



**Australian Government**

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**Australian Quarantine and Inspection Service**

**QUARANTINE APPROVED  
PREMISES CRITERIA 5.1  
FOR**

**QUARANTINE  
CONTAINMENT LEVEL 1  
(QC1) FACILITIES**

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**5.1 Specific Standards for Microbiological Containment and Indoor Animal Containment – Level 1 (QC1)**

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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 four parts:

- Explanatory Information,
- About QC1 Criteria and the Requirements for Approval,
- General Australian Quarantine and Inspection Service (AQIS) Requirements, and
- Specific AQIS Requirements.

The whole of Parts 1, 2 and 3 apply to **all** 5.1 facilities (unless otherwise stated). Part 4 has additional requirements for certain types of facilities (e.g. animal facilities). **Part 5 stipulates construction requirements applicable to QC1 facilities of all types.** Should your type of facility have a section in Part 4, all the additional specific requirements must be met.

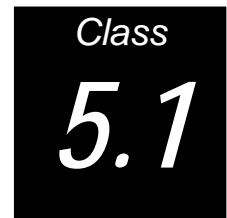
The requirements for each of the facility type combinations are outlined below:

<b>Requirements for approval as a QC1 facility</b>	
<b>Facility Type</b>	<b>Parts and Sections Applicable</b>
MICROBIOLOGICAL CONTAINMENT	PARTS 2, 3 & SECTION 4.1 ONLY OF PART 4
INDOOR ANIMAL CONTAINMENT (using imported biological material)	PARTS 2, 3 & SECTION 4.2 ONLY OF PART 4
OUTDOOR ANIMAL CONTAINMENT (using imported biological material)	PARTS 2, 3 & SECTION 4.3 ONLY OF PART 4

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

For example: If you have a QC1 Microbiological Facility, you will have to meet all the criteria from Parts 2 & 3 of this document. Additionally, criteria as listed under Part 4.1, 'Specific Requirements for Microbiological Containment' must also be satisfied.

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### **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, 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 5.1 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:

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

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### **Applying for approval**

Application forms are available from the AQIS website [www.aqis.gov.au](http://www.aqis.gov.au). For further details on this requirement, please refer to the 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 following AQIS website address:*

*[www.aqis.gov.au](http://www.aqis.gov.au) and then click on the following headings – Importing to Australia – Quarantine Approved Premises.*

### **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.

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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 QC1 Criteria and the Requirements for Approval**

### **2.1 Scope**

#### **5.1 Quarantine Containment (QC) Level 1:**

*Class 5.1* – premises used for quarantine goods of low hazard where standard safe containment practice is adequate to address quarantine risk.

Class 5.1 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 5.1 premises is not automatically approved as a commercial fumigation facility. This would require separate class approval under Class 4.6.

*Quarantine Containment Level 1 or Physical Containment Level 1 is the whole of the space approved by AQIS in accordance with AQIS's class Criteria for Quarantine Approved Premises 5.1.*

*A QC1 facility excludes lifts, stairs and corridors but may include lockable quarantine storage areas outside or separate to the quarantine area where the work is undertaken.*

*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:

- food products for in vitro analysis,
- soil and water samples for destructive analysis, and
- undertaking approved in vivo studies using imported biological material.

Premises in this class include:

- 'outdoor' grazing facilities (using Australian animals) attached to or separate from laboratories (which may be at a higher level of quarantine containment),
- facilities utilised for the research and analysis of food industry products, and
- laboratories undertaking research and analysis of soil for destruction and biological material.

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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 headings – Importing to Australia - co-regulationschemes/complianceagreements – 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

AQIS requires that documentary evidence be provided in the following situations:

### 2.4.1 Buildings (indoor containment)

Certification must be provided that the premises meets all relevant design and construction standards under the Australian Building Code as specified by the Australian Building Codes Board.

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

- a Local Government or Council Building Surveyor, or

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- 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.

#### **2.4.2 Open Areas** (Outdoor containment)

Where applicable the applicant must provide a copy of the land use planning approval permit.

*Note:* The land use planning approval permit can be obtained in each state or territory by contacting one of the following government authorities:

- local councils,
- relevant state or territory departments, or
- planning and land authorities.

#### **2.4.3 Buildings and Open Areas**

a) Applicants must provide information on the susceptibility of the premises to flooding or storm surges and the precautions taken to address these risks. This will require applicants providing:

- details about the magnitude and likelihood of flooding or storm surges, and
- the proximity of the proposed QAP to waterways in the vicinity.

If the premises is prone to flooding or storm surges the following must be provided:

- details of premises design features and risk management procedures that will be applied during a flood or storm surge event. This will need to include the likely effective warning time that the premises would have prior to inundation.

*Note:* Flooding includes:

- mainstream flooding (an event where water from a creek, river, lake, estuary or coastal waters overflows the natural or artificial banks of the principal watercourses in a catchment);

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- flash flooding (flooding that occurs within six hours of the rain which causes the flooding); and
- stormwater flooding (local runoff exceeding the capacity of an urban stormwater drainage system).

A storm surge is a rise in coastal water levels caused by the low pressure area of a storm or cyclone and wind driving water shorewards.

For the purposes of determining approval, AQIS will consider whether the location of the premises is prone to flooding or storm surges. This will depend on the frequency of these events. The premises will be regarded as being prone to flooding or storm surges if the floor of the facility would be inundated by a 100 year Average Recurrence Interval (ARI) flood or storm surge event. This equates to a 1 in 100 year flood level, (one flood in 100 years ratio) or an Annual Exceedence Probability (AEP) of 1%.

The documentary evidence to meet the flood prone precautions can be obtained in each state or territory by contacting one of the following government authorities (the agency/authority to contact will vary depending on the State or Territory):

- Planning and Land Authorities;
- Local Councils – town planning sections;
- Relevant State or Territory Departments; and

requesting a 'Property Information Certificate' or equivalent documentation.

If it is not possible to obtain a 100 year ARI or AEP flood level from the relevant local authority, then the highest ARI or defined flood level used by that authority will be taken to be the level for determining if the location is prone to flooding or storm surges.

Risk management procedures might include, removal or destruction of quarantine goods, and the decontamination of containers or equipment which has been utilised with the quarantine material, well before inundation occurs.

The type of goods and the scale of the dealings will be taken into consideration.

- b) Premises holders must submit a transport plan, detailing how the consignment will be taken from the port of arrival to the premises. When developing the plan premises holders will need to ensure the following requirements are met:
- The transport route is the most direct route between the two sites, and
  - the route taken is on sealed roads only.

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- c) The premises and all operations must comply with all Local, State and Federal regulations and the relevant State Environmental Protection Agency Requirements.

## 2.5 Requirements to maintain approval

### 2.5.1 Buildings (indoor containment)

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,
- the conditions of approval, and
- continues to comply with the relevant design and construction standards in the Australian Building Code.

*Note:* A change that significantly affects the overall containment system requires re-certification. This would include structural changes to 40% or more 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.

To ensure conformance to the QAP Criteria, AQIS must be:

- notified in writing no less than 15 working days prior to any alterations to QAP operating arrangements (Standard Operating Procedures),
- notified in writing within 15 working days of any alterations to QAP management arrangements.

Additionally, an AQIS Officer may request that documented evidence be provided for compliance with the Australian Building Code when additions or modifications have been made to the facility.

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.

### 2.5.2 Buildings (indoor containment) and Open Areas (Outdoor containment)

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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 premises. This can be achieved by AQIS approved methods.

Note: Examples of how quarantine area separation can be defined in a particular class of premises include, isolation from main thoroughfares with yellow lines, structural separation, a lockable room or building, a person proof security fence, separate benches or similar structures.

Examples of how *storage* separation can be achieved in a particular class of premises include, cupboards, coolrooms, refrigerators, and freezers.

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, refrigerators, freezers or other storage units located outside the area where the work is undertaken. Where this is necessary, the premises will need to have more than one quarantine area.

For QC1 premises this additional quarantine storage area may be located outside the designated facility but must be within the one physical site. To be within one physical site the facility must be within the same common boundary as the approved storage area and must be approved under the one organisation or company.

Where quarantine material is stored outside the designated facility a transfer procedure (as per 3.5.3 point 3) must be in place to ensure the safe movement of quarantine goods.

Quarantine storage area(s) which is/are located outside the building that houses the facility must be a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be lockable and secure.

For QC2 premises the additional quarantine area must be located within the building that houses the facility and where practical must be lockable. Movement procedures must be applied as per 3.5.3 point 3.

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In 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 (*i.e. separate outside storage areas*) 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) The premises must be managed to ensure that effective separation is maintained between cleared imported goods, domestic goods, imported goods awaiting quarantine clearance, and (in the case of AQIS approved dual import and export premises), export goods. Premises holders must also recognise that specific Import Permit Conditions and inspection procedures for some commodities may also apply in addition to these criteria.

Effective separation of all goods can be achieved by:

- an impervious physical barrier, or
- other AQIS approved methods.

Note: Effective separation will depend on the class of goods, not all methods listed are applicable to all classes of premises, Examples of effective separation for some classes of premises include but is not limited to:

- sealed containers,
- storage in separate rooms,
- plywood, sheet metal or heavy gauge plastic sheeting that provides complete and unbroken physical separation between consignments,
- double plastic wrap including a space separation between consignments of 1.2 metres, or
- remain consolidated within the shipping container.

The use of a method must be approved by AQIS and 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. **As a minimum this will**

require the premises to implement, and keep associated records of a periodic inspection regime and ensure 'knock-down' spray (ie standard household aerosol insecticide spray) is kept on-site at all times. A document outlining all pest control measures must be available to AQIS for audit purposes (example attached). In addition to details of the inspection regime and the on-site location of the 'knock-down' spray, 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.

**Note:** The operations of adjacent facilities must be considered when determining any additional pest control measures to be implemented.

### 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).

Note: Accessible means goods must be able to be inspected as directed by an AQIS Officer. Generally, block stacking will not be regarded as being accessible.

### 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,

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- of a professional standard,
- 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 25mm height, and
- be weatherproof and resistant to the elements

Signs within structures must be a minimum 295mm x 210mm with lettering a minimum 8mm height (example Attached).

- 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;
- 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.

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Note: Quarantine related spills include any spillage of quarantine goods, waste or waste water. These spills must be disposed of in a manner as per the section on quarantine waste.

Equipment used for the clean-up of quarantine related spills must be provided.

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 headings – Importing to Australia – Quarantine Approved Premises.

- 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.
- d) A procedure must be in place which ensures that AQIS is notified of any pest or disease infestation.
- e) Premises must ensure that, where waste cannot be rendered safe at the QAP, it is transported by an AQIS-approved waste transporter or under AQIS supervision.

### **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.

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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

a) 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 (*AS2675-1983: Portable first aid kits for use by consumers*),
- providing vehicle parking for visiting Quarantine Officers,

Note: This may require AQIS identified parking or providing a parking permit.

- 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.

b) The premises must comply with all relevant safety codes and occupational health and safety legislation.

### 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.

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- 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 will need to apply in writing requesting authority to transfer quarantine goods to a premises not co-located when a direction, written approval or an applicable Import Permit has not been issued. This will require details of proposed suitable transport containers if applicable, 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.

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 QC1 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 QC1 Criteria, the Requirements for Approval), and Part 3 (General AQIS Requirements).

### **4.1 Specific Requirements for Microbiological Containment – Level 1 (QC1) Facilities**

The holder of Microbiological Containment Approval must also meet Part 2 (About QC1 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,
- biological products for *in vitro* analysis as approved by AQIS, and
- food products for *in vitro* analysis.

#### **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.

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*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,

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- Local Council, and
- the Water Board (if applicable).

#### **4.1.3 Security**

- a) To assist in effectively managing the security of the facility a quarantine sign must also be displayed on the entry door to the facility. Such signs are to include:
  - all requirements as stated in Part 3.2 (a) above, and
  - in addition, state 'Microbiological Containment - QC1 Facility'.
- b) To prevent the unauthorised removal of quarantined material or the escape of pest and disease organisms, the doors to the facility must be closed while quarantine work is in progress.

#### **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.

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- 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.

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

- e) 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 (eg 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.

- f) The annual checking and certification of sterilisers or heat ovens 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 4.1.4 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.

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## 4.2 Specific Requirements for Indoor Animal Containment – Level 1 (QC1) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC1 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 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) 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).

#### 4.2.3 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 a quarantine sign must also be displayed on the entry door to the facility. Such signs are to include:
- all requirements as stated in Part 3.2 (a) above, and
  - in addition, state 'Animal Containment - QC1 Facility'.

#### 4.2.4 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).

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- 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.
- d) Unexpected animal mortalities or incidence of disease must be reported to AQIS immediately and investigated. AQIS must be kept up-to-date on the progress of the investigation, and must be provided a report at the conclusion of the investigation.
- e) A means of washing hands after handling quarantine animals must be available.

#### **4.2.5 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 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
  - comprehensive details of any breaches of quarantine goods from the facility.
- ii. An up-to-date inventory of the animals present and a chronological record of procedures performed must be maintained.
- iii. Records should be kept of births, or hatchings (if applicable), mortalities, post-mortem findings, test results etc.

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### 4.3 Specific Requirements for Outdoor Animal Containment – Level 1 (QC1) Facilities

The holder of Outdoor Animal 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 outdoor animal containment includes in vivo studies in animals using imported biological material.

#### 4.3.2 Hygiene and Isolation

- a) Quarantine facilities for outdoor animals must be physically separated from other animals and activities by secure perimeter fencing, preventing escape or incursions by feral or predatory animals.

*Note:* Buried fencing may be required and electric fencing should be used where appropriate.

- b) Perimeter fencing, additional to enclosed housing, directly containing the animals must be provided so that grazing animals are effectively held within double fencing (with a minimum gap of 3 metres between the outer and inner fences) or housed animals are within a fenced compound. The perimeter fence must be a minimum of 3 metres from the housing.

#### 4.3.3 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:

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- a separate storage device/area. (Such areas and/or devices must be 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, or deep burial.

- b) Any additional procedures as outlined in the in vivo permit must be complied with (if applicable).
- c) Where animal waste is collected, written approval may be obtained from AQIS to permit its use as fertiliser within the bounds of the QAP. Approvals will not be granted for sale of animal waste or use as fertiliser outside the QAP boundary. Any collected waste proposed for removal off-site must be treated prior to movement.

#### 4.3.4 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 prior to approval and when a change in the nominated staff member occurs.
- b) All gates must be locked when animals are not under direct supervision.

#### 4.3.5 Operational Procedures

- a) Arrangements must be in place for animals undergoing in vivo trials involving imported biologicals that ensures daily checking.
- b) The external perimeter fence shall be checked at least every three months and after storms for any breaks or holes in the fence. Any holes or breaks must be repaired immediately.
- c) Identification must be possible for all animals under quarantine (e.g. by tattooing, microchip, permanent branding or through a cage labelling system).
- d) Procedures must be in place for the accounting of individual animals.
- e) 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 disinfectant.

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- f) Where handling facilities used for loading, holding, treating and inspection (including movement areas such as roadways/lanes) are utilized for both animals under quarantine and unrestricted animals there must be written procedures in place to ensure that:
- the handling facilities are not used simultaneously by quarantined and unrestricted animals,
  - a minimum animal traffic separation of 2 metres is maintained at all times between quarantined and unrestricted animals, and
  - handling facilities, roadways/lanes do not allow access for quarantine animals to have access to feed or water troughs used by unrestricted animals.
- g) Unexpected animal mortalities or incidence of disease must be reported to AQIS immediately and investigated. AQIS must be kept up-to-date on the progress of the investigation, and must be provided a report at the conclusion of the investigation.
- h) A means of washing hands after handling quarantine animals must be available.

#### 4.3.6 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
  - comprehensive details of any breaches of quarantine goods from the facility.

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- ii. An up-to-date inventory of the animals present and a chronological record of procedures performed must be maintained.
- iii. Records of external perimeter fence examinations must be available for audit by AQIS Officers.
- iv. Records should be kept of births, or hatchings (if applicable), mortalities, post-mortem findings, test results etc.

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## **PART 5: Applicable Construction Requirements**

This part outlines the specific construction 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 QC1 Criteria, the Requirements for Approval), Part 3 (General AQIS Requirements), and Part 4 (Specific AQIS Requirements for QC1 Approval of a particular facility type).

### **5.1 Specific Standards for Microbiological Containment and Indoor Animal Containment – Level 1 (QC1) Facilities**

#### **5.1.1 Construction**

- a) The facility must be a fully enclosable space contained within walls, doors, floors and ceilings (with or without windows).
- b) Washbasins/sinks must be provided within the facility where goods subject to quarantine are analysed or some other means of decontaminating hands.

Note: Alternatives to washbasins, such as dispensers filled with antiseptic solutions, are considered suitable.

- c) All access doors to the facility must be fitted with self-closing devices.
- d) All floors in areas where goods subject to quarantine are analysed must be finished with materials which are smooth, impervious, and easy to clean.
- e) Where openings in floors are required they must be designed to prevent the penetration of liquid other than into floor wastes.
- f) Where the facility has an opening window, flyscreens must be fitted.
- g) All benches within the quarantine area must be finished with materials which are smooth, impervious, easy to clean and free from joints as far as possible but, where unavoidable, joints must be sealed. Where applicable sinks or similar must also be sealed to walls and benches.