Standard Operating Procedures –
Irradiation Treatment of Indian Mangoes for export to USA

IFC Irradiator
Vashi, Navi Mumbai, (Maharashtra State)

INDEX

Introduction :

These Standard Operating Procedures (SOPs) are for use of irradiation of mangoes for export purpose for USA. The SOPs developed in accordance with the ISPM-18: Guidelines for the use of irradiation as a Phytosanitary measures established under IPPC and Irradiation Operational Work Plan of USDA. These SOPs are routinely monitored by the officials of Dte of PPQS (NPPO) of Department of Agriculture and Cooperation and the Atomic Energy Regulatory Board (AERB). These SOPs are periodically reviewed and have been approved by the Directorate of Plant Protection, Quarantine & Storage (NPPO) of Department of Agriculture & Cooperation.

These standard operating procedures (SOPs) are organized into various sections. This will allow revision of individual sections without dealing with modification of whole document. These SOPs are under continues scrutiny by the Dte of PPQS (NPPO) and they can be modified in cooperation with Irradiation facility and the Dte of PPQS and the USDA-APHIS.

1. **Scope**:
   From the arrival of the consignment from a packing house to the unloading at the unloading area of the irradiation facility

2. **Definition of Term**s:
   2.1. **APHIS**: Animal & Plant Health Inspection Service-US Department of Agriculture

   2.2. **APEDA**: Agricultural & Processed Food Products Export Development Authority (Cooperator)

   2.3. **Cooperator**: The officially recognized organization that will represent the exporters, packers and the treatment facilities and will sign (with the APHIS) the Cooperative Agreement and financial plan for the management of the accounting system.

   2.4. **Dte of PPQS**: Directorate of Plant Protection, Quarantine & Storage

   2.5. **Non-programme articles**: Plant products not covered under the irradiation operational work plan

   2.6. **NPPO**: National Plant Protection Organization
   2.7. **MSAMB**: Maharashtra State Agricultural Marketing Board
   2.8. **Programme articles**: Plant products covered under the irradiation operational work plan

   2.9. **Standard operating procedures (SOPs)**: Procedures developed and documented by each facility that address irradiation of commodities for mitigation of plant pests. This document must be in place before the facilities are offered for certification. It must include the "how to" for all the facets of handling, safeguarding and treating the commodities. Critical control points are dose, dosimetry and safeguards. SOPs will be reviewed along with facility specifications and personnel qualifications in determining the acceptability for certification.

3. **Responsibility and Authority**:

   3.1. **Security Officer** is responsible for providing entry to materials and actual users or the operating personnel of the plant. He is responsible for physical check of transport vehicles for providing entry to the facility.

Plant-In-charge/Quality Control Officer/Radiological Safety Officer is responsible for granting permission to deliver the consignment at the unloading area of the irradiation facility after verification and registration of programme articles for treatment

4. **Activity**:

4.1. Security Officer will allow the entry of conveyance after necessary verification of documents and after physical check of the vehicle and after ensuring that only programme articles are transported in closed conveyance for the treatment in Export Facility Centre and that no non-programme articles are transported in the same conveyance. He will make necessary entries in security register and issue a pass to the vehicle for entry and permit the vehicle for secured docking at unloading area. He will ensure that only programmed articles for irradiation are unloaded from docking at unloading area of irradiation facility.

4.2. Plant In-charge/Quality Control Officer/Radiological Safety Officer will receive the application (Annex-1) from the representative of packing house facility along with a detailed post-harvest process sheet (Annex-2) from packing house facility registered with APEDA. He will verify the application to ensure that it is correct and complete. He will grant permission to open the entry door to facilitate delivery of programme articles after ensuring secured docking of vehicle at unloading area and further the space between unloading conveyance and the entry door is covered with a insect-proof screen of 30 meshes per linear inch to prevent entry of hitch hiking pests.

4.3 Plant In-charge/Quality Control Officer/Radiological Safety Officer will verify that the programme articles are packed in insect-proof packages and securely sealed and appropriately labeled/marked as per the Irradiation Operation Work Plan (Only programme articles from packing houses and production units that are registered with APEDA (the Cooperator) in compliance with approved Irradiation Operational Work Plan, are permitted delivery at the unloading area).

4.4 Plant In-charge/Quality Control Officer/Radiological Safety Officer will register complete and correct application for irradiation treatment of programme articles after realizing the treatment fees. Each registered application is assigned a Treatment Identification Number and the particulars are recorded in a product log book (Annex-3), which is a serially page numbered and calico-bound.

4.5 Plant In-charge /Quality Control Officer /Radiological Safety Officer will notify the inspectors of APHIS and the Dte of PPQS regarding the receipt of consignment at the unloading area

4.6 Programmed articles arrived in refrigerated condition will be unloaded in cold storage and non-refrigerated articles will be unloaded in ambient condition.

1. **Scope**:

From initial sampling of programmed articles to the completion of inspection of consignment at untreated article storage area.

2. **Definition of Term**s:

2.1. **PPA:** Plant Protection Adviser to the Government of India

2.2. **Dte of PPQS:** Directorate of Plant Protection, Quarantine & Storage (NPPO)

2.3. **IPPC**: International Plant Protection Convention

2.4. **Lot:** A shipment of articles sent from a single production area to a packing house in one day and allotted by a unique code number by the packing house facility before it leaves for the treatment facility

2.5. **Pre-treatment inspection**: Inspection of commodity prior to irradiation treatment

2.6. Production area: Area in which the programmed articles (Refer to Section-1) are produced

2.7. Target Quarantine Pest: Quarantine pest against which irradiation treatment is targeted.

2.8. **Non-target Quarantine Pest:** Quarantine pest against which irradiation treatment is not targeted.

3. **Responsibility and Authority**:

3.1. **Officer of Dte PPQS (NPPO)** is responsible for conducting pre-treatment inspection of consignment at the facility in cooperation with inspectors of APHIS.

3.2. **Inspector of APHIS** is responsible to provide recommendations and operational guidance for conducting pre-treatment inspection.

4. **Activity**:

4.1. The officer of Dte of PPQS posted at the irradiation facility will receive from the exporter/packing house facility a separate application for export inspection and Phytosanitary certification of programme articles (Annex-1). He will verify the accompanied documents such as invoice, air way/shipping bill with respect to quantity and the production area and register the application after realizing the inspection fees at the prescribed rates. He will enter the particulars in an export inspection register (Annex-2), which is serially paged numbered and calico-bound.

4.2. The officer of Dte of PPQS in association with inspector of APHIS will draw appropriate samples of cartons from each lot stored at untreated article storage area for inspection (The sampling of each lot is as per addenda of Irradiation Operation Work Plan). The APHIS inspector will randomly select mango boxes and will ensure that weight & size of mangoes and boxes are as per specifications.

4.3. The officer of Dte of PPQS jointly with inspector of APHIS will check thoroughly the sampled cartons at the inspection room for hitch hiking pests as per Irradiation Operational Work Plan. Also further examine each fruit of sampled cartons under the illuminated magnifier for the non-targeted quarantine pests viz., *Cytosphaera mangiferae*, *Macrophoma mangiferae* & *Xanthomonas campestris pv. mangiferaeindicae* (Reference: Rule 7 CFR Parts 305 and 519 [Docket No. APHIS-2006-0121] RIN 0579-AC 19 published in Federal Register, Vol.72, No., 47: 10902-10903). Any suspected fruit is cut and further examined for internal pests.

4.4. The officer of Dte of PPQS (NPPO) will inspect the fruits and take action as per the addendum.

4.5. The officer of Dte PPQS will record the results of inspection of each lot and also the action taken, in an export inspection register (Annex-2), which is serially page numbered and calico-bound.

5. **References**:
   5.1. Irradiation Operational Work Plan

   5.2. Export Inspection Manual (PQ 15)

6. **Records**:
   6.1. Record of Export Inspection Application (Approved/Rejected)

   6.2. Export Inspection Register

7. **Annexes**:
   7.1. Format of Export Inspection Application (Annex-1)

   7.2. Format of Export Inspection Register (Annex-2)

1. **Scope**:

From the storage of packaged articles in untreated article storage area to the movement of articles for loading in product boxes on conveyor.

2. **Definition of Term**s:

3. **Responsibility and Authority**:

3.1. **Quality Control Officer/Plant In-charge/Radiological Safety Officer** is responsible for proper verification/storage of packaged articles in untreated area prior to treatment.

4. **Activity**:

4.1. Prior to storage of packages in untreated article storage area, Plant In-charge/quality control officer /Radiological Safety Officer will ensure that the area is cleaned and mopped to maintain a high level of sanitation as per the procedures specified in Section-9.

4.2. Plant In-charge/Quality control officer/Radiological Safety Officer will verify adequate insect-proofness of the area and that no non-programme articles stored in the area. He will ensure that adequate numbers of fruit fly traps are installed in the untreated article storage area and the area is clearly segregated and safeguarded to prevent any entry or escape of hitch hiking pests, if any accidentally introduced, to other area.

4.3. Plant In-charge/Quality control officer/Radiological Safety Officer will verify that only programme articles are stored lot-wise in untreated article storage area and that the packages are intact and secured.

4.4. Plant In-charge/Quality control officer/Radiological Safety Officer will check and ensure that all openings of packages are covered with insect-proof screen of a minimum of 30 meshes per linear inch and the sides of packages are sealed with adhesive tape. Also he will verify that the packages carry Product Identification Number (Packing House Code (PHC-16 digits), Production Unit Code (PUC-15 digits), Date of Packing (DoP-8 digits) and Lot No. (8 digits) assigned by the packing house registered with APEDA and packing material conforms to US-FDA requirements.(Label is given below)

5. **References**:
   5.1. Irradiation Operational Work Plan

Fig. 1

Template of Label required on each box or carton treated with Irradiation:

FACILITY NAME **CITY, COUNTRY**	
Treated by Irradiation	
PUC:	TFC:
PHC:	TIN:
Packing Date:	Treatment Date:
Lot Number:	
Area for Country- specific requirements, if necessary	

Key (Refer to Irradiation Operational Work Plan for further descriptions):

PUC = Grower/Production Unit Code

PHC = Packing House Code

TFC = Treatment Facility Code

TIN = Treatment Identification Number

1. **Scope**:

From the initial loading of untreated programmed articles into product boxes on the conveyor to the accomplishment of irradiation treatment process.

2. **Definition of Term**s:

2.1. **BARC:** Bhabha Atomic Research Institute

2.2. **MSAMB:** Maharashtra State Agricultural Marketing Board

2.3. **D^{max}:** The localized maximum absorbed dose within the process load [ISPM No. 18, 2003]

2.4. **D^{min}:** The localized minimum absorbed dose within the process load [ISPM No. 18, 2003]

2.5. **Dosimetrist:** A trained personnel responsible for carrying out dose mapping and dosimetry.

2.6. **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]

2.7. **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]

2.8. 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]

2.9. 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)

2.10. **Irradiation:** Treatment with any type of ionizing radiation [ISPM No.18, 2003]

2.11. **Process load**: A volume of material with a specified loading configuration and treated as a single entity [ISPM No. 18, 2003]

2.12. **Programme articles:** Refer to S-1

2.13. **RADURA**: internationally recognized symbol used to indicate when a food product has been irradiated

2.14. **TLD:** Thermo-Luminescence Dosimeter

3. **Responsibility and Authority**:

3.1. **Dosimetrist** is responsible for dose mapping of product box and routine dosimetry.

3.2. **Plant Operator** is responsible for carrying out treatment operations at the irradiation facility

3.3. **Radiological Safety Officer** is responsible for carry out radiological surveillance and personnel monitoring at the irradiation facility and maintain records of personal exposure to radiation.

3.4. **Quality Control Officer** is responsible for ensuring that good quality of programme articles is delivered for irradiation and good radiation practice are followed during the treatment.

3.5. **Plant In-charge** is responsible for supervising operation and maintenance of irradiation facility

4. **Activity**:

4.1. Plant In-charge/Quality control officer/Radiological Safety Officer at the facility will supervise loading of insect-proof packages of mangoes into the product boxes carried out on the conveyor.

4.2. Plant In-charge/Quality control officer/Radiological Safety Officer will ensure that the product boxes are as per specification.

4.3. Dummy product consisting of boxes of raisins loaded in the same boxes with the same weight and density of mango boxes will be loaded into totes with the stacking configuration used for magoes.

4.4. Ten totes of dummy product will lead and follow each treatment of mangoes.

4.5. Dosimetrist will place dosimeters at reference positions in the product box for each lot of product to ensure that the mangoes are treated with a minimum absorbed dose of 400 Gy (Reference: Rule 7 CFR Parts 305 and 519 [Docket No. APHIS-2006-0121] RIN 0579-AC 19 published in Federal Register, Vol.72, No., 47: 10902-10903).

4.6. Dosimeters will be placed in the reference location on totes with mango boxes.

4.7. The first and last tote will always have a set of three optichromic dosimeters.

4.8. The placement of the remaining dosimeters will be determined by the following:

4.9. A minimum of three totes with a set of three optichromic dosimeters is required for every process run.

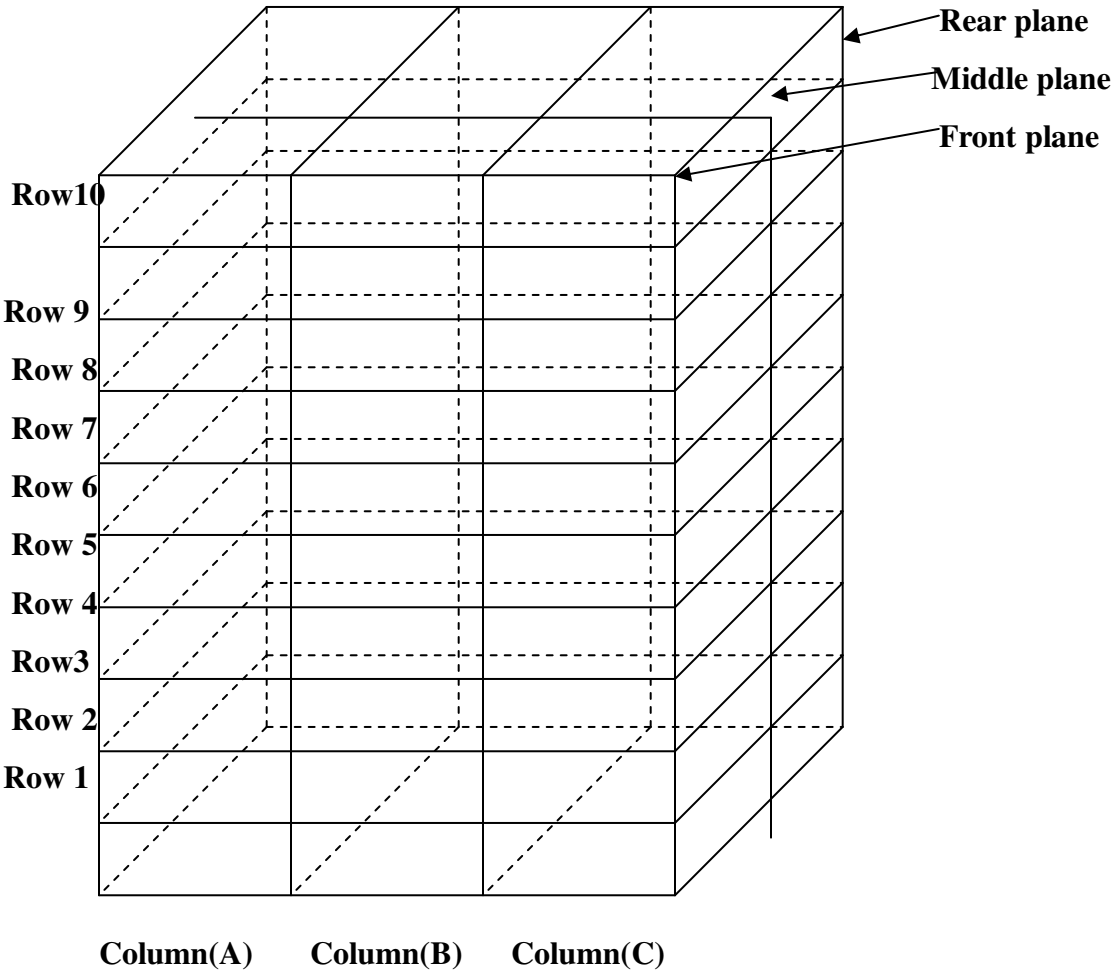
4.10. The first and last tote must always have a set of three optichromic dosimeters.

4.11. If the number of totes in the run is less than 10, a set of three optichromic dosimeters will be placed in the first, last, and middle totes of the run.

4.12. If the number of totes is 10 or greater begin by placing a set of three optichromic dosimeters in the first and last totes in the load. Then, divide the total number by 5. Take the result, round it, and place that many sets of three optichromic dosimeters evenly throughout the load.

4.13. Each set of optichromic dosimeters will be numbered and the number and location recorded in the “USDA/NPPO Treatment Log Book” on the back of the page titled “Treatment Record”.

4.14. The reference position is located on the outside bottom of the box located at row 4, column B, plane R (B4R4, see the diagram below).



4.15 Plant Operator in consultation with dosimetrist will set the speed of conveyor and the cycle time at the beginning of each treatment process. Whenever the belt speed is changed, he will verify the speed of the conveyor to ensure that correct dosage is delivered. Conveyor speed is controlled through a programmable logic control (PLC) unit, which takes into account the source decay and required minimum dose.

4.16 Cycle time is the time taken by the product box to move from its position to next box position. Any time the speed of the conveyor is changed; it is verified by a time out logic that is displayed in terms of supply frequency. The cycle time is set on the basis of minimum dose required to be delivered.

4.17 Before start up of process, plant operator will conduct a search operation starting from control room to the inside of irradiation cell to check the presence of any person inside the cell and quickly punch the locks positioned at various places inside the cell and finally ensure that the double door entry to the irradiation cell is properly locked. He will wear TLD badge and carry the radiation monitor in all such operations. The whole process of search operation is completed in 5 minutes time.

4.18 Plant operator will register each step of irradiation process through the computer-controlled microprocessor located at the control room, which is air-conditioned and is locked to prevent unauthorized entry. However the officer of Dte of PPQS and the inspector of APHIS will have free access to control room to verify treatment data.

4.19 Radiological safety officer will closely monitor the radiation levels at all delineated areas that may be exposed to radiation above ambient levels. RSO will ensure that all radiation workers are provided TLD badges. He will submit the exposed badges at periodic intervals to Personnel Monitoring Section, Radiological Physics & Advisory Division, BARC for their evaluation from safety angle.

4.20 At the end of irradiation process, dosimetrist will retrieve the exposed dosimeters that are kept at reference position and perform dosimetry in order to verify that the exact dosage is given to the treated product. The dosimetry analysis is carried out at the climate controlled dosimetry lab as per the procedure specified in Section-12.

4.21 Dmin and Dmax are will be estimated using the equation Rmin * Ref Dose = Dmin and Rmax * RefDose = Dmax.

4.22 If the absorbed doses fall outside of the acceptable limits, dosimetrist will intimate the Plant In-charge/quality control officer/Radiological Safety Officer about the treatment failure. The Plant In-charge/quality control officer will mark the rejected articles "Rejected" on the cartons and enter the particulars of rejected articles in the product log book. The rejected articles are immediately removed to rejected article storage area to prevent their shipment to USA. He will notify the officer of Dte PPQS and the inspector of APHIS about such treatment failure and further investigate the cause of treatment failure and take preventive measures for such failures.

4.23 At the end of irradiation treatment, Plant In-charge/Quality control officer/Radiological Safety Officer will verify that the RADURA labels on the irradiated packages of mangoes (programme articles) contains the unique Treatment Identification Number (assigned to each lot), Name of Irradiation Facility, Treatment Facility Code, Product treated and Treatment Date/Time. (fig.1)

4.25 The dosimetrist will enter the data in a serially page numbered "USDA/NPPO treatment log book" (Annex-1), which is calico-bound and issue a treatment certificate (Annex-2) to each treated lot.

5. **References**:

5.1. Irradiation Operational Work Plan

5.2. Guidelines for Certification of Irradiation Treatment Facilities to meet the Phytosanitary Requirements (Dte of PPQS)

6. **Records:**

6.1. Record of Treatment Register

6.2. Record of Dose Mapping

6.3. Dosimetry Data (D^{min} & D^{max})

7. **Annexes:**

7.1. Format of Treatment Register (Annex-1)

7.2. Format of Treatment Certificate (Annex-2)

Dosimetry Record

TIN No :

Number of Dosimeters	Location of Dosimeters	Dose Received

Signature of Dosimetrist

Name :

Date :

1. **Scope**:

From receipt of treated article at the treated article storage area to delivery of treated product at loading/shipping area

2. **Definition of Term**s:

2.1. Post-treatment Storage: Storage of programme articles after treatment.

3. **Responsibility and Authority**:

3.1. **Plant In-charge/Quality control officer/Radiological Safety Officer** Quality Control Officer is responsible for ensuring that good quality of articles delivered at the facility for irradiation and good radiation practice has been followed during the treatment.

4. **Activity**:

4.1. Plant In-charge/Quality control officer/Radiological Safety Officer will verify that only treated articles covered under the programme are stored in the treated article storage area and each package carry a treatment label affixed on the side of box and the treated lots are stocked lot-wise.

4.2. Plant In-charge/Quality control officer/Radiological Safety Officer will immediately notify the officer of Dte of PPQS (NPPO) and the inspector of APHIS about the receipt of treated articles at the treated article storage area. The treated articles storage area is a secured area, which is distinct and physically separated from the untreated articles storage area by a physical partition

4.3. The officer of Dte of PPQS jointly with inspector of APHIS will verify the treated articles stored in treated article storage area to ensure that all the treatment requirements and post-treatment security requirements of the product have been met with and maintained. He will issue a phytosanitary certificate for treated lot and endorse the irradiation treatment on the phytosanitary certificate. In addition the inspector of APHIS will issue PPQ Form 203 for the treated lot. After the successful completion of the treatment ensure that the following documents are issued and maintained

4.3.1. Irradiation certificate

4.3.2. Dosimetry report

4.3.3. PPQ form 203

4.3.4. Phytosanitary certificate

4.3.5. Afterwards the carrier will be sealed with date and time by APHIS/NPPQ officials.

5. **References**:

5.1. Irradiation Operational Work Plan

6. **Records:**

6.1. Export inspection Register

6.2. Copy of Phytosanitary Certificate issued

6.3. Copy of PPQ Form 203 issued

7. **Annexes:**

Format of Phytosanitary Certificate (Annex-1)

1. **Scope**:

From delivery of treated articles at the loading and shipping area of the treatment facility to shipping of programmed articles to the port in sealed container/closed conveyance

2. **Definition of Term**s:

3. **Responsibility and Authority**:

3.1. **Plant In-charge/Quality Control Officer/Radiological Safety Officer** is responsible for delivery of treated article to the exporter/representative of packing house facility at the loading port of the treatment facility.

3.2. **Transporter** is responsible for transport of treated articles to the port in sealed container/closed conveyance.

4. **Activity**:

4.1. Plant In-charge / Quality Control Officer/Radiological Safety Officer will supervise and permit the delivery of treated articles in the loading area of the facility by stationing the carrier inside the canopy after verifying the documents in respect of each shipment.

4.2. The mangoes brought to the facility in referred vans will be kept in cold chamber till the start of irradiation process.

4.3. Officer of Dte of PPQS jointly with inspector of APHIS will inspect the conveyance to ensure they are thoroughly cleaned, sound and free from hitchhiking pests.

4.4. At the end of loading, Plant In-charge / Quality Control Officer/Radiological Safety Officer will affix the seals on the doors of closed container or the conveyance and issue a gate pass for security clearance

4.5. The shipments are planned by air & sea consignments from Mumbai to USA .

5. **References**:

5.1. Irradiation Operational Work Plan

6. **Records:**

6.1. Product log book

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1. **Scope**:

From insect-proofing of the facility to fruit fly trapping at the facility

2. **Definition of Term**s:

2.1. Pest exclusion: is to exclude the pest

2.2. Trapping: Trapping fruit flies using pheromone traps

3. **Responsibility and Authority**:

3.1. **Plant In-charge/Quality control officer** is responsible for insect-proofing of all external openings and fruit fly trapping at the facility.

3.2. Quality Control Officer will inspect all fruit fly trapping facilities once in a week and record the data with respect to types of insects and their numbers. The NPPO Official will identify the insects.

4. **Activity**:

4.1. Plant In-charge/Quality control officer will ensure covering of all external openings viz., windows, ventilators/exhausts to the facility covered by insect-proof screen of 30 meshes for linear inch and also insect proofing of segregated storage area for untreated articles and treated article storage area

4.2. The officer of Dte of PPQS jointly with the inspector of APHIS will carry out weekly inspection of facility and testing to ensure that insect-proof conditions are maintained at the facility to exclude hitch hiking pests. Conditions will be noted in the “Safeguarding inspection record”.

4.3. Plant In-charge/Quality control officer will ensure installation of pheromone based (methyl euginol/Cue lure) fruit fly traps at the untreated article storage area and treated article storage area of the facility. He will regularly monitor the fruit fly traps at fortnightly intervals for fruit fly incidence during the processing of programme articles. If any fruit fly pest is caught in one of the trap, the Plant In-charge/quality control officer will immediately notify the officer of Dte of PPQS and inspector of APHIS. He will resort to supplementary trapping in the vicinity of area, where the fruit fly was caught

4.4. and will carry out intense monitoring of the traps until no fruit fly is detected in the trap and the case is further investigated to identify the source of infestation and take appropriate measures to eradicate the fruit fly pest.

4.5. Plant In-charge/Quality control officer will contract the services of pest control operator for undertaking general pest control operations in and around the facility.

4.6. Lures will be taken out far away from facility premises for destroying.

4.7. Add trap maintenance log

5. **References**:

5.1. Irradiation Operational Work Plan

6. **Records:**

6.1. Record of Pest Control Measures

No.	Location of Pest Trap	Identification no. of pest	Action Taken	QCO/NPPO

Safeguarding Inspection Record

Inspection Date	Inspector	Results

1. **Scope**:

From the identification of articles for rejection to the disposal of rejected articles

2. **Definition of Term**s:

2.1. **APEDA**: Agricultural & Processed Food Products Export Development Authority (Cooperator)

3. **Responsibility and Authority**:

3.1. **Plant In-charge/Quality control officer/Radiological Safety Officer** is responsible for the identification of articles for rejection and their disposal

4. **Activity**:

4.1. At the beginning quality control officer will physically check the articles received at untreated article storage area

4.1.1. If less than 1% packages found damaged, the same are segregated and marked "Rejected" on the cartons. The rejected cartons will be segregated and handed over to concerned exporter for immediate removal.

4.1.2. If more than 1% packages are found damaged in a single instance the entire lot will be rejected for treatment and rejected lot will be immediately segregated, handed over to concerned exporter for immediate removal.. The exporter or packing house facility will be asked to remove the rejected lot from the facility and further notified to undertake mitigating measures to prevent damage.

4.1.3. If damage of packages of fruits from an exporter or a packing house recorded on multiple occasions, the exports from that exporter or packing house will be temporarily suspended and it will be brought to the notice of APEDA for investigation of the case and to ensure that the corrective measures are implemented.

4.1.4 If any articles found damaged during treatment or handling or articles that do not pass treatment, the Plant In-charge/quality control officer/Radiological Safety Officer will segregate and mark "Rejected" on the cartons. The rejected articles will be segregated and handed over to exporter for immediate removal.

4.1.5 Plant In-charge/Quality control officer/Radiological Safety Officer will ensure the prompt removal of any rotten/over ripened fruits from the facility, and will be handed over to concerned exporter for immediate removal.

4.1.6 The fruit waste collected from the laboratory during inspection or debris collected from fallen fruits at the conveyor will be collected and disposed off through dustbins which will be handed over to Municipal Waste Management system.

4.1.7 The details of rejected articles are recorded in the product log book maintained at the facility at the end of each working day.

4.1.8 In case of over dose or improper / partial radiation, the product will be disposed off & will not be cleared for export. Quality control officer and plant in-charge will record the activity and material will be disposed off as mentioned in 4.1.7.

5. **References**:
   5.1. Irradiation Operational Work Plan

6. **Records:**

   6.1. Product Log Book.

1. **Scope**:

Procedures related to general cleanliness and sanitation at the facility.

2. **Definition of Term**s:

3. **Responsibility and Authority**:

3.1. **House Keeping Staff** is responsible for general cleanliness and sanitation of the facility

4. **Activity**:

4.1. The floors are swept and mopped once in a day using disinfectant solution such as Lysol.

4.2. The toilet areas are cleaned daily using the toilet disinfectant and appropriate deodorant are placed at regular intervals

4.3. Pest control activities are outsourced through a recognized pest-control service

1. **Scope**:

From the treatment documents and data identification to implement their control and the records generated from treatments and their control

2. **Definition of Term**s:

2.1. **Document**: Standards, Procedures, work instructions, references, specifications or regulatory material for the administration of the system.

2.2. **Data**: Quantified information in documents.

2.3. **Controlled document**: Documents formally identified. These documents are registered, maintained and their change, as well as, their implementation is regulated.

2.4. **Procedure**: Document that describes, "who does the job", "when", "where", and "why".

2.5. **Work instructions**: Document that identifies the procedures to perform a task or activity.

2.6. **Internal document**: Document generated outside the limits of the administrative system for example: a regulatory document that is referred to a procedure or work instruction.

2.7. **Master List of Documents**: List that contains information related to documents and includes information such as documents titles, revision number and document codes.

2.8. **Record**: Document (electronic or print), product or sample statement, which will confirm that a procedure (or part of the procedure) has been carried out.

2.9. **Controlled Record**: is a record that is kept and maintained under safeguard for future reference in an audit and/or for traceability of a result.

3. **Responsibility and Authority**:

3.1. **General Manager** is responsible for management and overall operation, maintenance of the facility.

3.2. **Plant In-charge/ Quality Control Officer/Radiological Safety Officer** is responsible for the operation and maintenance of plant and good irradiation practices

3.3 Quality Control Officer/Radiological Safety Officer is responsible for management of treatment documents and data.

4. **Activity**:

4.1. <u>Document Control Procedure</u>

4.1.1. The Plant In-charge/Quality control officer/Radiological Safety Officer will create and maintain master list of documents with the help of technical staff attached to him

4.1.2. If it does not exist in the master list of documents, the Plant In-charge/Quality Control Officer/Radiological Safety Officer will create new documents based on the request received from any technical officer of the treatment facility following the procedures and guidelines laid down by the Atomic Regulations Authority.

4.1.3. If document already exist, he will review the information to ensure it is current and achieves the need s of the system and if it is not adequate will modify the internal document as per document change application procedure.

4.1.4. Plant In-charge/Quality control officer/Radiological Safety Officer will not allow the changes in SOPs except the written instructions (protocols) and identification of responsibilities. Any changes to SOPs that affect processes related to treatment of programme articles covered under Irradiation Operational Work Plan are submitted to the APHIS inspector for review prior to implementation. Records of the changes in SOP, the reason for change and date of change will be maintained in a register.

4.1.5. General Manager in consultation with quality control officer will review and approve new document to verify its precision.

4.1.6 Plant In-charge/Quality control officer/Radiological Safety Officer assures that the master list of documents is kept both hard copy and electronically and that the controlled documents are available and identified in the master list and these documents are stamped “controlled document” and the obsolete documents are identified and clearly marked “obsolete” and filed separately to prevent use.

4.1.7 Confidential documents are identified by the Plant In-charge and stamped and are handled by authorized persons identified through the work instructions

4.1.8 Plant In-charge/Quality control officer/Radiological Safety Officer in consultation with the Plant In-charge determines the date to implement changed document and distribute the copies of changed document and inform the personnel and institutions concerned and ensure the access to the changed document.

4.2. <u>Record Control Procedure</u>

4.2.1. The Plant In-charge/Quality control officer/Radiological Safety Officer in consultation with the General Manager will identify the records to be controlled as indicated by administrative, operational and supportive procedure and are included in the master list of records.

4.2.2. Records specific to each treatment viz., Name of the product and quantity; Product Identification Number assigned by exporter (PHC/PUC/Date of Packing); Treatment Identification Number (TIN) and Treatment Facility Code (TFC); Prescribed treatment; Evidence of compliance with the prescribed treatment; Dosimetry data (D^{min} and D^{max}); Date of irradiation; and Treatment Certificate issued for each lot are maintained for one year. Records are made available for inspection by the regulatory officials viz., officer of Dte of PPQS and Inspector of USDA-APHIS. Records are maintained in the form of log book.

4.2.3. Records related to radiation source, approved plans of the facility and licences & certification of facilities will be maintained so long the facility is in use and as long the documents are valid/renewed.

4.2.4. Plant In-charge/Quality control officer/Radiological Safety Officer in consultation with the General manager will periodically review the records contained in the master list of records and will dispose the obsolete and unnecessary records.

5. **References**:
   5.1. Irradiation Operational Work Plan
6. **Records :**

   6.1. Master list of controlled documents

7. **Annexes:**

   7.1. Controlled Master List of Documents (Annex-1)

   7.2. Document change application (Annex-2)

   7.3. Master List of Records (Annex-3)

1. **Scope**:

From the initial placement of dosimeters at different positions and in varying numbers in product boxes in a process load and retrieval of dosimeters after exposing to ionizing radiation to the mapping of absorbed dosages with in a process load.

2. **Definition of Term**s:

2.1. **ISPM**: International Standard for Phytosanitary Measures.

2.2. **BRIT**: Board of Radiation &Isotope Technology

2.3. **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]

2.4. **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]

2.5. **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]

3. **Responsibility and Authority**:

3.1. **Dosimetrist** is responsible for dose mapping and dosimetry

4. **Activity**:

4.1. Extensive dose mapping and dosimetry studies are carried out during initial commissioning of irradiation plant and whenever source is loaded using actual or simulated product at the upper and lower limits of the density range for which the facility is intended to be used for under direct supervision of BARC & BRIT of Department of Atomic Energy to ensure compliance with Atomic Energy Act (Control of irradiation rules) Rules, 1996. Dosimeters used for dosimetry are Optichromic Wave Guide Dosimeters will be calibrated against Alanine Dosimeters from NIST before starting the Mango Season and Optichromic Reader is used as a read out system (ISO/ASTM 51310: 2004 (E).

4.2. Dosimetrist will ensure that the number of product boxes carrying dosimeters (dosimetry boxes) in actual or simulated product is sufficient in number to provide statistically validation of dose mapping results.

4.3. Adequate number of cartons is filled with the process product (food material or dummy food equivalent material to simulate the density of the product being processed in the facility). Each product box is weighed and loaded on the product carriers to provide uniform product density.

4.4. Dosimetry boxes will contain the above packaging material but also contain dosimeters at different positions and in varying numbers as specified in 'X', 'Y' and 'Z' set of experiments. Dosimeters are firmly affixed on cardboard sheets that are placed inside the dosimetry boxes in vertical planes.

4.5. Optichromic dosimeters in triplicate are placed in a well-defined three-dimensional grid through out the product load covering the entire volume of the product container during plant commissioning dosimetry while carrying out the dose mapping experiments. The use of multiple dosimeters at a given location increases the confidence in the dose at that location.

4.6. The dosimetrist will design 'X' set of experiment to find out (i) alignment of the source rack with respect to the position of the product in product carrier, (ii) radiation dose received at the geometric centre of each half of the carrier, and (iii) total dose in all the shelves of the carrier to set up the cycle time (conveyer speed) for the Y-Set of experiments (This set of experiment is applicable to both types of facilities – product overlap or source overlap. Product carrier can have 'n' number of shelves, where n = 1,2,3 or more).

4.7. For "X set of experiment, he will affix three dosimeters at the geometric center of the cardboard sheets that are placed in the vertical central plane of the product box filled with the dummy material (three sheets for n=3). All the three dosimetry boxes are loaded one above the other in a single product carrier. At this point of time all the other product carriers of the facility are loaded with the dummy boxes filled with the dummy material.

4.8. Dosimetrist will initially set the conveyer speed on the basis of Cobalt-60 source loading, product density and the other data provided by the designer of the facility and

run the plant, without box transfer mechanism (i.e.,'OFF' position), for 2-3 full cycles so as to receive adequate dose for measurement for dosimeter used. After completion of

Irradiation, dose is measured and mapped.

4.9. Dosimetrist will design 'Y' set of experiment to find out the minimum and maximum dose positions inside the product box. For this purpose the entire box is sub-divided into small segments by making a grid of dosimeters with the help of several vertical planes created by inserting odd number of cardboard sheets with a pair of dosimeter firmly affixing at the cross section of odd number of columns and rows (n > or = 3). The Choice of number of columns and rows in cardboard sheets depends on how closely one wants to monitor the dose pattern. Ideally speaking the whole volume is divided into segments of a litre or more capacity for dose mapping purpose. (For example, let the product box be divided into 5 equidistant plains by inserting 5 cardboard sheets with a pair of dosimeter affixed at the cross section of 3 columns and 5 rows at equal distances. If dose mapping is planned in three such boxes (Y-1, Y-2 and Y-3), there are 450 dose measurements. While loading on to the conveyer each dosimetry box is followed by 5 dummy boxes. In the case of Y1, A-8 is the maximum and C-8 is the minimum dose position).

4.10. Dosimetrist will perform 'Z' set of experiment for (i) statistical evaluation of dose in the maximum and minimum dose positions as identified by dose mapping experiment in Y-Set of experiment, (ii) determining overdose ratio, (iii) ultimate dose uniformity ratio in the product box, and (iv) to finally set the cycle time or conveyer speed of the facility to deliver a specified radiation dose to the product processed.

4.11. For this purpose, about 30% of the number of product carriers are chosen as the number of dosimetry boxes. A pair of dosimeter are affixed on to the cardboard sheets at the minimum and maximum dose positions and placed inside the dosimetry boxes and one of the dosimetry boxes are placed. The conveyer speed is set on the basis of the Y-Set of experiment and the irradiation plant is run with box transfer mechanism in 'ON' position. After completing one full cycle of irradiation, dosimeters are removed and dose is measured and mapped.

4.12. Dosimetrist, at the end of 'X', 'Y' and 'Z' set of experiments will evaluate all the dose measurement data to determine the following parameters viz.,

a. Standard deviation in dose measurement
b. % Co-efficient variation
c. Minimum and maximum dose positions in the product container
d. Ultimate dose uniformity ratio
e. Cycle time for setting the speed of the conveyer

4.13 Dummy material (Dried Rasin) once replaced before the commencement of the Mango Season can be used for the entire season. Only damaged dummy boxes will be replaced during processing.

5. **References**:

5.1. ISO/ASTM Standard 51205-2002 (E): Practice for the Application of Dosimetry in the Characterization of a Gamma Irradiation Facility for Food Processing

6. **Records :**

6.1. Record of Dose Mapping

6.2. Dosimetry Data

Dosimetrist

KRUSHAK IRRADIATION FACILITY(Facility code 1001)

Lasalgaon, Maharashtra, India

2010 Mango Pre-Clearance

RECORD OF DOSIMETER READINGS

Treatment date: TIN:

Product Identification Number(PIN):PHC/PUC/DoP

PIN		No of boxes
PHC(16)		
PUC(15)		
DoP(8)		

Total No of totes in treatment :

Treatment START Time: Treatment END Time:

Calibration Curve

Intercept

X Variable

Position ID	Stick	A_0,600nm	A_I,600nm	Mean Ai-Ao	CV%	Irrad Temp	TCF	Dose (Gy)
1	1							
	2							
	3							
2	1							
	2							
	3							
3	1							
	2							
	3							
4	1							
	2							
	3							
5	1							
	2							
	3							
6	1							
	2							
	3							
7	1							
	2							
	3							

Dose Minimum : Dose Maximum :

Signature of dosimetrist with date

1. **Scope**:

Dosimetry consists of dosimeter read out system and computation and analysis of absorbed dosage

2. **Definition of Term**s:

2.1. **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 [ISO/ASTM 51310: 2004(E)]

2.2. **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]

2.3. **Dosimetrist:** A trained personnel responsible for carrying out dose mapping and dosimetry.

2.4. **Reference Dosimeter:** Dosimeters used for calibration of routine dosimeters, which are traceable to national and international standards

2.5. **Routine Dosimeter:** Calibrated Dosimeters that are used in plant commissioning and routine dosimetry studies

2.6. **Plant Commissioning Dosimetry:** Dosimetry studies that are carried out for commissioning irradiation plant

2.7. **Routine Dosimetry:** Dosimetry studies that are carried out for determining minimum absorbed dosage in irradiated product. It is a verification process for establishing that the irradiation process is in compliance.

3. **Responsibility and Authority**:

3.1. **Dosimetrist** is responsible for dosimetry

4. **Activity**:

4.1. Routine dosimetry as well as dose mapping is carried out by Optichromic dosimeters (FWT 70-83M), which are calibrated by using Alanine transfer standard dosimeters from NIST, USA. The photometer FWT-200 will be used to read the dosimeters. (ISO/ASTM 51310: 2004 (E))

4.2. At the beginning of the day, the performance of the reader FWT-200 is checked using Neutral Density Filters provided along with the instrument. The readings are noted and it is ensured that the reader is working properly. Major shift from the actual reading, if any, will be rectified by consultation with the manufacturer.

4.3. Before measuring initial absorbance, each dosimeter will be labeled with a unique serial number for identification.

4.4. At the beginning, the dosimetrist will take the pre-irradiation response of the dosimeters, note the readings and place the dosimeters in the holder. Each holder will contain at least 3 labeled dosimeters. The holders are serially numbered for identification before placing in product boxes. He will note the average irradiation temperature.

4.5. The dosimeters are stored at climate controlled condition in a closed container and also ensure that they are not open to direct sunlight. Fluorescent lights in the dosimetry lab will be turned off during dosimetry work. While the dosimeters are outside of packages, ensure that they are not exposed to UV light.

4.6. At the end of irradiation process, the exposed dosimeters are retrieved from the dosimetry boxes (product boxes containing dosimeters) and taken to climate controlled dosimetry lab for reading.

4.7. At the climate controlled dosimetry lab, the dosimetry tubes are uncapped and read for post irradiation response using the reader FWT-200.

4.8. The pre-irradiation response is subtracted from the post irradiation response and Dosimetrist will compute the absorbed dose from the standard calibration curve as calibrated by NIST.

4.9. Dosimetrist will use dosimeters to measure the dose at the reference location for each process load in order to ensure that the programmed articles receive minimum absorbed dose specified under Irradiation Operation Work Plan

5. **References**:

5.1. Irradiation Operation Work Plan

6. **Records :**

6.1. Dosimetry Data

Performance check of FWT reader –200

Date → NDF filter ↓													
1203A (Light)	600 nm												
	656 nm												
	750 nm												
1203B (Medium)	600 nm												
	656 nm												
	750 nm												
1203C (Dark)	600 nm												
	656 nm												
	750 nm												

Dosimetrist

KRUSHAK IRRADIATION FACILITY(Facility code 1001)

Lasalgaon, Maharashtra, India

2010 Mango Pre-Clearance

RECORD OF DOSIMETER READINGS

Treatment date: TIN:

Product Identification Number(PIN):PHC/PUC/DoP

PIN		No of boxes
PHC(16)		
PUC(15)		
DoP(8)		

Total No of totes in treatment :

Treatment START Time: Treatment END Time:

Calibration Curve

Intercept

X Variable

Position ID	Stick	A_0,600nm	A_I,600nm	Mean Ai-Ao	CV%	Irrad Temp	TCF	Dose (Gy)
1	1							
	2							
	3							
2	1							
	2							
	3							
3	1							
	2							
	3							
4	1							
	2							
	3							
5	1							
	2							
	3							
6	1							
	2							
	3							
7	1							
	2							
	3							

Dose Minimum : Dose Maximum :

Signature of dosimetrist with date

1. **Scope**:

From initial setting of conveyor speed to timer or cycle validation based on dose mapping and dosimetry studies

2. **Definition of Term**s:

3. **Responsibility and Authority**:

3.1. **Dosimetrist** is responsible for verification of conveyor speed once in a month or exposure times (timer or cycle validation) based on dose mapping and dosimetry studies. All records will be kept regarding conveyor speed.

3.2. **Plant Operator** is responsible for setting the speed of conveyor and cycle time

4. **Activity**:

4.1. Plant Operator in consultation with Dosimetrist initially will set the speed of conveyor, on the basis of Cobalt-60 source loading, product density and the other data provided by the designer of the facility in compliance with atomic regulations of India under the guidance and close supervision of BARC & BRIT.

4.2. He will verify the conveyer speed during plant commissioning dosimetry studies with the help of a stopwatch, which is calibrated by a certifying agency annually.

4.3. He will conduct dose mapping studies involving ‘X’, ‘Y’ and ‘Z’ set of experiments as per procedures described under Section-11.

4.4. Based on these results of dose mapping studies, cycle time or conveyer speed of the facility, to deliver a specified radiation dose within limits to the product processed and the conveyer speed is adjusted after taking into consideration of decay of cobalt-60 source.

Conveyor Speed Check

No.	**Date**	**Theoratically**		**Actual**		**Checked By**
		Cycle time	**Speed**	**Cycle time**	**Speed**	

Scope:

From the identification of training needs to the accomplinishment of training.

1. **Definition of Term**s:

   1.1. **External training**: training organized with external resources

   1.2. **Internal training**: training organized with internal resources

2. **Responsibility and Authority**:

   2.1. **Plant In-charge** is responsible for determining the training needs of personnel and preparing the budget, planning, conducting and evaluating the training program

   2.2. **Plant In-charge/Quality Control Officer/Radiological Safety Officer** is responsible for maintaining the training records and evaluation of results of training

3. **Activity**:

   3.1. General Manager, through the management review, will identify the internal/external training needs of personnel and record the training needs

   3.2. General Manager will establish internal/external training programme based on the training needs and resources

   3.3. General Manager will identify the resources for internal/external training

   3.4. If resources are available, he with the assistance of Plant In-charge/quality control officer/Radiological Safety Officer will prepare training schedules and will develop budget plan for organizing training workshop

3.5. If resources not available, he will identify human resources to develop training programme and will maintain an updated list of human resources base on the training program that is required for external training programme (All the personnel with treatment related responsibilities will have proper credentials, training according to applicable international standards and authority for application of irradiation treatments. Such training programmes in the area of dose mapping and dosimetry are organized at BARC in compliance with Atomic Energy Act (Control of irradiation rules) Rules, 1996).

3.6. The trainer will conduct the training work shop according to the training programme at the specified place, prepare and distribute training material and exercises and at the end evaluate the training programme

3.7. Plant In-charge/Quality control officer/Radiological Safety Officer evaluates the training results and submit to the general manager of the facility and will maintain an official list of individuals who attended to the training workshops and distribute the training certificates for successful participants.

4. **References**:

4.1. Atomic Energy Act (Control of irradiation rules) Rules, 1996

4.2. Irradiation Operational Work Plan

5. **Annexes:**

5.1. Schedule of Internal/External training workshops.

Annex-1

Schedule of Internal /External Workshops

Title of Workshops /Training	Place	Date/Time	Instructor