



**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

ISPM No. 18

***GUIDELINES FOR THE USE OF IRRADIATION
AS A PHYTOSANITARY MEASURE***

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CONTENTS

ENDORSEMENT	209
INTRODUCTION	
SCOPE	209
REFERENCES	209
DEFINITIONS	209
OUTLINE OF REQUIREMENTS	209
GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE	
1. Authority	210
2. Treatment Objective	210
2.1 Efficacy	210
3. Treatment	210
3.1 Application	211
4. Dosimetry	211
4.1 Calibration of components of the dosimetry system	211
4.2 Dose mapping	211
4.3 Routine dosimetry	212
5. Approval of Facilities	212
6. Phytosanitary System Integrity	212
6.1 Phytosanitary security measures at the treatment facility	212
6.2 Labelling	212
6.3 Verification	212
7. Documentation by the Treatment Facility	212
7.1 Documentation of procedures	213
7.2 Facility records and traceability	213
8. Inspection and Phytosanitary Certification by the NPPO	213
8.1 Export inspection	213
8.2 Phytosanitary certification	213
8.3 Import inspection	214
8.4 Verification methods for treatment efficacy in export and import inspection	214
8.5 Administration and documentation by the NPPO	214
9. Research	214
ANNEX 1	
Specific Approved Treatments	215
ANNEX 2	
Checklist for Facility Approval	216
APPENDIX 1	
Estimated Minimum Absorbed Doses for Certain Responses for Selected Pest Groups	218
APPENDIX 2	
Research Protocol	219

ENDORSEMENT

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2003.

INTRODUCTION

SCOPE

This standard¹ provides technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles. This does not include treatments used for:

- the production of sterile organisms for pest control;
- sanitary treatments (food safety and animal health);
- the preservation or improvement of commodity quality (e.g. shelf life extension); or
- inducing mutagenesis.

REFERENCES

Export certification system, 1997. ISPM No. 7, FAO, Rome.

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.

Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest Risk Analysis for quarantine pests including analysis of environmental risks, 2003. ISPM No. 11 Rev. 1, FAO, Rome.

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Treatment with ionizing radiation (irradiation) may be used for pest risk management. NPPOs should be assured that the efficacy of the treatment is scientifically demonstrated for the regulated pest(s) of concern and the required response. Application of the treatment requires dosimetry and dose mapping to ensure that the treatment is effective in particular facilities and with specific commodity configurations. The NPPO is responsible for ensuring that facilities are appropriately designed for phytosanitary treatments. Procedures should be in place to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified to ensure that phytosanitary security is maintained. Recordkeeping by the treatment facility and documentation requirements for the facility and NPPO are required, and should include a compliance agreement between facility operator and the NPPO stipulating in particular the specific requirements for phytosanitary measures.

¹ Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements or national legislation, including those applicable to irradiation of food.

GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY MEASURE**1. Authority**

The NPPO is responsible for the phytosanitary aspects of evaluation, adoption and use of irradiation as a phytosanitary measure. To the extent necessary, it is the NPPO's responsibility to cooperate with other national and international regulatory agencies concerned with the development, approval, safety and application of irradiation, or the distribution, use or consumption of irradiated products. Their respective responsibilities should be identified to avoid overlapping, conflicting, inconsistent or unjustified requirements.

2. Treatment Objective

The objective of using irradiation as a phytosanitary measure is to prevent the introduction or spread of regulated pests. This may be realized by achieving certain responses in the targeted pest(s) such as:

- mortality;
- preventing successful development (e.g. non-emergence of adults);
- inability to reproduce (e.g. sterility); or
- inactivation.

Phytosanitary uses of irradiation also include the devitalization of plants (e.g. seeds may germinate but seedlings do not grow; or tubers, bulbs or cuttings do not sprout).

2.1 Efficacy

The required treatment efficacy should be specifically defined by the NPPO of the importing country. It consists of two distinct components:

- a precise description of required response;
- the statistical level of response required.

It is not sufficient to only specify a response without also describing how this is to be measured.

The choice of a required response is based on the risk as assessed through PRA, considering in particular the biological factors leading to establishment and taking into account the principle of minimal impact. A response such as mortality may be appropriate where the treatment is for the vector of a pathogen, whereas sterility may be an appropriate response for pest(s) that are not vectors and remain on or in the commodity.

If the required response is mortality, time limits for the effect of the treatment should be established.

A range of specific options may be specified where the required response is the inability of the pest to reproduce. These may include:

- complete sterility;
- limited fertility of only one sex;
- egg laying and/or hatching without further development;
- altered behaviour; and
- sterility of F₁ generation.

3. Treatment

Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources (up to 10 MeV), or by x-rays (up to 5 MeV) (limits set by Codex Alimentarius²). The unit of measurement for absorbed dose should be gray (Gy).

Variables to consider when implementing treatments include the dose rate, treatment time, temperature, humidity, ventilation, and modified atmospheres; these should be compatible with treatment effectiveness. Modified atmospheres may reduce treatment efficacy at a prescribed dose.

Treatment procedures should also ensure that the minimum absorbed dose (D_{min}) is fully attained throughout the commodity to provide the prescribed level of efficacy. Owing to the differences in the configuration of treatment lots, higher doses than the D_{min} may be required to ensure that the D_{min} is achieved throughout the configured consignment or lot. The intended end use of the product should be considered when conducting irradiation treatments.

² Codex general standard for irradiated food: Codex Stand. 106-1983. Codex Alimentarius, Section 7.1, Col. 1A (currently under revision).

Because mortality will rarely be technically justified as the required response, live target pests may be found. Therefore it is essential that the irradiation treatment ensures they are unable to reproduce. In addition, it is preferable that such pest(s) are unable to emerge or escape from the commodity unless they can be practically distinguished from non-irradiated pest(s).

3.1 Application

Irradiation can be applied:

- as an integral part of packing operations;
- to bulk unpackaged commodities (such as grain moving over a belt);
- at centralized locations such as the port of embarkation.

When safeguards are adequate and transit movement of the untreated commodity is operationally feasible, treatment may also be performed at:

- the point of entry;
- a designated location in a third country;
- a designated location within the country of final destination.

Treated commodities should be certified and released only after dosimetry measurements confirm that the Dmin was met. Where appropriate, re-treatment of consignments may be allowed, provided that the maximum absorbed dose is within the limits allowed by the importing country.

The purpose of Annex 1 [to be completed] is to list the doses for specific approved treatments as part of this ISPM. Appendix 1, which is attached for information only, provides some published information on absorbed dose ranges for certain pest groups.

According to the pest risks to be addressed and the available options for pest risk management, irradiation can be used as a single treatment or combined with other treatments as part of a systems approach to meet the level of efficacy required (see ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*).

4. Dosimetry

Dosimetry ensures that the required Dmin for a particular commodity was delivered to all parts of the consignment. The selection of the dosimetry system should be such that the dosimeter response covers the entire range of doses likely to be received by the product. In addition, the dosimetry system should be 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*).

Dosimeters should be appropriate for the treatment conditions. Dosimeters should be evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required.

Dosimetry should consider variations due to density and composition of the material treated, variations in shape and size, variations in orientation of the product, stacking, volume and packaging. Dose mapping of the product in each geometric packing configuration, arrangement and product density that will be used during routine treatments should be required by the NPPO prior to the approval of a facility for the treatment application. Only the configurations approved by the NPPO should be used for actual treatments.

4.1 Calibration of components of the dosimetry system

All components of the dosimetry system should be calibrated according to documented standard operating procedures. An independent organization recognized by the NPPO should assess performance of the dosimetry system.

4.2 Dose mapping

Dose mapping studies should be conducted to fully characterize the dose distribution within the irradiation chambers and commodity, and demonstrate that the treatment consistently meets the prescribed requirements under defined and controlled conditions. Dose mapping should be done in accordance with documented standard operating procedures. The information from the dose mapping studies is used in the selection of locations for dosimeters during routine processing.

Independent dose mapping for incomplete (partially-filled) as well as first and last process loads is required to determine if the absorbed-dose distribution is significantly different from a routine load and to adjust the treatment accordingly.

4.3 Routine dosimetry

An accurate measurement of absorbed dose in a consignment is critical for determining and monitoring efficacy and is part of the verification process. The required number, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.

5. Approval of Facilities

Treatment facilities should be approved by relevant nuclear regulatory authorities where appropriate. Treatment facilities should also be subject to approval (qualification, certification or accreditation) by the NPPO in the country where the facility is located prior to applying phytosanitary treatments. Phytosanitary approval should be based on a common set of criteria plus those specific to the site and commodity programmes (see Annex 2).

Phytosanitary re-approval should be done on an appropriate regular basis. Documented dose mapping should be done following repairs, modifications or adjustments in equipment or processes that affect the absorbed dose.

6. Phytosanitary System Integrity

Confidence in the adequacy of an irradiation treatment is primarily based on assurance that the treatment is effective against the pest(s) of concern under specific conditions and the treatment has been properly applied and the commodity adequately safeguarded. The NPPO of the country where the facility is located is responsible for ensuring system integrity, so that treatments meet the phytosanitary requirements of the importing country.

Efficacy research and dosimetry provide assurance that only effective treatments are used. Well-designed and closely monitored systems for treatment delivery and safeguarding assure that treatments are properly conducted and consignments protected from infestation, reinfestation or loss of integrity.

6.1 Phytosanitary security measures at the treatment facility

Because it is not usually possible to visually distinguish irradiated from non-irradiated products, treated commodities should be adequately segregated, clearly identified, and handled under conditions that will safeguard against contamination and/or infestation, or misidentification.

A secure means of moving the commodity from receiving areas to treatment areas without misidentification or risk of cross-contamination and/or infestation is essential. Appropriate procedures specific to each facility and commodity treatment programme should be agreed upon in advance. Commodities that are unpackaged or exposed in packaging require safeguarding immediately following treatment to ensure that they are not subject to infestation, reinfestation or contamination afterwards.

Packaging prior to irradiation may be useful to prevent reinfestation if irradiation is done prior to export, or to prevent the accidental escape of target pest(s) if treatment is done at the destination.

6.2 Labelling

Packages should be labelled with treatment lot numbers and other identifying features allowing the identification of treatment lots and trace-back (i.e. packing and treatment facility identification and location, dates of packing and treatment).

6.3 Verification

The adequacy of treatment facilities and processes should be verified through monitoring and audit of facility treatment records that include, as necessary, direct treatment oversight. Direct, continuous supervision of treatments should not be necessary provided treatment programmes are properly designed to ensure a high degree of system integrity for the facility, process and commodity in question. The level of oversight should be sufficient to detect and correct deficiencies promptly.

A compliance agreement should be concluded between the facility and the NPPO of the country where the facility is located. Such an agreement may include the following elements:

- approval of the facility by the NPPO of the country where the facility is located;
- the monitoring programme as administered by the NPPO of the country where treatments are conducted;
- audit provisions including unannounced visits;
- free access to documentation and records of the treatment facility; and
- corrective action to be taken in cases of non-compliance.

7. Documentation by the Treatment Facility

The NPPO of the country where the facility is located is responsible for monitoring recordkeeping and documentation

by the treatment facility and ensuring that records are available to concerned parties. As in the case of any phytosanitary treatment, trace-back capability is essential.

7.1 Documentation of procedures

Documented procedures help to ensure that commodities are consistently treated as required. Process controls and operational parameters are usually established to provide the operational details necessary for a specific authorization and/or facility. Calibration and quality control programmes should be documented by the facility operator. At a minimum, an agreed written procedure should address the following:

- consignment handling procedures before, during and after treatment;
- orientation and configuration of the commodity during treatment;
- critical process parameters and the means for their monitoring;
- dosimetry;
- contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- procedures for handling rejected lots;
- labelling, recordkeeping, and documentation requirements.

7.2 Facility records and traceability

Packers and treatment facility operators should be required to keep records. These records should be available to the NPPO for review, e.g. when a trace-back is necessary.

Appropriate treatment records for phytosanitary purposes should be kept by the irradiation facility for at least one year to ensure traceability of treated lots. The facility operator should keep all records for every treatment. Dosimetry records should be kept by the treatment facility for at least one full year after treatment. In most cases, these records are required under other authorities, but these records should also be available to the NPPO for review. Other information that may be required to be recorded includes:

- identification of facility and responsible parties;
- identity of commodities treated;
- purpose of treatment;
- target regulated pest(s);
- packer, grower and identification of the place of production of the commodity;
- lot size, volume and identification, including number of articles or packages;
- identifying markings or characteristics;
- quantity in lot;
- absorbed doses (target and measured);
- date of treatment;
- any observed deviation from treatment specification.

8. Inspection and Phytosanitary Certification by the NPPO

8.1 Export inspection

Inspection to ensure the consignment meets the phytosanitary requirements of the importing country should include:

- documentation verification; and
- examination for non-target pests.

Documentation is checked for completeness and accuracy as the basis for certifying the treatment. Inspection is done to detect any non-target pests. This inspection may be done before or after the treatment. Where non-target pests are found, the NPPO should verify whether these are regulated by the importing country.

Live target pests may be found after treatment but should not result in the certification being refused except when mortality is the required response. Where mortality is required, live target pests may be found during the period immediately following the treatment application depending on the specification for efficacy (see section 2.1). If live pests are found, certification could be based on audit checks which confirm that mortality will be attained. When mortality is not the required response, it is more likely that live target pests may persist in the treated consignment. This should also not result in the certification being refused. Audit checks, including laboratory analyses, may be undertaken to ensure that the required response is achieved. Such checks may be part of the normal verification programme.

8.2 Phytosanitary certification

Certification in accordance with the IPPC validates the successful completion of a treatment when required by the importing country. The Phytosanitary Certificate or its associated documentation should at least specifically identify the

treated lot(s), date of treatment, the target minimum dose and the verified Dmin.

The NPPO may issue Phytosanitary Certificates based on treatment information provided to it by an entity approved by the NPPO. It should be recognized that the Phytosanitary Certificate may require other information supplied to verify that additional phytosanitary requirements have also been met (see ISPM No. 7: *Export certification system* and ISPM No.12: *Guidelines for Phytosanitary Certificates*).

8.3 Import inspection

When mortality is not the required response, the detection of live stages of target pests in import inspection should not be considered to represent treatment failure resulting in non-compliance unless evidence exists to indicate that the integrity of the treatment system was inadequate. Laboratory or other analyses may be performed on surviving target pest(s) to verify treatment efficacy. Such analyses should only be required infrequently as part of monitoring unless there is evidence to indicate problems in the treatment process. Where mortality is the required response, this may be confirmed. Where mortality is required, live target pests may be found when transport times are short, but should not normally result in the consignment being refused, unless the established mortality time has been exceeded.

The detection of pests other than target pest(s) on import should be assessed for the risk posed and appropriate measures taken, considering in particular the effect the treatment may have had on the non-target pest(s). The consignment may be detained and any other appropriate action may be taken by the NPPO of the importing country. NPPOs should clearly identify the contingency actions to be taken if live pests are found:

- target pests—no action to be taken unless the required response was not achieved;
- non-target regulated pests:
 - no action if the treatment is believed to have been effective;
 - action if there is insufficient data on efficacy or the treatment is not known to be effective;
- non-target non-regulated pests—no action, or emergency action for new pests.

In case of non-compliance or emergency action, the NPPO of the importing country should notify the NPPO of the exporting country as soon as possible (see ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

8.4 Verification methods for treatment efficacy in export and import inspection

Verification methods, including laboratory tests or analysis to determine if the required response has been achieved should be described by the exporting country at the request of the importing country.

8.5 Administration and documentation by the NPPO

The NPPO should have the ability and resources to evaluate, monitor, and authorize irradiation undertaken for phytosanitary purposes. Policies, procedures and requirements developed for irradiation should be consistent with those associated with other phytosanitary measures, except where the use of irradiation requires a different approach because of unique circumstances.

The monitoring, certification, accreditation and approval of facilities for phytosanitary treatments is normally undertaken by the NPPO where the facility is located, but by cooperative agreement may be undertaken by:

- the NPPO of the importing country;
- the NPPO of the exporting country; or
- other national authorities.

Memoranda of Understanding (MOUs), compliance agreements, or similar documented agreements between the NPPO and the treatment applicator/facility should be used to specify process requirements and to assure that responsibilities, liabilities and the consequences of non-compliance are clearly understood. Such documents also strengthen the enforcement capability of the NPPO if corrective action may be necessary. The NPPO of the importing country may establish cooperative approval and audit procedures with the NPPO of the exporting country to verify requirements.

All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and Phytosanitary Certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available as described in ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*.

9. Research

Appendix 2 provides guidance on undertaking research for the irradiation of regulated pests.

ANNEX 1

SPECIFIC APPROVED TREATMENTS

This annex is a prescriptive part of the standard. Its purpose is to list irradiation treatments that may be approved for specified applications. Treatment schedules to be added as agreed by the ICPM in future.

ANNEX 2

CHECKLIST FOR FACILITY APPROVAL

This annex is a prescriptive part of the standard. The following checklist is intended to assist persons inspecting or monitoring facilities seeking to establish/maintain facility approval and certification of irradiated commodities for international trade. The failure to receive an affirmative response to any item should result in the refusal to establish, or the termination of, an approval or certification.

Criteria	Yes	No
<i>1. Premises</i>		
Irradiation facility meets the approval of the NPPO as regards phytosanitary requirements. The NPPO has reasonable access to the facility and appropriate records as necessary to validate phytosanitary treatments		
Facility buildings are designed and built to be suitable in size, materials, and placement of equipment to facilitate proper maintenance and operations for the lots to be treated		
Appropriate means, integral to the facility design, are available to maintain non-irradiated consignments and/or lots separate from treated consignments and/or lots		
Appropriate facilities are available for perishable commodities before and after treatment		
Buildings, equipment, and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent contamination of the consignments and/or lots being treated		
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamination or infestation of consignments and/or lots being stored or processed		
Adequate measures are in place to handle breakage, spills, or the loss of lot integrity		
Adequate systems are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment		
Adequate systems are in place to control non-compliant consignments and/or lots and when necessary to suspend facility approval		
<i>2. Personnel</i>		
The facility is adequately staffed with trained, competent personnel		
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes		
<i>3. Product handling, storage and segregation</i>		
Commodities are inspected upon receipt to ensure that they are suitable for irradiation treatment		
Commodities are handled in an environment that does not increase the risk of contamination from physical, chemical or biological hazards		
Commodities are appropriately stored and adequately identified. Procedures and facilities are in place to ensure the segregation of treated and untreated consignments and/or lots. There is a physical separation between incoming and outgoing holding areas where required		
<i>4. Irradiation treatment</i>		
Facility is able to perform required treatments in conformity with a scheduled process. A process control system is in place providing criteria to assess irradiation efficacy		
Proper process parameters are established for each type of commodity or consignment to be treated. Written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel		
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry. Dosimetry records are kept and made available to the NPPO as needed		
<i>5. Packaging and labeling</i>		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Treated consignments and/or lots are adequately identified or labelled (if required) and adequately documented		
Each consignments and/or lot carries an identification number or other code to distinguish it from all other consignments and/or lots		

Criteria	Yes	No
<i>6. Documentation</i>		
All records about each consignment and/or lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed		
The NPPO has a written compliance agreement with the facility		

APPENDIX 1

This appendix is for reference purposes only and is not a prescriptive part of the standard. The list is not exhaustive and should be adapted to specific circumstances. The references here are widely available, easily accessible and generally recognized as authoritative. The list is not comprehensive or static; nor is it endorsed as a standard under this ISPM.

ESTIMATED MINIMUM ABSORBED DOSES FOR CERTAIN RESPONSES FOR SELECTED PEST GROUPS³

The following table identifies ranges of minimum absorbed dose for pest groups based on treatment research reported in the scientific literature. Minimum doses are taken from many publications that are in the references listed below. Confirmatory testing should be done before adopting the minimum dose for a specific pest treatment.

To ensure the minimum absorbed dose is achieved for phytosanitary purposes, it is recommended to seek information about the Dmin for a particular target species and also to take into consideration the note in Appendix 2.

Pest group	Required response	Minimum dose range (Gy)
Aphids and whiteflies (Homoptera)	Sterilize actively reproducing adult	50-100
Seed weevils (Bruchidae)	Sterilize actively reproducing adult	70-300
Scarab beetles (Scarabidae)	Sterilize actively reproducing adult	50-150
Fruit flies (Tephritidae)	Prevent adult emergence from 3rd instar	50-250
Weevils (Curculionidae)	Sterilize actively reproducing adult	80-165
Borers (Lepidoptera)	Prevent adult development from late larva	100-280
Thrips (Thysanoptera)	Sterilize actively reproducing adult	150-250
Borers (Lepidoptera)	Sterilize late pupa	200-350
Spider mites (Acaridae)	Sterilize actively reproducing adult	200-350
Stored product beetles (Coleoptera)	Sterilize actively reproducing adult	50-400
Stored product moths (Lepidoptera)	Sterilize actively reproducing adult	100-1,000
Nematodes (Nematoda)	Sterilize actively reproducing adult	~4,000

REFERENCES

- International Atomic Energy Agency. 2002. International Database on Insect Disinfestation and Sterilization. (available at <http://www-ididas.iaea.org>).
- Hallman, G. J. 2001. Irradiation as a quarantine treatment. In: Molins, R.A. (ed.) *Food Irradiation Principles and Applications*. New York: J. Wiley & Sons. p. 113-130.
- Hallman, G. J. 2000. Expanding radiation quarantine treatments beyond fruit flies. *Agricultural and Forest Entomology*. 2:85-95.
- <http://www.iaea.org/icgfi> is also a useful website for technical information on food irradiation.

³ Not conclusively demonstrated with large scale testing. Based on literature review by Hallman, 2001.

APPENDIX 2

This appendix is for reference purposes only and is not a prescriptive part of the standard.

RESEARCH PROTOCOL⁴**Research materials**

It is recommended to archive samples of the different developmental stages of the pests studied in order to, among other reasons, resolve possible future disputes on identification. The commodity to be used should be of normal commercial condition.

To perform treatment research to control quarantine pests it is necessary to know its basic biology as well as define how the pests used in the research will be obtained. The experiments with irradiation should be carried out on the commodity infested naturally in the field and/or with laboratory-reared pests that are used to infest the commodity preferably in a natural form. The method of rearing and feeding should be carefully detailed.

Note: Studies done with pests *in vitro* are not recommended because the results could be different from those obtained when irradiating the pests in commodities unless preliminary testing indicates that results from *in vitro* treatments are no different than *in situ*.

Dosimetry

The dosimetry system should be calibrated, certified and used according to recognized international standards. The minimum and maximum doses absorbed by the irradiated product should be determined striving for dose uniformity. Routine dosimetry should be conducted periodically.

International ISO Guidelines are available for conducting dosimetry research on food and agricultural products (see Standard ISO/ASTM 51261 *Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing*).

Estimation and confirmation of minimum absorbed dose for treatment*Preliminary Tests*

The following steps should be carried out to estimate the dose required to ensure quarantine security:

- Radiosensitivity of the different stages of development of the pest in question that may be present in the commodity that is marketed must be established with the purpose of determining the most resistant stage. The most resistant stage, even if it is not the most common one occurring in the commodity, is the stage for which the quarantine treatment dose is established.
- The minimum absorbed dose will be determined experimentally. If pertinent data do not already exist, it is recommended to use at least five (5) dose levels and a control for each developmental stage, with a minimum of 50 individuals where possible for each of the doses and a minimum of three (3) replicates. The relationship between dose and response for each stage will be determined to identify the most resistant stage. The optimum dose to interrupt the development of the most resistant stage and/or to avoid the reproduction of the pests needs to be determined. The remainder of the research will be conducted on the most radiotolerant stage.
- During the period of post-treatment observation of the commodities and associated pests, both treated and control, must remain under favorable conditions for survival, development, and reproduction of the pests so that these parameters can be measured. The untreated controls must develop and/or reproduce normally for a given replicate for the experiment to be valid. Any study where the control or check mortalities are high indicates that the organisms were held and handled under sub-optimal conditions. These organisms may give misleading results if their treatment mortality is used to predict an optimum treatment dose. In general, mortality in the control or check should not exceed 10%.

Large Scale (Confirmatory) Tests

- To confirm if the estimated minimum dose to provide quarantine security is valid, it is necessary to treat a large number of individuals of the most resistant stage of the organism while achieving the desired result, be it prevention of pest development or sterility. The number treated will depend on the required level of confidence. The level of efficacy of the treatment should be established between the exporting and importing countries and be technically justifiable.

⁴ Based primarily on insect pest treatment research.

- Because the maximum dose measured during the confirmatory part of the research will be the minimum dose required for the approved treatment, it is recommended to keep the maximum-minimum dose ratio as low as possible.

Recordkeeping

Test records and data need to be kept to validate the data requirements and should upon request be presented to interested parties, for example the NPPO of the importing country, for consideration in establishing an agreed commodity treatment.