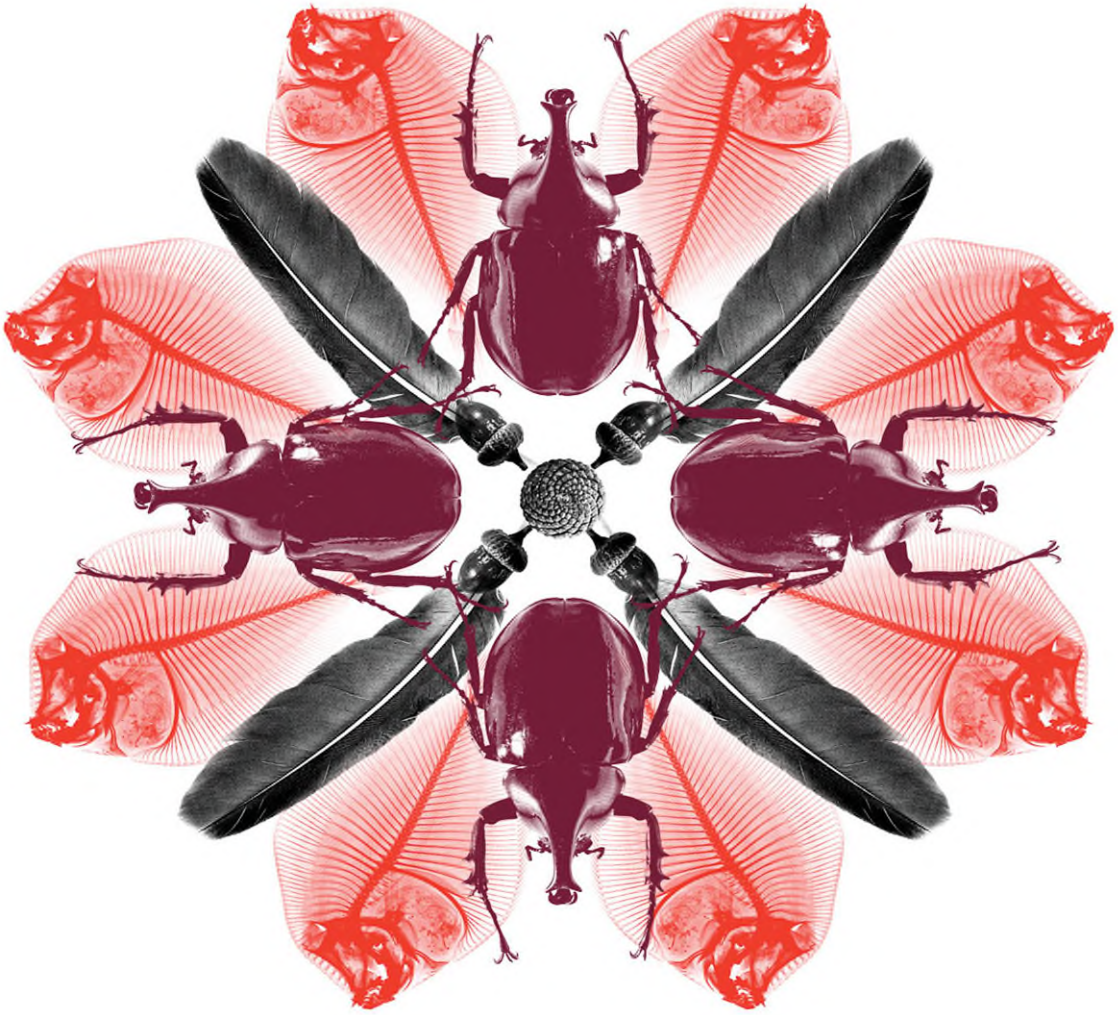
Australian Government
Department of Agriculture, Fisheries and Forestry

Offshore Irradiation Treatment Providers Scheme

Version 1.1



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Acknowledgement of Country

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

Contents

1. Purpose

The purpose of this Offshore Irradiation Treatment Providers scheme is to:

1.1 set out the process for the Australian Department of Agriculture, Fisheries and Forestry (the department) to determine suitability of the Other Party to be able to perform offshore irradiation treatments of goods to be imported into Australia
1.2 effectively manage biosecurity risks of irradiated goods imported into Australia
1.3 define the Other Party's ongoing compliance requirements.

2. Scope

The scheme is only applicable to:

2.1 registered offshore irradiation treatment providers
2.2 the treatment of goods where irradiation is listed as an approved treatment option in the Biosecurity Import Conditions Database (BICON) and relevant import permits
2.3 high dose irradiation of goods at a dose rate of 5 kGray or higher.

The scheme is not applicable to:

2.4 the treatment of goods that require Phytosanitary certification.

3. Definitions

Definitions can be found within the Approved Arrangements Glossary located on the department's website.

Please note: the Other Party is defined as the irradiation treatment provider that has registered on the scheme.

4. Responsibilities

Under this scheme, the Other Party will be responsible for:

4.1 The treatment of goods in accordance with the requirements set out in BICON, relevant import permits and this scheme.
4.2 Ensuring that operations comply with relevant domestic and international regulatory requirements.

5. Eligibility for registration

To be considered for registration, the Other Party must provide:

5.1 the following information:

- facility name (including branch if relevant)
- facility contact (name and position title) that is responsible for compliance with this scheme
- facility address, phone number and email address

- website address.

5.2 current registration/accreditation with the appropriate national and/or international regulatory agency/s

5.3 current International Organisation for Standardisation (ISO) Quality Management System (QMS) registration/s appropriate to irradiation treatments and facilities management

5.4 the following standard operating procedures (SOP) for assessment:

- conducting irradiation treatments
- managing facilities
- commodity integrity/security
- dosimetry
- dose mapping
- failed treatments
- calibration of dosimetry
- record keeping

5.5 any additional information deemed relevant or necessary by the department

5.6 all documentation in English.

6. Registration suitability assessment

Once the eligibility criteria has been received:

6.1 The department will determine the Other Party's suitability for registration against International Standards for Phytosanitary Measures (ISPM) 18 and recognised international irradiation standards.

6.2 The department reserves the right to require an on-site compliance assessment to confirm that a treatment provider's facilities and procedures, including all equipment and operating procedures, meet the department's requirements as per section 14 of this document. This will be conducted at the Other Party's expense as per section 15 of this document.

If the Other Party:

6.3 fails to meet any of the eligibility criteria, the department has the right to refuse registration approval.

6.4 is deemed unsuitable, it will be notified in writing.

7. Registration

7.1 If the Other Party is deemed suitable for registration by the department, they will be listed as approved on the List of Treatment Providers on the department's website and be allocated an Entity Identifier (AEI).

7.2 The department will require the Other Party to sign a letter of agreement acknowledging the scheme requirements in order to complete the registration process.

7.3 Registration will be granted for a period of time at the department's discretion. The registration expiry date will be published on the department's website.

7.4 For the Other Party to extend their registration beyond their registration expiry date, the department will require resubmission of eligibility documentation prior to the registration expiry date.

7.5 If the Other Party ceases to operate, they must notify the department in writing. The department will list the Other Party as 'withdrawn' on the List of Treatment Providers as per section 13 of this document.

8. Treatment and certification

To maintain scheme registration, the Other Party must ensure that:

8.1 All irradiation treatments conducted comply with the department's BICON, relevant import permits and scheme requirements.

8.2 Accurate treatment certification is issued for each treatment with the treatment provider AEI clearly recorded on all certification issued.

8.3 Accurate records of all irradiation treatments, dose mapping, equipment calibration and dosimetry conducted are created and maintained.

9. Records management

The Other Party must ensure that:

9.1 the following documents are made available to the department on request:

- signed letter of agreement and copy of the current Offshore Irradiation Treatment Providers scheme
- all documentation relating to the scheme as referenced in section 5 of this document
- individual treatment records, dose mapping, equipment calibration and dosimetry.

9.2 All records relating to the scheme are maintained for a minimum of two years.

9.3 All records relating to the scheme are available to the department upon request within 48 hours.

10. Non-compliance

10.1 The Other Party will receive a non-compliance notification if the department identifies that a consignment treated by the Other Party has not met the department's requirements.

10.2 Upon notification of non-compliance, the department will automatically refer the Other Party's next ten consignments for departmental intervention and list the Other Party as 'under review' on the List of treatment provider.

10.3 Where no further non-compliance is identified during this period, the Other Party will have their 'approved' status reinstated.

10.4 The department reserves the right to request records from the Other Party relating to non-compliance. These records must be provided to the department within 48 hours of request.

11.Suspension

11.1 The department may suspend the Other Party for failure to treat goods in line with the requirements set out in BICON, relevant import permits and this scheme.

11.2 The Other Party may be suspended when:

- Biosecurity risk material is detected and the Other Party is determined to be at fault.
- The Other Party fails to provide records requested by the department within 48 hours.
- Non-compliance is identified whilst the Other Party is 'under investigation'.
- During an on-site compliance assessment, the Other Party cannot demonstrate compliance with the scheme.

11.3 If suspended, the Other Party must provide satisfactory evidence of corrective actions before the department will consider its eligibility for reinstatement.

11.4 The department reserves the right to require an on-site compliance assessment to determine compliance. This will be conducted at the Other Party's expense as detailed in section 14 of the document.

12.Cancellation

12.1 The department may cancel the Other Party's registration following failure to treat goods in line with the requirements set out in BICON, relevant import permits and this scheme.

12.2 The Other Party's registration may be cancelled if:

- it is suspended on three separate occasions
- the treatment provider has not provided evidence supporting the extension of their registration
- the department considers this course of action justified after one or more significant detections of items of biosecurity concern.

13.Change in circumstance

The Other Party must:

13.1 notify the department in writing within 30 days of any significant changes to their operational circumstances. This includes changes in:

- ownership
- facilities location
- contact details
- operating procedures
- business closure
- national or international regulatory agency registration.

14. On-site compliance assessment

14.1 The department reserves the right to conduct an on-site compliance assessment to verify a treatment provider's ability to meet the requirements set out in BICON, relevant import permits and this scheme.

14.2 An on-site compliance assessment may be required:

- for initial scheme registration
- for the extension of existing scheme registration
- following a failed documentary compliance assessment
- for reinstatement following a period of suspension.

14.3 All costs incurred by the department in conducting on-site compliance assessments will be charged to the Other Party.

14.4 On-site compliance assessments will be conducted by a departmental officer or a third party accompanied by a departmental officer where appropriate.

14.5 On-site compliance assessments will include, but are not limited to, the assessment of the Other Party's:

- equipment and site
- operating procedures
- cleanliness and hygiene practices
- records management and procedures
- staff understanding and management structure to support activities.

14.6 The Other Party must provide a safe working environment at all times during a compliance assessment.

15. Fees and chargeable items

15.1 Compliance assessments will be charged in accordance with the approved arrangements section of the department's charging guidelines.

15.2 All services will be provided in accordance with standards applying to services undertaken in Australia.

15.3 In calculating the applicable rate, all time spent travelling between Australia and the Other Party's facilities shall form part of the services and be charged at the daily or weekly rate regardless of the time of day travel is undertaken.

15.4 In addition to fees for service, all direct costs associated with compliance assessments will be charged to the Other Party. These costs include, but are not limited to:

- third-party assessor charges (if required)
- airfares (business class)
- visa costs
- airport taxes/duties and insurance
- accommodation costs (4-star accommodation or equivalent)
- transport to and from site of inspection
- travel allowance (meals and incidentals)
- Interpreter/representative (if required).