NSPM-21

Guidelines for Certification of Irradiation Treatment Facilities to meet the Phytosanitary Requirements

Government of India
Ministry of Agriculture & Farmers' Welfare
Department of Agriculture & Cooperation
Directorate of Plant Protection, Quarantine & Storage
N.H.IV, Faridabad –121001 (Haryana)

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Contents

Endorsement

This standard entitled **'Guidelines for Certification of Irradiation Treatment Facilities to meet the Phytosanitary Requirements'** has been prepared by the Directorate of Plant Protection, Quarantine & Storage (Dte of PPQ&S), Faridabad-121001. This standard describes the guidelines/procedures for certification of irradiation facilities to meet the phytosanitary requirements in line with the international standards established under IPPC, FAO, Rome.

This standard was duly approved for adoption on _____ by:

_____

Plant Protection Adviser
Dte of PPQ&S
Faridabad -121001.

Review & Amendment

This standard will be subjected to periodic review by the Plant Protection Adviser (PPA) and amended or revised as necessary. The standard holders should ensure that the current edition of the standard being used.

Control & Distribution of the Standard

PPA will hold the master copy of this standard. Additional Plant Protection Adviser (PQ) will distribute the controlled copy of this standard to the officers of Plant Quarantine Stations listed below and to any other person specifically authorized by PPA. Any enquiries regarding this standard should be made to the PPA, Dte of PPQS, Faridabad-121001.

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INTRODUCTION

Scope

This standard provides technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles. However this standard does not cover the treatments applied 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

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.
Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.
Guidelines for the use of irradiation as a phytosanitary measure, 2003, ISPM No. 18, FAO, Rome.
Guidelines for Pest Risk Analysis, 1996. ISPM No. 2, FAO, Rome
Export certification system, 1997. ISPM No. 7, 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.
The Plant Quarantine (Regulation of Import into India) Order, 2003 as amended by S.O.No.167 (E), dated 6th February 2004

Definitions and Terms

Absorbed dose	Quantity of radiation energy (in gray) absorbed per unit of mass of a specified target [ISPM No. 18, 2003]
Authority	An official organization vested with legal powers for implementation of regulations
Commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
Devitalization	A procedure rendering plants or plant products incapable of germination, growth or further reproduction [ICPM, 2001]
Dose mapping	Measurement of the absorbed dose distribution within a process load through the use of dosimeters placed at specific locations within the process load [ISPM No. 18, 2003]

Dosimeter	A device that, when irradiated, exhibits a quantifiable change in some property of the device which can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques [ISPM No. 18, 2003]
Dosimetry	A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use [ISPM No. 18, 2003]
Efficacy (treatment)	A defined, measurable, and reproducible effect by a prescribed treatment [ISPM No. 18, 2003]
Gray (Gy)	Unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram (1 Gy = 1 J.kg-1)
Inactivation	Rendering micro-organisms incapable of development [ISPM No. 18, 2003]
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect]
Ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction create ions by either primary or secondary processes [ISPM No. 18, 2003]
Irradiation	Treatment with any type of ionizing radiation [ISPM No.18, 2003]
Irradiator	A facility that provides ionizing radiation
Maximum absorbed dose (Dmax)	The localized maximum absorbed dose within the process load
Minimum absorbed dose (Dmin)	The localized minimum absorbed dose within the process load [ISPM No. 18, 2003]
NPPO	National Plant Protection Organization [FAO, 1990;ICPM, 2001]
Official	Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

Phytosanitary certification	Use of phytosanitary procedures leading to the issue of a Phytosanitary Certificate [FAO, 1990]
Phytosanitary measure (agreed interpretation)	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 [FAO, 1995; revised IPPC, 1997; ICPM, 2002]

The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. *This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997).*

PRA	Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]
Process load	A volume of material with a specified loading configuration and treated as a single entity [ISPM No. 18, 2003]
Regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
Required response	A specified level of effect for a treatment [ISPM No. 18, 2003]
Target pest	Pest species against which the irradiation treatment is directed.
Treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

OUTLINE OF REQUIREMENTS

Treatment with ionizing radiation (irradiation) may be used for pest risk management. Dte of PPQS 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 Dte of PPQS will be responsible for ensuring that facilities are appropriately designed for carrying out treatments to meet the phytosanitary requirements. The irradiation facility will be responsible for documentation of procedures, which would ensure that the treatments can be conducted properly and commodity lots are handled, stored and identified to ensure that phytosanitary security is maintained. The facility should maintain appropriate treatment/dosimetry records to ensure the traceability. A compliance agreement between facility operator and the Dte of PPQS should be used to specify process requirements and to assure that responsibilities, liabilities and the consequences of non-compliance are clearly understood for ensuring appropriate phytosanitary measures and the recognition of foreign facilities would involve entering a cooperative agreement or work plan in order to verify the treatments and auditing of procedures to ensure the phytosanitary security.

1.0. GENERAL REQUIREMENTS

1.1. Background

Irradiation has been demonstrated to be effective in killing or devitalizing organisms that may contaminate and do harm to commodities or the ecosystems to which the commodities move. This energy source can thus be authorized for use in the treatment of regulated pests. Treatment may be mandatory, as a condition for the entry or movement of consignments, or it may be prescribed, based on the detection of regulated pests in commodities intended for transport. Alternatively, importers or exporters may voluntarily subject commodities to irradiation treatments in order to prolong their acceptability and desirability. Irradiation may thus be a treatment option, or it may be the only treatment, which is approved for the pest and commodity in question. As with all pest mitigation treatments, the objective is to minimize the risk of pest introduction through the use of exclusionary measures. The minimization of pest risk may be achieved through the use of treatments that have an acceptable level of efficacy. Irradiation treatments are approved to minimize the impact on the commodity and its ultimate use as a pest mitigation treatment. The purpose of these treatments is to minimize the pest risk and to maximize the safety associated with the movement and use of the commodity. Treatments and associated procedures are based upon science, and are no more restrictive than necessary to protect plant health.

This standard provides appropriate guidance for approval/recognition of irradiation facilities for performance of appropriate phytosanitary treatments to mitigate the pest risks associated with international trade in agriculture commodities.

1.2. Regulatory Requirements

As per clause 3 (17) of the 'Plant Quarantine (Regulation of Import into India) Order, 2003 as amended by S.O.No.167 (E), dated 6th February, 2004', where irradiation is necessary in respect of any consignment of fresh fruits or vegetables or other plant products, the same shall be carried out by the importer at his own cost, at an irradiation facility, established as per the regulations of the "Atomic Energy Regulatory Board" and duly approved by the Plant Protection Adviser (PPA) under the International Standards established under the "International Plant Protection Convention" and at the scheduled dosage approved by the Plant Protection Adviser under supervision of an officer authorized by him.

1.3. Authority to Approve/Recognize the Facility

The Dte of PPQS established under the Ministry of Agriculture & Farmers' Welfare (NPPO) will be responsible for approval/recognition of the irradiation facility for phytosanitary aspects of evaluation, adoption and use of irradiation as a phytosanitary measure.

1.4. Minimum Requirements for Certification of Facility

The minimum requirements for certification of facility for carrying out treatment of commodities to meet the phytosanitary requirements to mitigate the regulated pests in commodities will include:

1.4.1. Current Licence

The facility must be currently licensed by the Atomic Energy Regulatory Board established under the Department of Atomic Energy of Ministry of Science & Technology and all other relevant state authorities.

1.4.2. Minimum Dosage

The facility must be capable of administering at least the minimum required absorbed ionizing radiation dose, as prescribed by the Dte of PPQS of Ministry of Agriculture & Farmers' Welfare for the particular pest complex/commodity to be treated.

1.4.3. Biological Safeguards

The facility must be constructed so as to provide physical separation of untreated and treated commodities, ensuring biological security. If mobile pests (such as adult fruit flies) are the target, the commodity should be in pest-proof containers or separated by a wall or by a screen with a mesh size fine enough to exclude flying insects. The Dte of PPQS may waive this requirement if one or more of the following three conditions apply:

- The irradiation facility is located in an area that would not support an infestation of the target pests
- The pests of concern are immobile
- The commodity to be irradiated arrives at the facility in pest-containment cartons.

1.4.4. Radiation Safety

The facility must meet the radiation safety norms established under the Safety Code of Atomic Energy Commission of Government of India

1.4.5. Documentation of Training

The facility must document the training of key employees on the operation of an irradiation processing facility, applicable to irradiation treatment of agricultural products. All personnel with treatment-related responsibilities should have proper credentials, training, and authority for application of irradiation treatments. Appropriate records should be made available for inspection by officials of the Dte of PPQS and or other officials of NPPO of importing country on request.

1.4.6. Documentation of Procedures

The irradiation facility should be required to have well documented standard operating procedures (SOPs) defining the processing, handling, and safeguarding of regulated agricultural commodities. The SOPs should be reviewed by the regulatory official during inspections, to ensure conformance to the Compliance Agreement, applicable treatment schedule(s), and other applicable regulations.

1.5. Application for Approval/Recognition/Recertification of the Facility

An application for approval/recognition/re-certification of the facility for undertaking phytosanitary treatments should be made to PPA, Dte of PPQS, N.H.IV, Faridabad-121001 in format prescribed in Appendix-1. The application should be accompanied by a bank draft for Rs 2000/- towards registration fee drawn in favour of the Accounts officer, Dte of PPQS, Faridabad-121001 and the Compliance Agreement (Appendix-II) duly signed by the facility manager, who has full authority to ensure compliance with the conditions of the agreement. The attachments to the application should include a plan of the facility and an outline of the processes and standard operating procedures (SOPs) to be used by the facility to meet the requirements described above. This information should be held in strict confidence by the office of PQ Division of Dte of PPQS, Faridabad-121001.

1.6. Site Approval Visit/Inspection of the Facility

An officer of the Dte of PPQS will review all documents for completeness, and correspond with the applicant, as needed. When all documents have been approved, an official site approval visit will be scheduled. During this visit, the officer will compare the floor plan schematic and product flow pattern with the actual installation, review the safeguards that are in place, and conduct an audit as per the checklist prescribed in Appendix-III. The site approval visit will be conducted in association with a representative from the Atomic Energy Regulatory Board of Department of Atomic Energy and the construction & design engineer of the facility. The inspecting officer at the end will submit a report of audited checklist to the PPA along with his recommendations for certification of facility. If any deficiencies are noticed the same will be communicated to the irradiation facility and the same will be re-audited to ensure the corrective actions are implemented before recommending the facility for certification.

1.7. Issue of Certificate of Approval/Recognition/Recertification of the Facility

Upon approval of the facility, PPA will issue a Certificate of Approval in the format prescribed in Appendix-IV, outlining the terms, conditions, and restrictions of the approval. This certificate should remain valid unless revoked or withdrawn. Annual recertification of facility will not be required unless reinstatement is requested by a facility or if the facility has a significant change in either its ownership, plant management, equipment or other key operating procedures. However the approved/recognized facilities will be subjected to annual verification to ensure compliance with the requirements of this standard. PPA will issue a recognition certificate in respect of foreign facilities after verification of the facilities and thereafter Dte of PPQS may audit the operation of the facility on a periodic basis in association with technical counterpart of

the foreign country in which the facility is located and for this purpose will enter a Framework Equivalency Work Plan with NPPO of the country in which the foreign facilities located.

1.8. Refusal/Withdrawal of Certification

PPA will refuse or withdraw certification of irradiation treatment facility, when any provisions of this standard is not met with or complied with. Before any refusal or withdrawal of certification, PPA will inform the facility owner in writing the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. PPA will give the irradiation processor an opportunity for hearing any dispute of a material fact, in accordance with applicable rules that will be adopted for proceeding. However, PPA will suspend certification pending final determination in the proceeding, if in his opinion suspension is considered necessary to prevent the spread of any dangerous pest. The suspension will come into force upon written notification to the irradiation processor and continue in effect pending final determination in the proceeding.

1.9. Official Verification & Auditing

Dte of PPQS will verify the adequacy of irradiation treatment facilities and processes through monitoring and audit of facility treatment records that include, as necessary, direct treatment oversight. However, direct continuous supervision of treatments may not be considered necessary provided that 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 Framework Equivalency Work Plan will be concluded between the Dte of PPQS, 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.

The irradiation facilities will be subject to surprise checks (un-announced audits) at periodical intervals by the officers of Dte of PPQS to ensure proper phytosanitary safe guards are in place and the treatments are carried out as per the protocols approved by PPA or as specified by the NPPO importing country.

1.10. Administration and Documentation by the NPPO

The Dte of PPQS will undertake the monitoring, certification, accreditation and approval of facilities for phytosanitary treatments. Where the facility is located outside the country, Dte of PPQS will enter into a Framework Equivalency Work Plan or Cooperative Agreement with NPPO of the host country in which facilities are located and which will involve a Facility Compliance Agreement signed by the NPPO of the country in which foreign irradiation treatment facility is located and the facility operator and an Operational Work Plan. If the

irradiation treatment facility located within India, Dte of PPQS will enter Compliance Agreement with the facility operator and a separate agreement with the importer or exporter as the case may be.

The Compliance Agreement will specify the process requirements and to assure that responsibilities, liabilities and the consequences of non-compliance are clearly understood. The Operational Work Plan will detail the specific requirements for approval of the treatment facilities, the application of quarantine treatments, safe guards, documentation and audit procedures with the NPPO of the country in which foreign facilities are located in order to verify the requirements. Dte of PQS in consultation with Ministry of Agriculture & Farmers' Welfare will establish a separate cooperative agreement with NPPO of the country in which foreign facilities are located to pay in advance all costs, which the Dte of PPQS propose to incur towards providing inspection and treatment monitoring services, which include travel costs of the quarantine experts, per diem subsistence allowances (DSA) and other incidental expenses as per the Agreement.

2.0. SPECIFIC REQUIREMENTS

2.1. Approved Sources of Irradiation

The sources for energy commonly used in irradiation come from gamma-emitting isotopes (radio nuclides) of cobalt-60 or cesium-137; or from machine-generated sources which include (x-rays [bremsstrahlung] operated at or below an energy level of 5.0 MeV, or electron beams operated at or below an energy level of 10 MeV). Any of these sources can be effectively used to devitalize pests that may be contaminants, thus eliminating the risk of relocating alien invasive species that pose a threat to agriculture or other ecosystems. The source and equipment used for pest mitigation treatments must be capable of safely and effectively irradiating the commodities to the specifications, which are required for the targeted pests.

2.2. Location of the Facility

The facility should be located as for as possible near to the port of shipment or well connected to packing house facilities for easy transport of commodity. The phytosanitary safeguards required to be met with by the facility will vary with different scenario of location of the facility i.e either within an infested area or not within the infested area but surrounded by susceptible hosts or not within infested area and not surrounded by susceptible hosts as discussed under Section 2.6.11.

2.3. Efficacy (Treatment)

Dte of PPQS or the NPPO of the importing country (in respect of export consignments) will specify the required treatment efficacy. 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:

- Mortality (level 3);
- Non-emergency of adults (prevention of successful development) (level 2);
- Sterility (inability to reproduce) (level 1);

An estimated minimum absorbed doses for certain responses for selected pest groups based on laboratory studies are given in Appendix-V, for information. However large scale (confirmatory) tests are required 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. 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.

2.4. Approval of Treatment Protocols by the NPPO

The facility should use the treatment protocols that are either approved by the Dte of PPQS or the NPPO of importing country. Treatment procedures should also ensure that the minimum absorbed dose (Dmin) 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 Dmin may be required to ensure that the Dmin is achieved throughout the configured consignment or lot. The intended end use of the product should be considered when conducting irradiation treatments. 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 should ensure 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).

2.5. Dosimetry

Dosimetry should ensure 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 used by the facility 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 Dte of PPQS prior to the approval of a facility for the treatment application. Only the configurations approved by the Dte of PPQS should be used for actual treatments.

2.5.1. Calibration of the Components of Dosimetry System

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

2.5.2. 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

2.5.3. Routine Dosimetry

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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 the phytosanitary requirements.

2.5.4. Timer or Cycle Validation

Irradiation exposure times to assure delivery of the specified dose should also be evaluated. In the case of radioisotope processing, this should involve validating timer settings upon which product container movements are based, or in the case of electron or x-ray processing, validating conveyor speeds. Timers should be calibrated to NIST Time Signals.

2.6. Phytosanitary Security Measures at the Treatment Facility

2.6.1 System Integrity of the 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, re-infestation or contamination afterwards. Packaging prior to irradiation may be useful to prevent re-infestation if irradiation is done prior to export, or to prevent the accidental escape of target pest(s) if treatment is done at the destination.

2.6.2 Product Receiving at the Facility

A record of origin (growing and shipping points) must accompany all arrivals at the facility. For Scenarios 1 and 2 listed in Section 2.6.11, the truck vans and sea containers used for delivery should form a pest-secure connection with the receiving area of the building, if pests are mobile. However, this would not be necessary if the commodity arrives in pest-proof cartons, or is wrapped in polyethylene (or equivalent) sheeting or insect netting. For Scenario 2, the irradiation facility should not be allowed to receive the product that arrives non-containerized (e.g., in an automobile or pickup truck). If a pest-secure connection is not possible, then the receiving door should be opened for the minimum time possible, while the unloading is being expedited. (These precautions are not necessary in Scenario 3.) When empty, the sea containers, truck vans, and air cargo containers in which the commodity arrived should be swept clean, and the sweepings bagged and irradiated to at least the minimum dose designated for the product, or destroyed in a manner approved by Dte of PPQS. If pests are at large in the emptied container, the container should be treated immediately with a suitable insecticide, followed by visual inspection. (Use an aerosol insecticide for mobile pests, or a residual spray for others, following instructions on the label.) Irradiation processing of agricultural commodities should be expedited, to retard the development and possible emergence of pests from the commodity. Dte of PPQS recommends that the consignment be kept in temporary cool storage if it is not possible to irradiate it within 24 hours of arrival.

2.6.3. General sanitation at the facility

A high level of sanitation should be maintained around the facility, as well as within the pre- and post-treatment storage areas, and the equipment used for transporting the product through the irradiator. Windows, if they are going to be opened, must be equipped with screens. Facilities should install black light traps for flying insects or appropriate fruit fly monitoring traps and to contract with a pest control firm for periodical undertaking of general pest control measures. Critical concerns of Dte of PPQS include pest monitoring and minimizing the attractiveness of treatment facilities for pests. Disposal procedures should be in place for rotted produce, produce with damaged packing, and produce that has been improperly irradiated. These materials should be irradiated, at a dose sufficient to mitigate the potential pest risk, prior to disposal by incineration or burial in a sanitary landfill, if required by Dte of PPQS. The area of the floor where the commodity is loaded onto the conveyor should be swept clean at the end of the day, and the debris should be bagged and irradiated to at least the minimum dose designated for the product.

2.6.4. Segregation of untreated and treated product areas

The facility should have a reliable system for separating treated from untreated products, to safeguard against commingling, cross-infestation, mistaken identity, and release without treatment. In Scenarios 1 and 2, the physical barrier should also be a pest-proof (biological) barrier (i.e., a solid wall or a screen with a mesh size fine enough to exclude flying insects), unless the commodity arrives in pest-proof cartons, or if the target pests are immobile. In Scenario 3, a 6-ft barrier, such as a chain link fence, is adequate for all pests, and the type of carton is of minor importance

2.6.5. Packing

The commodity should arrive at the facility in pest-proof packing if the pests are mobile, except if a pest-proof barrier (between pretreatment and post-treatment storage areas) is in place at the facility. This provision would apply only in Scenarios 1 and 2. If pests are not mobile, or if the surrounding area is not susceptible to infestation by the target pests in Scenario 3, then the type of packaging becomes less important. Seals or other devices may be used to visually indicate if packages have been opened. For pests that are not mobile, simple containment is the key, and the integrity of the container load is the main concern. Pest-proof packages, if required, may be constructed of any material that prevents the entry or escape of the pest, prevents egg laying into the carton, and the dispersal of pupae. If openings in the carton are needed in order to maintain freshness of the commodity, they should be double screened.

2.6.6. Marking/Labeling

In order to enable trace-back of shipments, unit loads should be labeled or coded with identifiable treatment lot or batch numbers, packing and treatment facility identification and location, and the dates of packing and treatment. In addition, each carton (or smallest containment unit) should bear a stamp identifying the lot or batch number and treatment facility. The markings on individual packages may be encrypted (e.g., bar coding). If the pallet load is broken down into smaller units before or during the process of shipment, the individual cartons must be labeled with the same information as the original pallet load.

2.6.7. Post-treatment Handling &Storage

The facility should have a secured area for post-treatment handling of commodity to prevent re-infestation of treated commodity and adequate pre-cooling and cold storage facilities for holding perishable commodities until loading into the containers for shipment. The pre-cooling and cold storage facilities should be integrated with the treatment facility.

2.6.8. Wrapping/palletalization

The integrity of the pallet load or other configuration of packages representing a treatment unit should be maintained by wrapping it with thin plastic sheeting or insect-proof netting before it leaves the irradiation facility. In Scenarios 2 and 3, (where the irradiation facility is not located within an infested area), a suitable method of wrapping would be to use strapping, so that each

carton on an outside row of the pallet load is constrained by a metal or plastic strap. In Scenario 1, (where the irradiation facility is located in an infested area), the treatment unit should be wrapped in polyethylene (or equivalent) sheet wrap or fine net wrapping. Dte of PPQS, however, may waive the requirement for post-treatment wrapping if the cartons are pest-proof, and the pallet load is to be broken down into smaller shipping units, such as LD-3 air cargo containers or individual cartons. If wooden pallets are used, they should be treated and marked as per ISPM15, FAO (*Guidelines for regulating wood packaging material in international trade***)** in a facility approved by PPA.

2.6.9. Loading Containers

Empty containers or vans should be carefully inspected, and decontaminated (if necessary), prior to loading with treated product. Empty containers should be swept clean, and the sweepings bagged and put through the irradiator. If pests are at large in the empty container, the container should be treated immediately with a suitable insecticide, followed by visual inspection. (Use an aerosol insecticide for mobile pests, or a residual spray for others, following instructions on the label.) In Scenario 1 (where the facility is located in an infested area), if the pests are mobile, special care should be taken to prevent the reentry of untreated pests into the treated product. The conveyance should be pest-proof. In addition, the driver should make every effort to form a pest-secure connection between the conveyance and the building. If this is not possible, then the door to the loading dock should be opened for the minimum time possible, while loading is being expedited. This precaution is not needed in Scenarios 2 and 3 (where the irradiation facility is not located in an infested area).

2.6.10. Official Sealing

The containers should be appropriately sealed by the PQ officer of the Dte of PPQS immediately after completion of loading at the irradiation treatment facility. The Irradiated or untreated shipments leaving foreign country for India should bear the seals of NPPO of that country in which the facilities are located.

2.6.11. Phytosanitary Safeguards- Three Scenarios

Scenario-1: The irradiation facility is located within an infested area

The purpose of the safeguards, in this instance, is to protect the treated commodity from becoming re-infested. The following safeguarding topics would all seem to apply in scenario 1:
. receiving
. separation of treated from untreated commodities
. packing
. marking/labeling
. general sanitation
. wrapping
. loading containers

For "separation of treated from untreated commodities", a screen or solid wall would be an important feature only if pests are mobile. Pest-proof "packing" would also be an option in this case. Also, if the pests of concern are mobile, an appropriate "wrapping" option would be polyethylene (or equivalent) sheet wrap or net wrap. When "loading containers" a pest-secure connection to the building would be appropriate only if the pests are mobile and could fly in from outside the building.

Scenario-2: The irradiation facility is not located within an infested area, but the surrounding environment is susceptible to the target pests.

The purpose of safeguards, in this instance, is to protect the surrounding environment from escaping pests that have not been treated. However, owing to the high level of pest risk posed by this scenario, Dte PPQS may not allow importation of untreated (potentially infested) commodities to an irradiation facility located within a sensitive, receptive environment, without stringent safeguards and quality assurance activities. If this scenario were allowed, then the following safeguarding topics would be critically enforced:

. marking/labeling
. general sanitation
. wrapping

If the pests are mobile, then the following safeguarding topics would certainly apply, as well:

. receiving
. separation of treated from untreated commodities
. packaging

"Loading of containers" would not apply, since any surviving pests that escape into the environment would be sterile, and pose no risk.

Scenario-3: The irradiation facility is not located within an infested area, and the surrounding environment is not susceptible to the target pests.

Applicable safeguarding, in this instance, includes:

. separation of treated from untreated commodities
. general sanitation
. wrapping

For "separation of treated from untreated commodities", a 6-ft high barrier would suffice, except for mobile pests. For "wrapping", the strapping option may provide adequate quarantine security, though polyethylene (or equivalent) sheet wrap or netting could also be suitable.

2.7 Documentation by the Treatment Facility

The facility should be responsible for proper record keeping and documentation and ensuring that records are available to Dte of PPQS and other concerned regulating authorities at the time of monitoring for verification. As in the case of any phytosanitary treatment, trace-back capability is essential.

2.7.1. Documentation of Procedures

2.7.1.1. Standard Operating Procedures

The facility should develop and document Standard Operating Procedures (SOP) that address irradiation of commodities for mitigation of pests of plants. This document must be in place before the facility is offered for certification. It must include the "how to" for all facets of handling, safeguarding and treating the commodities. This document list out critical control points of processing, which include product receiving protocols, dosimetry system protocols, treatment protocols and post-treatment storage/handling protocols, documentation and safeguards. Critical control points are points where errors will definitely reduce the long-term effectiveness of the treatment. (On the other hand, effort to ensure correct procedure at these points will result in substantially more effective treatments.) The SOP will be reviewed and scrutinized along with the facility and personnel qualifications in determining the acceptability for certification. Any required changes in this document should be made before a compliance agreement can be issued. This document will be referenced as a part of a formal, written agreement between the Dte of PPQS and the facility. Such agreements should be reviewed periodically, modified as needed, and treated as confidential.

2.7.1.2. Compliance Agreement/Framework Equivalency Work Plan

Before operating as an approved irradiation plant pest treatment facility, a formal, written agreement should be developed between the irradiation facility and Dte of PPQS. This document is called a compliance agreement (Appendix-II) when applied to facilities established in India. For foreign facilities, this document may be called a Cooperative Agreement or Framework Equivalency Work Plan. The signatories to a bi-national agreement with foreign facilities will include a representative of the irradiation facility, the NPPO of the country in which the facility is located and the Dte of PPQS. The officers of Dte of PPQS and other concerned regulatory authorities will have a copy of Framework Equivalency Work Plan on hand and the approved treatment schedule for the particular pest and commodity being treated, in order to perform their duties as a regulatory official. Importers also need to sign a separate Compliance Agreement with Dte of PPQS, to ensure that they move articles safely to the irradiation facility. A Compliance Agreement (or equivalent) will be valid until terminated by a request from the facility. Dte of PPQS, however, will suspend or terminate the agreement when any provision is not being met, or is being willfully violated.

The Operational Work Plan will describe the pertinent safeguards applicable to the particular facility. Safeguarding topics fall into three general categories:

1. Pretreatment
    - receiving
    - separation of treated from untreated commodities
    - packaging
    - marking/labeling
2. Processing
    - general sanitation
3. Post-treatment
    - wrapping
    - loading containers
    - Sealing

Dte of PPQS (or the host country's NPPO counterpart agency) should be notified by the irradiation facility at least 30 days for regulated foreign agricultural commodities, except if the treatments are ongoing or scheduled. Treatments should be subject to scrutiny by a PQ officer authorized by PPA. During the initial phase, it is considered important for a PQ officer to be on site. Phase out of the PQ officer's presence can be accomplished over a period of time, after the level of confidence is built up that proper procedures are in place, and are working to achieve their goal. Thereafter, a PQ officer will usually not be physically present to monitor individual treatment procedures. The PQ officer visits may be announced or unannounced, and should include an examination of treatment records, and spot-checks to verify that biological safeguards are being conducted.

2.7.2. Facility records & traceability

The facility should maintain the following records and be available to the officer of Dte PPQS for review:

- **Product Receipt/Delivery Register** (Name of the Product, Quantity, No of packages & Size, Batch No/Product Identification Number/Marks, Name of Customer, Invoice Particulars/Bill of lading, Date/time of receipt, Prescribed treatment, Date/time of Irradiation, Date/time of product delivery, Container Particulars, if any)
- **Dosimetry Records** (Dmin/Dmax)
- **Dosimetry System Calibration Records**
- **Dose Mapping Records**
- **Treatment Records (**Name of the Product, Quantity, No of packages, product identification Numbers/Marks, Source of Radiation, target minimum dose, verified Dmin, target pest species, Date & Time of Treatment, and the Name & Signature of Treatment Operator
- **Treatment Certificates** (Name of the Product, Quantity, No of packages & Size, Product Identification Numbers/Marks, Source of Irradiation, Dose applied (Dmin/Dmax), Target pest species, Date & Time of Treatment, Name & Signature of Treatment Operator)

The facility should keep all the treatment/dosimetry records for phytosanitary purposes for at least one year to ensure traceability of treated lots and issue certificates evidencing the treatment applied.

2.8. Inspection and Phytosanitary certification by the NPPO

2.8.1. Export Inspection

Pre-shipment inspection of consignment will be carried out by PQ officer of Dte of PPQS at the treatment facility prior to loading of containers to verify the treatment and ensure that consignment meets the phytosanitary requirements of the importing country. This will include the 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, Dte of PPQS will verify whether these are regulated by the importing country. If live target pests are found after treatment the certification will be refused where

mortality is the required response. 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 should be part of the normal verification programme.

2.8.2. Phytosanitary Certification

Dte of PPQS will issue Phytosanitary Certificates based on treatment certificates provided to it by the approved/recognised irradiation facility. 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. 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*).

2.8.3. Import inspection & Quarantine Clearance

In the case of commodities irradiated at a foreign offshore facility, the PQ officer at the port of entry will review the bill of lading, phytosanitary certificate, or other documentation accompanying the shipment, determine whether or not the shipment is pre-cleared, and decide whether to inspect the commodity for actionable pests that might not have been mitigated by the treatment and might be pest-vectors present in the shipment. If non-target pests are encountered, the inspector should make inquiry to be irradiated. However a perishable commodity cannot be re-irradiated.

In the case of commodities arriving untreated (to be irradiated in India), the PQ officer should:

- review the documentation accompanying the shipment
- ensure compliance with biologically sound safeguards
- facilitate the planned movement of the shipment to an approved
- treatment facility

Importers should secure a valid permit before offering for entry of irradiated commodities or commodities intended for irradiation treatment in India. Permits may be obtained from:

The Plant Protection Adviser
Directorate of Plant Protection, Quarantine & Storage,
N.H.IV, Faridabad-121001.

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 PQ officer concerned under intimation to Dte of PPQS. The concerned PQ officer will 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 Dte of PPQS will 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*).

Appendix-I

Application for Approval/Recognition of Irradiation Treatment Facility to meet the Phytosanitary Requirements

1. Details of Applicant							
Name of Facility:							
Location/Address							
Street							
Town/City							
District/State							
Postal Code							
Facility Manager							
Name							
Contact Tel/Fax							
E-Mail							
Type of Facility							
Government							
Public Undertaking							
Private owned							
Construction & Design by							
Name							
Address							
Contact Tel/Fax							
E-mail							
II. Current Licensing							
Licence Number							
Date of issue							
Date of Expiry							
Licensing Authority							
III. Infrastructure Facility (Attach floor plans & elevation drawings including physical barrier)							
Total carpet area of the facility (m^2)							
Office Area (m^2)	**Laboratory Area** (m^2)	**Control Room** (m^2)	**Receiving Area** (m^2)	**Treatment cell** (m^2)	**T/P Storage Area** (m^2)	**Generator Room** (m^2)	**DM plant** (m^2)
Pre-cooling Area (m^2)/Capacity (MTs)							
Cold Storage Area (m^2)/Capacity (MTs)							

IV. Irradiation Plant					
Source of Radiation (*tick out the appropriate source)*	Gamma (Cobalt-60 or Cesium-137) Electronic beams (at or below 10 MeV) X-Rays [Bremsstrahlung] (5 MeV)				
Designed Radiation Capacity of the Plant (in Curies)					
Total Number of Curies installed					
Date of installation/installed by					
Anticipated Date of Replacement (*Total/Partial*)					
Conveyor Speed (metres/h)	Lowest_____Highest_____				
No of Carriages/Dimensions/Type					
No of Packages per Carriage &Dimensions of package/package type					
Product density (g/c.c)	Lowest_____ Highest_____				
Treatment Capacity of the Facility (tons/hour)	Lowest_____Highest_____				
V. Dosimetry					
Dosage Rate of Radiation (in Grays)	Min_____Max_____				
Type of Dosimeters used.					
Range of Dosimeter (in Grays	Lowest_____Highest_____				
Dosimetry System Standards followed (*tick out appropriate one*)	ASTM_____ISO_____Others_____				
VI. Biological safeguards					
Physical barrier (to separate treated and treated consignments)	Type_____Height_____Size of mesh (If wire or cloth screen)_____				
Double door entry	Yes/No				
Insect-proof screening of all external openings	Yes/No				
Insect traps (UV light traps) (Pre-treatment/ Post-treatment)/fruit fly monitoring traps (chemical traps) (external to the building)	Yes/No				
Insect-proof packages (netting/plastic wrapping)	Yes/No				
Seals or padding around the doors (unloading/ loading dock)	Yes/No				
VII. Documentation of Training (enclose documentary proof)					
Name/Designation of Staff	**Areas of training**				
	Food Irradiation	**Dosimetry**	**Radiation Safety**	**GMP**	**Others**

VIII. Documentation of Procedures				
Documented Standard Operating Procedures exist at the facility (*copy enclosed*)	Yes/No			
Compliance Agreement/Cooperative Agreement or Work Plan duly signed (c*opies enclosed)*	Yes/No			
XI. Additional Information				
Whether the application made is for the new facility?	Yes/No			
If new facility, whether site plans approved by the PPA, Dte of PPQS, Faridabad? (*enclose approved site plans/drawings*)	Yes/No			
If established facility, whether the application made is for approval for the first time or re-certification or reinstatement?				
Any alterations/modifications to the facility (*enclose revised plans/drawings*)				
Details of payment of fee				
Name of Bank	Branch	DD/PO/BC No.	Dated	Amount (Rs.)
Name & Signature of Facility Manager/ date/seal				

Appendix-II.

COMPLIANCE AGREEMENT

1. From	**2. To** The Plant Protection Adviser Dte of Plant Protection Quarantine & Storage, N.H-Faridabad-121001

3. Agreement related to:
Certification of Irradiation Treatment Facilities to meet the Phytosanitary Requirements

4. Applicable Phytosanitary Regulatory Requirements
To meet the PPQ regulations

5. I/we agree to the following:

-to carry out all treatments through trained & qualified technical operator
-to ensure periodical calibration of all components of dosimetry and maintain general sanitation of the facility in satisfactory condition
-to give ready access to the facility and provide all necessary assistance and extend cooperation to the officer of Dte of PPQS and other regulatory authorities during the visit to the facility for site approval/inspection of the facility and verification of treatments and procedures
-to follow all safety requirements or procedures during treatment operations and abide by the instructions and procedures required by the Plant Protection Adviser in the planning, set-up and conduct of phytosanitary treatments
- to carry out irradiation treatment of perishable commodities as per the protocols duly approved by the Plant Protection Adviser
-to maintain treatment/dosimetry records and calibration records of dosimetry and preserve for at least for a period of one year for traceability of treated lots for future verification
-to pay TA/DA for the inspecting PQ officers as per admissible rules for carrying out site approval visit/inspection of the facility for certification and subsequent annual verification for re-certification or whenever reinstatement of certification of facility is required.

6. Date:	**8. Authorized Signatory of the Facility:**
7. Place:	_____ **(Name/Signature/Designation/Seal)**

9. Signed in presence of:

_____
(Name/Signature of Officer of Dte PPQS/ Designation/date)

10. Approved by

_____
( )
Plant protection Adviser
Directorate of Plant Protection, Quarantine & Storage
N.H-IV, Faridabad-121001

Appendix-III.

Checklist for approval of Irradiation Treatment Facility to meet the Phytosanitary Requirements

Name of the Facility	
Location/Address	
Street	
Town/City	
Dist./State	
Postal Code)	
Facility Manager	
Name	
Tel/Fax	
E-Mail	
Audited by	

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	Comments
1. Premises		
Irradiation facility meets the approval of the Dte of PPQS as regards phytosanitary requirements. The Dte of PPQS 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 (such as insect proof netting from floor to ceiling), integral to the facility design, are available to maintain non-irradiated consignments and/or lots separate from treated consignments and/or lots		
Appropriate storage 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 (such as insect proofing of all vents/openings) 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		
Is there any fruit fly monitoring traps installed at the treatment facility?		

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		
2. Current Licence		
The facility got approval and holds current licence from the Atomic Energy Regulatory Board established under Department of Atomic Energy or state or other authorities		
The facility adopts the radiation safety norms prescribed by the Radiation Safety Committee of the Atomic Energy Regulatory Board		
3. Personnel		
The facility is adequately staffed with trained, competent personnel, who are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes		
4. Product handling, storage and segregation		
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		
5. Dosimetry		
Is this facility capable of administering at least the minimum required absorbed dose of ionizing radiation as prescribed by Dte of PPQS for the target pest in the commodity to be treated? (Dose range 1000 Grays or less).		
Does this facility have documentation that their dosimetry system is compliant with recognised national or international standard?		
6. Irradiation treatment		
Facility is able to perform required treatments in conformity with a scheduled process. A process control system is in place providing criteria to assess rradiation efficacy		

Proper process parameters are established for each type of commodity or consignment to be treated. Written procedures have been submitted to the Dte of PPQS 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 Dte of PPQS as needed		
7. Packing and labeling		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Will insect-proof packaging is used for the treated commodity?		
If boxes or crates contain air vents will they be taped or covered with cloth mess?		
Will the flaps of the boxes or crates be sealed with tape to cover the open seems?		
Are the treated boxes or crates are palletized and wrapped insect proof material?		
Treated consignments and/or lots are adequately identified or labeled (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		
8. Documentation of Procedures		
Appropriate Standard Operating Procedures (SOPs) developed and documented by the facility that address irradiation of commodities for mitigation of pests of plants. and available for inspection by the Dte of PPQS as needed		
9. Facility Records keeping & traceability		
Appropriate records are maintained at the facility as per the guidelines prescribed in this standard.		
Appropriate facilities exist for storage of the treatment records for phytosanitary purposes at the irradiation facility for at least one year to ensure traceability of treated lots and also dosimetry records and also the copies of treatment certificates issued.		
10. Recommendations of Inspecting Officer	**11. Name/Signature/Date with Seal**	
	_____ ( )	

Appendix-IV.

	Government of India Ministry of Agriculture & Farmers' Welfare Department of Agriculture & Cooperation **Directorate of Plant Protection, Quarantine & Storage** **N.H-IV Faridabad-121001**

Certificate No.	**Date of Issue:** **Valid up to:**

Certificate of Approval/Recognition of Irradiation Facility to meet the Phytosanitary Requirements

This is to certify that the irradiation treatment facility as described below has been inspected and approved for treating products as described below in line with the requirements of this standard and subject to terms and conditions specified below:

Date:
Place

_____
( )
Plant Protection Adviser

Description of Facility	
Name of facility	
Location/Address of Facility	
Source of Radiation	
Capacity of Facility	
Products intended to be treated at the facility	

Terms & Conditions:

1. The Certificate should be displayed at prominent place and available for verification during inspections to the facility;
2. Any changes or modifications or additions to the facility shall be made with the written approval of the Plant Protection Adviser
3. The certificate shall be valid for a period of one year from the date of issue unless otherwise revalidated prior to expiry.
4. All the treatment operations should be performed by a qualified and trained technical operator of the firm and necessary treatment/dosimetry records are maintained and made available to inspecting officer of Dte of PPQS for necessary verification
5. All the treatments should be performed as per the dose minimum (Dmin) protocols approved by the Plant Protection Adviser against the targeted pest.
6. The certified facility should abide by the instructions and guidelines issued by the Plant Protection Adviser from time to time
7. The certified facility shall comply with the requirements and conditions stipulated in the Compliance Agreement.

Endorsements:

Re-certified Vide Ref. No _____ dated_____ by_____

Re-certified Vide Ref . No _____dated_____by_____

Re-certified Vide Ref. No _____ dated_____ by_____

Re-certified Vide Ref. No _____ dated_____ by_____

Re-certified Vide Ref. No _____ dated_____ by_____

Suspended Vide Ref. No _____ dated_____ by_____

Re-instated Vide Ref. No _____ dated_____ by_____

Cancelled Vide Ref. No _____ dated_____ by_____

Copy to:

Appendix-V

Estimated Minimum Absorbed Doses for Certain Responses for Selected Pest Groups (ISPM 18)*

Note:-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.

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 Large Scale (Confirmatory) Tests

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

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
Borers (Lepidoptera)	Sterilize late pupa	200-350
Thrips (Thysanoptera)	Sterilize actively reproducing adult	150-250
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.

Appendix-VI

Agriculture Products approved for Irradiation under Prevention of Food Adulteration (PFA) Act, 1954 and Rules, 1955.

Name of Agriculture Product	Purpose of Irradiation	Radiation dose (kGy)	
		Minimum	Maximum
Onion	Sprout inhibition	0.03	0.09
Potato	Sprout inhibition	0.06	0.15
Ginger	Sprout inhibition	0.03	0.15
Garlic	Sprout inhibition	0.03	0.15
Shallot (small onions)	Sprout inhibition	0.03	0.15
Mango	Disinfestation	0.25	0.75
Rice	Disinfestation	0.25	1.0
Semolina (sooji, rawa)	Disinfestation	0.25	1.0
Wheat flour (atta and maida)	Disinfestation	0.25	1.0
Raisins, figs and dried dates	Disinfestation	0.25	0.75
Pulses	Disinfestation	0.25	1.0
Spices	Microbial decontamination	6.0	14.0