

**MAF REGULATORY AUTHORITY
Animal Health and Welfare**

STANDARD 154.02.17

**Standard -
Transitional Facilities
for Biological Products**

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

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ENDORSEMENT

The forms on pages 21, 22, & 23 of this Standard have been approved by the Director-General on 28 April 1998 pursuant to sections 39 and 40 of the Biosecurity Act 1993.

This Standard is approved pursuant to sections 39 and 40 of the Biosecurity Act 1993.

B D O'Neil
Chief Veterinary Officer
[acting pursuant to delegated authority]

Date:

REVIEW

This MAF Reg 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.

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

| Amendment No: | Entered by: | Date: |
|---------------|-------------|-------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

1. INTRODUCTION

SCOPE OF PART ONE

This MAF Reg 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.]

SCOPE OF PART TWO

The supplier shall provide the Chief Veterinary 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 sections 39 and 40 of the Biosecurity Act, 1993.

The following publications are referred to in this MAF Reg 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 MAF Reg Standard the following definitions apply:

Approval

Means approved by the Director-General, MAF, or his/her delegate. The Chief Veterinary Officer, National Manager (Animal Quarantine) and National Adviser (Animal Quarantine) are delegates for this Standard. The National Manager (Animal Quarantine) (see below) is the contact person 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 they are risk goods which have been directed as a requirement of an import health standard to a transitional facility approved under this Standard. They may be microorganisms or products derived from organisms such as cell lines, antigens, and animal sera.

Biosecurity clearance

“Means a clearance under section 26 of this Act for the entry of goods into New Zealand.” Biosecurity Act, 1993.

Biosecurity direction

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

Chief Veterinary Officer

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

Director-General

Means the chief executive of the Ministry of Agriculture and Forestry or his/her delegate.

Experimental animals

Includes all mammals, birds and bees.

Import Health Standard

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

Inspector

A person appointed as an inspector under 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.

MAF Regulatory Authority (MAF Reg)

The body within the Ministry of Agriculture and Forestry responsible for regulatory functions.

National Manager (Animal Quarantine)

The contact person for matters relating to this Standard.

Address: National Manager (Animal Quarantine)

MAF Regulatory Authority

P. O. Box 2526

Wellington

Fax: (04) 4744 133

E-mail: corrink@maf.govt.nz

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

A numbered document, issued as a requirement of the import health standard.

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 [See 5.2.2].

Supplier

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

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. From 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.

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 Chief Veterinary Officer 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 Chief Veterinary Officer.

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 Principle 3 of 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 of Agriculture and Forestry, PO Box 2526, Wellington.
- . You are reminded that under Principles 6 and 7 of the Privacy Act, 1993, you have the right of access to, and correction of, any personal information which has been provided.

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 Chief Veterinary Officer.]

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 forms on pages 21, 22 & 23 of this Standard have been completed by the prospective operator. [Note the additional documentation required.]

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 Veterinary 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 Chief Veterinary Officer 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 Chief Veterinary Officer 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 MAF Reg 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 Chief Veterinary Officer 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 Chief Veterinary Officer.

The Chief Veterinary Officer 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 Chief Veterinary Officer.

[Note: any work involving the manipulation of animals shall be in accordance with a code of ethical conduct approved by the Minister of Agriculture as per the Animal Protection (Codes of Ethical Conduct) Regulations, 1987. This requirement is independent of this Standard.]

4.3 TREATMENT OR PROCESSING OF THE BIOLOGICAL PRODUCT FOR BIOSECURITY CLEARANCE

Requirements will be specified in the import health standard.

4.4 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.

4.5 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.

4.6 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.

4.7 EXTERNAL AUDIT

The operator shall provide the supervisor or any other representative of the Chief Veterinary Officer, 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 MAF 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 Veterinary 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 Chief Veterinary Officer 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.

4.9 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.

4.10 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 MAF Reg 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 Chief Veterinary Officer 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 Chief Veterinary Officer 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 Chief Veterinary Officer.

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 Chief Veterinary Officer 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 Chief Veterinary Officer.

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 Chief Veterinary Officer is to be advised so that central records can be updated.

6.1.2 Renewal of approval

The Chief Veterinary Officer 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 be 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 Chief Veterinary Officer 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 Chief Veterinary Officer 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 Chief Veterinary Officer 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 Chief Veterinary Officer 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 Chief Veterinary Officer.

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 Chief Veterinary Officer shall be advised immediately and the Chief Veterinary Officer 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 Chief Veterinary Officer, 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.

APPLICATION FOR APPROVAL OF A TRANSITIONAL FACILITY FOR BIOLOGICAL PRODUCTS - PURSUANT TO SECTION 39 OF THE BIOSECURITY ACT, 1993.

Name of the transitional facility:

Physical location of facility [In addition attach a site plan showing relationship of the facility to other rooms or buildings]:

.....

Proposed physical containment level (as per AS/NZS Standard 2243.3 [1995] Part 3):

Transitional facility operator's name:

Organisation:

Postal address:

Telephone No: Facsimile:

I,, being the applicant, declaring that the above facility meets the requirements of MAF Reg Standard 154.02.17: Standard for Transitional Facilities for Biological Products, apply to have it approved as a transitional facility. I include with this application:

- . A recommendation from the supervisor stating that the procedures in the quarantine manual [copy included] or accredited quality system meet the requirements of this Standard.
- . A description of the biological products that will be held in the transitional facility, the purpose of the products and an outline of the manner in which they will be used.
- . If an experimental animal is to be exposed to the biological product an outline of the work proposed including the proposed level of physical containment.
- . An outline of the treatment or processing of the biological product if biosecurity clearance or export is to be sought.

.....
Signature of applicant

Date

Form approved by the Director-General pursuant to section 39 of the Biosecurity Act, 1993.

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

Applicant's name:

Designation:

Organisation:

Postal address:

Telephone No: Facsimile:

Name of transitional facility:

Location of the transitional facility:

I , being the person [the proposed operator] responsible for the transitional facility named above, declare that:

- . I have read and understand MAF Reg Standard 154.02.17. I will ensure that the operation of the transitional facility is in accordance with this Standard.
- . I have the technical and financial resourcing mechanisms in place to maintain that facility and include a resume of my qualifications and experience.
- . I hereby apply for approval as an operator.

.....
Signature of applicant

Date

Form approved by the Director-General pursuant to section 40 of the Biosecurity Act, 1993.



The applicant shall complete this form and send to:
Border Standards
Biosecurity NZ
PO Box 2526
Wellington

CONSENT TO DISCLOSURE OF INFORMATION

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

I,
[Surname] [Fore Names]

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

Sex [M/F] Date and place of birth

Nationality Address

NZ Drivers Licence number

hereby consent to the disclosure by the New Zealand Police of any information they may have pursuant to this application to Border Standards, Biosecurity New Zealand, Ministry of Agriculture and Forestry. I understand that any record of criminal convictions I might have will automatically be concealed if I meet the eligibility criteria stipulated in Section 7 of the Criminal Records (Clean Slate) Act 2004.

Signed Date

COMMENTS OF THE NEW ZEALAND POLICE