RAP PUBLICATION 2014/09

REGIONAL STANDARDS FOR PHYTOSANITARY MEASURES

APPROVAL OF IRRADIATION FACILITIES

APPPC RSPM No. 9

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The Asia and Pacific Plant Protection Commission (APPPC)
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
Bangkok 2014

ISBN 978-92-5-108265-2 (print)
E-ISBN 978-92-5-108266-9 (PDF)

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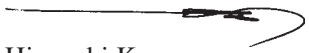
Endorsement

Regional standards for phytosanitary measures are developed and adopted by the Asia and Pacific Plant Protection Commission as part of the plant protection programme of the Commission's contracting parties. This programme makes available to contracting and other interested parties regional standards for phytosanitary measures to support regional harmonization, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade.

This standard was endorsed by the twenty-eight session of the Asia and Pacific Plant Protection Commission in September 2013.



Hiroyuki Konuma
Assistant Director-General and
FAO Regional Representative for
Asia and the Pacific

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Endorsement

This Asia and Pacific Plant Protection Commission (APPPC) Regional Standard for Phytosanitary Measures was endorsed by the twenty-eighth session of the APPPC held from 23–27 September 2013 in Jeju, Republic of Korea.

Review

APPPC Regional Standards for Phytosanitary Measures are subject to periodic review. The next review date for this standard is 2015. The standard may be reviewed earlier if the APPPC decides this is necessary.

Distribution

APPPC Regional Standards for Phytosanitary Measures are distributed by the Executive Secretariat of the APPPC to all APPPC members, the Administrative Heads of Regional Plant Protection Organizations and the FAO International Plant Protection Convention (IPPC) Secretariat. This standard is available on the APPPC webpage found within the International Phytosanitary Portal: http://www.ippc.int/En/rppo/jsp

INTRODUCTION

Scope

This standard provides guidelines to National Plant Protection Organizations (NPPOs) for approval (certification or accreditation) of facilities irradiating commodities for phytosanitary purposes consistent with ISPM No.18 *Guidelines for the use of irradiation as a phytosanitary measure* and ISPM No. 28 *Phytosanitary treatments for regulated pests*.

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ISPM 28. 2007. *Phytosanitary treatments for regulated pests*. Rome, IPPC, FAO.

Definitions and abbreviations

Except where noted, the definitions are specific to this standard.

absorbed dose Quantity of radiating energy absorbed per unit of mass of a specified target. [Note, for the purposes of this Standard, the term dose is used to mean absorbed dose and the unit of absorbed dose is the

	gray (Gy) where 1 Gy is equivalent to the absorption of 1 joule per kilogram]. [ISO 11137-1:2006]
ASTM	Standards development organization originally known as the American Society for Testing and Materials but now known as "ASTM International".
calibration	Set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. [ISO 11137-1:2006]
commodity	A type of plant, plant product or other article being moved for trade or other purpose. [ISPM 5]
contamination	Presence, in a commodity, storage place, conveyance or container, of pests or other regulated articles not constituting an infestation. [ISPM 5]
correction	Action to eliminate a detected non-conformity. A correction can be made in conjunction with a corrective action. [ISO 9000:2005]
corrective action	Action to eliminate the cause of a non-conformity or other undesirable situation. There can be more than one cause of non-conformity. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (There is a distinction between correction and corrective action). [ISO 9000:2005]
cross-contamination	Process where one product is contaminated directly or indirectly by the exchange of contaminants from another product and/or raw material.
customer	Organization or person that requests the irradiation treatment of a product to the irradiator operator under specified requirements.

dose	The term dose refers to absorbed dose.
dose distribution	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	Measurement of dose distribution and variability in material irradiated under defined conditions. [ISO 11137-1:2006]
dose uniformity ratio	Ratio of the maximum absorbed dose to the minimum absorbed dose (Dmax:Dmin) within a process load.
dosimeter	Device having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system. [ISO 11137-1:2006]
dosimetry	Measurement of absorbed dose by the use of dosimeters. [ISO 11137-1:2006]
dosimetry system	The procedures and interrelated elements used for determining absorbed dose, including dosimeters, instruments and associated reference standards. [ISO 11137-3:2006]
installation qualification (IQ)	Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. [ISO 11137-1: 2006]
irradiation	Treatment with any type of ionizing radiation. [ISPM 5]
irradiation container	Holder in which product is transported through the irradiator. The holder can be a carrier, cart, tray, product carton, pallet, tote or other container. [ISO 11137-1:2006]

irradiation facility	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. An irradiation facility consists of an irradiator, shipping and receiving docks, storage zones for irradiated and non-irradiated products, conveyor system, safety systems and the infrastructure for personnel and facility services including record control.
irradiator	The assembly of equipment and its housing where product is exposed to ionizing radiation. The irradiator provides for safe and reliable radiation processing and includes the source of radiation and associated mechanisms together with the conveyor, safety devices and biological shield.
irradiator operator	Organization or body responsible for irradiating the product. [ISO 11137-1:2006]
ISPM	International Standards for Phytosanitary Measures. [ISPM 5]
loading configuration	Defined arrangement of product (food) 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. [Australian Interstate Certification Assurance document on Irradiation Treatment.]
NPPO	National Plant Protection Organization. [ISPM 5] Note: For the purposes of this standard activities designated for the NPPO may be performed by other organizations approved by the NPPO.
operational qualification (OQ)	Process of obtaining and documenting evidence that installed equipment operates within predetermined

	limits when used in accordance with its operational procedures. [ISO 11137-1:2006]
performance qualification (PQ)	Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting itsspecification. [ISO 11137-1:2006]
phytosanitary measure	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. [ISPM 5]
preventive action	Action intended to eliminate the cause of a potential non-conformity or other undesirable potential situation. There can be more than one cause for a potential non-conformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent reoccurrence. [ISO 9000:2005]
process interruption	Intentional or unintentional stoppage that acts to prevent the irradiation process from proceeding continuously. [ISO 11137-1:2006]
process load	A volume of material with a specified loading configuration and treated as a single entity. [ISPM 5]
process parameter	Specified value for a process variable. The specification for a process includes the process parameters and their tolerances. [ISO 11137-1:2006]
radiation-sensitive indicator	Material which may be affixed to, or printed on, the process load and which undergoes a visual change when exposed to ionizing radiation. These indicators do not provide a quantitative measure of dose and may not work or be unreliable at low

	doses (for example in the dose range employed for phytosanitary treatments). [Adapted from ISO/ASTM 51539:2005]
radiation source	Device that emits ionizing radiation.
radionuclide	Radioactive isotope of an element (e.g. cobalt-60 or cesium-137).
requalification	Repetition of part of validation for the purpose of confirming the continued acceptability of a specified process. [ISO 11137-1:2006]
regulated pest	A quarantine pest or a regulated non-quarantine pest. [ISPM 5]
re-infestation	The renewed presence, in a commodity, of a living pest of the plant or plant product concerned. Re-infestation includes re-infection.
Sanitary and Phytosanitary (SPS)	The WTO Agreement on the Application of Sanitary and Phytosanitary Measures on how member governments apply food safety, animal and plant health measures.
specification	Approved document stipulating requirements. [ISO 11137-1:2006]
treatment	Official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile, or for devitalisation. [ISPM 5]
validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. [ISO 11137-1: 2006]
WTO	World Trade Organization

Outline of requirements

NPPO approval, in addition to those of nuclear agencies and food safety authorities, will be required. This includes a number of requirements audited when NPPOs conduct site assessments such as:

- Facilities should provide segregated storage for irradiation and non-irradiated commodities
- Additional specifications for gamma irradiation and for electron beam and x-ray irradiation should be available
- The irradiation and its mode of generation should be specified
- Validation exercises to show the facility is operating to design specification should be undertaken
- Performance qualification is carried out to show the facility consistently performs to predetermined criteria
- Process specification documents, including information from validation studies, should be available for each commodity
- Procedures for product handling and monitoring product integrity should be specified
- The product loading configuration shown in the process specification should be used
- There should be a process inventory control
- Personnel should be adequately trained
- Equipment should be subject to a maintenance plan and records reviewed by a designated person.

Dosimetry must be performed to ensure that specified doses are received by the commodities being treated. Dose mapping to determine does distribution and variability, using dosimetry, should be undertaken. Dosimeter location and placement frequency should be sufficient and verify the process is under control.

Quality management responsibilities will include a defined quality management system, methods for measurement and analysis, equipment calibration, procedures for commodity release, documentation and irradiation certificate and phytosanitary certificate provision.

Product security after treatment needs to be maintained.

BACKGROUND

This standard provides a common framework for NPPO's to approve irradiation facilities used for phytosanitary purposes by assess the effectiveness and ability of a facility to fulfil all the requirements for the irradiation of commodities. This is particularly important for irradiation phytosanitary treatments, as onshore inspection of a consignment treated by irradiation is an impractical means to evaluate treatment effectiveness, as live but non-viable insects may be present.

The standard addresses applications for phytosanitary treatment of non-food commodities (e.g. timber, flowers, cotton) as well as some food commodities (e.g. mango, papaya). NPPOs should note that where phytosanitary treatment overlaps with food treatments the regulations and controls imposed need to recognise national and international requirements for both applications (i.e. Codex Alimentarius).

This standard has been developed to be used in conjunction with ISPM 18.

Specific efficacy requirements for the control of quarantine pests are not dealt with in this standard and should be determined during bilateral discussions between exporting and importing NPPOs.

Purpose

This standard provides elements of a quality management system that are the minimum necessary for the operation of irradiation facilities using either radionuclides (cobalt-60 or cesium-137) or machine generated sources (electron beam or x-rays).

The application of the standard does not exempt compliance with current and applicable regulations. They do not specify requirements for occupational safety associated with the design and operation of irradiation facilities, nor specify a complete management system for the control of all stages of phytosanitary treatment.

Acknowledgement

These guidelines are, with permission, largely based on the *Guidelines for the Audit and Accreditation of Irradiation Facilities used for Sanitary*

and Phytosanitary Treatment of Food and Agricultural Products which were developed in an International Atomic Energy Agency funded project (RAS05/050).

REQUIREMENTS

1. Irradiation facility approval

A facility is approved by the relevant authorities (e.g. nuclear agencies and food safety authorities) in the country where the facility is located. For phytosanitary uses additional approval (certification or accreditation) will be required by NPPOs. The approval should be based on a common set of criteria plus those specific to the site and commodity programmes (see Annex 2 of ISPM No.18). NPPOs should conduct site assessments (audits) in order to establish the irradiation treatment provider's capacity to perform phytosanitary treatments to the specifications required and that the equipment used, and operating protocols undertaken, are sufficient to perform an effective treatment.

- Assessment for facility approval will include:
    a. equipment and site;
    b. ability to conduct treatments;
    c. cleanliness and safeguarding of integrity;
    d. evaluations on the level of risk from possible re-infestation or contamination following treatment; and
    e. documentation and record keeping.

The irradiator operator should agree, as part of the approval process, to immediately notify the NPPO of any problems, concerns or irregularities in commodity treatments.

Approved facilities should be periodically audited by NPPOs.

1.1 Facility requirements

Facilities should provide segregated storage for irradiated and non-irradiated commodity and prevent cross contamination and post treatment re-infestation. This separation can be accomplished by controlled, single direction movement of commodity through the facility and by separated storage areas for irradiated and non-irradiated commodities.

Irradiators must be able to provide the doses within the limits specified and prescribed for phytosanitary treatments. In addition, the NPPO may consider characteristics of each facility in assessing the degree to which unique physical and production process specifications are necessary to ensure adequate safeguarding.

1.2 Radiation source

The type of radiation (e.g. gamma) and radiation source (e.g. cobalt-60) should be specified. In the case of electron accelerators the energy of radiation should be specified.

1.3 Additional specifications for gamma irradiators

- For gamma irradiators, specifications should describe the:
    a. type of radionuclide, its activity, and source geometry;
    b. means of indicating the position of the gamma source;
    c. means of automatically returning the gamma source to the storage position and automatically ceasing conveyor movement if the process control timer or the conveyor system fails; and
    d. 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.

1.4 Additional specifications for electron beam and x-ray irradiators

- For electron beam and x-ray irradiators, specifications should also describe:
    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 commodity requirements; and

e. the means of ceasing conveyor movement or identifying affected commodity if any fault in the beam occurs.

1.5 Equipment

- The irradiator and its method of operation should be specified. The irradiator specification should be revised as necessary and retained for the life of the irradiator. The specifications should at least describe the:
    a. premises, including the location of the irradiator;
    b. means provided for the segregation of non-irradiated and irradiated commodities;
    c. construction and operation of any associated conveyor system;
    d. conveyor path(s) and the range of conveyor speed;
    e. dimensions, materials and construction of the irradiator container(s); and
    f. manner of operating and maintaining the irradiator and any associated conveyor system.

Software used to control and/or monitor the process should be in accordance with a quality management system with documentary evidence that the software meets its design intention (e.g. as documented by the software provider).

1.6 Validation

Validation encompasses a series of exercises designed to verify that an irradiation facility meets its installation requirements (installation qualification or IQ), operates to its design specification (operational qualification or OQ) and will consistently deliver the required process to a given loading configuration within predetermined tolerances (performance qualification or PQ). Validation of information generated during IQ and OQ is undertaken by other agencies. Information generated during PQ must be reviewed by NPPOs and the outcome of the review must be recorded.

1.7 Performance qualification

The purpose of PQ is to demonstrate that the facility, as installed and properly operated, consistently performs in accordance with predetermined criteria.

During PQ dose mapping is used to determine the appropriate process parameters (including timer setting, conveyor speed and product-loading configuration) for ensuring that the dose requirements for a particular commodity can be satisfied. This is accomplished by dose mapping of irradiation containers with specific commodity and loading configurations. The aim of which is to determine the value and locations of the minimum and maximum doses.

Dose mapping should comply with ISO/ASTM Standard 51204-2002(E) or current ISO/ASTM standards, Practice for the Application of Dosimetry in the Characterization of a Gamma Irradiation Facility for Food Processing, or ISO/ASTM Standard 51431-2002(E) or current ISO/ASTM standards, Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing.

1.8 Process specifications

- From a consideration of the information generated by the validation studies above and its review, a process specification should be documented and approved for each commodity. These documents should include:
    a. description of packaged product, including dimensions, density and orientation of product within the package and acceptable variations;
    b. loading configuration of product within the irradiation container;
    c. irradiator operating conditions and limits (e.g. beam characteristics, conveyor speed and source configuration);
    d. conveyor path(s) to be used;
    e. minimum and maximum doses;
    f. routine dosimeter monitoring position(s);
    g. relationship between the dose at the monitoring position(s) and the minimum and maximum doses;
    h. for a product that is to be given multiple exposures, documentation should include any special requirements needed between exposures (e.g. change of level within the carrier or time restrictions); and
    i. where applicable the handling and storage conditions required (e.g. temperature and humidity conditions).

1.9 Routine monitoring and control

Prior to processing, any specific periodic tests, calibrations, maintenance tasks and necessary requalification should be performed and outcomes recorded. Procedures for product handling and maintaining product integrity before, during and after irradiation should be specified.

Process parameters (e.g. irradiation time, conveyor speed, product loading configuration) should be set, controlled, monitored and documented, taking into account uncertainty in routine dosimetry, to ensure that the commodity in each process load is processed within specifications. If process parameters deviate outside prescribed processing limits appropriate actions should be taken. The NPPO should be informed and remedial action undertaken.

1.10 Process interruptions

If a process interruption occurs it should be recorded, the NPPO informed and remedial action undertaken.

1.11 Process loads

Commodities should be loaded in the product loading configuration according to the process specification. The effect of changes or variations in the product loading configuration on the dose distribution should be assessed. Commodities must be presented for processing in the same configuration to that which was used for dose mapping.

1.12 Processing inventory control

Systems for quantifying product and maintaining product inventory should be implemented throughout product receiving, loading, unloading, handling and release. Discrepancies in the inventory should be resolved before processing and/or release.

Incoming products should be logged and given a code related to the customer lot identification in order to identify products at each step in their path through the irradiation facility. Procedures should ensure that irradiated and non-irradiated products are segregated.

1.13 Personnel

The irradiator operator must be able to demonstrate the capability to conduct irradiation treatments. Personnel performing work affecting the effectiveness of the process should be competent on the basis of appropriate education, training, skills and experience.

1.14 Maintenance of equipment

A maintenance plan (including preventive actions), maintenance procedures and records should be reviewed at specified intervals by a designated person and the results of the review should be documented.

Equipment should not be used to process product until all specified maintenance tasks have been satisfactory completed and recorded.

2. Dosimetry

Dosimetry must be performed to ensure that the specified doses are received by the commodity. The selection and use of specific dosimetry systems in a given application should be justified, taking into account the dose range, radiation type, effect of influence quantities, required level of uncertainty and required spatial resolution (see ISO ASTM 51261, ISO ASTM 51707:2005).

2.1 Dose mapping

Dose mapping is carried out to determine dose distribution and variability by placing dosimeters throughout an irradiation container filled with homogenous material (OQ) or the commodity (PQ). The number of dosimeters and their placement should be such that the locations of the maximum and minimum doses can be properly determined.

Dose mapping should be carried out in a sufficient number of irradiation containers with the same loading configuration and irradiation conditions in order to estimate the variability of dose values and distribution. Dose mapping records should include a description of the irradiation container, product loading configuration, conveyor path, irradiator operating conditions, dose measurements and conclusions drawn.

For gamma irradiators, the relationship between the source activity, timer setting, conveyor speed and dose shall be established for each loading configuration taking into account uncertainties.

For electron beam and x-ray irradiators, the relationship between the beam characteristics, the conveyor speed and dose shall be established for each loading configuration taking into account uncertainties.

The effect on dose distribution when product of different densities is present in a gamma irradiator shall be determined to define products that can be processed together.

2.2 Routine dosimetry

Different types of dosimeters can be used for dose mapping and routine dosimetry. For phytosanitary applications reference should be made to ASTM F1355-06.

If the locations of dose extremes identified during dose mapping procedures are not readily accessible during production runs alternative positions may be used for dose monitoring. The relationships between the doses at these alternative reference positions and the maximum and minimum doses shall be reproducible, established and documented.

Dose mapping must be repeated whenever changes are made, either in the facility, its operation or to the loading configuration (commodity, packaging, arrangement of product within packaging etc.).

2.2.1 Dosimeter location

Dosimeter(s) should be placed in the process load at the predetermined maximum and minimum dose positions, or at a qualified reference dose location.

2.2.2 Placement frequency

The frequency of dosimeter placement in the process load should be sufficient to verify that the process is in control. For example, a placement frequency that ensures there is at least one dosimeter in the irradiator at any given moment, with at least one dosimeter on the first and last irradiation containers of each process load. The frequency and its rationale should be specified.

3. Quality management

3.1 General responsibilities

The irradiator operator should be approved by the NPPO to treat commodities. For phytosanitary treatments additional requirements may be defined by the NPPO.

3.2 Management system

- The facility should be managed in accordance with:
    a. a defined quality management system;
    b. relevant domestic regulations; and
    c. NPPO requirements.

3.3 Monitoring, measurement and analysis

Appropriate methods for monitoring, measuring and analysing the process should be applied by the irradiator operator.

3.4 Equipment calibration

Procedures should be established for implementing and documenting calibration and control systems. All systems should be periodically checked to ensure that they are functioning according to specifications. The calibrations should be traceable to national or international standards. Instrumentation used to control, indicate or record the irradiation process should be recalibrated at defined intervals.

Following any modification or servicing of the instruments they should be recalibrated.

3.5 Procedures for commodity release

Procedures for commodity release following irradiation treatment should be specified. Procedures should take into account the uncertainties of the measurement system.

Radiation sensitive indicators should not be used as a proof of satisfactory radiation processing or as the sole means of differentiating irradiated products from non-irradiated products.

3.5.1 Non-conforming commodity

Procedures for control of commodities designated as non-conforming and for correction, corrective or preventive action should be specified and documented. These procedures should comply with the applicable clauses of the quality management system. Documented procedures and records should be maintained and may be used to identify the causes of the non-conformities.

3.6 Documentation

The irradiator operator should manage documentation in accordance with Section 7 of ISPM No.18 and their quality management system.

A technical agreement between the irradiator operator and the customer should be undertaken as specified in Section 4.4 of ISO 14470.

3.6.1 Irradiation certificate or report

- Treatment certificates or reports should accompany all commodities treated by the irradiator operator. All details should be legible and free from erasures and non-certified alterations.
- The certificates or reports should be signed, dated and contain the following details:
    i. Description of the commodities including quantity and distinguishing numbers such as irradiation lot number, specification number or a reference to load configuration.
    ii. Target pest and purpose of treatment (e.g. mortality or devitalisation).
    iii. Radiation source, and energy level for electron beam and x-ray.
    iv. Date of treatment.
    v. Name of treatment facility.
    vi. Minimum and maximum doses (specified and actual).
    vii. Consignment owner.
    viii. Any deviation from the treatment specification.

3.6.2 Phytosanitary certificate

After the irradiator operator has completed the irradiation certificates or reports, phytosanitary certificates can be issued by the NPPO in accordance with the requirements of Section 8.2 of ISPM No.18.

4. Post treatment security

Product security needs to be maintained after treatment to prevent re-infestation or contamination of commodities. Procedures need to be in accordance with Section 6.1 of ISPM No.18.

All shipments using solid wood packing material should comply with ISPM No.15.

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ISBN 978-92-5-108265-2

9 789251 082652

I3707E/1/03.14