus and scope of those responsibilities on those responsible as well, especially if such responsibilities are part of the person's position description. It is important to remember that the approved operator remains ultimately responsible for compliance with the standards.

- It may be prudent for an operator/operator delegate to appoint a deputy to act in the capacity of operator/operator delegate should the need arise. This is a useful contingency measure, especially when the operator/operator delegate is absent, sick, suddenly resigns or unable to fully exercise their responsibilities at a particular point in time. Regardless of whether or not a deputy is appointed, the approved operator remains responsible for the facility.
- Positions rather than people can be referenced in the operating manual, but provision should be made to ensure that names of persons holding those positions are readily accessible to the MPI Inspector.

d) Contact information for the local MPI office, and the name and contact details of the primary MPI supervising Inspector.
e) Contact information for requesting movement authorisations of biological products, reporting non-compliances with this facility standard, breaches of containment and safety issues (related to uncleared biological products).

Guidance 3.1(4)(e)

- Contact information should include relevant names and email addresses of applicable personnel.
- Breaches of containment include, but are not limited to, breaches in the structural integrity of enclosed buildings and structures, and loss and/or unauthorised removal of the uncleared biological product.

f) A description of how the following will be met in relation to the uncleared biological products being held:

   i) This facility standard.
   ii) The relevant requirements of any applicable import health standard (IHS).
   iii) Any relevant import permit.
   iv) Any relevant measures approved in a CTO direction under section 27(1)(d)(iii) of the Act.

g) A description of any transitional areas, and areas where specific operations are undertaken.
h) Documented biosecurity risk assessment for each uncleared biological product (*see* clause 2.3(5)).
i) A copy of the transitional facility signage (see clause 2.4).
j) The operating manual must contain a description of how the following are managed:

   i) How the effectiveness of the policies, systems and procedures included in the operating manual will be measured, monitored and determined to be continually effective.

Guidance 3.1(4)(j)(i)

- The operating manual may refer to other documents (such as the internal operating procedures), all of which are part of the operating manual 'system' and subject to the requirements of this facility standard, provided the operating manual identifies where those documents are located.

   ii) The access and security procedures (see clause 3.2).
   iii) The procedures for receiving and moving uncleared biological products to and from the facility, and measures used in the event of spillage or contamination (see clause 3.3).

Guidance 3.1(j)(iii)

- The procedures for receipt and movement of uncleared biological products should describe the measures used to ensure that any import permit conditions are complied with and any accompanying BACC is correct.
- The operator of the transitional facility where the uncleared biological products are being transported from is responsible for the uncleared biological products until the products arrive at the receiving facility.

iv) The uncleared biological products inventory system (see clause 3.4).
v) The records system, what records will be kept and where they are located (see clause 3.4).
vi) How uncleared biological products will be kept separate from cleared biological products and domestic products at the transitional facility and during movement (if applicable; see clause 3.5).
vii) The waste treatment and disposal procedures, and identification of waste storage areas (see clause 3.6).
viii) The training programme (see clause 3.7).
ix) The cleaning and hygiene system and the decontamination processes used in the facility (see clause 3.8).
x) The pest control regime, and the measures implemented to ensure that uncleared biological products cannot be accessed by pests (see clause 3.9).
xi) The contingency plan that will be implemented in the event of a situation(s) arising that could compromise the biosecurity of the uncleared biological products being held within the transitional facility (see clause 3.10).
xii) The internal audit process, how the internal audit procedure will be reviewed, content of internal audit reports and how the results of internal audits will be incorporated into the operating manual review process (see clause 3.11).
xiii) The internal quality assurance system review process (see clause 3.12).

Guidance 3.1(j)(xiii)

- The procedure should outline who will be involved, the scope and frequency and reporting requirements including content, and ensuing actions.

xiv) The process for making changes to the operating manual, the person(s) responsible and how changes are approved by MPI and recorded.

Guidance 3.1(j)(xiv)

- If changes are being made to operations, this should be in conjunction with a review (and update, as required) of the relevant biosecurity risk assessment(s).

(5) The operating manual must have a documented review at least once a year to ensure its continuing suitability and effectiveness to meet the requirements of this facility standard. Any changes considered necessary must be incorporated into a revised manual and the changes recorded. The review must take into consideration the following:

a) Changes to the facility (structural and operational) and/or facility management.
b) Internal audit and quality assurance system reports.
c) External MPI inspection reports.
d) Non-compliances identified since the last review.
e) Regulatory changes
f) Any recommendations from facility users.
g) Any other relevant factors

Guidance 3.1(5)

- Regulatory changes should include consideration of changes to this facility standard and/or a relevant IHS.

(6) All changes to the operating manual must be notified to, and approved by, the MPI Inspector. Major changes must be approved by the MPI Inspector prior to those changes occurring. Minor changes may be implemented immediately, but must be approved by the MPI Inspector prior to, or at, the next external inspection.

Guidance 3.1(6)

- Major changes to the operating manual include, but are not limited to, change of ownership of the facility, structural changes that affect the integrity of containment, significant changes to the scope of activities, inclusion of new uncleared biological products, and identification of activities requiring additional risk management measures.
- Minor changes to the operating manual include structural changes that do not affect the integrity of containment, and minor changes to operating procedures and processes.
- Some changes may necessitate the issuance of a new facility approval and/or operator approval (for example, change of operator, relocation of facility, change of ownership).

3.2 Access and security

(1) The transitional facility must have an effective access and security procedure to ensure the security of uncleared biological products.

(2) Only persons authorised by the operator are permitted access to the transitional facility. The operator must ensure that these persons:

a) Adhere to access procedures.
b) Have been provided with, and understand, suitable training and instruction before access is permitted (see clause 3.7).
c) If visitors, contractors and tradespeople, are accompanied by a staff member while in the transitional facility (where possible).
d) Follow the instructions of the operator at all times.

(3) All visitor names, organisations, contact details (phone number or email address) and the date and purpose of the visit must be recorded in a visitors register.

(4) The operating manual must specify the location of the visitors register.

(5) The operator must provide access to the transitional facility for the MPI Inspector when required.

3.3 Receipt and movement of uncleared biological products

(1) Uncleared biological products held in the transitional facility are able to be exported or moved to another transitional facility, containment facility or biosecurity control area, subject to MPI authorisation.

Guidance 3.3(1)

- The scope of the receiving facility's operating manual should provide for the receipt of uncleared biological products and the type of activities within which the uncleared biological products will be used.

(2) The receipt and/or movement of all uncleared biological products received in, or moved from, the transitional facility, must have been authorised by an MPI Inspector prior to that receipt or movement occurring.

Guidance 3.3(2)

- The operator may obtain authorisation to move uncleared biological products by applying to MPI for a BACC redirection or using a movement authorisation request form. Applications will be granted provided authorisation requirements have been met.
- Authorisation for receipt or movement of uncleared biological products from an MPI Inspector may be in the form of a BACC or signed movement authorisation form.
- Movement authorisation forms are available at: http://www.mpi.govt.nz/importing/biological-products-and-organisms/biological-products/forms-and-templates/.

(3) The procedures used for receipt and movement of uncleared biological products must be documented and include procedures for identification and verification of accompanying documentation and how that verification occurs.

Guidance 3.3(3)

- Uncleared biological products should be unpacked at a dedicated place in the transitional facility, preferably where other uncleared risk goods are not stored and there is ready access to decontamination equipment, should that be required.
- Provision should be made for the secure storage of uncleared biological products if deliveries are outside working hours.

(4) Movement authorisation requests must be authorised by the operator or signatories authorised by the operator. Signatories from the receiving facility must also agree to receive the uncleared biological products prior to the application being approved by an MPI Inspector. The authorised signatories must be identified in the operating manual.

Guidance 3.3(4)

- A maximum of three authorised signatories (including the operator) is recommended in order to effectively manage the movement and receipt of uncleared biological products.

(5) If uncleared biological products are being moved to another facility, it must be demonstrated to the satisfaction of the authorising MPI Inspector that all import requirements in relation to the uncleared biological products can be met at the receiving facility, prior to authorisation for the movement being given. These requirements are those specified in the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.

(6) All movements of uncleared biological products must be in a secure and contained manner, appropriate to the nature of the uncleared biological product, to prevent loss and spillage or contamination of the transporting vehicle, other cargo and/or the environment.

Guidance 3.3(6)

- The operator of the transitional facility where the uncleared biological products are being transported from is responsible for the uncleared biological products until the products arrive at the receiving facility.

(7) Any loss, or suspected loss, spillage or leakage of uncleared biological products at receipt or that occurs during movement must be notified to the MPI Inspector as soon as reasonably possible. It must be confirmed that the MPI Inspector has received the notification. Contingency plans to manage such events must be implemented immediately.

Guidance 3.3(7)

- Confirmation that the MPI Inspector has received notification of any loss, or suspected loss, spillage or leakage of uncleared biological products includes an acknowledgement of an email.

(8) If uncleared biological products are received without MPI authorisation or the correct documentation, the MPI Inspector must be notified immediately, and the products held securely pending further direction from MPI as to what action(s) to be taken. This is not applicable if another MPI-approved process has been agreed to.

(9) In case of spillage or leakage of uncleared biological products while such products are being moved, the transporting vehicle and/or container must be cleaned and decontaminated. All waste must be disposed of as specified in the contingency plan section of the operating manual or as directed by the MPI Inspector.

3.4 Records and product inventory

(1) An effective record keeping system must be implemented and maintained that allows easy access to records for relevant staff and the MPI Inspector.

Guidance 3.4(1)

- The record keeping system should be electronic and incorporated into a wider records management system, if possible.

(2) Records of the following must be kept and maintained:

a) The name, address and other contact details of the legally identifiable owner of the transitional facility.
b) Certificates of facility and operator approvals.
c) Copies of any lease contracts/arrangements relating to the transitional facility or parts thereof and the land where the facility is located and/or users of the facility.
d) Copies of any delegations from the operator, if there is an operator delegate.
e) Copies of operator authorisations of the authorised signatories.
f) BACCs, movement authorisations, import permits and CTO directions.
g) All uncleared biological products received, being held in, moved and exported from, the transitional facility with the accompanying approval documents.
h) Official documents verifying compliance with the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
i) All products that have been processed to the requirements of the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
j) Records of destruction of uncleared biological products and accompanying imported waste material (see section 3.6).
k) Training and assessment records.
l) Pest control records.
m) Non-compliance reports.
n) Internal audit reports, quality assurance systems, review reports, and close out records.
o) MPI inspection reports.

Guidance 3.4(2)(m)

- Non-compliance reports encompasses Critical Situation Reports as well.

(3) Records must include dates and signatures of persons responsible for generating or updating the records.

(4) Records must be legible, readily identifiable, and kept for a minimum of seven years from receipt, preparation or amendment.

(5) The location of all records must be identified in the operating manual.

(6) The inventory of uncleared biological products received, held, moved, exported, and destroyed from/at the transitional facility must include (as applicable):

a) Nature, quantity, batch number(s) and other identifying descriptors of the products.
b) Date(s) of receipt, movement, export or destruction
c) Where the products are stored in the transitional facility.
d) BACC, import permit, any measures approved in a CTO direction and/or movement authorisation form that the products are received, moved or exported under.

(7) The uncleared biological product inventory must enable tracking from the point of product receipt through each stage of processing until the batch (including by-products and waste) is eligible for one or more of the following:

a) Release (biosecurity clearance).
b) Movement for further processing and/or testing.
c) Destruction.
d) Export.

(8) Uncleared biological product records must be easily accessible to relevant staff and the MPI Inspector.

Guidance 3.4(8)

- It is recommended that documents pertaining to each consignment are kept together.

3.5 Segregation of uncleared biological products

(1) Uncleared biological products must be stored in a manner that minimises the risk of cross-contamination to other products, goods and equipment, particularly cleared biological products and items that may be moved from the facility and not subject to decontamination. They must be clearly labelled.

(2) Other products, goods and equipment that are, or suspected to have been, exposed to uncleared biological products are regarded as a biosecurity risk and must be managed in a manner that ensures that risk is mitigated. This may include appropriate decontamination, destruction and disposal measures.

Guidance 3.5

- In addition to any other labelling, primary storage containers should be labelled with a unique identifier.
- Labelling should be sufficient to allow the tracking of the uncleared biological product to the import permit the product was imported under.
- Storage and management measures should take into account the:
  - Nature of the potential biosecurity contamination associated with the uncleared biological products and how other products, goods and equipment could be contaminated.
  - Nature and type of packaging of the uncleared biological products.
- Preventing contamination of cleared biological products can be achieved by:
  - Separating products using a physical barrier and, where appropriate, separate equipment.
  - Labelling products with a unique identifier
  - Secure packaging of uncleared biological products so that any potential contamination is contained and separated from other products.

3.6 Waste treatment and disposal

(1) Uncleared biological products that are no longer required, and all waste associated with uncleared biological products and generated from activities using those products, must be treated and disposed of as specified in this facility standard, the relevant IHS(s), the import permit and/or any measures approved in a CTO direction. Subject to any specific requirements of those documents, treatment and/or disposal must occur in the transitional facility or at another transitional facility following movement authorisation from the MPI Inspector.

(2) One of the following waste treatment methods must be used to ensure that any harmful or potentially harmful organisms present are destroyed prior to disposal:

a) Pressure steam sterilisation; or
b) MPI-approved chemical disinfection treatment; or
c) Other process as approved by the Director-General, or their delegate, in writing.

(3) If waste is being moved to another transitional facility for treatment and/or disposal, documented evidence must be provided to the MPI Inspector (through the movement authorisation process - see clause 3.3) that:

a) The operator of the receiving transitional facility has agreed to receive the waste for the purpose of movement and to fulfil that purpose.
b) The receiving transitional facility can treat and dispose of the waste in accordance with the requirements of this facility standard.

(4) The types of waste, approximate quantities and the treatment and/or disposal procedure for each waste stream must be described in the operating manual and evidence for its effectiveness must be verified and documented.

Guidance 3.6

- Sterilisation is the preferred method of waste treatment because it renders all organisms that may be present non-viable. However, this method may not be practical or necessary in all situations, especially for large volumes of material or where risk organisms of concern can be effectively destroyed without sterilisation (for example, through disinfection) or the risk mitigated by other means (for example, deep burial).
- The intention of waste treatment and disposal is to ensure that potentially harmful organisms are destroyed or are not inadvertently released so that potential is realised (for example, becoming incorporated into the food chain or agricultural/horticultural industries).
- The waste disposal process should either inactivate the potential risk organisms or completely render it unusable.
- Waste includes uncleared biological products that are no longer needed, packaging that has been in contact with uncleared biological products, goods accompanying the risk goods (for example, soil and other extraneous material), materials that have come into contact with the risk goods during activities using them (for example, disposable gloves, plastic syringes, pipette tips, plastic tubes), trim, by-products and liquid.
- Onsite treatment of waste should take into consideration any factors that may affect the ability to effectively manage and treat the waste involved, such as storage, frequency of treatment applications, quantity of waste material generated, suitability of the treatment area/conditions, security, pest control measures (for example, likelihood of vermin presence), and transport of the waste (for example, prevention of seepage/leakage during movement to treatment area).

3.7 Training

(1) All persons working in, or visiting, the transitional facility must be are aware of, understand, and comply with aspects of the following (as relevant to the purpose for their presence in the facility):

a) The requirements of this facility standard and the approved operating manual.
b) The documentation related to the management of uncleared biological products.
c) Their responsibilities and obligations while in the transitional facility in relation to the management of uncleared biological products.

(2) The operator must nominate a person or position within the organisation who is responsible for training of staff and visitors relating to the requirements of this facility standard.

(3) A training programme must be developed, implemented and maintained for all staff, personnel and visitors working in and/or visiting the transitional facility. The programme must describe the following:

a) What the training encompasses with respect to the different categories of facility user: staff members, contractors, tradespeople, and visitors.
b) How the training is to be delivered for each of the user categories above.
c) How the effectiveness of training is assessed.
d) The time period(s) for training delivery and refresher courses.

(4) All persons handling uncleared biological products must have undertaken the relevant training and determined to have understood the requirements, and the obligation to comply with those requirements, prior to handling those products.

(5) Refresher training must be undertaken at least annually, or if this facility standard is amended.

Guidance 3.7

- Visitors to the facility might include contractors undertaking repairs and maintenance work, persons delivering or removing goods, local body inspectors, members of the public, cleaners, emergency personnel and persons within the company who may not be in the transitional facility on a regular basis and do not have direct responsibilities for operations.
- The training provided for each person should only address what is needed in order for the requirements of this standard to be met. Contractors, for example, may only need to be provided with information about the facility and the precautions they must take to ensure the safe and secure management of uncleared biological products they may come in contact with.

3.8 Cleaning, hygiene and decontamination

(1) There must be a cleaning, hygiene and decontamination system in the transitional facility that ensures the facility is kept clean at all times, that the likelihood of activities undertaken by personnel to compromise the management of the uncleared biological products is minimised, and that there are effective decontamination measures.

(2) The system must identify the following:

a) Identification of any disinfectants used, their preparation and correct use
b) The identity and location of cleaning and decontamination equipment, and if any of this equipment is dedicated to the transitional facility, parts thereof, or for a specific purpose(s).
c) The procedures to be used in the event of spillage or decontamination of the facility, parts thereof, or specific equipment used with uncleared biological products.

Guidance 3.8

- The decontamination processes used in the facility should also describe how spills will be dealt with.
- While a wide range of disinfectants are effective on microorganisms or specific categories of microorganisms, it is important that the disinfectant(s) employed are effective against the target microorganisms and are prepared and used in accordance with the manufacturer instructions.

- It is particularly important that disinfectant contact times are adhered to and cautions around use with respect to the presence of organic material and on types of surfaces are followed. This may affect the ability to use some disinfectants in some situations and in some activities involving uncleared biological products.

3.9 Pest control

(1) The transitional facility must have an effective pest management system for managing, controlling and monitoring undesirable organisms, taking into consideration:

a) The organisms that present a risk to the uncleared biological products at the transitional facility
b) Appropriate procedures, measures and equipment that will be used to control these organisms
c) How the control measures will be monitored and determined to be effective, and what information will be provided to verify this.

(2) Transitional facilities holding or using bee products and other products that may attract flying or crawling insects must be fitted with insect proofing appropriate to the type of insects of concern to prevent entry into the transitional facility where such products are exposed or likely to be exposed.

(3) MPI must be notified as soon as practicable of the presence of any organism in or around the transitional facility not normally seen or otherwise detected in New Zealand, in accordance with section 44(1) of the Act.

Guidance 3.9

- The pest management system should take into account:
  - The type of uncleared biological products being received and used.
  - The nature of the use, by-products and waste.
  - The location of the transitional facility.
  - Alignment with the cleaning, hygiene and decontamination procedures.
- Insect proofing may include screens over windows and vents, doors flush with the floor, ceiling and walls, ensuring that the interior of the building is free from cracks or holes that would allow entry of insects, or a combination of these measures.
- If the control of undesirable organisms is contracted out to a third party, the operator should ensure that appropriate records are kept to demonstrate with the requirements of this standard.

3.10 Contingency plan

(1) There must be a system for contingency planning and preventative actions to ensure that contingencies are effectively managed in a timely manner.

(2) A contingency plan must be developed and maintained to manage any reasonable situation or incident which may compromise the biosecurity of uncleared biological products.

(3) The contingency plan must describe:

a) Identification of contingency events.
b) Identification of the risks associated with each contingency event, particularly as they relate to compliance with this standard and the management of uncleared biological products.
c) The equipment and resources required and where these are located.
d) The personnel involved in managing the contingency and who is to be contacted and how.
e) Any security and access arrangements related to the management of contingency events.
f) The procedures to be followed in the event of a contingency event occurring.
g) A description of how the contingency plan will be verified to ensure that it is effective and what evidence will be provided to demonstrate this.

h) Any other relevant factors.

(4) It must be demonstrated that the contingency plan is able to be implemented immediately in the event of an identified contingency event occurring.

(5) The contingency plan must be implemented immediately in the event of a contingency event occurring.

Guidance 3.10

- Examples of contingency event include, but are not limited to, fire, natural disasters (for example, earthquakes, flood), loss of operator, breaches of security (for example, theft, containment), unexpected arrival of uncleared biological products, loss of essential services (for example, electrical power, equipment malfunction), cancellation of facility approval, or inability to operate due to lack of financial resources.
- Contingency plans need to contain sufficient information to enable persons responsible for implementing the plan to respond as quickly as possible. The information needs to be clear and complete, including up to date contact details of key individuals and emergency services (if applicable).
- Testing of contingency plans should be carried out on a regular basis to ensure a smooth implementation of each plan (for example, undertaking a fire drill). Testing should also ensure that equipment and other resources are operational and staff know how to use them.

3.11 Internal audit

(1) An internal audit must be undertaken at least once every six months to verify ongoing compliance with this standard and the facility approval. There must a documented procedure for planning and conducting the internal audit, which must outline:

a) Who is to be involved.
b) The purpose and scope of the audit.
c) The documentation required.
d) How it is to be conducted.
e) The time-frame.
f) What must be included in the audit report.
g) Any other relevant factors.

(2) The internal audit must take into consideration:

a) The results of the previous internal audit.
b) Any non-compliances identified or notified since the previous internal audit.
c) Relevant aspects of quality assurance systems reports.
d) MPI inspection reports.
e) The transitional facility approval, including any conditions placed on that approval.
f) Technical advice received from MPI.
g) Amendments to this standard and applicable IHSs.
h) Any recommendations from transitional facility users.
i) Any other relevant factors.

(3) The internal audit findings must be documented in an internal audit report, which must be provided to the MPI Inspector within ten working days of the audit being completed, or in a timeframe agreed with the MPI Inspector. The report must outline:

a) The purpose, scope and date of the audit.
b) The names of the auditors and auditees.
c) Documentation and other matters that were taken into consideration (see clause 3.11(2)).
d) Any non-compliances and recommendations, including any corrective actions and the timelines for their completion.
e) The overall conclusions as to whether compliance has been met.

f) Signature of the operator and acknowledgement that they agree with the conclusions of the audit.
g) Any other relevant factors.

(4) Internal audit reports must be retained as part of the facility records.

Guidance 3.11

- The internal audit is the most effective mechanism by which the operator can verify, and demonstrate to MPI, that the requirements of this standard are being continually met. While it should identify any non-compliances, if conducted thoroughly, its focus should be around continual improvement not on finding fault.
- A record of corrective actions taken should identify the non-compliance, the action to be taken to address it, who is responsible for completing that action and the timeframe that the action is to be completed by.
- Internal audits should be conducted in sufficient time to enable the completed report to be sent and reviewed by the MPI Inspector prior to the next inspection. This is to allow the MPI Inspector to verify compliance with this facility standard.

3.12 Quality assurance system review

(1) A review of the quality assurance system must be conducted at least annually. The review must be focused on:

a) Ensuring that the most appropriate and effective policies, systems, procedures and processes are in place to meet the regulatory requirements.
b) Ensuring that there are effective methods to monitor, assess and evaluate those policies, systems, procedures and processes.
c) Ensuring that those policies, systems, procedures and processes are being complied with.
d) Identifying how the quality assurance system can be improved and how non-compliance can be prevented.

(2) There must a documented procedure for planning and conducting the quality assurance system review which must describe:

a) Who is to be involved.
b) The purpose and scope of the review.
c) The documentation required.
d) How it is to be conducted.
e) The time-frame.
f) What must be included in the review report.
g) Any other relevant factors.

(3) The quality assurance system review findings must be documented in a quality assurance system review report, which must be made available to the MPI Inspector on request. The report must describe:

a) The purpose, scope and date of the review.
b) The names of the reviewers.
c) The review procedure that was followed.
d) Documentation and other matters that were taken into consideration (see clause 3.12(2)).
e) Any recommendations and actions.
f) The overall conclusions against the purpose and scope.
g) Signature of the operator and acknowledgement that they agree with the conclusions of the review.
h) Any other relevant factors.

(4) The quality assurance systems review report must be retained as part of the facility records.

Guidance 3.12

- The annual quality assurance system review should coincide with every second internal audit. This allows a full and comprehensive review of the entire quality assurance system.

3.13 External MPI inspection

(1) The transitional facility must be inspected by MPI every six months unless an inspection frequency reduction has been granted by an MPI Inspector following a written request from the operator.

(2) Access to all parts of the transitional facility and all relevant records and documents must be made available to the MPI Inspector when requested to verify compliance with this facility standard. The operator or operator delegate must be present to facilitate the inspection. Previous MPI inspection reports must be included in the records presented.

(3) The current version of the operating manual must be made available to the MPI Inspector on request and at least five working days prior to the external inspection.

(4) Evidence must demonstrate that the requirements of this facility standard are being met.

Guidance 3.13

- An inspection frequency reduction may be granted following an application from the operator to the supervising MPI Inspector. Such requests will be assessed by the Inspector following consultation with an MPI Technical Adviser. Further information and criteria that will be taken into consideration can be obtained from the MPI Inspector but will include compliance history, numbers and types of non-compliances, volume and types of uncleared biological products being imported, quality assurance system reports, improvements towards compliance and the level of responsibility being taken towards compliance.
- The inspection will include an assessment of whether the provisions of the operating manual are being complied with, particularly because these provisions have been approved by MPI as meeting the descriptive and prescriptive requirements of the standard.
- MPI reserves the right to inspect at any time and inspections may be unscheduled.

3.14 Non-compliance

(1) There must be a system for effectively managing non-compliance. This must include:

a) A definition of what comprises a non-compliance, the categories of non-compliance and examples of each.
b) The procedures to be followed for reporting, assessing, addressing, documenting and closing out non-compliances and preventing them from recurring.
c) Any other relevant factors.

Guidance 3.14(1)

- Non-compliances may be identified at any time by the operator, facility users, the MPI Inspector and during regular work activities, internal audits, and quality assurance system reviews.
- Critical non-compliances may require further investigation and may lead to further actions, such as prosecution, cancellation or suspension of the facility and/or operator approval.
- It may not be practical to implement full corrective actions in a timely manner to address a non-compliance or prevent it from recurring. Some corrective actions may require significant structural work at significant cost. In such cases, appropriate measures should be taken to mitigate the risk as much as possible until the corrective action(s) can be completed.

- Where a transitional facility is not compliant with this facility standard, the MPI Inspector may recommend to the Director-General that the approval for that transitional facility and/or operator be suspended or cancelled.
  MPI reserves the option to increase inspection frequencies until being satisfied that the facility is fully compliant with this facility standard.

(2) If a critical non-compliance is identified or notified, the following steps must be taken:

a) The non-compliance must be reported to the MPI Inspector as soon as practicable and within 24 hours of being identified.
b) Immediate corrective action(s) must be taken to mitigate the risk and restore compliance.
c) All activities related to, or which may be jeopardised by, the non-compliance which present a biosecurity risk must be immediately discontinued.
d) Advice from the MPI Inspector must be sought to confirm corrective actions and determine any further corrective actions.
e) A Critical Situation Report must be prepared and sent to the MPI Inspector within 48 hours of the non-compliance being identified.
f) Record the non-compliance, any corrective actions taken and dates of close-out and any preventative actions implemented and/or to be implemented.

Guidance 3.14(2)

- A critical non-compliance could include, but is not limited to:
  - Releasing uncleared biological products from a facility without approval from the MPI Inspector.
  - A breach of containment.
  - Operating a facility without an approved operator.
  - Making significant modifications to the facility without MPI approval.
  - Failure to conduct internal audits.
  - Failure of the operator to detect significant and obvious non-compliances.
  - Cumulative major and minor non-compliances that have not been adequately addressed.

(3) If a major non-compliance is identified or notified, the following steps must be taken:

a) The non-compliance must be reported to the MPI Inspector as soon as practicable and within 24 hours of being identified.
b) Immediate corrective action(s) must be taken to mitigate the risk and restore compliance.
c) All activities related to, or which may be jeopardised by, the non-compliance which present a biosecurity risk must be immediately discontinued.
d) Advice from the MPI Inspector must be sought to confirm corrective actions and determine any further corrective actions.
e) Record the non-compliance, any corrective actions taken and dates of close-out and any preventative actions implemented and/or to be implemented.

Guidance 3.14(3)

- A major non-compliance includes, but is not limited to:
  - Moving uncleared biological products between facilities without movement authorisation from MPI.
  - Non-authorised persons working in the transitional facility.
  - Failure to keep appropriate records and copies of required documents.
  - Failure to comply with training requirements.
  - Failure to operate to the requirements of the operating manual.

(4) If a minor non-compliance is identified or notified, the following steps must be taken:

a) The non-compliance must be reported to the MPI Inspector by, or at, the next MPI inspection.
b) Corrective action(s) must be taken in a timely manner to mitigate the risk and restore compliance.
c) Record the non-compliance, any corrective actions taken and dates of close-out and any preventative actions implemented and/or to be implemented.

Guidance 3.14(4)

- A minor non-compliance could include, but is not limited to:
  - Failure to keep a transitional facility clean.
  - Failure to conduct refresher training or internal audits in a timely manner.

Schedule 1 – Document History

Date First Issued	Title	Shortcode
27 April 1998	Transitional Facilities for Biological Products	154.02.17
Date of Issued Amendments	**Title**	**Shortcode**
TBA	Facility Standard: Biological Products	MPI-STD-BIOLOGICAL

Schedule 2 – Definitions

Terms used in this standard that are defined in the Act have the meanings set out in the Act, unless a different meaning is given below.

Audit

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

Authorisation

Authority given by an Inspector under section 25 of the Biosecurity Act 1993 permitting uncleared goods to be moved from a transitional facility or biosecurity control area to another transitional facility, biosecurity control area or containment facility, or to be exported.

BACC

A biosecurity authority clearance certificate, which is a document that certifies an MPI Inspector has given a clearance or an authorisation for the goods the certificate relates to.

Biological Product

A non-viable (not capable of living, replicating, reproducing or developing) product derived from a living organism other than from a human being, and includes a sample of animal origin. It may also include biological products of plant origin such as soil, where no microbial work is to be undertaken on the samples.

Biosafety Level

A specific combination of work practices, safety equipment, and facilities which are designed to reduce the exposure of animal, human and environmental elements to risk goods.

Corrective Action

An action taken to correct a non-compliance.

Contained

Restricting an uncleared biological product or organism to a secure location or facility to prevent escape.

Contingency Plan

A plan devised for a specific situation where things could go wrong, containing information, tasks and procedures that are necessary for timely decision-making and response to an unexpected event or situation where the preferred plan fails.

Critical Non-compliance

A major failure in an operation or system that caused, or could have caused, a serious biosecurity risk.

Critical Situation Report

A report detailing a critical non-compliance and its causes, the immediate actions taken and any further actions proposed to be taken.

Decontamination

A process that destroys risk organisms or reduces them to a level where the risk they present is negligible.

Destroy

To ruin the structure, organic existence, or condition of a good so that it can no longer function or exist. Includes, but is not limited to, biological products incorporated with other products until they are no longer a risk good (as determined by a biosecurity risk assessment), using up a biological product, or appropriately disposing of a biological product as waste.

Director-General

The chief executive of the Ministry for Primary Industries or his/her delegate.

Experimental Animals

Includes all mammals, birds and bees.

General Import Permit

A permit issued by the Director-General of MPI pursuant to section 24D(2) of the Act where the product is assessed by MPI and concluded to be of negligible risk (and where that product is not listed as negligible risk within the relevant IHS).

Internal Audit

An audit carried out by the company or organisation approved to this facility standard to evaluate its own performance in relation to the standard or prescribed criteria.

In-vitro

Refers to a process or reaction carried out outside a living organism (including, but not limited to, in a culture dish, or test tube).

In-vivo

Refers to a process or reaction carried out inside a living organism.

Major Non-compliance

A major failure in an operation or system that may cause, or lead to, a biosecurity risk.

Minor Non-compliance

A situation that does not present a major failure of an operation or system but results in a decrease in confidence in the management of the facility and which may not immediately cause or lead to a biosecurity risk.

MPI

Ministry for Primary Industries, New Zealand.

Pest

For the purpose of this facility standard, a pest is defined as an organism that could compromise the ability to safely and securely manage risk goods. A pest includes, but is not limited to, insects and other invertebrates, birds, rodents, cats, dogs, weeds and microorganisms.

Procedure

A document that specifies, as applicable, the purpose and scope of an activity; what must be done and by whom; when, where, and how it must be done; what materials, equipment and documentation must be used; and how it must be controlled.

Restricted Import Permit

A permit issued by the Director-General of MPI pursuant to section 24D(2) of the Act where:

- The biosecurity risks associated with the product listed in the permit have been assessed by MPI;
- MPI has concluded the product poses a risk to New Zealand; and
- MPI has concluded that the risk can be mitigated by requiring the product to be held and/or used only in an appropriate approved transitional facility.

Sterilisation

A process that completely removes viable microorganisms or renders the microorganisms non-viable.