



Australian Government

Australian Quarantine and Inspection Service

**QUARANTINE APPROVED
PREMISES CRITERIA 5.3
FOR**

**QUARANTINE
CONTAINMENT LEVEL 3
(QC3) 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 QC3 Criteria and the Requirements for Approval;
- General Australian Quarantine and Inspection Service (AQIS) Requirements;
- Specific AQIS Requirements; and
- Applicable Australian/New Zealand Standards.

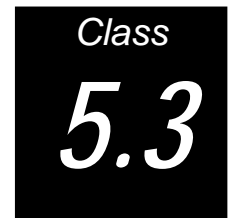
The whole of Parts 1, 2 and 3 apply to **all** 5.3 facilities (unless otherwise stated). Part 4 has additional requirements for certain types of facilities (e.g. animal facilities). Should your type of facility have a section in Part 4, all the additional specific requirements must be met.

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:

Requirements for approval as a QC3 facility	
Facility Type	Parts and Sections Applicable
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

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

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For Example: QC3 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 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™ 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 5.3 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. 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 following AQIS website address:

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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.

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 QC3 Criteria and the Requirements for Approval

2.1 Scope

5.3 Quarantine Containment (QC) Level 3:

Class 5.3 – premises utilised for quarantine goods which pose significant risks to animals, plants or humans if pest or disease associated with them spread outside the premises and from which significant economic impact would result in the community or environment.

The facility must meet the PC3 design and construction requirements as specified in Australian/New Zealand Standard™ 2243.3:2002 and 2982.1:1997. The applicable parts of these standards are outlined in Part 5 of this document.

Quarantine Containment Level 3 or Physical Containment Level 3 is the whole of the space approved by AQIS in accordance with AQIS's class criteria for Quarantine Approved Premises 5.3.

A QC3 facility may incorporate access and supporting rooms and interconnecting corridors or common space areas after entering through an airlock. It may comprise a number of like rooms such as three interconnecting microbiological laboratories but does not include combinations of different types of facilities such as animal, plant or insectary facilities within a physical containment barrier.

These facilities must be physically separate from offices used by containment facility personnel.

Body showers, toilet cubicles and drinking water appliances may be included.

Class 5.3 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 5.3 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:

- micro-organisms,
- approved plant material infected with quarantineable pathogens for in vitro and in vivo use,

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- infected fresh or frozen fruit and vegetable samples for in vitro use, and
- biological material for *in-vivo* work in animals.

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 5.3 premises will meet the requirements of a Class 5.1 (excluding outdoor animal facilities) and 5.2 premises of the same type. For example, a Class 5.3 Microbiological Facility will also meet all the requirements of a Class 5.1 and 5.2 Microbiological facility.

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

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 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.

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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.

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 TM (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

- c) An air leakage rate, at a differential pressure of 200Pa, of no more than 120L/min (upon facility commissioning).

- d) 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.

AQIS - QC3 Requirements

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);
- 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.

- e) 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.
- f) 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

- 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,
 - the conditions of approval, 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.

AQIS - QC3 Requirements

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 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.

Note: This will require the premises holder providing AQIS with a contingency plan detailing how the facility will contain the quarantine risk during alterations. The plan may include a decontamination aspect or instructions about how the quarantine material will be relocated into another room or facility.

- c) At all times after approval an air leakage rate of no more than 1200L/min should be maintained.

Note: To ensure that the air leakage rate is no more than 1200L/min, air leakage testing must be undertaken every 3 years.

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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**

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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,
- 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

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- 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. 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 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.

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 QC3 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 3 (QC3) Facilities

The holder of Microbiological Containment Approval must also meet Part 2 (About QC3 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:

- biological samples, and
- conducting research with micro-organisms.

4.1.2 Hygiene and Isolation

- a) ‘Write-up’ areas may be approved as part of a QC3 facility. To be eligible for approval, these areas must comply with QC3 requirements, be constructed such that horizontal surfaces are minimised (eg minimal shelving), must not be used for generic office functions and should hold only essential reference materials (eg technical equipment manuals).

4.1.3 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 which may include:

- a section on the disposal of waste that is not subject to import permit conditions;
- 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 waste must be bagged and placed in an unbreakable container with a secured lid for movement within 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 wastewater must be disposed of by an AQIS approved method.

Note: This will require a system to be in place which decontaminates all effluent from the Quarantine/work area, inner change room and, where applicable, shower before being discharged. An alarm must be provided to alert persons of any decontamination system malfunction. The use of a wastewater disposal method must be approved in writing by AQIS and may require 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

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- the Water Board (if applicable).

4.1.4 Security

- a) To assist in effectively managing the security of the facility the following must be applied:
- A logbook kept, recording visitor names, their company and the time and date of visits,
 - 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 – QC3 Facility'.
- b) Access to the facility for cleaning, servicing of equipment and repairs must not occur until potentially contaminated surfaces have been disinfected with an AQIS approved broad-spectrum disinfectant.

4.1.5 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,
 - disinfection using an AQIS approved broad-spectrum disinfectant.

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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 with soap and warm water after handling quarantine goods, working in a biological safety cabinet 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) Prior to entering the facility and in the anteroom, the following minimum requirements apply to clothing:
- personnel must put on covering clothes. Additionally, these garments must be:
 - removed on leaving the facility and kept in the anteroom (or laboratory) between uses,
 - laundered at appropriate intervals, and
 - where disposable protective clothing is used it must be disposed of in the manner described in waste disposal, of this document.

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

If a separate culture room within the facility exists and is dedicated to this work, then complete protective clothing including overshoes and hats is required within this room. Dedicated apparel should be used in this culture room and not removed except for laundering or disposal.

- f) When not in use, containers of regulated articles must be stored securely in the quarantine area (i.e. coolrooms, incubators, refrigerators, cupboards or similar structures).
- g) A document outlining an inspection regime for all goods must be provided to AQIS for audit purposes. The minimum requirements for this document include:
- The interval and personnel who conducted the inspection.
- h) 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, including HEPA filter integrity test reports and room pressure readings, and

- The personnel who conducted the inspection.

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

- i) A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the QAP facility relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the QAP facility is open.
- j) Annual testing and certification by a qualified technician must include:
 - i) testing of the pressure differentials in accordance with AS 1807.10,
 - ii) integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7,
 - iii) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes,
 - iv) the effectiveness of the effluent treatment and decontamination system.

Note: Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.

 - v) A report of the testing in items i) to iv) and of any maintenance conducted must be provided at the request of a Quarantine Officer.
- k) A manual listing procedures and documents applicable to quarantine, including emergency and maintenance procedures must be available within the facility in a prominent position.

Pressure steam sterilisers must comply with the following:

Note: Sterilisers must be located in the facility or within the building that houses the facility.

- l) 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.

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

Where there are biological safety cabinets at the QAP the following applies:

- n) 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.

Where there are flexible film isolators at the QAP the following applies

- o) Isolators must operate at a pressure below that of the room in which they are located and inlet and exhaust systems must be HEPA filtered.

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

4.1.6 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.

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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. **A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.**

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4.2 Specific Requirements for Indoor Animal Containment – Level 3 (QC3) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC3 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.
- c) Where the facility acts as the primary containment, a body shower and inner and outer change rooms must be incorporated.
- d) 'Write-up' areas may be approved as part of a QC3 facility. To be eligible for approval, these areas must comply with QC3 requirements, be constructed such that horizontal surfaces are minimised (eg minimal shelving), must not be used for generic office functions and should hold only essential reference materials (eg technical equipment manuals).

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: This will require a system to be in place which decontaminates all effluent from the Quarantine/work area, inner change room and, where applicable, shower before being discharged. An alarm must be provided to alert persons of any decontamination system malfunction. The use of a wastewater disposal method must be approved in writing by AQIS and may require demonstration of their efficacy to the satisfaction of AQIS. Such methods may require detailed scientific research at the QAP holders expense.

Where a facility performs a primary containment function and animal holding areas/pens/cages are plumbed to floor drains, these drains must be fitted with traps to

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ensure that all solids (eg bedding, faecal matter) are collected during research and at times of pen/cage washing and disinfection. Waste solids collected from drains must be treated by an AQIS approved method.

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.

Further, where the facility has floor drains, the drain traps should always be filled with water and a suitable AQIS approved broad spectrum disinfectant, and be secure against entry by pests.

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:
 - a logbook kept, recording visitor names, their company and the time and date of visits,
 - 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 – QC3 Facility'.
- c) Access to the facility for cleaning, servicing of equipment and repairs must not occur until potentially contaminated surfaces have been disinfected with an AQIS approved broad-spectrum disinfectant.

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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).
- c) Where applicable cages and racks must be labelled to indicate the identity and date of any inocula given.
- d) 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) Gloves shall be removed and hands thoroughly washed with soap and warm water after handling quarantine goods, working in a biological safety cabinet and before leaving the facility. Used gloves shall be discarded with the quarantine waste.
- g) Where the facility acts as the primary containment barrier, personnel must leave the facility through the clothing, change and shower rooms, except in cases of emergency where alternative exits may be used.

Note: All street clothing, including underwear, shall be removed and retained in the outer clothing change room. Complete protective clothing, including shoes must be used by all personnel entering the facility. When leaving the facility, personnel must remove their laboratory clothing and store or discard it in the inner change room before showering.

Where disposable protective clothing is used it must be disposed of in the manner described in the waste disposal section of this document. All other clothing must be laundered at appropriate intervals.

- h) Prior to entering the facility and in the anteroom, **or where applicable, inner change room**, the following minimum requirements apply to clothing and other apparel:
- personnel must put on overshoes,
 - personnel must wear covering clothes and a hat.

Additionally, these garments must be:

- removed on leaving the facility and kept in the anteroom between uses,
- laundered at appropriate intervals, and
- where disposable protective clothing is used it must be disposed of in the manner described in waste disposal, of this document.

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

- i) Where the facility has floor drains, the drain traps should always be filled with water and a suitable AQIS approved broad spectrum disinfectant, and be secure against entry by pests.
- j) A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the QAP facility relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the QAP facility is open.
- k) Annual testing and certification by a qualified technician must include:
- i) testing of the pressure differentials in accordance with AS 1807.10,
 - ii) integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7,
 - iii) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes,
 - iv) the effectiveness of the effluent treatment and decontamination system.

Note: Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.

- v) A report of the testing in items i) to iv) and of any maintenance conducted must be provided at the request of a Quarantine Officer.

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

Pressure steam sterilisers must comply with the following:

Note: Sterilisers must be located in the facility or within the building that houses the facility.

- m) 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
 - bacterial enzyme indicators be used at regular intervals (eg monthly), or
 - other AQIS approved method.

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 sterilisation conditions.

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

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
 - 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. **A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.**

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4.3 Specific Requirements for Plant Laboratory Containment – Level 3 (QC3) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 (About QC3 Criteria and the Requirements for Approval), and Part 3 (General AQIS Requirements).

4.3.1 General

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

- infected fresh or frozen fruit and vegetable samples for in vitro use, and
- conducting research and analysis of infected plant material for in vivo and in vitro use.

4.3.2 Hygiene and Isolation

- a) 'Write-up' areas may be approved as part of a QC3 facility. To be eligible for approval, these areas must comply with QC3 requirements, be constructed such that horizontal surfaces are minimised (eg minimal shelving), must not be used for generic office functions and should hold only essential reference materials (eg technical equipment manuals).

4.3.3 Waste Disposal

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

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

- that which is not subject to import permit conditions.
- 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 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:

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- 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 facility 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: This will require a system to be in place which decontaminates all effluent from the Quarantine/work area, inner change room and, where applicable, shower before being discharged. An alarm must be provided to alert persons of any decontamination system malfunction. The use of a wastewater disposal method must be approved in writing by AQIS and may require 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).

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4.3.4 Security

- a) To assist in effectively managing the security of the facility the following must be applied:
- 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 – QC3 Facility'.

4.3.5 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) Gloves shall be removed and hands thoroughly washed with soap and warm water after handling quarantine goods, working in a biological safety cabinet and before leaving the facility. Used gloves shall be discarded with the quarantine waste.
- e) Prior to entering the facility and in the anteroom, the following minimum requirements apply to clothing:
- personnel must put on covering clothes.

Additionally, these garments must be:

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- removed on leaving the facility and kept in the anteroom (or laboratory) between uses,
- laundered at appropriate intervals, and
- where disposable protective clothing is used it must be disposed of in the manner described in waste disposal, of this document.

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

If a separate culture room within the facility exists and is dedicated to this work, then complete protective clothing including overshoes and hats is required within this room. Dedicated apparel should be used in this culture room and not removed except for laundering or disposal.

- f) A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the QAP facility relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the QAP facility is open.
- g) Annual testing and certification by a qualified technician must include:
- i) testing of the pressure differentials in accordance with AS 1807.10,
 - ii) integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7,
 - iii) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes,
 - iv) the effectiveness of the effluent treatment and decontamination system.
- Note:* Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.
- v) A report of the testing in items i) to iv) and of any maintenance conducted must be provided at the request of a Quarantine Officer.
- h) A manual listing procedures and documents applicable to quarantine, including emergency and maintenance procedures must be available within the facility in a prominent position.

Pressure steam sterilisers must comply with the following:

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Note: Sterilisers must be located in the facility or within the building that houses the facility.

- i) 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
 - bacterial 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 sterilisation conditions.

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

Where there are biological safety cabinets at the QAP the following applies:

- k) 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.

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

Where there are flexible film isolators at the QAP the following applies

- 1) Isolators must operate at a pressure below that of the room in which they are located and inlet and exhaust systems be HEPA filtered.

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

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, 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. **A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.**

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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.

Where reference is made to an Australian/New Zealand Standard (or clause in an Australian/New Zealand Standard) in the requirements against which a facility is to be certified, that referenced standard (or clause) must also be met.

Note: These requirements are additional to Part 2 (About QC3 Criteria, the Requirements for Approval), Part 3 (General AQIS Requirements), and Part 4 (Specific AQIS Requirements for QC3 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 3.

5.1 Specific Standards for Microbiological Containment – Level 3 (QC3) Facilities

The holder of Microbiological Containment Approval must also meet Part 2 (About QC3 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 2982.1:1997 are the minimum for work with microbiological goods at the QC3 level.

Section 2. *General Laboratory Design and Construction Requirements*
(Excluding 2.2, 2.6, 2.7 (a) (vi) & (vii) & 2.7 (c), 2.9, 2.11, 2.12 and 2.13)

Section 3. *Reticulated Services*
(Excluding 3.7.3)

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

Section 5. *Ventilation and Air Quality*
(Excluding 5.1, 5.2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7)

Section 6. *Health and Safety Requirements*
(Excluding 6.1, 6.4, 6.5 and 6.6)

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In substitution for 6.2 Safety Showers, the following clause will be applied:
Clean up provisions are required which may be:

- Fixed appliances (eg. showers and eyewash stations), or
- Single use apparatus (eg. disinfectant swabs, squeeze bottles).

Note: Where safety showers and **fixed** eyewash facilities are **in use** they must comply with the requirements of 6.2.

The approach to all clean up provisions must be unobstructed.

In substitution for 6.3 Hand washing Facilities the following clause will be applied:

Work areas where Quarantine goods are handled must contain either a handwash basin fitted with handsfree tap(s), or some other means of decontaminating hands.

Note: Handwash basins must be located inside the laboratory, near to the exit serviced with hot and cold potable water. Potable water requirements must be met in accordance with AS 3500

Note: Alternatives to wash basins, include:

- dispensers fitted with approved antiseptic solutions, are considered suitable, provided the dispensers can be operated without using the hands, or
- a sink of hands-free operation.

Section 8. *Biological Laboratories*
(Only 8.3)

Appendix B. *Additional Requirements for Microbiological Facilities*
(Only B4 (f) & B5 (i) iv)

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

- where a basin is provided for washing hands an antiseptic handwash dispenser be supplied.

5.2 Specific Standards for Indoor Animal Containment – Level 3 (QC3) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC3 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 QC3 level.

Section 2. *General Laboratory Construction Requirements*

(Excluding 2.2, 2.6, 2.7 (a) (vi) & (vii) & 2.7 (c); 2.9, 2.10, 2.11, 2.12 and 2.13)

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Section 3. *Reticulated Services*
(Excluding 3.7.3)

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

Section 5. *Ventilation and Air Quality*
(Excluding 5.1, 5.2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7)

Section 6. *Health and Safety Requirements*
(Excluding 6.1, 6.4, 6.5 and 6.6)

In substitution for 6.2 Safety Showers, the following clause will be applied:
Clean up provisions are required which may be:

- Fixed appliances (eg. showers and eyewash stations), or
- Single use apparatus (eg. disinfectant swabs, squeeze bottles).

Note: Where safety showers and **fixed** eyewash facilities are **in use** they must comply with the requirements of 6.2.

The approach to all clean up provisions must be unobstructed.

In substitution for 6.3 Hand washing Facilities the following clause will be applied:
Work areas where Quarantine goods are handled must contain either a handwash basin fitted with handsfree tap(s), or some other means of decontaminating hands.

Note: Handwash basins must be located inside the laboratory, near to the exit serviced with hot and cold potable water. Potable water requirements must be met in accordance with AS 3500

Note: Alternatives to wash basins, include:

- dispensers fitted with approved antiseptic solutions, are considered suitable, provided the dispensers can be operated without using the hands, or
- a sink of hands-free operation.

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

Appendix C. *Additional Requirements for Animal Accommodation*
(Only C3 (f))

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

- where a basin is provided for washing hands an antiseptic handwash dispenser be provided.

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5.3 Specific Standards for Plant Laboratory Containment – Level 3 (QC3) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 (About QC3 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 QC3 level.

Section 2. *General Laboratory Construction Requirements*

(Excluding 2.2, 2.6, 2.7 (a) (vi) & (vii) & 2.7 (c); 2.9, 2.11, 2.12 and 2.13)

Section 3. *Reticulated Services*

(Excluding 3.7.3)

Section 4. *Electrical Services*

(Excluding 4.2 and 4.3)

Section 5. *Ventilation and Air Quality*

(Excluding 5.1, 5.2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7)

Section 6. *Health and Safety Requirements*

(Excluding 6.1, 6.4, 6.5 and 6.6)

In substitution for 6.2 Safety Showers, the following clause will be applied:

Clean up provisions are required which may be:

- Fixed appliances (eg. showers and eyewash stations), or
- Single use apparatus (eg. disinfectant swabs, squeeze bottles).

Note: Where safety showers and **fixed** eyewash facilities are **in use** they must comply with the requirements of 6.2.

The approach to all clean up provisions must be unobstructed.

In substitution for 6.3 Hand washing Facilities the following clause will be applied:

Work areas where Quarantine goods are handled must contain either a handwash basin fitted with handsfree tap(s), or some other means of decontaminating hands.

Note: Handwash basins must be located inside the laboratory, near to the exit serviced with hot and cold potable water. Potable water requirements must be met in accordance with AS 3500

Alternatives to wash basins, include:

- dispensers fitted with approved antiseptic solutions, are considered suitable, provided the dispensers can be operated without using the hands, or

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- a sink of hands-free operation.

Section 8. *Biological Laboratories*
(Only 8.3)

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

- where a basin is provided for washing hands an antiseptic handwash dispenser be provided.

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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 3.

5.4 Specific Standards for Microbiological Containment – Level 3 (QC3) Facilities

The holder of Microbiological Containment Approval must also meet Part 2 (About QC3 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 QC3 level.

Section 4.8 *Physical Containment Level 2 (PC2) Requirements* (Only 4.8.3 (b))

In addition to 4.8.3 (b) the following AQIS Note will apply:

Note: Large HVAC heat exchangers (eg chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination, if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or are used.

Section 4.9 *Physical Containment Level 3 (PC3) Requirements*

(Only 4.9.2 (a) – excluding the requirements for doors to open outwards, and be self closing. The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 **generic text &** (a), (b), (c), (d), (e), (f) and (i))

In Substitution for 4.9.3 (g) the following clause will be applied:

Each separate room within a facility must have:

- A room pressure gauge that can be viewed by personnel prior to entering the facility, and
- an audible alarm.

Notes:

- The room pressure gauge must measure the differential pressure relative to the ‘adjacent rooms’ external to the facility. The reference pressure should be taken from ‘adjacent rooms’, normally the access space not the ceiling space. The adjacent space should not be subject to significant variations in ambient static

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pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.

- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.
- The audible alarm is to indicate loss of negative room pressure in excess of 2 minutes.
- Where practicable other airconditioning control switches and exhaust fan speed setpoint control should also be located adjacent to the gauges.
- The HEPA filter gauge can also be mounted with the room gauges.
- If there is a closable door between two rooms they are separate.

5.5 Specific Standards for Indoor Animal Containment – Level 3 (QC3) Facilities

The holder of Indoor Animal Containment Approval must also meet Part 2 (About QC3 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 QC3 level.

Section 4.8 *Physical Containment Level 2 (PC2) Requirements*

(Only 4.8.3 (b))

In addition to 4.8.3 (b) the following AQIS Note will apply:

Note: Large HVAC heat exchangers (eg chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination, if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or are used.

Section 4.9 *Physical Containment Level 3 (PC3) Requirements*

(Only 4.9.2 (a) – excluding the requirement for doors to open outwards, and be self closing. The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 (a), (b), (c), (d), (e), (f) and (i))

In Substitution for 4.9.3 (g) the following clause will be applied:

Each separate room within a facility must have:

- A room pressure gauge that can be viewed by personnel prior to entering the facility, and
- an audible alarm.

Notes:

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- The room pressure gauge must measure the differential pressure relative to the 'adjacent rooms' external to the facility. The reference pressure should be taken from 'adjacent rooms', normally the access space not the ceiling space. The adjacent space should not be subject to significant variations in ambient static pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.
- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.
- The audible alarm is to indicate loss of negative room pressure in excess of 2 minutes.
- Where practicable other airconditioning control switches and exhaust fan speed setpoint control should also be located adjacent to the gauges.
- The HEPA filter gauge can also be mounted with the room gauges.
- If there is a closable door between two rooms they are separate.

Section 10 *Animals and Animal Containment Facilities*

(Only 10.8.1 (b) associated notes only and 10.9.2 (c) – paragraph 5 sentences 2 & 3 and associated note)

In substitution for 10.9.2 (c) paragraph 1, the following clause will be applied:

Doors to the facility airlock must be fitted with automatic closers unless "door open" alarms are fitted.

5.6 Specific Standards for Plant Laboratory Containment – Level 3 (QC3) Facilities

The holder of Plant Laboratory Containment Approval must also meet Part 2 (About QC3 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 QC3 level.

Section 4.8 *Physical Containment Level 2 (PC2) Requirements*

(Only 4.8.3 (b))

In addition to 4.8.3 (b) the following AQIS Note will apply:

Note: Large HVAC heat exchangers (eg chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination, if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or are used.

Section 4.9 *Physical Containment Level 3 (PC3) Requirements*

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(Only 4.9.2 (a) – excluding the requirements for doors to open outwards, and be self closing. The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 (a), (b), (c), (d), (e), (f) and (i))

In Substitution for 4.9.3 (g) the following clause will be applied:

Each separate room within a facility must have:

- A room pressure guage that can be viewed by personnel prior to entering the facility, and
- an audible alarm.

Notes:

- The room pressure guage must measure the differential pressure relative to the 'adjacent rooms' external to the facility. The reference pressure should be taken from 'adjacent rooms', normally the access space not the ceiling space. The adjacent space should not be subject to significant variations in ambient static pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.
- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.
- The audible alarm is to indicate loss of negative room pressure in excess of 2 minutes.
- Where practicable other airconditioning control switches and exhaust fan speed setpoint control should also be located adjacent to the gauges.
- The HEPA filter guage can also be mounted with the room gauges.
- If there is a closable door between two rooms they are separate.

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Additional AQIS Requirements

5.7 Specific AQIS Requirements for Quarantine Containment – Level 3 (QC3) Microbiological, Animal and Plant Facilities

- a) A facility must be constructed so that each room within achieves upon commissioning an air leakage rate, at a differential pressure of 200Pa, of no more than 120L/min. An air leakage test must be provided for new or refurbished facilities.

Note: a small ante-room / airlock of less than 10 m² floor area may be added with the adjacent room for the purpose of this requirement.

- b) Where drinking fountains are provided they must be of hands-free operation and be within a designated area where goods are not handled, stored or treated.
- c) 'Write-up' areas may be approved as part of a QC3 facility. To be eligible for approval, these areas must comply with QC3 requirements, be constructed such that horizontal surfaces are minimised (eg minimal shelving), must not be used for generic office functions and should hold only essential reference materials (eg technical equipment manuals).

HEPA Filters

- a) HEPA filters must be mounted in gas tight housing(s) located as close as possible to the containment facility to minimize the length of potentially contaminated ductwork. The interconnecting ductwork between the containment room and the HEPA filter housing must also be of gastight (stainless steel) construction.
- b) The design of the filter housing must facilitate the testing of the integrity of the HEPA filter element and mounting, and the periodic gaseous decontamination of the filter element and housing.

Note: Housings should be placed in fully accessible locations with clear access to facilitate filter integrity testing, physical handling of filter elements and operation of isolating valves. Installations in false ceilings should be avoided.

To enable testing and gaseous decontamination filter housings should incorporate the following features:

- sealed access doors for filter maintenance and integrity testing,
- Gastight isolating valves on the air inlet and outlet ducts,
- Secure filter element clamping and mounting tracks,

- Upstream and downstream valved ports,
- Upstream and downstream valved pressure tappings to permit monitoring of the filter air flow pressure drop,
- A differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm,
- A facility to introduce a test airflow and cold generated aerosol to establish the integrity of the filter element and its mounting.

Waste Service Piping

- a) Waste piping must be installed such that the length of horizontal piping is minimised. The pipe path should have the maximum practical fall (preferably vertical). The pipe should be routed via plant rooms and accessible building risers. The route should avoid ceiling spaces and occupied areas unless this is impractical.
- b) Piping must be conservatively selected to suit the fluid flow and pressure applicable. The pipe material should resist degradation from exposure to waste products or likely cleaning and disinfection agents.

Note: Fully welded 316l stainless steel piping of 1.0mm thickness is recommended. Single skin piping is considered satisfactory.

- c) Piping must be physically protected where exposed to mechanical damage.
- d) Piping must be labelled “Quarantine Containment Pipework – Do not disturb” throughout its length. Biohazard warning symbols should also be provided at regular intervals.
- e) Piping should be capable of being visually inspected throughout its length. Double skin pipe construction is recommended in any locations where visual inspection is unable to be undertaken. However this contingency should be avoided, where practical.
- f) A filtration system is required for removal of solids prior to liquid waste entering the holding tank. The filtration system must be capable of being removed for cleaning and decontamination. Solids removed from waste water are deemed to be quarantine waste and must be treated as such. Steam sterilisation is recommended.

Note: The efficacy of the waste treatment system in sterilising particulate matter should be considered when determining the filtration system screen size to be utilised for solids removal.

- g) The floor of the waste treatment plant room must be fully bunded to a volume that ensures retention of all waste in the event of a holding tank failure at full capacity. The bunded space should drain to a sealed sump. A submersible sump pump must be provided, along with flexible hosing to discharge the spillage after chemical disinfection.

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Note: Consideration should be given to the provision of a safety shower and eyewash station within the plant room.

- h) A 'continuous flow alarm' is desirable for water services connected to appliances draining to the treatment system.

Note: A suitable timer can warn users where water flow to a single appliance exceeds a reasonable period of time.

- i) All vents to the waste system must be fitted with sterile filters.

Note: Filters must be carefully selected to ensure that sufficient air is passed to ensure traps are not compromised. 0.2 micron hydrophobic membrane filters are recommended. These must be capable of being decontaminated, preferably by steam sterilisation.

- j) Where toilets are installed, it is recommended that these are urine only systems. Where urine only toilets are installed a 'Lady-San' or similar disposal station for small quantities of toilet paper and other minor solids should be supplied. Solid waste collected from disposal stations must be treated as quarantine waste.

5.8 Specific AQIS Requirements for Quarantine Containment – Level 3 (QC3) Animal and Plant Facilities

- c) Any openings in the walls, ceiling or roof, such as vents, drainage outlets and air conditioning or ventilation inlets and outlets, must be screened at the containment boundary with fine mesh screens having an aperture size small enough to prevent entry or egress of insects. Screens must be of suitable material to withstand the air flow load, to remain undamaged following cleaning and be resistance to attack by insects or corrosion.

Note: An aperture size small enough to prevent entry or egress of insects will require a maximum aperture size of 0.25 mm or 250 microns (um). Suitable material includes stainless steel mesh of 0.16 mm wire gauge (0.25 mm aperture).

The size of insects to which quarantinable plants and animals held within the facility are potential hosts must also be considered when determining the appropriate screen size.

Recommended Containment Requirements

- a) The facility should have an automatically-starting emergency power source to ensure continuing operation of the ventilation system, room access and if applicable shower controls.

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- b) Sufficient uninterruptible power should be provided for essential equipment such as Biological safety cabinets.

Notes:

- The emergency power source would need to be designed to enable an automatic changeover as soon as practicable. Any such system would need to ensure emergency lighting and communication systems are reactivated within the shortest practical timeframe.
- An uninterruptible power supply (UPS) for biosafety cabinets would ensure seamless supply is maintained.