



**Australian Government**

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**Australian Quarantine and Inspection Service**

**QUARANTINE APPROVED  
PREMISES CRITERIA 5.2  
FOR**

**QUARANTINE  
CONTAINMENT LEVEL 2  
(QC2) FACILITIES**

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## **PART 1: Explanatory Information**

### **1.1 About this criteria**

#### **How to read this criteria**

This document outlines the requirements for approval and is divided into five parts:

- Explanatory Information;
- About QC2 Criteria and the Requirements for Approval;
- General Australian Quarantine and Inspection Service (AQIS) Requirements;
- Specific AQIS Requirements; and
- Applicable Australian/New Zealand Standards.

The whole of Parts 1, 2 and 3 apply to **all** 5.2 facilities (unless otherwise stated). Part 4 has additional requirements for certain types of facilities (e.g. animal facilities). Should your type of facility have a section in Part 4, all the additional specific requirements must be met.

Part 5 outlines the specific sections of the **Australian/New Zealand Standards** that each type of facility is required to meet. There are two Standards outlined and each Standard is divided into three sections for the different types of facilities; Microbiological, Animal and Plant. You only need to meet the parts of the two Standards that are outlined under your 'type' of facility. If you are unsure what 'type' your facility falls into, please contact AQIS. The requirements for each of the facility type combinations are outlined below:

<b>Requirements for approval as a QC2 facility</b>	
<b>Facility Type</b>	<b>Parts and Sections Applicable</b>
MICROBIOLOGICAL CONTAINMENT	PARTS 2, 3 & SECTION 4.1 ONLY OF PART 4 & PART 5 SECTION 5.1 & SECTION 5.4
INDOOR ANIMAL CONTAINMENT (using imported biological material)	PARTS 2, 3 & SECTION 4.2 ONLY OF PART 4 & PART 5 SECTION 5.2 & SECTION 5.5
PLANT LABORATORY CONTAINMENT (using imported plant material)	PARTS 2, 3 & SECTION 4.3 ONLY OF PART 4 & PART 5 SECTION 5.3 & SECTION 5.6

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Other facility types may be added to the table as required.

For Example: QC2 Microbiological Facilities are required to meet all the criteria in Parts 2 & 3 of this document. In Part 4, there is a heading 'Specific Requirements for Microbiological Containment'. A Microbiological Facility will be required to meet all the criteria under this heading. In Part 5, under each of the two Standards, there is a heading 'Microbiological Facilities'. A Microbiological Facility will be required to meet all the Standard references under these headings.

The Australian/New Zealand Standards can be purchased from Standards Australia on [www.standards.com.au](http://www.standards.com.au) or phone 1300 65 46 46.

### **Class Five Criteria**

The Class Five Criteria sets out the requirements and responsibilities for containment facilities, where the premises is utilised for research, analysis and/or testing of imported biological material including micro-organisms, animal and human products and soil. This type of premises includes microbiological facilities, animal facilities and plant laboratories, whether integral or separate to the facility. Where applicable, the Class Five criteria should be read in conjunction with the appropriate Australian/New Zealand Standard <sup>TM</sup> as listed in individual classes.

### **Purpose of the criteria**

This document sets out the criteria which will achieve the structural and procedural requirements of a Class 5.2 Quarantine Approved Premises (QAP) under section 46A of the *Quarantine Act 1908* (the Act).

## **1.2 About Approval**

### **Purpose of approval**

As a condition of import, AQIS may impose post entry quarantine conditions which require that certain products be restricted for use within quarantine facilities. The purpose of approval is to satisfy AQIS that the facility protects Australia's animal, plant and human health status and to ensure that post entry quarantine procedures are followed.

### **Approval of facilities**

AQIS approval is subject to the facility satisfying all the requirements as set out in the criteria and any other conditions AQIS may set.

There are four levels of containment established by the criteria. These are in ascending order of the stringency of containment requirements, which reflect the level of risk:

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- Quarantine Containment Level 1 (QC1)
- Quarantine Containment Level 2 (QC2)
- Quarantine Containment Level 3 (QC3)
- Quarantine Containment Level 4 (QC4)

### **Applying for approval**

Applications should be made on behalf of a certified facility. Application forms are available from the AQIS website [www.aqis.gov.au](http://www.aqis.gov.au). In addition to the completed application form, AQIS requires that a certification report be provided by a third party assessor. For further details on this requirement, please refer to section 2.4, 'requirements for approval'.

### **Assessment of applications and audit for approval of facilities**

AQIS will audit and assess the facility within 90 days of receipt of the application. If AQIS needs to seek additional information from the applicant, this time may be extended.

### **Notification of approval**

If the application is successful, AQIS will issue an approval certificate detailing the name of the approved place, the approval number, the facility type and containment level, and the period for which the facility is approved.

### **Variation of conditions of approval**

The Act provides that AQIS may at any time, by notice in writing given to the holder of the approval, vary the conditions of approval. The variation may mean imposing additional conditions or removing or varying conditions that were previously required.

*PLEASE NOTE: The Quarantine Approved Premises Criteria are living documents which reflect changes in Quarantine regulations due to progress in science, technology and systems. To maintain their currency, all criteria are periodically reviewed, and new editions are produced. Between editions, amendments may be issued. It is important that QAP holders assure themselves they are using the current criteria.*

*Current criteria can be obtained from the regional Quarantine Approved Premises Officer in your State or Territory or via the AQIS website address ([www.aqis.gov.au](http://www.aqis.gov.au)) and then click on the following links:*

> [Import](#)

> [Quarantine Approved Premises.](#)

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### **Compliance with approval criteria and conditions**

In all cases, it is the responsibility of the holder of the approval to ensure compliance with the criteria and conditions for approval.

AQIS has authority under the Act to monitor compliance with the criteria for approval.

### **Suspension or cancellation of approval**

The suspension or cancellation of approval for a premises can be requested by the holder of the approval. This may be requested if the premises ceases quarantine dealings, while continuing other non-quarantine work.

Alternatively, the Act provides that AQIS, by notice in writing may suspend, vary or cancel the approval of a premises where the criteria for suspending or cancelling approvals has been met.

While a facility is approved by AQIS, it must comply with all requirements specified in the approval criteria at all times.

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## **PART 2: About QC2 Criteria and the Requirements for Approval**

### **2.1 Scope**

#### **5.2 Quarantine Containment (QC) Level 2:**

*Class 5.2* – premises utilised for quarantine goods of low to moderate risk to animals, plants or humans if disease is spread to the community or environment.

The facility must meet the PC2 design and construction requirements as specified in Australian/New Zealand Standard TM 2243.3:2002 and 2982.1:1997. The applicable parts of these standards are outlined in Part 5 of this document.

Class 5.2 premises are NOT approved for the distinctive needs of other quarantine operations, except where the establishment has separate approval under another class. For example a 5.2 premises is not automatically approved as a commercial fumigation facility. This would require separate class approval under Class 4.6.

*Note:* A premises holder may keep more than one kind of goods in the one facility, provided the applicable criteria for all those kinds of goods are met.

This kind of facility is appropriate for work with imported:

- soil and water samples for microbial isolation (not undergoing destructive analysis),
- biological samples,
- biological material for *in vivo* work in animals,
- seed samples, plant material and processed stock feed samples for *in vitro* use, and
- fresh and frozen fruit and vegetable samples for *in vitro* use only.

This criterion is intended to apply to a wide range of different containment facilities. It is recognised that certain structural requirements, criteria and procedures apply to facilities with quite different functions. As such, approval as a type of Class 5.2 premises will meet the requirements of a Class 5.1 (excluding outdoor animal facilities) premises of the same type. For example, a Class 5.2 Microbiological Facility will also meet all the requirements of a Class 5.1 Microbiological facility.

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## 2.2 Additional Materials to be read with this Document

This document should be read in-conjunction with the following:

- AQIS Metropolitan Postcodes List
- where applicable the Criteria for the Approval of Premises in Non-Metropolitan Areas
- The Generic Glossary
- QAP Conditions of Approval. Details on the QAP Conditions of Approval can be found at the following website:

> [www.aqis.gov.au/qapupdate](http://www.aqis.gov.au/qapupdate)

## 2.3 Premises Location

AQIS defines 'metropolitan areas' on the basis of postcode. A list of valid metropolitan postcodes for quarantine purposes can be found in the following section of the AQIS website ([www.aqis.gov.au](http://www.aqis.gov.au)) and then click on the following links:

> [Import](#)

> [Co-regulation \(import\) schemes implemented by AQIS](#)

> [Containerised Cargo Clearance Resources document](#). Within this document the delivery postcodes section.

Premises located outside of postcodes classified as 'metropolitan areas' will also have to show that they are able to comply with the additional criteria as outlined in the document, 'Criteria for the Approval of Premises in Non-Metropolitan Areas'. AQIS will consider the application on its individual merits with consideration being given to the quarantine risk and serviceability associated with each establishment's location.

## 2.4 Requirements for Approval

The applicant must provide AQIS with documentary evidence (certification) that the facility complies with:

- a) All relevant design and construction standards under the Australian Building Code as specified by the Australian Building Codes Board.

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To obtain certification, the applicant may choose to utilise the services of:

- a Local Government or Council Building Surveyor, or
- a suitably licensed engineer as listed on the National Professional Engineers Register.

*Note:* The certification requirements to meet the Australian Building Code can be obtained by:

- contacting your Local Government authority/agency (the authority/agency will vary depending on your State or Territory), or
- using a suitably licensed engineer to provide a certificate of structural adequacy.

- b) The applicable design and construction standards of the Australian/New Zealand Standard <sup>TM</sup> (AS/NZS) 2982.1:1997 and 2243.3:2002 (the relevant sections of these standards are listed in Part 5 of this document).

*Note:* The minimum requirement for obtaining this evidence is:

- By contracting an AQIS approved 'third party' assessor.
- AQIS approved 'third party' assessors can be found on the AQIS website: [www.aqis.gov.au](http://www.aqis.gov.au)

## 2.5 Requirements to maintain approval

- a) Any changes to the premises should be carried out in a manner which preserves consistency with:

- the third party certification,
- conformance to the QAP criteria,
- compliance with the relevant design and construction standards in the Australian Building Code, and
- continues to comply with any subsequent amendments or revisions to AS/NZS 2982.1:1997 and 2243.3:2002.

*Note:* A change that significantly affects the overall containment system requires re-certification, this would include structural changes to 40% of the building. If a QAP holder has any doubt as to whether a proposed change to:

- QAP operating procedures, or

- the physical structure of the premises,

has any potential to reduce the level of quarantine integrity, AQIS approval must be obtained before the change is implemented.

Additionally, an AQIS Officer may request that documented evidence be provided for compliance with the Australian Building Code or AS/NZS 2982.1:1997 & 2243.3:2002 when additions or modifications have been made to the facility.

- b) Where any structural alterations have been made the premises holder must, with the annual approval form, provide a written declaration outlining details of the alterations made.
- c) AQIS must be notified in writing, within 30 days of any changes made to QAP operating procedures and arrangements.

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## **PART 3: General AQIS Requirements**

This part outlines the General AQIS requirements that must be complied with by the holder of any approval for a facility, irrespective of the type of facility and the containment level to which the facility is approved.

### **3.1 Hygiene and Isolation**

- a) Quarantine Area(s) must be separate from other operations within the facility. This can be achieved by AQIS approved methods.

*Note:* Examples of how separation can be achieved in a particular class of premises include, coolrooms, incubators, refrigerators, isolators, freezers, biological safety cabinets, isolation from main thoroughfares with yellow lines, structural separation, a lockable room or building, a person proof security fence and cupboards or similar structures.

Please note that not all methods listed above are applicable to all classes of premises. The use of a method must be approved by AQIS

Additionally, for Class 5 premises, to achieve the necessary separation of work and goods, it may be necessary to have coolrooms, incubators, refrigerators, freezers, etc. outside the area where the work is undertaken. Where this is necessary, the premises will need to have more than one quarantine area. This additional quarantine area must be located within the building that houses the facility and where practical must be lockable.

For Class 5 premises, where a quarantine area is outside or separate to the area where the work is undertaken, the type of quarantine area (e.g. refrigerator, freezer) must be stated on the scale drawing.

The separation of work and goods is NOT applicable to QC3 (QC3 facilities may only have the autoclave outside the immediate facility but within the building) or QC4 facilities which must operate as a closed entity.

- b) Goods subject to quarantine must be kept adequately separated from other goods at all times. This can be achieved by:
- an impervious physical barrier, or
  - other AQIS approved methods.

Should cross-contamination occur, all goods shall be treated as quarantine goods.

- c) The QAP must be managed in a way that ensures that all buildings and/or structures are maintained in a state of good repair.
- d) An effective pest control system must be in place to ensure that facilities are managed in a way that effectively isolates goods subject to quarantine from environments in which pest and disease are likely to become established. A document outlining the control measures must be available to AQIS for audit purposes (example attached). This document may include:
- the use of insecticides, fumigation, rodenticides, periodic inspection, baits and/or traps,
  - a site plan with numbered bait stations, and
  - if applicable, contract details.

### 3.2 Quarantine Area

- a) The Quarantine Area must be of a size commensurate with the proposed quantity of goods being handled.
- b) Quarantine Areas must be managed to allow AQIS Officers to conduct adequate inspections of goods in a timely and effective manner. This can occur by:
- having illumination to a sufficient level (within a building this will require a minimum 400 lux in storage areas and 600 lux in quarantine inspection areas),
  - having goods accessible for inspection (this will require that goods be stored no more than 2.5 m high unless racks are used).

### 3.3 Security

- a) All Quarantine Areas where goods subject to quarantine are stored or handled must display a quarantine sign to assist in effectively managing the security of these goods. These signs are to be:
- secured on a building/s, racks, fences, gates and/or doors and be visible at all times.
  - permanently affixed,
  - professionally made,
  - made to state 'Quarantine Area – Authorised Persons Only, No Entry or Removal of Goods, Penalties Apply, (*Quarantine Act 1908*)' (or as directed for specific quarantine operations),

- on a yellow background, with black lettering.

*Note:* Cardboard and paper signs are not acceptable. Signs on external structures must be a minimum 600mm x 400mm with lettering a minimum 50mm height, and signs within structures must be a minimum 295mm x 210mm with lettering a minimum 25mm height.

- b) The following procedures must be applied to manage the QAP in a way that effectively secures goods subject to quarantine from movement or interference by unauthorised persons:

- AQIS must be immediately informed of any incidents which could significantly compromise the quarantine security of the facility. This may include structural damage, electrical breakdowns, escapes or unauthorised entry and the removal of quarantine material;
- visitors to the quarantine area(s) must be accompanied or supervised by an accredited person at all times;
- quarantine goods must be stored in an area that is securely locked when unattended.

*Note:* Video surveillance, alarms or other security monitoring methods may also be used.

### 3.4 Operating Procedures

- a) A document detailing procedures for the clean-up of quarantine related spills must be available to AQIS for audit purposes. This document must include:
- the equipment used, and
  - where applicable the cleaning of this equipment (via disinfectant, sterilisation, or other AQIS approved method) and the spillage area with an AQIS approved broad-spectrum disinfectant.

*Note:* Quarantine related spills include any spillage of quarantine goods, waste or waste water.

Broad-spectrum disinfectants can be found at the following website address: [www.aqis.gov.au](http://www.aqis.gov.au) and then click on the following links

> [Import](#)

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- b) Any major spillage or loss of quarantine material must be immediately reported to AQIS.

*Note:* A major spillage is classified as a loss of quarantine material outside the confines of the Quarantine Approved Premises, which cannot be readily cleaned up within 15 minutes, or which may be accessed by the general public.

- c) The premises holder must provide a document detailing the entire imported goods pathway. This document will need to include all the quarantine operations.

### 3.5 Administration and Management

#### 3.5.1 Record Requirements

Record keeping procedures must provide AQIS with the confidence that the system has adequate controls and the necessary evidence to verify identifiable links to goods. This can be achieved by:

- electronic or manual records of all quarantineable goods imported through the QAP. This includes retaining originals or copies of import permits, quarantine entries/directions or transfer approvals;
- retaining records for a minimum period of 18 months after quarantine clearance or disposal of the goods;
- ensuring that records are available within 48 hours for inspection by AQIS.

*Note:* AQIS will continue to assess whether activities and arrangements have been implemented effectively, and are achieving criteria requirements. If records are unavailable during an AQIS inspection/audit, AQIS will return to the premises within 48 hours to continue the assessment of documentation. This inspection will be charged at fee-for-service rates.

#### 3.5.2 Office and General Premises Requirements

Office and general premises requirements must provide AQIS with the confidence that applicable health and safety standards have been met, this is achieved by:

- providing a first aid cabinet/kit which is fully stocked and meets the minimum commercial Australian Standard,

- providing vehicle parking for visiting Quarantine Officers,
- ensuring adequate security for any AQIS technical equipment left on the premises,
- providing access and the availability of:
  - a desk, chair and a telephone with direct outside call access
  - toilet facilities
  - hand washing facilities and a hygienic means of drying hands, and
  - suitable arrangements to ensure amenities are clean.

*Note:* Additional mandatory requirements apply to premises with permanent Quarantine Officers.

### 3.5.3 Administration

Administration and documentation requirements must provide AQIS with assurance that there are adequate controls. This must include:

- applications being accompanied by scale drawings (with dimensions and locations of Quarantine Area(s)), identifying facilities for treatments, nearest main road and parking for Quarantine Officers.
- obtaining an AQIS direction or prior written approval to move, accept, transfer or release any quarantine goods from the approved facility to another AQIS approved facility that is not co-located, and
- where applicable, developing a transfer procedure for the safe movement of quarantine goods between co-located facilities. This procedure must be provided at application, and at the request of a Quarantine Officer.

*Note:* The nominated manager must apply in writing when requesting authority to transfer quarantine goods to a premises not co-located. This will require details of proposed suitable transport containers - if applicable, (for biological material Section 13 of AS/NZS 2243.3:2002 must be applied), the intended transport route and any other relevant information to support the case. AQIS may seek further information before making a decision.

### 3.5.4 Management

Control and security of the quarantine area is the responsibility of the nominated senior manager of the company/institution.

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*Note:* It is a factor in approving a facility under section 46A(4) of the Act that management of the premises be willing to enter into an agreement with AQIS including training courses and/or electronic initiatives as required. Failure to comply with the Approval Criteria or any breach of the Act may result in approval of the premises being withdrawn or suspended and legal action instigated.

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## **PART 4: Specific AQIS Requirements for QC2 Approval**

This part outlines the specific AQIS requirements that must be complied with for facilities to be approved to a specific facility type.

*Note:* These requirements are additional to Part 2 (About QC2 Criteria, the Requirements for Approval), and Part 3 (General AQIS Requirements).

### **4.1 Specific Requirements for Microbiological Containment – Level 2 (QC2) Facilities**

The holder of Microbiological Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), and Part 3 (General AQIS Requirements).

#### **4.1.1 General**

The goods that can be held in a facility that is approved for microbiological containment includes imported:

- soil and water samples for destructive analysis up to 1kg or litre in size per individual package,
- biological products for *in vitro* analysis as approved by AQIS, and
- conducting *in vitro* testing of food products.

#### **4.1.2 Waste Disposal**

- a) Where applicable any quarantine waste must be effectively contained and disposed of in a manner approved by AQIS and be detailed in a document outlining:

specific procedures for the disposal of any accumulated waste, this may include:

- a section on the disposal of waste that is not subject to import permit conditions;
- a section on waste transportation (where the waste has not been rendered safe at the QAP) by an AQIS approved transporter, or under AQIS supervision;
- a section on the movement of waste within the premises where an AQIS approved method is not available within the quarantine area/facility.

*Note:* Solid quarantine wastes must be bagged and placed in an unbreakable container with a secured lid for movement within or outside the building to the approved disposal place.

Where waste cannot be disposed of immediately, there must be as a minimum the provision for:

- a separate storage device/area for the temporary holding of goods;
- storage in lidded bins/containers of an appropriate size which are leak and pest proof,
- bins to be labelled 'Quarantine Waste', and
- double bagging of all waste.

*Note:* The separate storage device/area must be AQIS approved and be within the QAP to prevent loss, spillage or unauthorised access.

AQIS approved methods of solid quarantine waste disposal include incineration at a high temperature in a high efficiency Environmental Protection Agency (EPA) approved incineration facility, deep burial, or sterilisation by autoclaving.

Minimum autoclaving times after attainment of temperature for all goods, residues or quarantine waste shall be:

- 121°C (core temperature) for 15 minutes, or
- 121°C for 30 minutes where core temperature is not measured.

Where the 15 minute autoclaving time is used, the premises holder must specify how the core temperature has been reached and detail how this temperature was recorded.

- b) All quarantine waste water must be disposed of by an AQIS approved method

*Note:* AQIS approved methods include disposal of waste water by an approved municipal sewage system. The use of other waste disposal methods must be approved in writing by AQIS after demonstration of their efficacy to the satisfaction of AQIS. Such methods may require detailed scientific research at the QAP holders' expense.

Additionally, all quarantine waste water disposal must comply with requirements stated by:

- the State/Territory Environmental Protection Agency,
- Local Council, and

- the Water Board (if applicable).

#### 4.1.3 Security

- a) To assist in effectively managing the security of the facility the following must be applied:
- the doors must be closed when quarantine work is in progress and/or when quarantine goods are being held in the facility,
  - the name and telephone number of the facility manager or other responsible person must be displayed near all access doors, and
  - a quarantine sign be displayed on the entry door to the facility. Such signs are to include all requirements as stated in Part 3.2 (a), and in addition, state 'Microbiological Containment – QC2 Facility'.

#### 4.1.4 Operational Procedures

- a) Containers holding quarantine goods must be clearly labelled using standard scientific nomenclature. The labelling must enable clear reconciling of quarantine goods with the following information:
- Quarantine Entry Number (where relevant),
  - Import Permit Number or AQIS in vivo approval number and expiry dates,
  - importation date.
- If the containers cannot be labelled with this information due to constraints, such as size, then a suitable identification system may be used such as referring to a logbook that contains the required information.
- b) Equipment used or that has come into contact with quarantine goods must be cleaned or rendered safe by an AQIS approved method. AQIS approved methods include, but are not limited to:
- sterilisation,
  - incineration, as prescribed in part 4 – Section 4.1.2 (Waste Disposal), and
  - disinfection using an AQIS approved broad-spectrum disinfectant.

Equipment must be disinfected before being sent for repair or disposal and where appropriate, equipment may need to be disinfected at regular intervals.

- c) Gloves shall be removed and hands thoroughly washed after handling quarantine goods, and before leaving the facility. Used gloves shall be discarded with the quarantine waste.
- d) To prevent cross contamination while work is being undertaken, there must be separation of quarantine work from other work.
- e) When working with quarantine goods the following minimum requirements apply to clothing and other apparel:
- personnel must wear covering clothes,
  - closed footwear, and
  - dirty clothing must be removed and laundered before re-use.

*Note:* AQIS must be provided with a written procedure of how protective clothing will be laundered.

- f) To ensure the containment features of the facility are intact a document detailing annual inspection must be available to AQIS for audit purposes. The minimum requirements for this document include:
- an annual inspection report detailing findings, and
  - the personnel who conducted the inspection.

*Note:* Personnel include the holders of the approval, employees or the Biosafety Committee.

- g) A manual listing procedures and documents applicable to quarantine, including emergency and maintenance procedures must be available within the facility in a prominent position.

**Where there are pressure steam sterilisers at the QAP the following applies:**

- h) The QAP holder must provide AQIS with information concerning the calibration and certification of sterilisers, and the efficacy of treatment. The minimum requirements for sterilisers are that:
- relevant local regulations for pressure vessels be applied, including the timeframes for the regular certification of the steriliser.
  - Steriliser cycles be calibrated. This can be achieved by the use of:
    - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved, or

- chemical indicators which progressively change colour with the time exposed at the specified temperature, or
- biological indicators such as spore strips, or
- enzyme indicators be used at regular intervals (e.g. monthly), or
- other AQIS approved methods.

*Note:* The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.

Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilization conditions.

- i) The annual checking and certification of sterilisers or heat ovens must be carried out by a qualified technician.

**Where a biological safety cabinet is integral to quarantine functions the following applies:**

- j) The QAP holder must provide AQIS with information concerning the efficiency and safety of cabinets. The minimum requirements for biological safety cabinets are that:
- all cabinets be checked for containment efficiency and safety before initial use, after any modification including change of HEPA filters, after relocation and on an annual basis,
  - used filters be disposed of with quarantine waste, and
  - where class II cabinets are used they will need to pass the air barrier containment test in AS 1807.22.

*Note:* The annual checking and certification of cabinets must be carried out by a qualified technician.

#### **4.1.5 Administration and Management**

##### **a) Record Requirements**

- i. Records for each consignment of quarantine goods must include:
- Quarantine Entry Number (where relevant),

- Import Permit number or AQIS in vivo approval number for the regulated articles,
  - description of the regulated goods (using accurate scientific terminology),
  - date of receipt of goods and country of origin,
  - location or part of facility where each quarantine item is held, and the respective QC status,
  - records of any derivatives and additional cultures/material or substance grown from the original quarantine material,
  - where applicable quantities (e.g. kg, litres) of goods received, destroyed and in storage,
  - date of completion of research,
  - details of any treatments,
  - method and date of disposal/destruction of quarantine goods and any direct or indirect derivatives,
  - method, and date of waste disposal/destruction,
  - the date of movement and the AQIS permission for any movement (including transfer certificates) of goods from the facility, and
  - comprehensive details of any breaches of quarantine goods from the facility.
- ii: A bi-annual summary of records, which includes the information in 4.1.5 a) i), must be provided at audit or at the request of an AQIS Officer.
- iii: A logbook (electronic or manual) recording steriliser load, temperature and duration of sterilisation cycle must be maintained.
- iv. Calibration specifications for all equipment that has a bearing on the quarantine status of the material (e.g. autoclave), along with calibration records must be provided at audit and at the request of an AQIS Officer.

#### **b) Office and General Premises Requirements**

- i. Drinking water, food and toilets shall only be located within designated areas of the quarantine facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment.

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## 4.2 Specific Requirements for Indoor Animal Containment – Level 2 (QC2) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 – About QC2 Criteria and the Requirements for Approval, and Part 3 General AQIS Requirements.

### 4.2.1 General

The work that can be conducted in a facility that is approved for indoor animal containment includes *in vivo* studies in animals using imported biological material.

### 4.2.2 Isolation and Hygiene

- a) Where post-mortem examinations are undertaken the following conditions apply:
- a separate area from other activities such as animal production must be provided, and
  - adequate precautions taken to prevent cross-contamination.
- b) Secure housing/caging must be provided.

### 4.2.3 Waste Disposal

- a) A document must be provided to AQIS outlining how carcasses from animals under quarantine will be effectively contained and rendered safe prior to disposal in a manner approved by AQIS.

This should cover specific procedures for the disposal of any carcasses. This may include:

- transportation (where the carcass has not been rendered safe at the QAP) by an AQIS approved transporter, or under AQIS supervision.

Procedures where carcasses cannot be disposed of immediately should also be covered. This may include the provision for:

- a separate storage device/area. Such areas and/or devices must be insect, rodent and bird proof.

*Note:* The separate storage device/area must be AQIS approved and be within the QAP to prevent loss or unauthorised access.

AQIS approved methods of quarantine carcass disposal include incineration at a high temperature in a high efficiency Environmental Protection Agency (EPA) approved incineration facility, deep burial, or sterilisation by autoclaving.

Minimum autoclaving times after attainment of temperature for all goods, residues or quarantine waste shall be:

- 121°C (core temperature) for 15 minutes, or
- 121°C for 30 minutes where core temperature is not measured.

Where the 15 minute autoclaving time is used, the premises holder must specify how the core temperature has been reached and detail how this temperature was recorded.

- b) Animal bedding must be disposed of by an AQIS approved method. AQIS approved methods include but are not limited to, incineration at a high temperature, in a high efficiency EPA approved incineration facility, sterilisation or deep burial.
- c) Provision must be made for the decontamination of pens and cages. Decontamination can be achieved by:
- using an AQIS approved broad-spectrum disinfectant, or
  - by an AQIS approved method.
- d) All quarantine wastewater must be disposed of by an AQIS approved method.

*Note:* AQIS approved methods include disposal of waste water by an approved municipal sewage system. The use of other waste disposal methods must be approved in writing by AQIS after demonstration of their efficacy to the satisfaction of AQIS. Such methods may require detailed scientific research at the QAP holders' expense.

Additionally, all Quarantine wastewater disposal must comply with requirements stated by:

- the State/Territory Environmental Protection Agency,
- Local Council, and
- the Water Board (if applicable).

#### 4.2.4 Security

- a) A nominated staff member employed by the premises is responsible for gate, door or animal enclosure keys. The name, designation/position title and contact details of this person must be supplied with the application form and when a change in the nominated staff member occurs.
- b) To assist in effectively managing the security of the facility the following must be applied:
  - the doors be closed when quarantine work is in progress and/or when quarantine goods are being stored in the facility,
  - the name and telephone number of the facility manager or other responsible person must be displayed near all access doors, and
  - a quarantine sign be displayed on the entry door to the facility. Signs on the entry door to the facility must include all requirements as stated in Part 3.2 (a), and in addition, state 'Animal Containment – QC2 Facility'.

#### 4.2.5 Operational Procedures

- a) Arrangements must be in place for animals undergoing *in vivo* trials involving imported biologicals that ensures daily checking. A written record must be kept of daily checks.
- b) Identification must be possible for all animals under quarantine (e.g. by tattooing, microchip, permanent branding or through a cage labelling system).
- b) Where applicable cages and racks must be labelled to indicate the identity and date of any inocula given.
- c) Where it is necessary to transport animals (alive or dead) from the containment facility, in addition to the requirements in Part 3, Section b) Administration, procedures must include details on pens/cages used for transport and the decontamination of these with an AQIS approved broad-spectrum disinfectant.
- e) Unexpected animal mortalities or incidence of disease must be reported to AQIS immediately and investigated. This may require instructions regarding:
  - the animal(s) being labelled with day/date, and
  - where possible preserved (in a refrigerator, coolroom or freezer) for appropriate post mortem and examination by a Quarantine Officer or a suitably qualified veterinarian employed by the premises holder. In the case where the investigation is conducted by the premises operator, AQIS must be kept informed on the

progress of the investigation, and must be provided a report at the conclusion of the investigation.

- f) When working with quarantine goods the following minimum requirements apply to clothing and other apparel:
- personnel must wear covering clothes,
  - closed footwear, and
  - dirty clothing must be removed and laundered before re-use.

*Note:* AQIS must be provided with a written procedure of how covering clothes will be laundered.

- g) Hands must be washed after handling animals subject to quarantine.
- h) Where the facility has floor drains, the drain traps should always be filled with water and a suitable AQIS approved broad spectrum disinfectant.
- i) A manual listing procedures and documents applicable to quarantine, including emergency and maintenance procedures must be available within the facility in a prominent position.

#### 4.2.6 Administration and Management

##### a) Record requirements

- i. Records for each consignment of quarantine goods must include:
- date of receipt of goods and country of origin,
  - Import Permit number or *in vivo* approval,
  - location or part of facility where each quarantine item is held,
  - date of completion of research,
  - details of any treatments,
  - method and date of goods disposal/destruction (if applicable), and any direct or indirect derivatives,
  - the date and AQIS permission for any movement (including transfer certificates) of goods from the facility, and

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- comprehensive details of any breaches of quarantine goods from the facility.
- ii. A record must be maintained of an up-to-date inventory of the animals present and a chronological record of procedures performed.
- iii. Records should be kept of births, (if applicable), mortalities, post-mortem findings, test results etc.
- iv. Details of post mortem results must be made available at the request of a Quarantine Officer.

**b) Office and General Premises Requirements**

- i. Drinking water, food and toilets shall only be located within designated areas of the quarantine facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment.

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### 4.3 Specific Requirements for Plant Laboratory Containment – Level 2 (QC2) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 – About QC1 Criteria and the Requirements for Approval, and Part 3 General AQIS Requirements.

#### 4.3.1 General

The work that can be conducted in a facility that is approved for plant laboratory containment includes *in vitro* use in imported seed samples, plant material and processed stock feed samples.

#### 4.3.2 Waste Disposal

- a) A document must be provided to AQIS outlining quarantine waste will be effectively contained and rendered safe prior to disposal in a manner approved by AQIS

This should cover specific procedures for disposal of any accumulated waste. This may include:

- that which is not subject to import permit conditions.
- transportation (where the waste has not been rendered safe at the QAP) by an AQIS approved transporter, or under AQIS supervision.
- movement within the premises where an AQIS approved method is not available within the quarantine area/facility.

*Note:* Solid quarantine wastes must be bagged and placed in an unbreakable container with a secured lid for movement within or outside the building to the approved disposal place.

Procedures where waste cannot be disposed of immediately should also be covered. This must as a minimum include the provision for:

- a separate storage device/area for the temporary holding of goods,
- storage in lidded bins/containers of an appropriate size which are leak and pest proof,
- bins to be labelled 'Quarantine Waste', and

- all waste must be double bagged.

*Note:* The separate storage device/area must be AQIS approved and be within the QAP to prevent loss, spillage or unauthorised access.

AQIS approved methods of solid quarantine waste disposal include incineration at a high temperature, in a high efficiency Environmental Protection Agency (EPA) approved incineration facility, deep burial or sterilisation by autoclaving.

Minimum autoclaving times after attainment of temperature for all goods, residues or quarantine waste shall be:

- 121°C (core temperature) for 15 minutes, or
- 121°C for 30 minutes where core temperature is not measured.

Where the 15 minute autoclaving time is used the premises holder must specify how the core temperature has been reached and detail how this temperature was recorded.

- b) All quarantine wastewater must be disposed of by an AQIS approved method.

*Note:* AQIS approved methods include disposal of waste water by an approved municipal sewage system. The use of other waste disposal methods must be approved in writing by AQIS after demonstration of their efficacy to the satisfaction of AQIS. Such methods may require detailed scientific research at the QAP holders' expense.

Additionally, all quarantine waste water disposal must comply with requirements stated by:

- the State/Territory Environmental Protection Agency,
- Local Council, and
- the Water Board (if applicable).

#### 4.3.3 Security

- a) To assist in effectively managing the security of the facility the following must be applied:
- the doors be closed when quarantine work is in progress and/or when quarantine goods are being stored in the facility,
  - the name and telephone number of the facility manager or other responsible person must be displayed near all access doors, and

- a quarantine sign be displayed on the entry door to the facility. Signs on the entry door to the facility must include all requirements as stated in Part 3.2 (a), and in addition, state 'Plant Containment – QC2 Facility'.

#### 4.3.4 Operational Procedures

- a) To ensure the containment features of the facility are intact a document detailing annual inspection must be available to AQIS for audit purposes. The minimum requirements for this document include:

- an annual inspection report detailing findings, and
- the personnel who conducted the inspection.

*Note:* Personnel include the holders of the approval, employees or the Biosafety Committee.

- b) The holder of the premises must provide documentary evidence that screens, filters and similar equipment have been cleaned in accordance with the manufacturer's specified frequency and procedures. This can be achieved by:

- supplying the frequency plan and procedures provided by the manufacturer, and
- recording the date that the cleaning occurred.

- c) Unexpected incidences of pest or disease must be reported to AQIS immediately.

- d) When working with quarantine goods the following minimum requirements apply to clothing and other apparel:

- personnel must wear covering clothes,
- closed footwear, and
- dirty clothing must be removed and laundered before re-use.

*Note:* AQIS must be provided with a written procedure of how protective clothing will be laundered.

- e) Hands must be washed after handling plant quarantine material.

- f) Where the facility has floor drains, the drain traps should always be filled with water and a suitable AQIS approved broad spectrum disinfectant.

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- g) A manual listing procedures and documents applicable to quarantine, including emergency and maintenance procedures must be available within the facility in a prominent position.

**Where there are pressure steam sterilisers at the QAP the following applies:**

- h) The QAP holder must provide AQIS with information concerning the calibration and certification of sterilisers, and the efficacy of treatment. The minimum requirements for sterilisers are that:
- relevant local regulations for pressure vessels be applied, including the timeframes for the regular certification of the steriliser.
  - Steriliser cycles be calibrated. This can be achieved by the use of:
    - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved, or
    - chemical indicators which progressively change colour with the time exposed at the specified temperature, or
    - biological indicators such as spore strips, or
    - enzyme indicators be used at regular intervals (e.g. monthly), or
    - other AQIS approved methods.

*Note:* The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.

Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilization conditions.

- i) The annual checking and certification of sterilisers or heat ovens must be carried out by a qualified technician.

**Where a biological safety cabinet is integral to quarantine functions the following applies:**

- j) The QAP holder must provide AQIS with information concerning the efficiency and safety of cabinets. The minimum requirements for biological safety cabinets are that:
- all cabinets be checked for containment efficiency and safety before initial use, after any modification including change of HEPA filters, after relocation and on an annual basis,

- used filters be disposed of with quarantine waste, and
- where class II cabinets are used they will need to pass the air barrier containment test in AS 1807.22.

*Note:* The annual checking and certification of cabinets must be carried out by a qualified technician.

#### 4.3.5 Administration and Management

##### a) Record requirements

- i. Records for each consignment of quarantine goods must include:
  - date of receipt of goods and country of origin,
  - Import Permit number, *in vivo* approval number or transfer approval,
  - plant material type (where applicable include scientific name),
  - location or part of facility where each quarantine item is held,
  - date of completion of research,
  - details of any treatments,
  - method and date of disposal/destruction of quarantine goods (if applicable) and any direct or indirect derivatives,
  - the date of movement and the AQIS permission for any movement (including transfer certificates) of goods from the facility, and
  - comprehensive details of any breaches of quarantine goods from the facility.
- ii. A record must be maintained of an up-to-date inventory of the plant material present and a chronological record of procedures performed.
- iii. A logbook (electronic or manual) recording steriliser load, temperature and duration of sterilisation cycle must be maintained.

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**b) Office and General Premises Requirements**

- i. Drinking water, food and toilets shall only be located within designated areas of the quarantine facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment.

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## **PART 5: Applicable Australian/New Zealand Standards**

This part outlines the specific standards that an AQIS approved 'third party' assessor will certify. The applicable parts of the standards must be complied with for facilities to be approved to a specific facility type.

*Note:* These requirements are additional to Part 2 (About QC2 Criteria, the Requirements for Approval), Part 3 (General AQIS Requirements), and Part 4 (Specific AQIS Requirements for QC2 Approval of a particular facility type).

### **Australian/New Zealand Standard – Laboratory Design and Construction Part 1: General Requirements (AS/NZS 2982.1:1997)**

The following structural parts of this standard (AS/NZS 2982.1:1997) are applicable to Quarantine Containment (QC) Level 2.

#### **5.1 Specific Standards for Microbiological Containment – Level 2 (QC2) Facilities**

The holder of Microbiological Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.1 (Specific Requirements for Microbiological Containment).

The following structural standards from AS/NZS 2982.1:1997 are the minimum for work with microbiological goods at the QC2 level.

Section 2. *General Laboratory Design and Construction Requirements*  
(Excluding 2.2, 2.5, 2.7 (a) (vii) & 2.7 (c), 2.9, 2.11, 2.12 and 2.13)

Section 3. *Reticulated Services*  
(Excluding 3.7.1 and 3.7.3)

Section 4. *Electrical Services*  
(Excluding 4.2 and 4.3 paragraph 1)

Section 5. *Ventilation and Air Quality*  
(Excluding 5.2 paragraph 2, 5.3 (f), 5.5.1, 5.5.3 and 5.7)

Section 6 *Health and Safety Requirements*

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(Excluding 6.1, 6.3 – only the requirement for hot water with hand washing facilities, 6.4, 6.5 and 6.6)

Section 8. *Biological Laboratories*  
(Only 8.3)

Appendix B. *Additional Requirements for Microbiological Facilities*  
(Excluding B1, B2, B3, B4 (a), (c), (e), B5 and B6)

In addition to the above standards, the following requirements must be met:

- an antiseptic handwash dispenser must be provided, and
- all access doors to the facility must be fitted with self-closing devices.

## 5.2 Specific Standards for Indoor Animal Containment – Level 2 (QC2) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.2 (Specific Requirements for Indoor Animal Containment).

The following standards from AS/NZS 2982.1:1997 are the minimum for work with Indoor animal goods at the QC2 level.

Section 2. *General Laboratory Construction Requirements*  
(Excluding 2.2, 2.7 (a) (vii) & 2.7 (c); 2.9, 2.10, 2.11, 2.12 and 2.13)

Section 3. *Reticulated Services*  
(Excluding 3.7.1, 3.7.3 and 3.7.4)

Section 4. *Electrical Services*  
(Excluding 4.2 and 4.3 paragraph 1)

Section 5. *Ventilation and Air Quality*  
(Excluding 5.2 paragraph 2, 5.3 (f), 5.5.1, 5.5.3 and 5.7)

Section 6. *Health and Safety Requirements*  
(Excluding 6.1, 6.3 – only the requirement for hot water with hand washing facilities and the location of the handbasin, 6.4, 6.5 and 6.6)

Section 8. *Biological Laboratories*  
(Only 8.6.7, 8.6.8, 8.6.9, 8.6.10 and 8.6.11)

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Appendix C. *Additional Requirements for Animal Accommodation*  
(Excluding C1, C2 (a), (c) paragraph 3 and C3)

In addition to the above standards, the following requirement must be met:

- an antiseptic handwash dispenser must be provided.

### 5.3 Specific Standards for Plant Laboratory Containment – Level 2 (QC2) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.3 (Specific Requirements for Plant Containment).

The following standards from AS/NZS 2982.1:1997 are the minimum for work with Plant goods at the QC2 level.

Section 2. *General Laboratory Construction Requirements*  
(Excluding 2.2; 2.5, 2.7 (a) (vii) & 2.7 (c); 2.9, 2.11, 2.12 and 2.13)

Section 3. *Reticulated Services*  
(Excluding 3.7.1, 3.7.3 and 3.7.4)

Section 4. *Electrical Services*  
(Excluding 4.2 and 4.3 paragraph 1)

Section 5. *Ventilation and Air Quality*  
(Excluding 5.2 paragraph 2, 5.3 (f), 5.5.1, 5.5.3 and 5.7)

Section 6. *Health and Safety Requirements*  
(Excluding 6.1, 6.3 – only the requirement for hot water with hand washing facilities and the location of the hand basin, 6.4, 6.5 and 6.6)

In addition to the above standards, the following requirements must be met:

- an antiseptic handwash dispenser must be provided, and
- all access doors to the facility must be fitted with self-closing devices.

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## **Australian/New Zealand Standard – Safety in Laboratories Part 3: Microbiological aspects and Containment Facilities (AS/NZS 2243.3:2002)**

The following parts of this standard (AS/NZS 2243.3:2002) are applicable to Quarantine Containment (QC) Level 2.

### **5.4 Specific Standards for Microbiological Containment – Level 2 (QC2) Facilities**

The holder of Microbiological Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.1 (Specific Requirements for Microbiological Containment).

The following standards from AS/NZS 2243.3:2002 are the minimum for work with microbiological goods at the QC2 level.

Section 4.7 *Physical Containment Level 1 (PC1) Requirements*  
(Only 4.7.2 (d) applies)

Section 4.8 *Physical Containment Level 2 (PC2) Requirements*  
(Only 4.8.3 (b), (c), (e) and (f))

### **5.5 Specific Standards for Indoor Animal Containment – Level 2 (QC2) Facilities**

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.2 (Specific Requirements for Indoor Animal Containment).

The following standards from AS/NZS 2243.3:2002 are the minimum for work with Indoor animal goods at the QC2 level.

Section 4.7 *Physical Containment Level 1 (PC1) Requirements*  
(Only 4.7.2 (d) applies)

Section 4.8 *Physical Containment Level 2 (PC2) Requirements*  
(Only 4.8.3 (b), (c), (e) and (f))

Section 10. *Animals and Animal Containment Facilities*  
(Only 10.8.1 (b), (c), (e))

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## 5.6 Specific Standards for Plant Laboratory Containment – Level 2 (QC2) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 (About QC2 Criteria and the Requirements for Approval), Part 3 (General AQIS Requirements) and Part 4 Section 4.3 (Specific Requirements for Plant Containment).

The following standards from AS/NZS 2243.3:2002 are the minimum for work with Plant goods at the QC2 level.

Section 4.7 *Physical Containment Level 1 (PC1) Requirements*  
(Only 4.7.2 (d) applies)

Section 4.8 *Physical Containment Level 2 (PC2) Requirements*  
(Only 4.8.3 (b), (c), (e) and (f))