ICA-55: Irradiation Treatment

REVISION REGISTER

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22/08/2019	Version 1.0: New Procedure
31/12/2020	Version 1.1: update procedure to new format; addition of the Act to references (3)
05/10/2022	Version 1.2: update of reference (3) change name of PSW-02 to SOP, update of host product list to include cut flowers, change of produce to product, add definition for Serpentine leafminer and definition of pupate internally.
12/05/2023	Version 1.3: review and update of department name; inclusion for entry into Tasmania with the acceptance of one label affixed to a secure pallet (7.10.1); update of labelling for entry into Tas (7.10.1).

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AGRICULTURE VICTORIA

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1 Purpose

The purpose of this procedure is to describe:

- the principles of operation, design features and standards required for irradiation facilities; and
- 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 Victoria.

This procedure covers the requirements for fruit fly and other plant pests where the requirements in section 6 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 Act 2005 and the Food Act 1984.

Certification of irradiated product under this 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 produce to ensure compliance with all applicable quarantine requirements.

Information on intrastate quarantine requirements can be obtained from a local Agriculture Victoria Inspector.

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

Agriculture Victoria and interstate quarantine authorities maintain the right to inspect at any time produce and to refuse to accept a certificate where produce is found not to conform to specified requirements.

3 References

Act	The Plant Biosecurity Act 2010 (the Act)
FSANZ Standard 1.5.3	Food Standard Australia New Zealand, Irradiation of Food (Issue 53)

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

ISPM No. 18, FAO Rome	Guidelines for the use of irradiation as a phytosanitary measure, 2003.
ISO/ASTM 51261	Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing
ISO/ASTM 51275	Practice for using Radiochromic film

ISO/ASTM 51276	Practice for use of a polymethylmethacrylate dosimetry system
ISO/ASTM 51538	Practice for use of the ethanol-chlorobenzene dosimetry system
ISO/ASTM 51607	Practice for use of the alanine-EPR dosimetry system
ISO/ASTM 51631	Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations
ISO/ASTM F1355-06	Standard guide for irradiation of fresh agricultural produce as a phytosanitary treatment

Standard Operating Procedure - Completion of Plant Health Assurance Certificates

4 Definitions

Accredit	means to authorise nominated staff within a business to issue assurance certificates.
Accrediting Authority	means the government department responsible for accrediting a business under this protocol in the exporting State or Territory.
Act	means the Plant Biosecurity Act 2010 (the Act).
Application for Accreditation	means an Application for Accreditation of a business for an Interstate Certification Assurance (ICA) arrangement.
Assurance Certificate	means a Plant Health Assurance Certificate (PHAC).
ASTM	American Society for Testing and Materials.
Audit	means the verification activity for evaluation of conformance or non-conformance with accreditation requirements.
Authorised Inspector	means an inspector authorised under the Act.
Authorised Signatory	means an employee of an ICA accredited business whose name and specimen signature is provided on the business's Authorised Signatory form.
Business	means the legal entity responsible for the operation of the facility and ICA arrangement detailed on the business's Application for Accreditation.
Calibration	means values represented by a material measure or a reference material, and the corresponding values realised by standards.
Certification Assurance	means a voluntary arrangement between the Accrediting Authority and a business that demonstrates effective in-house quality management and provides assurance through documented procedures and records that product meets specified requirements.
Certified/Certification	means covered by a valid Plant Health Assurance Certificate.

Certified product	means product certified under this procedure.
Consignment	means a quantity of product presented on one Plant Health Assurance Certificate. A consignment may contain a number of lots.
Commodity	means a type of plant, plant product or other article being moved for trade or other purpose.
Cross- contamination	means a process where one product is contaminated directly or indirectly by the exchange of contaminants from another product and/or raw material.
Dose or absorbed dose	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.
Dose distribution	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).
Dose mapping	means the measurement of dose distribution and variability in material irradiated under specified conditions.
Dosimeter	means a device which has a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system.
Dosimetry	means the measurement of absorbed dose by the use of dosimeters.
Dosimetry system	means the procedures and interrelated elements used for determining absorbed dose, including dosimeters, instruments and associated reference standards.
Food irradiation	means the process of exposing food to ionizing radiation.
Fruit fly	means fruit fly of the family Tephritidae.
FSANZ	means Food Standards Australia New Zealand.
ICA	means Interstate Certification Assurance.
Interstate Certification Assurance (ICA)	means a system of Certification Assurance developed to meet the requirements of State and Territory governments for the certification of product for interstate and intrastate quarantine purposes.
Inspector	means an inspector appointed under the Plant Biosecurity Act (2010).
Irradiation	means a process of exposing material to ionizing radiation.
Irradiation container	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.
Irradiation facility	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.

Irradiation operator	means an individual who has undergone a training program approved by the relevant nuclear regulatory authority.
Irradiator	means the assembly of equipment and its housing where product is exposed to ionizing radiation.
ISO	International Organisation for Standardisation.
ISPM	means International Standards for Phytosanitary Measures, produced by the secretariat of the International Plant Protection Convention.
Loading configuration	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.
Lot	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.
Nonconformance	means a nonfulfillment of a specified requirement.
Pests	means fruit fly, mango seed weevil and other animals of the phylum Arthropoda (excluding Lepidopteron that pupate internally).
Phytosanitary measure	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.
Plant Health Assurance Certificate (PHAC)	means certification issued by an Authorised Signatory of an accredited business.
Product	means fresh fruit and vegetables approved by Food Standards Australia New Zealand (FSANZ) to be irradiated and cut flowers.
Pupate internally	means the complete development or part of the lifecycle inside a fruit, vegetable or leafy plant material
Radiation source	means a device that emits ionizing radiation.
Radionuclide	means a radioactive isotope of an element (e.g., cobalt-60 or cesium-137).
Regulated pest	means a quarantine pest or a regulated non- quarantine pest.
Re-infestation	the renewed presence, in a commodity, of a living pest of the plant or plant product concerned. Re-infestation includes re-infection.
Secure conditions	means secured in a manner that prevents pest infestation and/or re-infestation.
Serpentine leafminer	means all stages of the species Liriomyza huidobrensis belonging to the family Agromyzidae
Treatment	means an official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalisation.

5 Responsibility

The position titles used reflect responsibilities of staff under this arrangement. These positions may not be present in all businesses, or different titles may be used for staff who carry out these responsibilities. 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 7.1);
- ensuring the irradiation source records are maintained (refer 7.1.2)
- ensuring the Irradiation Operator has carried out maintenance in accordance with this Operational Procedure (refer 7.1.3);
- ensuring equipment and calibration records are maintained (refer 7.2).

The **Irradiation Operator** is responsible for:

- ensuring irradiation treatments of product are conducted in accordance with this Operational Procedure (refer 6 and 7.6);
- ensuring dose mapping and dosimetry are conducted in accordance with this Operational Procedure (refer 7.3 and 7.4);
- ensuring the maintenance plan is conducted in accordance with the Operational Procedure (refer 7.1.3);
- ensuring records of treatment are maintained (refer 7.8)
- ensuring nonconforming product is managed in accordance with the Operational Procedure (refer 7.7).

The **Product Receival Officer** is responsible for:

- ensuring product receival records are maintained (refer 7.5.1);
- identifying and controlling treated and untreated product at the facility (refer 7.5.2).

The **Authorised Dispatcher** is responsible for:

- ensuring all packages covered by an Assurance Certificate issued by the business are identified (refer 7.10.1);
- maintaining copies of all Assurance Certificates issued by the business under the ICA arrangement (refer 9.1).

The **Authorised Signatory** is 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 the details on the certificate are true and correct in every particular (refer 7.10.3).

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 plant pests of the class Insecta except pupae and adults of the order Lepidoptera, including Serpentine leafminer (Liriomyza huidobrensis)

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.

This procedure sets out the steps required for compliance with the relevant law(s) or regulatory standards. Before following this procedure, you should:

- assess the effects of irradiation treatment on small quantities of your plants or plant product to eliminate the risk of any damage to plant or plant product; and
- ensure all personal protection and safety measures are in place to prevent injury to person(s) carrying out the treatments.

When carrying out treatments, you will be responsible for ensuring compliance with the procedure, taking into account each applicable standard, manufacturing guideline or recommended operating procedure, all workplace health and safety requirements, and compliance with each applicable interstate or national requirement.

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.

Agriculture Victoria will not be responsible for any damage to plant or plant product or any personal injury that may result from your use or application of treatments.

For further information contact the Customer Service Centre on or visit www.agriculture.vic.gov.au.

7 Procedure

7.1 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, receival 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:

- be able to provide doses within limits specified and prescribed for phytosanitary requirements; and
- 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.

7.1.1 Facility Plan

Each irradiation facility that irradiates product for certification under this procedure must maintain a facility plan which includes the following details:

- the street address of the facility;
- the location of the irradiator in the facility;
- the dimensions, materials and construction of the irradiator container(s);
- the means provided for the segregation of non-irradiated product from irradiated product;
- the conveyor path(s) and the range of conveyor speed; and
- the manner of operating and maintaining the irradiator and any associated conveyor system.

7.1.2 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:

- the type of radionuclide, its activity, and source geometry;
- the means of indicating the position of the gamma source;
- 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
- 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:

- the characteristics of the beam (electron or X-ray energy, and if applicable average beam current, dose rate, scan width and scan uniformity);
- for X-ray irradiators, the dimensions, materials and construction of the X-ray converter;
- the means of indicating that the beam and the conveyor system are operating;
- the means of ceasing irradiation if any failure of the conveyor occurs which affects the dose and product requirements; and
- the means of ceasing conveyor movement or identifying affected product if any fault in the beam occurs.

7.1.3 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 2) or records which capture the same information.

The maintenance plan shall provide the following details:

- the accredited business name and address;
- the date of the maintenance task/routine check;
- the identification of the equipment that the maintenance task/routine check was performed on;
- actions taken to perform the maintenance task/routine check;
- intervals specifying when the maintenance/routine checks are performed; and
- the printed name and signature of the Irradiator Operator that conducted the maintenance task.

7.2 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 3) or records which capture the same information.

The calibration and test record shall provide the following details:

- the accredited business name and address;
- the date of the calibration and test;
- the identification of the equipment that the calibration was performed on;
- intervals specifying when the calibrations are performed; and
- 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).

7.3 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 4) or records which capture the same information.

The dose mapping record shall provide the following details:

- the name and address of the accredited business;
- the time and date when the dose mapping occurred;
- the dimensions and packaging of the product;
- geometric packaging configuration;
- the loading pattern of the dose mapped product;
- loading pattern of the irradiator around the source of pathway through the cell;
- the location of the dosimeters within the product;
- the type of dosimeter;
- the duration of irradiation;
- the minimum and maximum absorbed doses in the product; and
- 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 an operation mode that could affect the magnitudes or locations of the maximum and minimum doses.

7.4 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 7.8) 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).

7.5 Pre-Treatment

7.5.1 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:

- product name, quantity and description;
- package dimensions, weight, shape, configuration and packaging;
- purpose of the irradiation treatment;
- information and necessary means of identifying the product to be irradiated; and
- 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.

7.5.2 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:

- locating untreated product in a clearly identified area separate to treated product and maintaining separation until dispatch; or
- 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 7.10.1).

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

7.6 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.

The Irradiation Operator shall record the minimum and maximum absorbed dose using the Irradiation Treatment Record (refer 7.8) 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).

7.7 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:

- all product from the treatment lot shall be rejected for certification;
- all rejected product shall be isolated and clearly identified to prevent mixing with any other product;
- 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.

7.8 Treatment Records

The Irradiation Operator must record each irradiation treatment using an Irradiation Treatment Record (refer Attachment 5) 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 grower's name; and
- any observed deviation from the treatment specification.

7.9 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) shrink-wrapped and sealed as a palletised unit;

(e) fully enclosed or screened buildings, cold-rooms, 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.

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 shrink wrap 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.

7.10 Dispatch

7.10.1 Package Identification

Prior to the issuing an Assurance Certificate under this procedure, 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.

Packages may be marked prior to irradiation; however, any packages containing product that has not been treated in accordance with the requirements of this procedure must not leave the irradiation facility if marked as stated above.

For entry into Tasmania the acceptance of one label which can be affixed to the outer surface of a secure pallet unit may be available in lieu of the individual package markings. This label must include

- 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.

The secure palletised unit must be shrink wrapped and have the top layer secured by applying a row of tape over the shrink wrap. Applied to the tape in waterproof ink shall be the signature of the Authorised Signatory and the number of the Plant Health Assurance Certificate covering the consignment and the date of issue of the consignment.
Note: If the external label was to be lost in transport, the entire pallet would be deemed not treated and may be either re-exported or destroyed.

7.10.2 Package Labelling

The labelling of packages or product for consumption 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 and/or FSANZ Standard 1.5.3 must have package identification removed or obscured.

7.10.3 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. A completed example is shown as Attachment 1.

Individual Assurance Certificates shall be issued to cover each consignment (i.e., 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 Standard Operating Procedure - Completion of Plant Health Assurance Certificates.

7.10.4 Assurance Certificate Distribution

The **original** (yellow copy) must accompany the consignment.

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

8 Accreditation

In order to become accredited, the Application for Accreditation must be signed and returned. The application form includes the terms and conditions applying to this agreement.

8.1 Application for Accreditation

A business seeking accreditation for an ICA arrangement under this procedure must make an application for accreditation at least 10 working days prior to the intended date of commencement of certification of product.

8.1.1 Required application documents

A business may apply for accreditation by lodging a completed application package which must include the following documents:

- a fully completed Application for Accreditation form; and
- proof of business registration.

Failure to provide any of the above documentation may result in delays to your application for accreditation.

8.2 Audit process

8.2.1 Initial audit

Prior to accrediting a business, an Authorised Inspector shall conduct an initial audit of the business to verify the system is implemented and capable of operating in accordance with the requirements of this ICA procedure, and the system is effective in ensuring compliance with the specified requirements of the arrangement.

On completion of a successful initial audit, applicants will be granted provisional accreditation and issued a Certificate of Accreditation.

8.2.2 Compliance Audits

Compliance Audits are conducted to verify that the ICA system continues to operate in accordance with the requirements of this procedure. Compliance audits are, wherever practical, conducted when the system is operating.

A compliance audit is conducted:

- within four (4) weeks of the initial audit and accreditation or issue of the first PHAC; and
- within twelve (12) weeks of the business being re-accredited; and
- in the case of a business operating for more than six (6) months of a year, between six (6) and nine (9) months after accreditation or re-accreditation.

Upon completion of a successful initial compliance audit, accreditation is granted to cover the current season, up to a maximum of twelve (12) months.

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 certified product, ICA system records or ICA system documentation.

Unscheduled compliance audits may be conducted at any time to investigate reported or suspected non-conformances.

8.2.3 Re-Accreditation

Accredited businesses are required to re-apply for accreditation each year the business seeks to operate under the 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 arrangement.

A compliance audit is conducted within twelve (12) weeks of the business applying for re-accreditation each year.

A compliance audit is conducted between six (6) and nine (9) months after the date of re-accreditation for an arrangement that operates for more than six (6) months of the year.

8.3 Certificate of Accreditation

An accredited business will receive a Certificate of Accreditation detailing the facility location, procedure, scope (type of product covered) and period of accreditation. This Certificate of Accreditation will also detail which interstate markets the business is permitted to send to.

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

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

8.4 Non-conformances and Sanctions

8.4.1 Non-conformances

Audits are regularly undertaken to evaluate the effectiveness of implementation requirements. If, in the opinion of the auditor, there is evidence indicating that there has been a failure to meet one or more accreditation requirements, the auditor may raise a Non-conformance Report (NCR). Actions required to address the non-conformance shall be discussed and recorded on the NCR.

If the integrity of the accreditation has been significantly compromised, the non-conformance may provide grounds for the suspension or cancellation of the accreditation and prosecution.

8.4.2 Incident Reports

Incident Reports may be raised by interstate quarantine authorities to report the detection of a non-conformance in product certified under this arrangement. An investigation into the incident shall be conducted and findings reported back to the originator.

If the integrity of the accreditation has been significantly compromised, the incident may provide grounds for the suspension or cancellation of the accreditation and prosecution.

8.4.3 Suspension and Cancellation

Agriculture Victoria may suspend or cancel an accreditation when an accredited business is found, for example, to have:

- obtained accreditation through the provision of false or misleading information;
- not paid fees owing to Agriculture Victoria;
- contravened a requirement that compromises the integrity of the arrangement; and
- not rectified a non-conformance.

Any action taken by Agriculture Victoria to suspend or cancel an accreditation shall be provided in writing to the business. This shall also provide guidance on the lodgement of a written appeal requesting that the decision be reviewed.

8.4.4 Prosecution

Businesses found to be operating contrary to the Act may be liable for prosecution.

8.5 Charging Policy

The business will be charged for all audit and investigation activities and an annual accreditation fee.

A fee will be charged for all scheduled audits conducted. Unannounced audits will not be charged. Agriculture Victoria can be contacted for a schedule of fees.

9 Records and Document Control

9.1 ICA System Records

The business shall maintain the following records:

- a copy of each Plant Health Assurance Certificate issued by the business (refer 7.10.4 – Attachment 1);
- Irradiator and Irradiator Equipment Maintenance Plan (refer Attachment 2);
- Equipment Calibration and Test Record (refer Attachment 3);
- Dose Mapping Record (refer Attachment 4); and
- Irradiation Treatment Record (refer Attachment 5).

ICA system records shall be retained for a period of at least 24 months from completion, or until the next compliance audit of the ICA arrangement, whichever is the later.

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

9.2 ICA System Documentation

The business shall maintain the following documentation:

- a copy of the business's current endorsed Application for Accreditation;
- a copy of the current endorsed Authorised Signatory forms;
- a current copy of this Operational Procedure;
- a current Certificate of Accreditation;
- a current Facility Plan (refer 7.1.1)
- evidence that the facility has current approval from a relevant nuclear authority (refer 7.1);
- evidence of the irradiation source used at the facility (refer 7.1.2); and
- evidence of the product receival system implemented at the facility (refer 7.5.1).

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

10 Attachments

Attachment 1	Plant Health Assurance Certificate (PSE-040)
Attachment 2	Irradiator and Irradiator Equipment Maintenance Plan Record (PSF-459)
Attachment 3	Equipment Calibration and Test Record (PSF-456)
Attachment 4	Dose Mapping Record (PSF-457)
Attachment 5	Irradiation Treatment Record (PSF-458)

Plant Health Assurance Certificate

Certificate number
XXXXXXXX

Consignment details (please print)

Consignor
Name **ABC PTY LTD**
Address **STORE 21, STREET ROAD, MELBOURNE, VIC 3000**

Consignee
Name **TOMATO PRODUCE**
Address **221 PRODUCE ROAD, ADELAIDE, SA**

Reconsigned to (splitting consignments or reconsigning whole consignments)
Name
Address

Certificate details (please print)

IP Number	**Facility number**	**Procedure**
V9999	**01**	**ICA-55**

Accredited business that prepared the produce
Name **ABC PTY LTD**
Address **STORE 21, STREET ROAD, MELBOURNE, VIC 3000**

Grower or Packer
Name **ABC PTY LTD**
Address **STORE 21, STREET ROAD, MELBOURNE, VIC 3000**

Other facilities supplying produce

Brand name OR identifying marks (as marked on packages)	**Date OR date code** (as marked on packages)
ABC PRODUCE	**12/09/2018**

Number of packages	**Type of packages** (e.g. trays, cartons)	**Type of produce**	**Authorisation for split consignment**
20	**cartons**	**mangoes**	

Treatment details

Treatment date	**Treatment**	**Chemical** (active ingredient)	**Concentration / duration and temperature**
15/08/2019	Irradiation		150Gy

Additional certification / Codes

Declaration: I, an Authorised Signatory of the accredited business that prepared the plants or plant products described above, hereby declare that the plants or plant products have been prepared in the business' approved facility in accordance with the business' Certification Assurance arrangement and that the details shown above are true and correct in every particular. I acknowledge that it is an offence under the ***Plant Biosecurity Act 2010*** to issue assurance certificates without being accredited and/or to make false statements in certificates and declarations.

Authorised Signatory (print name)	**Signature**	**Date**
A. Signature	***A. Sign***	**15 / 08 / 2019**

IRRADIATOR AND IRRADIATOR EQUIPMENT MAINTENANCE PLAN RECORD

Accredited Business Name and Address:			Interstate Produce No.:	**V**
Date of Maintenance Task/ Routine Check	Identification of Equipment that the Maintenance Task/Routine Check was Performed on	Actions Taken to Perform the Maintenance Task/Routine Check	Intervals Specifying When Maintenance/ Routine Checks are Performed	Printed Name and Signature of Irradiator Operator that Conducted the Maintenance Task

EQUIPMENT CALIBRATION AND TEST RECORD

Accredited Business Name and Address:		Interstate Produce No.:	**V**

Date of Calibration and Test	Identification of Equipment that the Calibration was Performed on	Intervals Specifying when Calibrations are Performed	Printed Name and Signature of Operator that Conducted the Maintenance Task

DOSE MAPPING RECORD

Accredited Business Name and Address:								Interstate Produce No.:	**V**
Time and Date when Dose Mapping Occurred	Dimensions and Packaging of Product	Geometric Packaging Configuration	Loading Pattern of the Product Within the Irradiator	Loading Pattern of the Irradiator Around the Source of Pathway Through the Cell	Location of dosimeters within product	Type of dosimeter	Duration of Irradiation	Minimum and Maximum Absorbed Dose	Printed Name and Signature of the Operator that Conducted the Dose Mapping

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IRRADIATION TREATMENT RECORD

Accredited Business Name:				Interstate Produce No.:	**V**
Date of Treatment:	/ /	ID of Facility:		Place of Treatment:	
Irradiator Operator Name and Signature:				Purpose of Treatment (Pest):	
Consignment Owner:				Radiation Source:	
	Maximum Dose Gy	Minimum Dose Gy		Observed Deviation from Treatment Schedule:	Y / N

Grower/Packer Name	Number of Packages	Product Type (eg Banana)	Type of Packages (Cartons, Bins etc.)	Time Treatment Commenced	Time Treatment Finished	ID Code *(If applicable)*

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