STANDARD 154.02.17

Transitional Facilities

for Biological Products

Ministry for Primary Industries
P O Box 2526
Wellington
New Zealand

CONTENTS

ENDORSEMENT

This Standard is approved pursuant to section 39 of the Biosecurity Act 1993.

_____
Manager Import and Export Animals Date
Howard Pharo
Ministry for Primary Industries (MPI)

For Director General
Ministry for Primary Industries
(Pursuant to delegated authority)

REVIEW

This MPI Standard is subject to review and amendment at any time, to ensure that it continues to meet current needs. Amendments will be issued to holders of controlled copies and operators of transitional facilities approved under this Standard.

AMENDMENT RECORD

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

Amendment No:	Details:	Date:
1	Amended the definition of biological products to align with Standard for Facilities for Microorganisms and Cell Cultures: 2007a (154.03.02) Updated the following definitions: • Replacing Chief Veterinary Officer with Chief Techincal Officer (CTO) • MAF Regulatory Authority • National Manager	21 February 2014

	Replaced references to the Ministry of Agriculture and Forestry (MAF) and Biosecurity New Zealand (MAFBNZ; BNZ) with the Ministry for Primary Industries (MPI) Updated references to the Biosecurity Act 1993 in light of the Biosecurity Act Reform Bill. Replaced reference to the Animal Protection (Codes of Ethical Conduct) Regulations 1987 with the Animal Welfare Act 1999.	
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1. INTRODUCTION

SCOPE OF PART ONE

This MPI Standard specifies the structural and operating requirements for facilities using, holding or processing imported biological products [ie. risk goods] which have been directed on arrival in New Zealand to a transitional facility approved to this Standard as a requirement of an import health standard. This Standard also specifies how these facilities and their operators may be approved.

The primary purpose for the quarantine of imported biological products is to minimise the risk that any associated organism will:

. 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. [From the definition of risk goods, section 2, Biosecurity Act, 1993.]

Microorganism isolation, enrichment and/or culturing is not permitted in transitional facilities approved to this Standard (154.02.17). In order to do undertake such work, the facility must be approved to the Standard for *Facilities for Microorganisms and Cell Cultures: 2007a* (154.03.02) which also allows 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.

SCOPE OF PART TWO

The supplier shall provide the Chief Technical Officer with a service to supervise the operation of transitional facilities for biological products which are required to operate according to Part One of this Standard.

1.1 REFERENCES

This Standard is an approved standard in terms of section 39 of the Biosecurity Act, 1993.

The following publications are referred to in this MPI Standard:

AS/NZS Standard 9002 [1994]: Quality Systems - Model for quality assurance in production, installation and servicing. Published by Standards New Zealand.

AS/NZS Standard 2243.3 [1995]: Safety in laboratories. Part 3: Microbiology.

British Standard EN45004: (1995) General criteria for the operation of various types of bodies performing inspection.

Import health standards for biological products which have a requirement for post arrival quarantine in transitional facilities.

1.2 DEFINITIONS

For the purposes of this MPI Standard the following definitions apply:

Approval

Means approved by the Director-General, MPI, or his/her delegate. The Chief Technical Officer and the Manager, Import and Export Animals are delegates for this Standard.

Audit

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

Biological products

For the purposes of this Standard, biological products are risk goods which are non-viable products (not capable of living, replicating, reproducing or developing) derived from living organisms, including samples of animal origin.

Biosecurity clearance

"Means a clearance under section 26 of the Biosecurity Act 1993 for the entry of goods into New Zealand:"

Biosecurity direction

Authority from an inspector, given under section 25 of the Biosecurity Act 1993, to move uncleared goods to a transitional facility, containment facility or biosecurity control area.

Chief Technical Officer (CTO)

Is the chief technical officer [as defined in section 101 of the Biosecurity Act 1993] of MPI with animal health and other responsibilities.

Director-General

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

Experimental animals

Includes all mammals, birds and bees.

Import Health Standard

A document issued under section 24A 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 as an inspector under section 103 of the Biosecurity Act 1993.

Internal audit

An audit carried out by the company or organisation to evaluate its own performance in relation to the Standard or prescribed criteria.

In-vitro

Refers to a process or reaction carried out in a culture dish, test tube etc.

In-vivo

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

MPI

Ministry for Primary Industries.

Manager Import and Export Animals

The Manager Import and Export Animals, Ministry for Primary Industries (MPI), New Zealand, or any person who for the time being may lawfully exercise and perform the powers and functions of the Manager Imports and Export Animals.

Operator

The person who has overall responsibility for the facility, its maintenance and operation in terms of section 40 of the Biosecurity Act 1993.

Organism

(a) Does not include a human being or a genetic structure derived from a human being:
(b) Includes a micro-organism:
(c) Subject to paragraph (a) of this definition, includes a genetic structure that is capable of replicating itself (whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity):
(d) Includes an entity (other than a human being) declared by the Governor-General by Order in Council to be an organism for the purposes of this Act:
(e) Includes a reproductive cell or developmental stage of an organism:
(f) Includes any particle that is a prion: Section 2, Biosecurity Act, 1993.

Permit to Import

A permit issued by the Director-General of MPI pursuant to section 24D of the Biosecurity Act 1993.

Procedure

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

Quarantine

Means confinement of organisms or organic material that may be harbouring pests or unwanted organisms. (section 2, Biosecurity Act 1993).

Risk goods

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

(a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or

(b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms: (Section 2, Biosecurity Act 1993).

Supervisor

The person employed by the supplier who inspects the transitional facility and audits the operation of quarantine.

Supplier

The party responsible for the performance of the inspection and the audit work under a contractual arrangement with MPI.

Transitional facility

Any place approved as a transitional facility in accordance with section 39 for the purpose of inspection, storage, treatment, quarantine, holding, or destruction of specified types of uncleared goods; or part of a port declared to be a transitional facility in accordance with section 39. (section 2, Biosecurity Act 1993). In the context of this Standard transitional facility means a transitional facility approved under this Standard.

Uncleared goods

Means imported goods for which no biosecurity clearance has been given. (section 2, Biosecurity Act 1993).

Unwanted organisms

Means 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: (section 2, Biosecurity Act 1993).

PART ONE: REQUIREMENTS OF THE OPERATOR

2. APPROVAL OF A TRANSITIONAL FACILITY AND OPERATOR

2.1 APPROVAL OF A TRANSITIONAL FACILITY

A transitional facility shall be approved in accordance with section 39 of the Biosecurity Act, 1993. It shall have an approved operator and be constructed and operated in accordance with this Standard. [It is expected that the facility will comply with the requirements of the Resource Management Act 1991, Building Act 1991 and any other relevant legislation.]

The supervisor is prepared to consider applications before construction or alteration of a facility in order to provide advice on whether the proposed facility is likely to comply with this Standard.

When the facility and operational procedures [detailed in the quarantine manual or alternative quality system] meet the requirements of this Standard the supervisor shall recommend to the CTO that the facility be approved as a transitional facility.

Approval will be in writing and usually for twelve months.

2.1.1 Modifications to an approved facility

If, subsequent to approval, the facility is to be modified, the supervisor is to be advised. A new floor plan may be required and the facility may be inspected to check that it meets the Standard.

2.1.2 Renewal of approval

Approval of the facility for another 12 months is dependent on a satisfactory external audit and a recommendation from the supervisor to the CTO.

2.2 APPROVAL OF AN OPERATOR

A transitional facility operator shall be approved in accordance with section 40 of the Biosecurity Act 1993.

The operator is responsible for the operation of the transitional facility and ensuring that mechanisms are in place for resourcing the facility. If the facility is leased, the lessee, responsible for the operation of the transitional facility, shall apply to be the operator and the contract with the owner shall clearly identify who is responsible for the maintenance of the premises and the resourcing of the operation. No part of the lease contract shall override the requirements of this Standard in the operation of

quarantine. This contract shall be made available to the supervisor who shall be satisfied that the contract does not override the requirements of this Standard.

Approval will be in writing.

2.2.1 Collection of personal information on individuals

In regard to any information being collected on the application for approval of an operator, this is personal information [being information identifying or being capable of identifying an individual person]. Notification is hereby provided, in accordance with the Privacy Act 1993, to individuals of the following matters:

. This information is being collected for the purposes relating to the approval of an operator as per section 40 of the Biosecurity Act 1993.

. The recipient of this information, which is also the agency that will collect and hold the information is the Ministry for Primary Industries, PO Box 2526, Wellington.

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

2.3 PROCEDURE FOR APPROVAL OF A FACILITY AND AN OPERATOR

Any person wishing to have a transitional facility approved and to be approved as an operator shall establish contact with the supervisor or supplier. [The supplier's identity may be obtained from the CTO.]

An application for approval of a facility and operator shall be made by the applicant when the following requirements have been met:

. the facility meets the specifications of this Standard,

. a quarantine manual or an alternative quality assurance programme has been approved by the supervisor as meeting the required elements set down in section 3 of this Standard,

. the application has been completed by the prospective operator. [Note the additional documentation required.]. Information, including the application form, can be found at http://www.biosecurity.govt.nz/regs/trans.

When the applicant is able to satisfy the supervisor that the requirements for approval have been met, the supervisor will forward the completed application forms and make a recommendation to the Chief Technical Officer for approval of the facility and operator. [Note: if the quality system is accredited by an external agency as described in section 3 then it is not necessary to forward all of the documentation if

the requirements of this Standard are addressed, but proof of accreditation is required.]

2.4 CANCELLATION OF APPROVAL

Expiry of approval for a facility occurs when the time specified in the approval expires or an event specified in the approval occurs.

The CTO may cancel approval of a **facility**,

. if the facility no longer complies with this Standard,

. if satisfied that the facility is no longer used for the purpose or one or more of the purposes specified in the approval,

. if the operator ceases to be an operator of the facility,

. if the operator is no longer a fit and proper person,

. if the operator requests cancellation.

The CTO may cancel approval of an **operator**,

. if no longer satisfied that the facility is being operated according to this Standard,

. if the operator ceases to be an operator of the facility,

. if the operator is no longer a fit and proper person,

. if the operator requests cancellation.

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

3. QUARANTINE MANUAL

The operator shall prepare, maintain and implement a quality assurance programme and procedures based on the principles of AS/NZ 9002, a code of good manufacturing practice or similar quality system. Accreditation with other agencies such as TELARC is not required.

The quality assurance programme and any amendments shall address the requirements of this Standard. It shall be documented in a quarantine manual or in an alternative quality assurance programme. Facilities with, for example, laboratory accreditation to ISO Guide 25 or TELARC's Code of Laboratory Management

Practice, do not need a separate quarantine manual provided the requirements of this Standard are covered in their quality system.

The quality assurance programme and any amendments shall be approved by the supervisor.

The items listed below are the minimum requirements for the quarantine manual.

3.1 GENERAL

Describe the main functions of the organisation importing the biological products.

3.2 QUARANTINE REQUIREMENTS

Document the procedures used in the transitional facility to meet all of the requirements of the import health standard and section 4 in this Standard.

Provide a floor plan showing the general layout of the facility and show the areas where biological products are used or stored.

Describe with reference to AS/NZS 2243.3 the physical containment level of the facility or indicate which requirements described in that standard are provided in the facility [see 4.1].

If *in-vivo* work is proposed, describe with reference to AS/NZS 2243.3 the physical containment level of the facility or indicate which requirements described in that standard are met in the facility. Show on the plan where organisms will be held and how the requirements will be met.

3.3 MANAGEMENT

Identify the operator.

Identify the manager if one is nominated by the operator.

Specify and document the responsibilities of the operator and also the manager if one is appointed. Identify other users of the transitional facility.

3.4 TRAINING

Nominate a person or position responsible for training. Describe how the training programme is to be implemented, the time scale for implementation and refresher courses.

Training must be available to new and existing staff. Document training records for all staff.

3.5 INTERNAL CONTROLS

Identify quality systems used in the facility.

The operator shall carry out an internal audit of its activities at least once every six months to verify that its activities continue to comply with the requirements of the quarantine manual. Facilities with laboratory accreditation to ISO Guide 25 or TELARC's Code of Laboratory Management Practice shall be subject to internal audit every 12 months.

The quality assurance programme adopted to satisfy the requirements of this Standard shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

All audit and review findings and any corrective actions that arise from them shall be documented.

3.6 VERSION

Record the version number and issue date of the quarantine manual on each page. Updates are to be approved by the supervisor who shall also hold an up to date copy of the quarantine manual.

4. STRUCTURAL AND OPERATIONAL REQUIREMENTS

4.1 PHYSICAL CONTAINMENT LEVEL REQUIREMENTS

The transitional facility shall be constructed and operated in a manner to ensure that biological products are securely contained and used only within the transitional facility. They may not be removed from the facility unless for export, destruction, they are given an authority to move to another approved transitional facility or a biosecurity clearance.

4.1.1 *In-vitro* use of biological products

The minimum containment level of the transitional facility, as described in AS/NZS Standard 2243.3, is ideally determined by the risk level of the material imported.

The minimum containment level of the transitional facility shall be physical containment level 2 [PC2] as described in AS/NZS Standard 2243.3 unless the physical containment level has been assigned in the import health standard.

In view of the diverse range of biological products and purposes of importation, PC2 may not be justified. If the operator can show through the procedures in the quarantine manual that the requirements of this MPI Standard are addressed for a particular biological product or products then this will be considered in the assessment for approval [refer to 3.1].

The CTO reserves the right to require additional safeguards.

4.1.2 *In-vivo* use of biological products

Experimental animals shall not be exposed to biological products unless approved by the CTO.

The CTO shall be advised, at the time of application of the permit to import or approval of the transitional facility, the species of experimental animal which are to be exposed to the biological product. The application shall include details of the work planned and the proposed measures for physical containment.

For biological products used *in vivo* the minimum containment level of the transitional facility shall be PC2 as described in AS/NZS Standard 2243.3 [see section 11 & 13].

Additional requirements for containment based on the assessment of each project may be required by the CTO.

[Note: any work involving the manipulation of animals shall be in accordance with a code of ethical conduct approved by the Minister for Primary Industries as per the Animal Welfare Act 1999. This requirement is independent of this Standard.]

4.2 TREATMENT OR PROCESSING OF THE BIOLOGICAL PRODUCT FOR BIOSECURITY CLEARANCE

Requirements will be specified in the import health standard.

4.3 DISPOSAL OF THE BIOLOGICAL PRODUCT AND WASTE PRODUCTS

Biological product and all waste products associated with their use shall be disposed of as specified in the import health standard. If this is not specified, products shall be classed as infectious material and disposed of as described in section 7 of AS/NZS Standard 2243.3.

4.4 TRANSFER OF A BIOLOGICAL PRODUCT TO ANOTHER TRANSITIONAL FACILITY

Biological products shall not be transferred to another transitional facility unless with written authority from the supervisor. An application for this authority shall be made in writing to the supervisor. Permits to transfer may be for a specified time, but not for a period longer than the approval period of the facility.

4.5 TRANSPORT OF BIOLOGICAL PRODUCTS

Transport of biological products by all modes (air, land, sea) shall be as described in AS/NZS Standard 2243.3. The minimum requirement is that products shall be packaged according to Packing Instruction No. 650 of the IATA Dangerous Goods Regulations.

All products that are infectious or thought to be infectious for humans or animals shall be packaged according to Packaging Instructions No. 602 of the IATA Dangerous Goods Regulations. 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 UN number] and the details to be included in the attached Shippers Declaration for Dangerous Goods.

4.6 EXTERNAL AUDIT

The operator shall provide the supervisor or any other representative of the CTO, access to the facility, records and documents for the purpose of audit. During these audits the operator shall be available to assist and ensure that all relevant procedures and records are made available to the supervisor.

Laboratories that have been accredited by TELARC or International Accreditation of New Zealand (IANZ) to ISO Guide 25 or TELARC's Code of Laboratory Management Practice will be exempt from audit by MPI every 12 months. However, they will be subject to an annual visit by the supervisor with an audit every two to three years.

Otherwise on-site audits will be conducted by the supervisor or the Chief Technical Officer at least once every 12 months at the expense of the operator.

Additional audits will be conducted as required especially if non-compliance is found.

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

. a critical situation report for situations that may present a serious risk to biosecurity. The CTO may direct that all work using biological products will cease immediately and may not be permitted to recommence until the non-

conformity is rectified and measures taken to prevent recurrence, eg. biological products being used on animals without approval.

. a corrective action request or equivalent [CAR] for a non-compliance which is not a serious risk to biosecurity. Work will be permitted to continue but the facility will be given a specified period of time to rectify the non-conformity, eg. training of staff does not occur at the frequency stated in the quarantine manual.

4.7 COSTS

The operator is required to pay all costs associated with the approval and supervision of a facility in accordance with the Biosecurity (Cost) Regulations 1993.

4.8 RECORDS

The operator is required to demonstrate compliance with this Standard by keeping records as required for the quality assurance programme. Such records should be kept for a minimum of five years after biosecurity clearance, export or destruction of the biological product and include as a minimum:

. Records of transitional facility and operator approvals.

. Copies of permits to import, import health standards, biosecurity directions, export certification and biosecurity clearances.

. For biological products, records are required of the identity, quantity, date of import or transfer and method of disposal. The operator shall have a system which enables biological products and their derivatives to be tracked or located. This system shall also include records associated with the use of experimental animals.

. Records of proposals and approvals for the use of biological products on experimental animals.

. If products are transferred the originating and receiving facilities shall record the approvals and name of the receiving or originating transitional facility as appropriate.

. Records of internal audits and corrective actions.

. Records of external audits and corrective actions.

PART TWO: REQUIREMENTS OF THE SUPPLIER

SCOPE OF PART TWO

Part Two of this MPI Standard specifies the requirements for the supplier of supervision of transitional facilities for biological products in New Zealand to ensure that they are operating in compliance with Part One of this Standard.

SERVICE OUTLINE

The supplier shall provide the CTO with a service to supervise the operation of transitional facilities which are required to operate according to Part One of this Standard.

5. SERVICE REQUIREMENTS

5.1 GENERAL REQUIREMENTS

Supervision shall be administered in accordance with standard EN45004, this Standard, a national quality system based on ISO 9002 and any relevant legislation.

The supplier shall maintain a register of transitional facilities and supervisors for which they are responsible.

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

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

The supplier’s quality system may be audited annually and each supervisor may be audited at a transitional facility by the CTO.

5.2 KEY PERSONNEL

Within one month of receipt of this Standard, the supplier shall make formal arrangements for provision of the key personnel listed below. The CTO shall be notified in writing of these arrangements.

5.2.1 Management representative

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

5.2.2 Supervisors

Supervisors shall be approved by the CTO.

Qualifications: The supervisor shall be an inspector as defined by the Biosecurity Act 1993, who has a science degree or similar training. The supervisor shall also have an understanding of the principles of quarantine, quality systems and auditing, the import health standard, the relevant legislation and some appreciation of the business and objectives of the operator.

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

6. TECHNICAL REQUIREMENTS

6.1 APPROVAL OF A TRANSITIONAL FACILITY

The supervisor shall be prepared to consider applications before construction of a facility, in order to provide advice on whether the proposed facility is likely to comply with the Standard.

The requirements for approval are described in sections 2.1 & 2.3 of this Standard and the supervisor shall inspect the facility before making a recommendation on approval.

If the quality system is accredited by an external agency as described in section 3, the supervisor shall satisfy him/herself that the requirements of this Standard are addressed in the quality assurance programme.

6.1.1 Modifications to a facility

If, subsequent to approval, the facility is to be modified, a new floor plan may be required and any new procedures shall be approved by supervisor in order to ensure that the facility continues to meet the Standard. The CTO is to be advised so that central records can be updated.

6.1.2 Renewal of approval

The CTO shall be advised when the results of the audit or visit are satisfactory and the facility meets the requirements of this Standard. Approval for the facility can renewed and, if appropriate, the permit to import the biological products can also be renewed.

6.2 APPROVAL OF AN OPERATOR

Section 40 of the Biosecurity Act provides that if the CTO is satisfied:

. that the applicant is a fit and proper person to be the operator of the transitional facility or containment facility specified in the application; and

. the applicant is able to comply with the operating standards for that facility,

s/he may approve the applicant as the operator of the facility.

In order to meet the second criterion above, the operator shall have the technical and financial resourcing mechanisms in place to maintain that facility.

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

The supervisor shall make a recommendation to the CTO taking these requirements into consideration.

6.3 CANCELLATION OF APPROVAL OF A FACILITY AND/OR AN OPERATOR

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

Also, if the supervisor is satisfied that the transitional **facility**,

. no longer complies with this Standard or

. is no longer being used for the purpose or one or more of the purposes specified in the approval,

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

If the supervisor is satisfied that the **operator**,

. is not operating the facility according to this Standard or

. is no longer a fit and proper person or

. ceases to act as the operator or requests cancellation,

he/she shall discuss the issue with the operator. Then, if necessary, and after informing the operator of his/her intention in writing, the supervisor shall make a recommendation to the CTO that approval of the operator should be cancelled. If an alternative operator cannot be approved then approval of the facility shall also be cancelled.

6.4 SUPERVISION OF A TRANSITIONAL FACILITY

6.4.1 Audit and inspections

The supervisor shall inspect the transitional facility at least once every twelve months. If it is not accredited to an external agency it shall be audited at least once every twelve months.

Particular attention shall be given to:

. the procedures and records as required in the quarantine manual,

. the structural requirements as set out in this Standard (see section 4),

. requirements of the import health standard.

The supervisor shall make a recommendation for annual renewal of approval of the facility if it meets these requirements - see 6.1.2.

If **experimental animals** are exposed to a biological product then the supervisor shall make that at least one visit prior to the period of exposure and another during the exposure period, or more frequently as required by the CTO.

6.4.2 Non-compliance

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

. a critical situation report for situations that may present a serious risk to biosecurity, eg. uncleared biological products being moved out of a transitional facility without approval.

The CTO shall be advised immediately and the CTO may direct that all work using biological products is to cease immediately and may not be permitted to recommence until the non-conformity is rectified.

. a corrective action request [CAR] for a non-compliance which is not a serious risk to biosecurity, eg. training of staff has not occurred as stated in the quarantine manual.

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

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

The results of six monthly internal audits organised by the operator shall be evaluated and if necessary these should be discussed with the operator.

6.4.3 Issue of biosecurity clearance

When the imported biological product is processed according to the requirements of the import health standard the supervisor may issue a biosecurity clearance for the product.

6.4.4 Transfer of biological products between transitional facilities

When an application is made for a written authority to transfer a biological product between transitional facilities the supervisor shall, by communication with the supervisor of the receiving facility, be satisfied that:

. the facility is an approved transitional facility for biological products with the required physical containment level for the biological product,

. the method of transfer shall be of comparable security to that of the originating facility,

. the supervisor of the receiving facility approves the transfer and confirms that facility can accommodate the biological product,

. provision has been made for appropriate inventory control on dispatch and on arrival.

The written authority may be for single or multiple transfers within a specified time not exceeding the approval period of the facility.

6.4.5 Cost recovery

The supplier shall recover the costs associated with administering this Standard in accordance with the Biosecurity (Costs) Regulations, 1993.

6.4.6 Reporting requirements

As the re-issue of the permit to import and renewal of the approval of the transitional facility may be dependent on satisfactory results of external audit the supervisor shall advise the CTO, as soon as practicable, on the final outcome of each audit. It shall include a report on the biosecurity clearances issued and any major non-conformities encountered during that period.

6.4.7 Records

The supervisor is required to keep records of visits and audits of the operator for a period of three years. These records shall include any biosecurity clearances, audit findings and reports of critical situation or CARs and the results of follow-up visits.

INFORMATION AND APPLICATION FORMS

Information and application forms relating to registering as a transitional facility can be found at http://www.biosecurity.govt.nz/regs/trans.

Information and application forms relating to registering as an operator can be found at http://www.biosecurity.govt.nz/regs/trans/register.