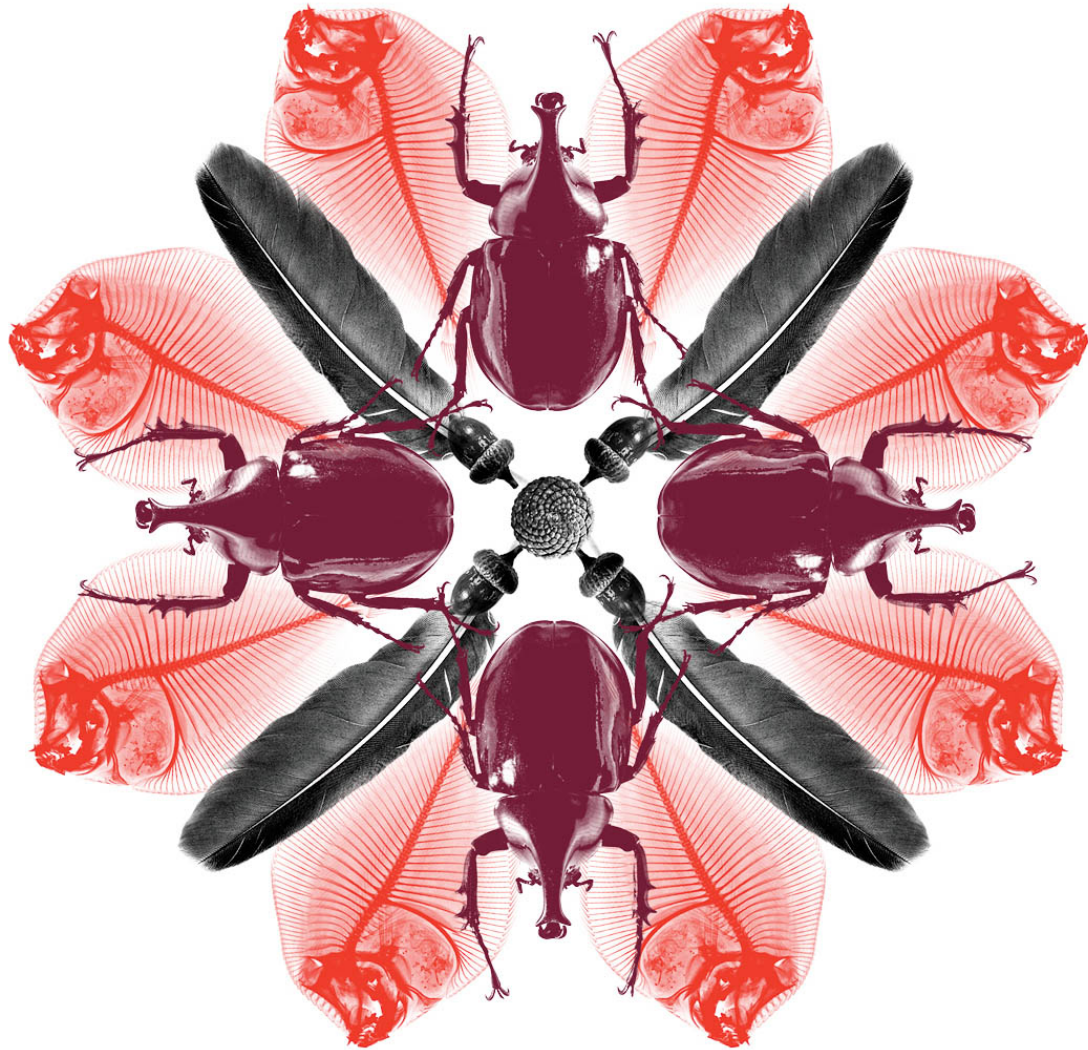


# Approved Arrangements

For 4.2—Gamma irradiation  
Requirements—Version 3.0



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### **Department of Agriculture and Water Resources**

Postal address GPO Box 858

Canberra ACT 2601

Switchboard +61 2 6272 3933

Web [agriculture.gov.au](http://agriculture.gov.au)

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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: 4.2—Gamma irradiation

<b>Date</b>	<b>Version</b>	<b>Amendments</b>	<b>Approved by</b>
9 May 2011	1.0	Revised document	Co-regulation and Support Program
30 Jun 2013	1.1	Updated to reflect DAFF branding	Industry Arrangements Reform Program
8 Feb 2016	2.0	Updated template	Approved Arrangements section
16 Jun 2016	3.0	Updated references to the department and the Biosecurity Act 2015.	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 Purpose**

Requirements	Nonconformity guide
1.1 AA sites utilised for gamma irradiation treatment of goods and packaging, as required by the department. Examples of the types of commodities which may be treated at this type of establishment are rawhide articles.	Not applicable

**Table 2 Site location**

Requirements	Nonconformity guide
2.1 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 3 Biosecurity area**

Requirements	Nonconformity guide
3.1 The biosecurity area must be structurally separated from operations undertaken by legal entities other than the entity operating the AA. The structure/barrier employed to provide the required separation must ensure security of goods subject to biosecurity control and prevent against access by unauthorised persons.	Major

**Table 4 Building and storage areas**

Requirements	Nonconformity guide
4.1 Areas where goods subject to biosecurity control are stored, handled or treated must display a sign to effectively convey that status.	Minor
4.2 Buildings and structures must be maintained in a state of good repair and be weather-proof. Wall and floor junctions must be sealed, or some other measure must be in place to ensure that vegetation does not grow into the building.	Major
4.3 Buildings, designated biosecurity areas and biosecurity inspection areas (including storage and receival zones, chutes etc.), must be kept clean. Cargo and packaging residues, contaminants and spillages must be cleaned up and correctly disposed of as biosecurity waste without delay.	Major

**Table 5 Inspection area**

<b>Requirements</b>	<b>Nonconformity guide</b>
5.1 The biosecurity inspection area must be of a size commensurate with the proposed quantity of goods being handled and must be located within a lockable building, or within a building that is located in an area surrounded by a lockable person-proof security fence.	Critical
5.2 The biosecurity and inspection areas must allow for biosecurity officers to easily inspect goods without work health and safety risks.	Major

**Table 6 Hygiene**

<b>Requirements</b>	<b>Nonconformity guide</b>
<p>6.1 An effective pest control system must be in place to ensure that sites are managed in a way that effectively isolates goods subject to biosecurity control from environments in which pest and disease are likely to become established. As a minimum this will require the sites to implement, and keep associated records of a periodic inspection regime and ensure knockdown spray (i.e. standard household aerosol insecticide spray) is kept onsite. In addition to details of the inspection regime and the onsite location of the knockdown spray, the pest control system may include:</p> <ul style="list-style-type: none"> <li>• the use of insecticides, fumigation, rodenticides, periodic inspection, baits and/or traps</li> <li>• a site plan with numbered bait stations</li> <li>• if applicable, contract details.</li> </ul> <p>Note: The operations of adjacent facilities must be considered when determining any additional pest control measures to be implemented.</p>	Major

**Table 7 Inspection and treatment facilities**

<b>Requirements</b>	<b>Nonconformity guide</b>
7.1 The inspection and treatment facilities must be located within a lockable building or behind a permanently affixed man-proof security fence. Goods subject to biosecurity control must be kept isolated from any other material on the site.	Major
7.2 The equipment must be able to perform to specifications set out in the department's treatment schedule.	Major
7.3 Treated and untreated material that is subject to biosecurity control must be labelled accordingly.	Major
7.4 The gamma irradiation equipment must be regularly maintained. Documented evidence of maintenance must be presented to the biosecurity officer on request.	Major
7.5 The equipment must be fitted with a measuring device which can record the level of irradiation applied to the product at each treatment.	Major

**Table 8 Dunnage and waste**

<b>Requirements</b>	<b>Nonconformity guide</b>
8.1 For any dunnage, packing material and waste inspected and found to contain pests or disease agents, a biosecurity control order will be issued describing the treatment required, location of the treatment and disposal methodology.	Not applicable

**Table 9 Waste disposal**

<b>Requirements</b>	<b>Nonconformity guide</b>
9.1 Sufficient containers of an appropriate size labelled: Biosecurity Waste, are to be provided for loose items, residues, spillages or material of biosecurity concern. Such containers must have lids that remain closed and are to be emptied and if required, disinfected in accordance with any provisions set by the department.	Major or critical



**Table 10 Office and record requirements**

<b>Requirements</b>	<b>Nonconformity guide</b>
10.1 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.	Major
10.2 Records (electronic or manual) of goods subject to biosecurity control imported through the site must be maintained (these can be commercial documents).	Major
<p>10.3 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:</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• providing vehicle parking for visiting biosecurity officers (note: this may require department identified parking or providing a parking permit)</li> <li>• ensuring adequate security for any departmental technical equipment left on the site</li> <li>• providing access and the availability of: <ul style="list-style-type: none"> <li>- a desk, chair and a telephone with direct outside call access</li> <li>- toilet facilities</li> <li>- hand washing facilities and a hygienic means of drying hands</li> <li>- suitable arrangements to ensure amenities are clean.</li> </ul> </li> </ul>	Minor or major
<p>10.4 Records for each consignment of goods subject to biosecurity control must include:</p> <ul style="list-style-type: none"> <li>• biosecurity direction</li> <li>• Import Permit number (if applicable)</li> <li>• description of the goods subject to biosecurity control (including scientific names and quantities, if applicable)</li> <li>• date of receipt of goods and country of origin</li> <li>• details of any treatments</li> <li>• method and date of disposal/destruction of goods subject to biosecurity control and/or biosecurity waste</li> <li>• the date of movement and the department's permission for any movement of goods subject to biosecurity control</li> <li>• comprehensive details of any breaches of goods subject to biosecurity control from the site.</li> </ul>	Major

**Table 11 Administration**

<b>Requirements</b>	<b>Nonconformity guide</b>
11.1 Sites must be securely locked when unattended and after hour access to the sites must be limited to authorised persons only.	Critical
11.2 Control and security of the biosecurity area is the responsibility of the nominated senior person of the company. The name, designation/position title and contact details of the nominated person must be supplied with the application and at each renewal.	Minor
11.3 Department instructions and relevant department Import Permit conditions must be complied with. Where goods are handled for a third party, it is a requirement of approval that the biosecurity industry participant (BIP) have an arrangement in place that ensures they are aware of any relevant permit conditions.	Minor, major or critical
11.4 Applications are to be accompanied by scale drawings of the proposed area and biosecurity storage, treatment/processing facilities including parking for biosecurity officers. In the case of new constructions these plans must be approved before any construction is undertaken.	Minor or major
11.5 To ensure conformance to the AA site requirements, the department must be notified in writing, at least 15 working days prior to any: <ul style="list-style-type: none"> <li>• alterations to site management arrangements</li> <li>• modification to, or closure of, biosecurity areas where goods subject to biosecurity control are stored or treated/processed or otherwise dealt with.</li> </ul>	Major or critical

**Table 12A General**

<b>Requirements</b>	<b>Nonconformity guide</b>
12.1 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
12.2 Goods subject to biosecurity control must be maintained and processed in accordance with the requirements of the relevant AA class.	Minor, major or critical
12.3 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
12.4 Goods subject to biosecurity control must be maintained and processed in accordance with an Import Permit.	Minor, major or critical
12.5 Goods subject to biosecurity control must be maintained and processed in accordance with any other direction from the department.	Minor, major or critical
12.6 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
12.7 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"> <li>• imported items that have been released from biosecurity control</li> <li>• domestic items</li> <li>• the Australian environment.</li> </ul> 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
12.8 The standard of hygiene at the AA site must be appropriate for the nature of the goods subject to biosecurity control.	Major or critical
12.9 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 12B General (continued)**

<b>Requirements</b>	<b>Nonconformity guide</b>
<p>12.10 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"> <li>• moving directly and securely to another AA site, of the appropriate AA class, with prior written approval from the department</li> </ul>	Critical
<ul style="list-style-type: none"> <li>• 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</li> </ul>	
<ul style="list-style-type: none"> <li>• transport of biosecurity waste by a department approved waste transport company (operating under an AA for biosecurity waste transport).</li> </ul> <p>If the items are being transported by a non-accredited person (e.g. a truck driver), the forwarding BIP must ensure that this person is made aware of the conditions relating to the transport of the items.</p>	Major
<p>12.11 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>12.12 An accredited person must personally conduct or directly supervise activities involving physical contact with, or handling of items, subject to biosecurity control.</p> <p>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"> <li>• visually verify for themselves that the items are being handled in accordance with the department's requirements</li> <li>• communicate immediately and effectively with the persons being supervised.</li> </ul>	Major
<p>12.13 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>12.14 Records must be maintained of accredited persons.</p>	Minor
<p>12.15 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

**Table 12C General (continued)**

<b>Requirements</b>	<b>Nonconformity guide</b>
12.16 Ensure records are kept for a minimum of 18 months for goods subject to biosecurity control at the AA site.	Minor or major
12.17 Ensure goods subject to biosecurity control are traceable in terms of (where applicable):	
<ul style="list-style-type: none"> <li>• declaration/entry number</li> <li>• import Permit number</li> <li>• Air Waybill or Bill of Lading number</li> <li>• date of receipt</li> <li>• processing (including inspection, treatment, testing) details</li> <li>• release from biosecurity control</li> <li>• disposal details</li> <li>• storage location</li> <li>• accredited person responsible for the items.</li> </ul>	<ul style="list-style-type: none"> <li>• Major</li> <li>• Major</li> <li>• Minor</li> <li>• Major</li> <li>• Major</li> <li>• Major</li> <li>• Major</li> <li>• Major</li> </ul>
12.18 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
12.19 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"> <li>• appearance of pests or symptoms of disease</li> <li>• structural damage (for example, due to storms)</li> <li>• unauthorised removal of goods subject to biosecurity control</li> <li>• spillages of goods subject to biosecurity control</li> <li>• sudden unavailability of an accredited person.</li> </ul>	<ul style="list-style-type: none"> <li>• Major</li> <li>• Major</li> <li>• Major</li> <li>• Major</li> <li>• Minor</li> </ul>
12.20 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"> <li>• closure of a current AA site</li> <li>• relocation of the business, including the AA class function</li> </ul>	
<ul style="list-style-type: none"> <li>• ceasing of operation as a AA site.</li> </ul> <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 12D General (continued)**

Requirements	Nonconformity guides
<p>12.21 If there is any doubt as to whether goods:</p> <ul style="list-style-type: none"> <li>• are subject to biosecurity control</li> <li>• remain subject to biosecurity control</li> <li>• become subject to biosecurity control</li> </ul> <p>then the goods must be handled in accordance with requirements for goods subject to biosecurity control.</p>	Major
<p>12.22 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:</p> <ul style="list-style-type: none"> <li>• 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></li> <li>• 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></li> <li>• 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>.</li> </ul>	Critical
<p>12.23 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.</p>	Critical
<p>12.24 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.</p>	Major or critical
<p>12.25 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.</p>	Critical
<p>12.26 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.</p>	Major or critical