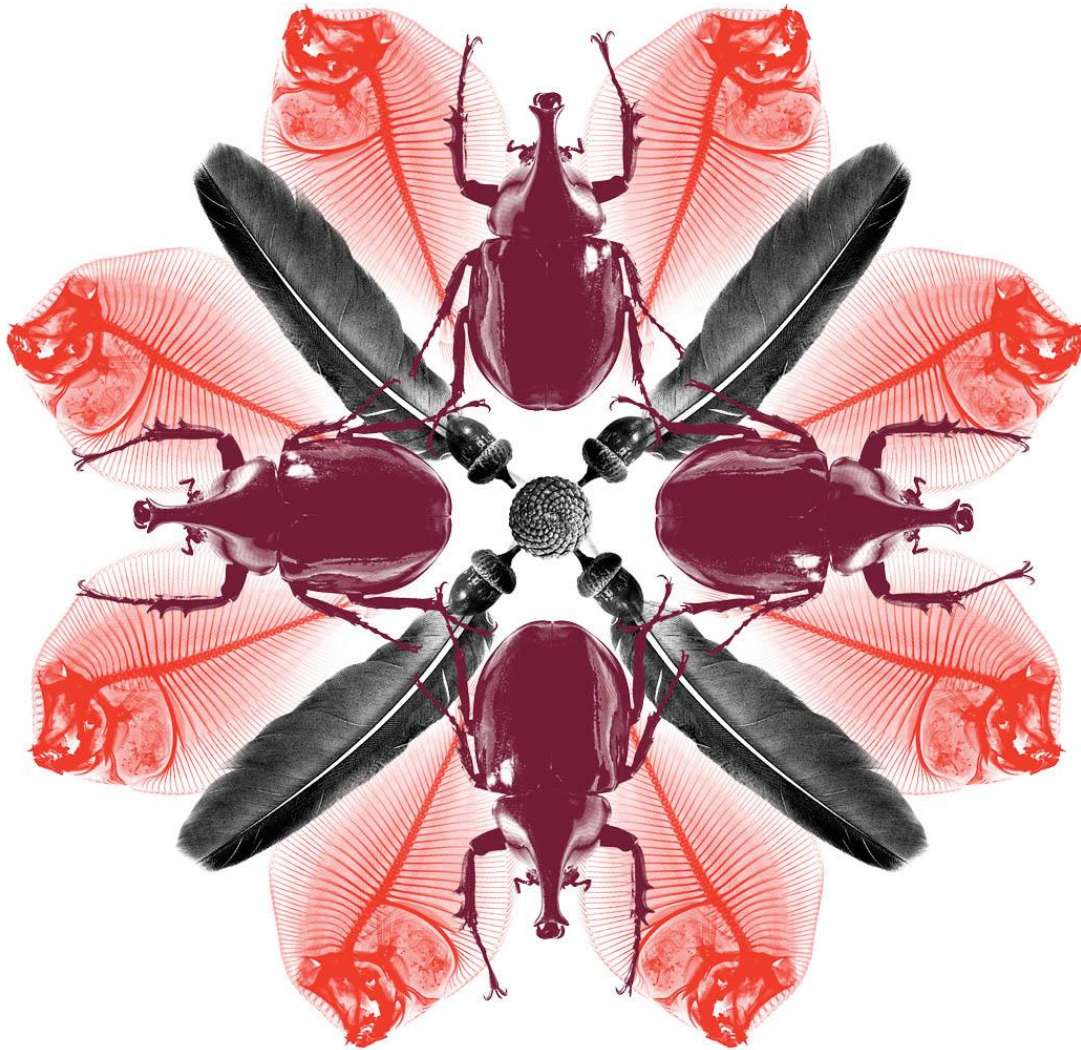


Approved Arrangements

For 7.6—Laboratory xenopus
Requirements—Version 5.0



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Version control

Updates to this document will occur automatically on the department's website and the revision table below will list the amendments as they are approved.

Approved Arrangements: 7.6—Laboratory xenopus

Date	Version	Amendments	Approved by
9 May 2011	1.0	Revised document.	Co-regulation and Support Program
30 Jun 2013	1.1	Updated departmental branding.	Industry Arrangements Reform Program
14 Jun 2014	2.0	Removal of criterion.	Approved Arrangements section
21 Aug 2014	3.0	Updated departmental branding. Criteria reviewed and updated.	Approved Arrangements section
Sept 2015	4.0	Updated departmental branding and template	Approved Arrangements section
16 Jun 2016	5.0	Updated references to the department and the <i>Biosecurity Act</i> <i>2015</i> .	Approved Arrangements section

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Guide to using this document

This document sets out the requirements that must be met before the relevant Director will consider approval for the provision of biosecurity activities under section 406 of the *Biosecurity Act 2015*, otherwise known as an approved arrangement (AA).

This document specifies the requirements to be met for the approval, operation and audit of this class of AA. Compliance with the requirements will be assessed by audit.

In the event of any inconsistency between these requirements and any Import Permit condition, the Import Permit condition applies. If the applicant chooses to use automatic language translation services in connection with this document, it is done so at the applicant's risk.

Unless specified otherwise, any references to 'the department' or 'departmental' means the Department of Agriculture and Water Resources. Any references to contacting the department mean contacting your closest regional office.

Further information on AAs, AA regional contact details and copies of relevant AA documentation is available on the [department's website](#).

Definitions

Definitions that are not contained within the Approved Arrangements Glossary can be found in the *Biosecurity Act 2015* or the most recent edition of the Macquarie Dictionary.

Other documents

The AA general policies should be read in conjunction with these requirements. They will assist in understanding and complying with the obligations and requirements for the establishment and operation of an AA.

Nonconformity guide

The nonconformity classification against each criterion is provided as a guide only. If more than one nonconformity is listed against a requirement, the actual nonconformity applied will correspond to the gravity of the issue. The nonconformity recorded against any requirement remains at the discretion of the biosecurity officer.

Nonconformity classifications are detailed in the AA general policies.

AA Requirements

Table 1 Site location

Requirements	Nonconformity guide
1.1 Sites must generally be located within the metropolitan area of a declared port that has a permanently based biosecurity officer. Applications are subject to approval by the Director of biosecurity and will be considered on their individual merits, with consideration being given to the biosecurity risk and serviceability associated with the location of each site.	Not applicable

Table 2 Access and security

Requirements	Nonconformity guide
2.1 The site housing the animals must be constructed in order to provide complete physical isolation from domestic and native animals and insects.	Critical
2.2 External windows must be sealed and fitted with metal security bars or mesh.	Critical
2.3 Openings in the walls, floor or ceiling (e.g. window and vents) must be screened with fine screens (60 x 40 swg mesh = 51% free area or finer).	Critical
2.4 The entrance to the animal room/house must be posted with a professionally prepared sign which clearly identifies the types of animals kept at the site and lists emergency and maintenance procedures.	Major
2.5 The doors to the animal room/house must open inwards, be self-closing, lockable and preferably with a viewing panel. The door should also be sealable for decontamination, if necessary, and sufficient to prevent entry of vermin.	Major
2.6 Cages/enclosures must be constructed of heavy duty metal or other suitable material for the secure holding of live animals (cages/enclosures must be kept locked at all times).	Major
2.7 Security alarms should be installed in the site.	Minor

Table 3 Facilities and equipment

Requirements	Nonconformity guide
3.1 The lighting and air-conditioning must be adequate.	Minor
3.2 Floors, walls, bench tops and ceilings must have impervious surfaces.	Major
3.3 There must be a lockable deep freezer for pathology specimens/bodies located within a functional proximity to the biosecurity house/room.	Minor
3.4 There must be a sink for hand washing with elbow/foot/thigh operated taps.	Major
3.5 There must be suitable closed and lockable live animal/animal tissue transport containers.	Minor
3.6 Animals involved in genetic manipulation experiments are not to be used for other purposes or to provide tissues for other purposes.	Critical
3.7 Live animals or tissues derived from animals held at the animal house/room shall not be removed from the animal house/room unless departmental approval has been granted.	Critical

Table 4 Waste disposal

Requirements	Nonconformity guide
4.1 Animal room/house floors must drain to a central drain. This drain should always contain water or disinfectant in the trap.	Critical
4.2 Each room must have its own sanitation equipment.	Minor
4.3 Bedding should be absorbent.	Minor
4.4 Bedding and other waste material must be removed in a manner that minimises the creation of aerosols.	Major
4.5 Cage cleaning areas must be close to animal rooms.	Major
4.6 Residues, packaging, bedding and absorbent material must be destroyed either by incineration or autoclaving.	Major
4.7 Dead bodies, tissues or unhatched eggs are to be disposed of by incineration, sterilisation in an autoclave or by high temperature isolation before leaving the biosecurity area.	Critical
4.8 A recommended method of solid waste disposal is by bag autoclaving, re-bagged, and transporting for incineration or deep burial. If material is bulky and heat penetration is in doubt, then it should be autoclaved, bagged again and then incinerated or deep buried. Alternatively the waste can be packed into biohazard bags and then left in a UV airlock overnight, then removed and autoclaved before disposal.	Critical

Table 5 Air quality and air flow patterns

Requirements	Nonconformity guide
5.1 Air flow patterns must be such as to prevent air from flowing from biosecurity isolation areas to other areas unless HEPA filtered and prevent dead pockets.	Major
5.2 Ventilation must give negative pressure in the lab. Inward flow is required if imported animals are sharing a common air supply with non-imported animals (except in the case of specific pathogen free (SPF) animals where they would be in an isolator of SPF barrier).	Major
5.3 Intake air should be 100 per cent fresh (non-recycled to avoid cross-contamination by infectious agents and to dispose of irritating chemicals, primarily ammonia).	Minor
5.4 Intake air should not be contaminated by exhaust air from the site, incinerator smoke, or other contaminated air.	Minor
5.5 There must be at least eight fresh air changes each hour.	Minor
5.6 Vacuum lines and air outlets should, where necessary, be protected by high efficiency particulate air filters (HEPA) and liquid disinfectant traps.	Minor

Table 6 Office and record requirements

Requirements	Nonconformity guide
6.1 Records are to be made available, within a reasonable time, for inspection by biosecurity officers. In addition, these records must be retained at these sites for a minimum period of 18 months during which time they will, upon request, be made available to a biosecurity officer.	Critical
6.2 Records of goods subject to biosecurity control imported through the site must be maintained.	Critical
6.3 Records for each consignment of goods must include: biosecurity entry number, Import Permit number (if applicable), name and address of importer, date of arrival, country of origin, details of any treatments, method of waste disposal, and date of waste disposal/destruction.	Critical
6.4 A log book is to be kept, with importations, births (or hatchings), deaths, destructions and transfers.	Critical
6.5 Details of post mortem results and other test results must also be available.	Critical
6.6 Office and general site requirements must provide the department with the confidence that applicable work health and safety standards have been met, this is achieved by: <ul style="list-style-type: none"> • 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 biosecurity officers (note: this may require department identified parking or providing a parking permit) • ensuring adequate security for any departmental technical equipment left on the premises • providing access and the availability of: <ul style="list-style-type: none"> - a desk, chair and a telephone with direct outside call access - toilet facilities - hand washing facilities and a hygienic means of drying hands - suitable arrangements to ensure amenities are clean. 	Minor

Table 7 Administration

Requirements	Nonconformity guide
7.1 Sites must be securely locked when unattended and after-hours access to the site must be limited to authorised persons only.	Major or critical

Table 8A General

Requirements	Nonconformity guide
8.1 Goods subject to biosecurity control must be maintained and processed at an AA site appropriate for the biosecurity risk associated with the items.	Major or critical
8.2 Goods subject to biosecurity control must be maintained and processed in accordance with the requirements of the relevant AA class.	Minor, major or critical
8.3 Goods subject to biosecurity control must be maintained and processed in accordance with import conditions specified in the department's Biosecurity Import Conditions Database (BICON).	Minor, major or critical
8.4 Goods subject to biosecurity control must be maintained and processed in accordance with an Import Permit.	Minor, major or critical
8.5 Goods subject to biosecurity control must be maintained and processed in accordance with any other direction from the department.	Minor, major or critical
8.6 Goods subject to biosecurity control must be maintained and processed in accordance with the <i>Biosecurity Act 2015</i> and subordinate legislation.	Major or critical
8.7 Goods subject to biosecurity control must be kept physically separated from other goods (including during transport), to ensure negligible risk of cross contamination to: <ul style="list-style-type: none"> • imported items that have been released from biosecurity control • domestic items • the Australian environment. Note: Isolation can be achieved through the use of distance or physical barriers. The amount of distance or type of physical barrier required will depend on the nature of the goods subject to biosecurity control.	Major or critical
8.8 The standard of hygiene at the AA site must be appropriate for the nature of the goods subject to biosecurity control.	Major or critical
8.9 Any equipment that has been used or brought in contact with imported items subject to biosecurity control, or which could have been potentially contaminated by the imported items, must not leave the biosecurity area until it has been processed (cleaned, disinfested, decontaminated) or disposed of in accordance with relevant AA requirements, import conditions and departmental directions.	Major or critical

Table 8B General (continued)

Requirements	Nonconformity guide
<p>8.10 Goods subject to biosecurity control are not permitted to be moved outside an AA site except for the purpose of:</p> <ul style="list-style-type: none"> • moving directly and securely to another AA site, of the appropriate AA class, with prior written approval from the department 	Critical
<ul style="list-style-type: none"> • moving directly and securely to an AA site of the same class (or of the same class but a higher biosecurity containment level sub-class) that is co-located with the original AA site 	
<ul style="list-style-type: none"> • transport of biosecurity waste by a department approved waste transport company (operating under an AA for biosecurity waste transport). <p>If the items are being transported by a non-accredited person (such as a truck driver), the forwarding biosecurity industry participant must ensure that this person is made aware of the conditions relating to the transport of the items.</p>	Major
<p>8.11 Goods subject to biosecurity control are not permitted to leave the biosecurity area of an AA site, inadvertently or deliberately, without prior written direction or approval from the department.</p>	Critical
<p>8.12 An accredited person must personally conduct or directly supervise activities involving physical contact with, or handling of items, subject to biosecurity control. Directly supervise means that the accredited person must be present in the area where the items subject to biosecurity control are being handled and must be able to:</p> <ul style="list-style-type: none"> • visually verify for themselves that the items are being handled in accordance with the department's requirements • communicate immediately and effectively with the persons being supervised. 	Major
<p>8.13 Persons performing the function of an accredited person must have successfully completed the department's approved training to obtain and maintain accredited person status.</p>	Major
<p>8.14 Records must be maintained of accredited persons.</p>	Minor
<p>8.15 Goods subject to biosecurity control must be clearly and visibly identified as being under biosecurity control to persons who can physically access the goods or the containers holding the goods. The measures taken must ensure that persons having physical access to goods subject to biosecurity control can differentiate between goods subject to biosecurity control and goods that are not subject to biosecurity control.</p>	Major
<p>8.16 Ensure records are kept for a minimum of 18 months for goods subject to biosecurity control at the AA site.</p>	Minor or major

Table 8C General (continued)

Requirements	Nonconformity guide
8.17 Ensure goods subject to biosecurity control are traceable in terms of (where applicable):	
<ul style="list-style-type: none"> • declaration/entry number • Import Permit number • Air Waybill or Bill of Lading number • date of receipt • processing (including inspection, treatment, testing) details • release from biosecurity control • disposal details • storage location • accredited person responsible for the items. 	<ul style="list-style-type: none"> • Major • Major • Minor • Major • Major • Major • Major • Major • Major
8.18 The BIP must ensure that persons having physical access to goods subject to biosecurity control are aware that such items must only be handled by an accredited person or under the direct supervision of an accredited person.	Major
8.19 A contingency plan must be in place to manage unexpected events that threaten to compromise biosecurity integrity of the AA site. Unexpected events include:	
<ul style="list-style-type: none"> • appearance of pests or symptoms of disease • structural damage (for example, due to storms) • unauthorised removal of goods subject to biosecurity control • spillages of goods subject to biosecurity control • sudden unavailability of an accredited person. 	<ul style="list-style-type: none"> • Major • Major • Major • Major • Minor
8.20 Ceasing or transferring operations. The department must be informed in writing, at least 15 working days prior to intended:	Major
<ul style="list-style-type: none"> • closure of a current AA site • relocation of the business, including the AA class function 	
<ul style="list-style-type: none"> • ceasing of operation as a AA site. <p>Any goods subject to biosecurity control that remain at the AA site must be treated or destroyed in accordance with a department approved method or transferred to another AA site with prior approval from the department. The BIP will be liable for associated costs.</p>	Critical

Table 8D General (continued)

Requirements	Nonconformity guide
8.21 If there is any doubt as to whether goods: <ul style="list-style-type: none"> • are subject to biosecurity control • remain subject to biosecurity control • become subject to biosecurity control then the goods must be handled in accordance with requirements for goods subject to biosecurity control.	Major
8.22 The BIP must notify the department in writing as soon as practicable within 15 working days of becoming aware of any change of status, not previously been notified to the department, of the BIP or their associates relevant to the operation of the AA in relation to any of the following matters: <ul style="list-style-type: none"> • conviction of an offence or order to pay a pecuniary penalty under the <i>Biosecurity Act 2015</i>, <i>Quarantine Act 1908</i>, <i>Customs Act 1901</i>, the Criminal Code or the <i>Crimes Act 1914</i> • debt to the to the Commonwealth that is more than 28 days overdue under the <i>Biosecurity Act 2015</i>, <i>Quarantine Act 1908</i>, <i>Customs Act 1901</i>, the Criminal Code or the <i>Crimes Act 1914</i> • refusal, involuntary suspension, involuntary revocation/cancellation or involuntary variation of an Import Permit, quarantine approved premises, compliance agreement or AA under the <i>Quarantine Act 1908</i> or the <i>Biosecurity Act 2015</i>. 	Critical
8.23 Biosecurity officers, biosecurity enforcement officers and department-approved auditors must be provided access to the AA site to perform the functions and exercise the powers conferred on them by the Biosecurity Act or another law of the Commonwealth.	Critical
8.24 Departmental auditors or department-approved auditors must be provided with facilities and assistance as requested, and any required documents, records or things relevant to the audit.	Major or critical
8.25 The department must be notified of any reportable biosecurity incident as soon as practicable, in accordance with the determination made by the Director of Biosecurity.	Critical
8.26 Department-approved auditors must be permitted to collect evidence of compliance and noncompliance with AA requirements through actions including the copying of documents and taking of photographs.	Major or critical