IRRADIATION TREATMENT

REVISION REGISTER

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1. PURPOSE

The purpose of this procedure is to describe -

(a) the principles of operation, design features and standards required for irradiation facilities; and

(b) the responsibilities and actions of personnel;

that apply to the certification of irradiated product under an Interstate Certification Assurance (ICA) arrangement.

2. SCOPE

This procedure covers all certification of irradiated product by a Business operating under an ICA arrangement in Queensland.

This procedure covers the requirements for fruit fly and other plant pests where the requirements in section 6. Requirement are a specified condition of entry of an interstate quarantine authority.

This procedure does not abrogate or override the responsibility of irradiation facilities to comply with the legislative requirements as prescribed in the Radiation Safety Act 1999 and the Food Act 2006.

Certification of irradiated product under this Operational Procedure may not be an accepted quarantine entry condition for all product to all intrastate or interstate markets.

Some intrastate or interstate markets may require additional quarantine certification as a condition of entry.

It is the responsibility of the Business consigning the product to ensure compliance with all applicable quarantine requirements.

Information on interstate quarantine requirements can be obtained from the plant quarantine service in the destination state or territory.

3. REFERENCES

WI-02 Guidelines for Completion of Plant Health Assurance Certificates

Guidelines for the Audit and Accreditation of Irradiation Facilities used for Sanitary and Phytosanitary Treatment of Food and Agricultural Products, 2010. Vienna, Austria.

4. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
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<tbody>
<tr>
<td>accredit</td>
<td>means to accredit persons to issue Assurance Certificates under section 21 of the Plant Protection Act 1989.</td>
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<tr>
<td>Accrediting Authority</td>
<td>means the government department responsible for accrediting a Business under this protocol in the exporting State or Territory.</td>
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<tr>
<td>Application for Accreditation</td>
<td>means an Application for Accreditation of a Business for an Interstate Certification Assurance (ICA) Arrangement [FDU 385].</td>
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<tr>
<td>Assurance Certificate</td>
<td>means a Plant Health Assurance Certificate [FDU 384].</td>
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<tr>
<td>Authorised Signatory</td>
<td>means a person whose name and specimen signature is included as an Authorised Signatory on the Business’s application for accreditation.</td>
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<tr>
<td>Business</td>
<td>means the legal entity responsible for the operation of the facility and ICA arrangement detailed in the business’s Application for Accreditation.</td>
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<tr>
<td>Certification Assurance</td>
<td>means a voluntary arrangement between the Department of Employment, Economic Development and Innovation and a business that demonstrates effective in-house quality management and provides assurance through documented procedures and records that product meets specified requirements.</td>
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<td>Term</td>
<td>Definition</td>
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<tr>
<td>certified/certification</td>
<td>means covered by a valid Plant Health Assurance Certificate [FDU 384].</td>
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<tr>
<td>certified product</td>
<td>means product certified under this procedure.</td>
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<tr>
<td>calibration</td>
<td>means values represented by a material measure or a reference material, and the corresponding values realised by standards.</td>
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<tr>
<td>consignment</td>
<td>means a quantity of product presented on one Plant Health Assurance Certificate. A consignment may contain a number of lots.</td>
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<tr>
<td>commodity</td>
<td>means a type of plant, plant product or other article being moved for trade or other purpose.</td>
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<tr>
<td>cross-contamination</td>
<td>means a process where one product is contaminated directly or indirectly by the exchange of contaminants from another product and/or raw material.</td>
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<tr>
<td>dose or absorbed dose</td>
<td>means the quantity of ionizing radiation energy imparted per unit mass of a specified material. The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 joule per kilogram.</td>
</tr>
<tr>
<td>dose distribution</td>
<td>means the spatial variation of absorbed dose throughout the process load, integrated over a complete treatment. The extreme values are the maximum dose (Dmax) and the minimum dose (Dmin).</td>
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<tr>
<td>dose mapping</td>
<td>means the measurement of dose distribution and variability in material irradiated under specified conditions.</td>
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<tr>
<td>dosimeter</td>
<td>means a device which has a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system.</td>
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<td>dosimetry</td>
<td>means the measurement of absorbed dose by the use of dosimeters.</td>
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<tr>
<td>dosimetry system</td>
<td>means the procedures and interrelated elements used for determining absorbed dose, including dosimeters, instruments and associated reference standards.</td>
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<tr>
<td>food irradiation</td>
<td>means the process of exposing food to ionizing radiation.</td>
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<tr>
<td>fruit fly</td>
<td>means fruit fly of the family Tephritidae.</td>
</tr>
<tr>
<td>FSANZ</td>
<td>means Food Standards Australia New Zealand.</td>
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<tr>
<td>ICA</td>
<td>means Interstate Certification Assurance.</td>
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<td>Term</td>
<td>Definition</td>
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<tr>
<td>Interstate Certification Assurance</td>
<td>means a system of Certification Assurance developed to meet the requirements of State and Territory governments for the certification of produce for interstate and intrastate quarantine purposes.</td>
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<tr>
<td>Inspector</td>
<td>means an inspector appointed under the Plant Protection Act 1989.</td>
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<tr>
<td>irradiation</td>
<td>means a process of exposing material to ionizing radiation.</td>
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<tr>
<td>irradiation container</td>
<td>means a holder in which product is transported through the irradiator. The holder can be a carrier, cart, tray, product carton, pallet, tote or other container.</td>
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<tr>
<td>irradiation facility</td>
<td>means an establishment where the irradiation process is performed. There are different types of irradiation facilities depending on the irradiator type, the radiation source, the conveyor system, and the operating mode.</td>
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<tr>
<td>irradiation operator</td>
<td>means an individual who has undergone a training program approved by the relevant nuclear regulatory authority.</td>
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<tr>
<td>irradiator</td>
<td>means the assembly of equipment and its housing where product is exposed to ionizing radiation.</td>
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<tr>
<td>ISO</td>
<td>International Organisation for Standardisation.</td>
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<tr>
<td>loading configuration</td>
<td>means defined arrangement of product placed in or on the irradiation container. Dose mapping is carried out for a particular loading configuration and this loading configuration is replicated to ensure consistent irradiation of product.</td>
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<tr>
<td>lot</td>
<td>means a quantity of homogeneous product assembled for treatment at one place at one time. A lot could consist of product from one or more growers/blocks/properties.</td>
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<tr>
<td>nonconformance</td>
<td>means a nonfulfilment of a specified requirement.</td>
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<tr>
<td>pests</td>
<td>means fruit fly, mango seed weevil and other animals of the phylum Arthropoda (excluding Lepidopteron that pupate internally).</td>
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<tr>
<td>phytosanitary measure</td>
<td>means any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.</td>
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<tr>
<td><strong>Name</strong></td>
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<tr>
<td>product</td>
<td>means fresh fruit and vegetables approved by Food Standards Australia New Zealand (FSANZ) to be irradiated.</td>
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<tr>
<td>radiation source</td>
<td>means a device that emits ionizing radiation.</td>
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<tr>
<td>radionuclide</td>
<td>means a radioactive isotope of an element (e.g. cobalt-60 or cesium-137).</td>
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<tr>
<td>regulated pest</td>
<td>means a quarantine pest or a regulated non-quarantine pest.</td>
</tr>
<tr>
<td>re-infestation</td>
<td>the renewed presence, in a commodity, of a living pest of the plant or plant product concerned. Re-infestation includes re-infection.</td>
</tr>
<tr>
<td>secure conditions</td>
<td>means secured in a manner that prevents pest infestation and/or re-infestation.</td>
</tr>
<tr>
<td>treatment</td>
<td>means an official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalisation.</td>
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5. **RESPONSIBILITY**

*These position titles have been used to reflect the responsibilities of staff under the ICA arrangement. These positions may not be present in all Businesses, or different titles may be used for staff who carry out these responsibilities. In some Businesses one person may carry out the responsibilities of more than one position.*

The **Certification Controller** is responsible for -

- representing the Business during audits and other matters relevant to ICA accreditation;
- ensuring the Business has current accreditation for an Interstate Certification Assurance arrangement under this Operational Procedure;
- training staff in their responsibilities and duties under this Operational Procedure;
- ensuring the Business and its staff comply with their responsibilities under this Operational Procedure;
- ensuring that all irradiation treatment of product certified under the Business’s ICA arrangement is carried out in accordance with this Operational Procedure;
- ensuring all irradiation treatments are performed by a qualified Irradiation Operator (refer 6);
- ensuring the irradiation facility has been approved by the relevant nuclear regulatory Authority (as applicable) (refer 7.2);
- ensuring the irradiation source records are maintained (refer 7.2.1);
- ensuring the Irradiation Operator has carried out maintenance in accordance with this Operational Procedure (refer 7.2.2);
- ensuring equipment and calibration records are maintained (refer 7.3)
The **Irradiation Operator** is responsible for -

- ensuring radiation treatments of products are conducted in accordance with this Operational Procedure (refer 7.7);
- ensuring dose mapping and dosimetry are conducted in accordance with this Operational Procedure (refer 7.4 and 7.5);
- ensuring the maintenance plan is conducted in accordance with the Operational Procedure (refer 7.2.2);
- ensuring records of treatment are maintained (refer 7.9);
- ensuring nonconforming produce is managed in accordance with the Operational Procedure (refer 7.8).

The **Product Recieval Officer** is responsible for –

- ensuring product recieval records are maintained (refer 7.6.1);
- identifying and controlling treated and untreated product at the facility (refer 7.6.2).

The **Authorised Dispatcher** is responsible for -

- ensuring all packages covered by an Assurance Certificate issued by the Business are identified (refer 7.11.1);
- maintaining copies of all Assurance Certificates issued by the Business under the ICA arrangement (refer 7.12).

**Authorised Signatories** are responsible for -

- ensuring, prior to signing and issuing an Assurance Certificate, that product covered by the certificate has been prepared in accordance with the Business’s ICA arrangement and that the details on the certificate are true and correct in every particular (refer 7.11.3).

6. **REQUIREMENT**

Fresh fruit and vegetables certified under this Operational Procedure must be approved by FSANZ to be irradiated and must be treated in accordance with the following requirements –

Minimum absorbed dose of 150 Gy for fruit flies of the family Tephritidae (Diptera – Tephritidae)

Minimum absorbed dose of 300 Gy for Mango Seed Weevil (*Stemochetus mangiferae*)

Minimum absorbed dose of 400 Gy for all pests of the phylum Arthropoda (excluding Lepidopteron that pupate internally).

All irradiation treatments must be carried out by an appropriately qualified Irradiation Operator.

Irradiation facilities operating under this Operational Procedure must comply with all relevant requirements of the local, state and Commonwealth government, environmental and workplace health and safety authorities.
Irradiation sterilises or prevents further life cycle development of the target pest. The use of a pest sterilisation dose, rather than a pest mortality dose, has been adopted as an international standard to ensure that products are exposed to the minimum dose possible in consideration of food safety standards, while still meeting phytosanitary requirements.

The Department of Employment, Economic Development and Innovation and interstate quarantine authorities maintain the right to inspect at any time certified product and to refuse to accept a certificate where product is found not to conform to specified requirements.

Some product may be damaged by irradiation treatments. Businesses applying irradiation treatments should check with experienced persons such as departmental officers for any available information. Testing of small quantities is recommended.

Following the required treatments in this procedure does not absolve the Business from the responsibility of ensuring that treated product does not exceed the maximum dose specified by FSANZ Standard 1.5.3 Irradiation of Food.

7. PROCEDURE

7.1 Accreditation

7.1.1 Application for Accreditation

A Business seeking accreditation for an ICA arrangement under this Operational Procedure shall make application for accreditation (refer Attachment 1) at least 10 working days prior to the intended date of commencement of certification of product.

7.1.2 Audit Process

Initial Audit

Prior to accrediting a Business, an initial audit of the Business is carried out to verify the ICA system is implemented and capable of operating in accordance with the requirements of the Operational Procedure, and the system is effective in ensuring compliance with the specified requirements of the ICA arrangement.
On completion of a successful initial audit, applicants will be granted provisional accreditation and provided a Certificate of Accreditation (refer 7.1.3 Certificate of Accreditation).

**Compliance Audits**

Compliance audits are conducted to verify that the ICA system continues to operate in accordance with the requirements of the Operational Procedure.

Compliance audits are, wherever practical, conducted when the ICA system is operating.

A compliance audit is conducted within four weeks of the initial audit and accreditation of the Business.

On completion of a successful compliance audit, annual accreditation is granted to cover the current season, up to a maximum of twelve months from the date of provisional accreditation, and a new Certificate of Accreditation issued (refer 7.1.3 Certificate of Accreditation).

A compliance audit is conducted between six and nine months after the date of accreditation for an ICA arrangement that operates for more than six months of the year.

Random audits are conducted on a selected number of accredited Businesses each year. Random audits may take the form of a full compliance audit, or audits of limited scope to sample treatment mixtures, certified product, ICA system records or ICA system documentation.

Unscheduled compliance audits may be conducted at any time to investigate reported or suspected nonconformances.

**Re-Accreditation**

Accredited Businesses are required to re-apply for accreditation each year the Business seeks to operate under the ICA arrangement. Businesses seeking re-accreditation must lodge a renewal application prior to accreditation lapsing, or if accreditation has lapsed, prior to commencing further certification of product under the ICA arrangement.

A compliance audit is conducted within twelve weeks of the Business applying for re-accreditation each year.

A compliance audit is conducted between six and nine months after the date of re-accreditation for an ICA arrangement that operates for more than six months of the year.
7.1.3 Certificate of Accreditation

An accredited Business will receive a Certificate of Accreditation for an Interstate Certification Assurance Arrangement detailing the scope of the arrangement including –

- the facility location;
- the Operational Procedure;
- any restrictions on the accreditation such as –
  - type of product,
  - treatment covered; and
- the period of accreditation.

The Business must maintain a current Certificate of Accreditation and make this available on request by an Inspector.

A Business may not commence or continue certification of product under the ICA arrangement unless it is in possession of a valid and current Certificate of Accreditation for the facility, procedure, product type and chemical covered by the Assurance Certificate.

7.2 Irradiation Facility Requirements

The Certification Controller shall maintain documentary evidence that the irradiation facility has current approval by the relevant nuclear regulatory authority. An irradiation facility consists of an irradiator, receive and dispatch areas, storage areas for irradiated and non-irradiated products, conveyor systems, safety systems and the infrastructure for personnel and facility services including record control.

Each irradiation facility under this Operational Procedure must -

(a) be able to provide doses within limits specified and prescribed for phytosanitary requirements; and

(b) be designed to provide segregated storage for irradiated and non-irradiated products and prevent cross contamination and post treatment re-infestation.

The irradiator shall provide for the safe and reliable radiation processing and includes the source of radiation and associated mechanisms together with the conveyor, safety devices and biological shield.

7.2.1 Radiation Source

The Business shall not exceed the maximum energy level for the purpose of food irradiation set by FSANZ. The Certification Controller shall maintain records that specify the radiation source (e.g. gamma) and in the case of X-rays or electron beams, the energy of radiation shall be specified.
For a gamma irradiation irradiator, the Certification Controller shall maintain records that provide the following details-
(a) the type of radionuclide, its activity, and source geometry;
(b) the means of indicating the position of the gamma source;
(c) the means of returning the gamma source to the storage position and ceasing conveyor movement if the process control timer or the conveyor system fails; and
(d) the means of returning the gamma source to the storage position, and automatically ceasing conveyor movement or identifying affected product if the gamma source is not at its intended position.

For an electron beam or X-ray irradiator, the Certification Controller shall maintain records that provide the following details-
(a) the characteristics of the beam (electron or X-ray energy, and if applicable average beam current, dose rate, scan width and scan uniformity);
(b) for X-ray irradiators, the dimensions, materials and construction of the X-ray converter;
(c) the means of indicating that the beam and the conveyor system are operating;
(d) the means of ceasing irradiation if any failure of the conveyor occurs which affects the dose and product requirements; and
(e) the means of ceasing conveyor movement or identifying affected product if any fault in the beam occurs.

### 7.2.2 Irradiator and Irradiator Equipment Maintenance

A maintenance plan (including preventive actions, procedures and records) shall be maintained by the Business. Equipment shall not be used to treat product until all specified maintenance tasks have been satisfactorily completed and recorded. The Certification Controller must record irradiator and irradiator equipment maintenance using an Irradiator and Irradiator Equipment Maintenance Plan Record (refer Attachment 3) or records which capture the same information.

The maintenance plan shall provide the following details-
(a) the accredited Business name and address;
(b) the date of the maintenance task/routine check;
(c) the identification of the equipment that the maintenance task/routine check was performed on;
(d) actions taken to perform the maintenance task/routine check;
(e) intervals specifying when the maintenance/routine checks are performed; and
(f) the printed name and signature of the Irradiator Operator that conducted the maintenance task.

7.3 Equipment calibration and test

The Certification Controller shall maintain equipment calibration and test records for plant and equipment used in the irradiation process. Equipment shall not be used unless calibrated satisfactory and recorded. The Certification Controller must record equipment calibration using an Equipment Calibration and Test Record (refer Attachment 4) or records which capture the same information.

The calibration and test record shall provide the following details-
(a) the accredited Business name and address;
(b) the date of the calibration and test;
(c) the identification of the equipment that the calibration was performed on;
(d) intervals specifying when the calibrations are performed; and
(e) the printed name and signature of the operator that conducted the calibration and test.

The Certification Controller shall ensure the dosimetry system is calibrated in accordance with international standards or appropriate national standards (e.g. Standard ISO/ASTM 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing).

7.4 Dose Mapping

The Irradiation Officer shall perform dose mapping to establish the dose distribution within the product to demonstrate that the treatment consistently meets the prescribed requirements under defined and controlled conditions.

For dose mapping, the Irradiation Officer shall place sufficient dosimeters throughout the product that is to be passed through the irradiator. The positioning of the dosimeters will depend on the composition, density, configuration of the packaging and shape and or size of the product.

The variations in dose shall be determined by mapping the dose distribution in at least three process loads with the same product loading configuration and irradiation conditions.

The Irradiation Officer must record dose mapping using a Dose Mapping Record (refer Attachment 5) or records which capture the same information.

The dose mapping record shall provide the following details-
(a) the name and address of the accredited Business;
(b) the time and date when the dose mapping occurred;
(c) the dimensions and packaging of the product;
(d) geometric packaging configuration;
(e) the loading pattern of the dose mapped product;
(f) the location of the dosimeters within the product;
(g) the type of dosimeter;
(h) the duration of irradiation;
(i) the minimum and maximum absorbed doses in the product; and
(j) the printed name and signature of the operator that conducted dose mapping.

The product dose mapping shall be repeated if changes are made, either in the facility or in a operation mode that could affect the magnitudes or locations of the maximum and minimum doses.

7.5 Dosimetry

The Irradiation Officer shall perform routine dosimetry to ensure that the specified dose is received by the product. Dosimeter(s) shall be placed, in the process load, at the predetermined maximum and minimum dose positions, or at a qualified reference dose location. Dosimetry shall be performed for each lot.

The Irradiation Officer shall record the minimum and maximum absorbed dose from the routine dosimetry using the Irradiation Treatment Record (refer 7.9 Treatment Records) or records which capture the same information.

The Irradiation Officer shall ensure dosimetry is in accordance with international standards or appropriate national standards (ISO/ASTM 51275, ISO/ASTM 51276, ISO/ASTM 51538, ISO/ASTM 51607, ISO/ASTM 51631 and ASTM F1355-06).

7.6 Pre Treatment

7.6.1 Product receival

The Product Receival Officer shall maintain a product receival record for quantifying product and maintaining product inventory throughout product receiving, loading, unloading, handling and release.

The product receival record shall provide the following details:
(a) product name, quantity and description;
(b) package dimensions, weight, shape, configuration and packaging;
(c) purpose of the irradiation treatment;
(d) information and necessary means of identifying the product to be irradiated; and
(e) required minimum absorbed dose.
Incoming product shall be logged and given a unique identification code related to each customer lot that will identify the lot at each step as the lot passes through the facility. The facility design and administrative procedures shall ensure that irradiated and non-irradiated products are segregated at all times.

### 7.6.2 Identification and Control of Treated and Untreated Product

The Product Receival Officer shall have procedures in place which prevent mixing of treated and untreated product at the facility.

Examples of acceptable methods of identifying the treatment status of treated and untreated product include:

(a) locating untreated product in a clearly identified area separate to treated product and maintaining separation until dispatch; or

(b) marking each package of treated product in a manner that clearly identifies the product as conforming to the requirements specified under this Operational Procedure (refer 7.11.1 Package Identification).

Other methods may be used provided they clearly identify and segregate treated and untreated product.

### 7.7 Treatment

The Irradiation Operator shall ensure product to be irradiated is assembled in accordance with the specified packaging configuration established during dose mapping. The treatment procedure shall ensure that the minimum absorbed dose is attained throughout the product in accordance with the requirements specified in Section 6 Requirement.

The Irradiation Operator shall record the minimum and maximum absorbed dose using the Irradiation Treatment Record (refer 7.9 Treatment Records) or records which capture the same information.

The Irradiation Operator shall ensure irradiation treatment is in accordance with international standards or appropriate national standards (refer ISO/ASTM 51275, ISO/ASTM 51276, ISO/ASTM 51538, ISO/ASTM 51607, ISO/ASTM 51631 and ASTM F1355-06).

### 7.8 Nonconforming Product

Where the absorbed dose recorded during treatment does not meet FSANZ and/or quarantine requirements the following actions shall be taken by the Irradiation Operator:

(a) all product from the treatment lot shall be rejected for certification;

(b) all rejected product shall be isolated and clearly identified to prevent mixing with any other product;
(c) as soon as practicable and not more than one (1) working day from the time of detection, the nonconformance shall be reported to the Accrediting Authority so an investigation may be carried out to determine the cause and rectify any problems.

**It is the responsibility of the Accredited Business to ensure non conforming and rejected product does not breach the requirements specified by the FSANZ Standard 1.5.3 Irradiation of Food.**

### 7.9 Treatment Records

The Irradiation Operator must record each irradiation treatment using an Irradiation Treatment Record (refer Attachment 6) or records which capture the same information.

Treatment records must identify -

- accredited Business name;
- name and signature of the Irradiation Operator;
- description of goods;
- grower brand name or identifying marks;
- quantity treated;
- pest to be treated;
- radiation source;
- date of treatment;
- place of treatment;
- identification of treatment facility;
- minimum and maximum absorbed dose (specified and actual);
- lot number;
- owner of the consignment if different from the growers name; and
- any observed deviation from the treatment specification.

### 7.10 Post Treatment Security

Treated fruit shall be held for the minimum practical period after treatment before it must be secured against infestation.

Completed pallets shall be held for the minimum practical period before placing in secure conditions that prevent infestation.

Certified fruit must be transported from the facility in secure conditions which prevent infestation by fruit fly.

Secure conditions include-

(a) unvented packages;

(b) vented packages with the vents secured with gauze/mesh with a maximum aperture of 1.6 mm;
(c) fully enclosed under tarpaulins, hessian, shade cloth, mesh or other covering which provides a maximum aperture of 1.6 mm;
(d) shrinkwrapped and sealed as a palletised unit;
(e) fully enclosed or screened buildings, coldrooms, vehicles or other facilities free from gaps or other entry points greater than 1.6 mm.

Fruit consigned to Tasmania must be transported in full container lots sealed prior to transport, or as lesser container lots in accordance with the requirements of (a), (b) or (d) above.

Where consignments are transported to Tasmania as full container lots, the seal number must be included in the Brand Name or Identifying Marks section of the Assurance Certificate covering the consignment (refer Attachment 2).

Where consignments are transported in vented packages that are sealed as a palletised unit in accordance with (d) above, the Business must secure the top layer of the pallet by applying a continuous band of tape over the shrinkwrap and have applied to the tape in waterproof ink the signature of an Authorised Signatory, the number of the Plant Health Assurance Certificate covering the consignment and the date of treatment.

7.11 Dispatch

7.11.1 Package Identification

The Authorised Dispatcher shall ensure that each package of certified product is marked in indelible and legible characters of at least 5 mm, with:
- the Interstate Product number of the Business that operates the approved facility in which the product was treated;
- the words “MEETS ICA-55”; and
- the date (or date code) on which the product was treated.

prior to the issuance of an Assurance Certificate by the Business under this Operational Procedure.

7.11.2 Package labelling

The labelling of packages must comply with Food Standard Australia New Zealand Standard 1.5.3. Irradiation of Food (Issue 53).

Packages may be marked prior to irradiation treatment, however any packages containing product that has not been treated in accordance with the requirements of this Operational Procedure or FSANZ Standard 1.5.3 must have package identification removed or obscured.
7.11.3 Assurance Certificates

The Authorised Dispatcher shall ensure an Assurance Certificate is completed and signed by an Authorised Signatory of the Business prior to dispatch of the consignment from the facility to a market requiring certification for irradiation.

Assurance Certificates shall be in the form of a *Plant Health Assurance Certificate* [FDU 384]. A completed example is shown as Attachment 2.

Individual Assurance Certificates shall be issued to cover each consignment (ie. a discrete quantity of product transported to a single consignee at one time) to avoid splitting of consignments.

Assurance Certificates shall be completed, issued and distributed in accordance with the Work Instruction *Guidelines for Completion of Plant Health Assurance Certificates* [WI-02].

7.11.4 Assurance Certificate Distribution

The original (yellow copy) must accompany the consignment.

The duplicate (white copy) must be retained by the Business.

7.12 ICA System Records

The Business shall maintain the following records: -

(a) a copy of each *Plant Health Assurance Certificate* [FDU 384] issued by the Business (refer 7.11.4);
(b) Irradiator and Irradiatory Equipment Maintenance Plan (refer Attachment 3);
(c) Equipment Calibration and Test Record (refer Attachment 4);
(d) Dose Mapping Record (refer Attachment 5); and
(e) Irradiation Treatment record (refer Attachment 6)

ICA system records shall be retained for a period of at least 12 months from completion, or until the next compliance audit of the ICA arrangement, whichever is the later.

An accredited Business must hold a minimum of 12 months ICA system records at the time of any compliance audit. If the compliance audit is conducted more than 12 months from the last compliance audit, the Business must maintain all records completed since the previous compliance audit.

ICA system records shall be made available on request by an Inspector.
7.13 ICA System Documentation

The Business shall maintain the following documentation-

(a) a copy of the Business’s current Application for Accreditation (refer Attachment 1);

(b) a current copy of this Operational Procedure;

(c) a current Certificate of Accreditation for an Interstate Certification Assurance (ICA) Arrangement;

(d) evidence that the facility has current approval from a relevant nuclear authority (refer 7.2);

(e) evidence of the irradiation source used at the facility (refer 7.2.1); and

(f) evidence of the product recieval system implemented at the facility (refer 7.6.1).

ICA system documentation shall be made available on request by an Inspector.

8. ATTACHMENTS

Attachment 1 Application for Accreditation of a Business for an Interstate Certification Assurance (ICA) Arrangement FDU 385 (FRONT PAGE ONLY)

Attachment 2 Plant Health Assurance Certificate FDU 384 (COMPLETED EXAMPLE)

Attachment 3 Irradiator and Irradiator Equipment Maintenance Plan (BLANK)

Attachment 4 Equipment Calibration and Test Record (BLANK)

Attachment 5 Dose Mapping Record (BLANK)

Attachment 6 Irradiation Treatment Record (BLANK)
Application for Accreditation of a Business for an Interstate Certification Assurance (ICA) Arrangement

Indicate the type of application being made

- [ ] New
- [ ] Renewal
- [ ] Amendment

Tick each box that describes your business and the type of application and provide specific details where required. Only one ICA arrangement, that is one Operational Procedure at one facility, may be covered in one application.

1. **Business Details**

(a) **Type of Ownership of Business**
- [ ] Individual
- [ ] Incorporated Company
- [ ] Partnership
- [ ] Cooperative Association
- [ ] Other

(b) **Name of Applicant/s**
(Print your full name including any given names. For partnerships, print the full name of each partner in their normal order. For incorporated companies and cooperatives, print the full registered name of the organisation.)

(c) **Trading Name/s of the business**
.include any business or brand names used by the business on packages of certified produce"

(d) **Postal address of the business**

- [ ] Telephone: ( )
- [ ] Facsimile: ( )
- [ ] Mobile:

(e) **Has the business been registered previously in Q’ld for the interstate movement of produce?**
- [ ] No
- [ ] Yes ✗

   If yes, give the business's Interstate Produce (IP) Number

2. **Operational Procedure and Facility Details**

(a) **Operational Procedure used in this ICA arrangement**
(refer to list of Operational Procedures)

   - [ ] ICA Part A
   - [ ] ICA Part B
   - [ ] ICA Parts A & B

   If the Operational Procedure is documented in two parts, indicate the part or parts for which you are seeking accreditation.

   **Title of Operational Procedure**
   (print the full title of the Operational Procedure)

(b) **Street address of the facility**

- [ ] Telephone: ( )
- [ ] Facsimile: ( )
- [ ] Mobile:

3. **Authorised Signatories**

   **(for Assurance Certificates)**

   - [ ] Certification Controller
   - [ ] Back-Up Certification Controller
   - [ ] Additional Authorised Signatories

   **Family Name**
   **Given Name/s**
   **Specimen Signature**

Form FDU 385  03/00  Page 1 of 2  © State of Queensland 2000

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ATTACHMENT 1
# Plant Health Assurance Certificate

**Consignor**

Name: Mal's Mangoes P/L  
Address: 123 Mango Road, Bowen QLD 4805

**Consignee**

Name: F&V Wholesalers P/L  
Address: Melbourne Markets, Footscray VIC 3011

**Reconsignment (Splitting consignments or reconsigning whole consignment)**

Name:  
Address:  

**Method of Transport (Provide details where known)**

- [x] Road
- [ ] Rail
- [ ] Air
- [ ] Sea

**Certification Details**

**Accredited Business that Prepared the Produce**

Name: Gray’s Irradiation P/L  
Address: Smith St, Rocklea QLD 4106

**Grower or Packer**

Name: Mal’s Mangoes P/L  
Address: 123 Mango Road, Bowen QLD 4805

**IP No. of Acc. Business**  
Q 9999

**Brand Name or Identifying Marks (as marked on packages)**  
Mal’s Mangoes P/L

**Date Code (as marked on packages)**  
110124

<table>
<thead>
<tr>
<th>Facility No.</th>
<th>Procedure Code</th>
<th>Expiry Date</th>
<th>Facility No.</th>
<th>Procedure Code</th>
<th>Expiry Date</th>
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</thead>
<tbody>
<tr>
<td>01</td>
<td>ICA-55</td>
<td>10/09/11</td>
<td>/</td>
<td></td>
<td>/</td>
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</tbody>
</table>

**Number of Packages**  
200 cartons

**Type of Produce**  
mangoes

**Authorisation for Split Consignment**

<table>
<thead>
<tr>
<th>Date</th>
<th>Treatment</th>
<th>Chemical (Active Ingredient)</th>
<th>Concentration</th>
<th>Duration and Temperature</th>
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<tbody>
<tr>
<td>24/01/11</td>
<td>Irradiation</td>
<td>150 Gy</td>
<td></td>
<td></td>
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</tbody>
</table>

**Additional Certification**

- Bananas in a hard green condition with unbroken skin

**Declaration**

I, an Authorised Signatory of the accredited business that prepared the plants or plant produce described above, hereby declare that the plants or plant produce have been prepared in the business’s approved facilities in accordance with the accreditation(s) granted to the business under the Plant Protection Act 1982 and that the details shown above are true and correct in every particular.

**Authorised Signatory’s Name** (Please print)  
Arthur John Signatory

**Signature**  
Aj Signatory

**Date**  
24/01/11

**Form** FDU 384  
0708

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Forms Management Unit

**ATTACHMENT 2**
<table>
<thead>
<tr>
<th>Accredited Business Name and Address</th>
<th>Interstate Product No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of maintenance task/routine check</td>
<td>Q</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Identification of equipment that the maintenance task/routine check was performed on</th>
<th>Actions taken to perform the maintenance task/routine check</th>
<th>Intervals specifying when maintenance/routine checks are performed</th>
<th>Printed name and signature of Irradiator Operator that conducted the maintenance task</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>
## EQUIPMENT CALIBRATION AND TEST RECORD

<table>
<thead>
<tr>
<th>Accredited Business Name and Address</th>
<th>Interstate Product No: Q</th>
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</thead>
<tbody>
<tr>
<td>Date of calibration and test</td>
<td>Identification of Equipment that the calibration was performed on</td>
</tr>
<tr>
<td></td>
<td>Intervals specifying when calibrations are performed</td>
</tr>
<tr>
<td></td>
<td>Printed name and signature of operator that conducted the maintenance task</td>
</tr>
</tbody>
</table>

<p>| | | | |
|                                      |                                      |                                      |                                      |</p>
<table>
<thead>
<tr>
<th>Accredited Business Name and Address</th>
<th>Interstate Product No: Q</th>
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</thead>
<tbody>
<tr>
<td><strong>DOSE MAPPING RECORD</strong></td>
<td></td>
</tr>
<tr>
<td>Time and date when dose mapping occurred</td>
<td>Dimensions and packaging of product</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------------------</td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Accredited Business Name</td>
<td>Interstate Product No:</td>
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<tr>
<td>-------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Date of Treatment:</td>
<td>/ /</td>
</tr>
<tr>
<td>Irradiator Operator Name and Signature:</td>
<td></td>
</tr>
<tr>
<td>Consignment Owner:</td>
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</tr>
<tr>
<td>Maximum Dose Gy</td>
<td>Minimum Dose Gy</td>
</tr>
<tr>
<td>Grower/Packer Name</td>
<td>Grower/Packer Name</td>
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<tr>
<td>Number of Packages</td>
<td>Product Type (eg Banana)</td>
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<tr>
<td>Time Treatment Commence</td>
<td>Time Treatment Finished</td>
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<tr>
<td>Time Treatment Finished</td>
<td>ID Code (if applicable)</td>
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</tbody>
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