

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

Name of the Facility
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Introduction:

These standard Operating procedures (SOPs) are for use for irradiation of mangoes for export purposes 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 Bhabha Atomic Research Center Safety Council (BSC). 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 continuous 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.

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1.1. Scope:

From the arrival of the consignment from a packing house to the unloading at the unloading area of the irradiation facility

1.2. Definition of terms:

- 1.2.1. **APHIS:** Animal & Plant Health Inspection Service-US Department of Agriculture
- 1.2.2. **APEDA:** Agricultural & Processed Food Products Export Development Authority (Cooperator)
- 1.2.3. **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.
- 1.2.4. **Dte of PPQS:** Directorate of Plant Protection, Quarantine & Storage
- 1.2.5. **Non-programme articles:** Plant products not covered under the irradiation operational work plan
- 1.2.6. **NPPO:** National Plant Protection Organization
- 1.2.7. **Programme articles:** Plant products covered under the irradiation operational work plan
- 1.2.8. **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, safe guarding 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.

1.3. Responsibility and Authrity:

- 1.3.1. **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.
- 1.3.2. **Plant-In-charge** is responsible for granting permission to deliver the consignment at the unloading area (# 1) of the irradiation facility after verification and registration of programme articles for treatment
- 1.3.3.

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1.4. Activity:

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 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 (# 1) of the irradiation facility, The unloading area has a double door entry and each fitted with an air curtain to prevent the entry of hitchhiking pests. If any non-programme articles are arrived for treatment at the facility, he will refuse the entry of the vehicle and further intimate in-charge of the irradiation facility.

- 1.4.1. Plant In-charge 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 (#1) 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.
- 1.4.2. Plant In-charge 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 that are registered with APEDA (the Cooperator) in compliance with approved Irradiation Operational Work Plan, are permitted delivery at the unloading area).
- 1.4.3. Plant In-charge 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.
- 1.4.4. Plant In-charge will notify the inspectors of APHIS and the Dte of PPQS regarding the receipt of consignment at the unloading area (# 1).

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1.5. References:

1.5.1 Irradiation Operational Work Plan

1.6. Records:

1.6.1. Record of application for irradiation treatment approved

1.6.2. Record of Post-harvest processing information sheet

1.6.2. Product log book

1.7. Annexes:

1.7.1. Format of Application for irradiation treatment (Annex-1)

1.7.2. Format of Post-harvest processing information sheet (Annex-2)

1.7.3. Format of Product Log book (Annex-3)

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Annexure-1

Application for Irradiation Treatment of Programmed Articles

1. Name & Address of the Packing House Facility: _____
2. Name of Plant Product (Common / Botanical name)/variety: _____
3. Product Identification Number:
(PHC (2)/PUC (2)/DoP (4))

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4. Quantity (in metric tones) / Number of Packages: _____
5. Package Dimensions: _____
6. Registered with APEDA: **Yes / No**
7. Is the Packing House Facility in compliance with approved irradiation Operational Work Plan : **Yes/No**
8. Target Dose (Gy): _____
9. Target Regulated Pest (s): _____
10. Purpose of treatment: _____
11. Post Harvest Process Sheet enclosed: **Yes/No**.
12. Authorized Signatory of Packing House Facility: _____

(Name/Signature/seal/Date)

For Office Use of Treatment Facility

Name of Treatment Facility: _____
 Treatment Facility Code (Assigned by NPPO): _____
 Treatment Identification Number (Assigned by the Facility)/Date: _____
 Treatment Fees Received: Amount in Rs. _____ (Rupees _____)
 by _____

(Demand Draft/Banker's Check/Pay Order No/Date/Bank/ Branch)

(Name/ Signature of Plant In-charge/date)

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Annex-2

Post-harvest Processing Information Sheet

1. Name & Address of Packing House Facility: _____
2. Contact Person (Name/Tel/Fax/E-Mail): _____
3. Product Identification Number:

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(PHC (2)/PUC (3)/DoP (4))
4. Production Unit (Orchard Name/Location): _____
5. Name of the Product (Common/Botanical Name)/Variety: _____
6. Quantity (No. of Packages/metric tones) processed: _____
7. Date/time of arrival of commodity at packing house: _____
8. Temperature of fruit on arrival at Packing House: _____
9. Temperature/humidity condition at which the fruits are held during processing: _____
10. Date/time of completion of processing: _____
11. Details of Processing:
 - 11.1. Desapping: **Yes/No**
 - 11.2. Cleaning & Washing of Fruits: **Yes/No**
 (Specify water quality/chemical used): _____
 - 11.3. Hot water treatment with fungicide: **Yes/No**
 (Specify temp/exposure time): _____
 (Specify name of fungicide/concentration): _____
 - 11.4. Air-drying/brushing: **Yes/No**
 - 11.5. Weighing/sorting/grading: **Yes/No**
12. Details of packaging/labeling/marketing:
 - 12.1. Packing material used conforms to USDA-FDA standard: **Yes/No**
 (Specify packing material used): _____
 - 12.2. All Ventilators of package covered by insect-proof screen of 30 meshes per linear inch and all the sides sealed with adhesive tape: **Yes/No**
 - 12.3. Dimensions of Package box used: _____
 - 12.4. Average Number of fruits /Weight of fruits per box: _____
 - 12.5. Labeling/marketing (9 digit code as per APEDA): **Yes/No**
 - 12.6. Individual fruits are sleeved with polypropylene sleeve to avoid bruising: **Yes/No:**
13. Details of transportation from packing house to treatment facility:
 - 13.1. Transport by Closed conveyance: **Yes/No**
 - 13.2. Transport vehicle No: _____
 - 13.3. Date/Time of loading: _____
14. Authorized Signatory of Packing House Facility: _____

(Name/Signature/Seal/Date)

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Annex-3
Product Log Book

Treatment Id No.	Name of the Plant Product/ Variety	Quantity/ No of Packages Received for treatment	Product Identification Number (PHC (2)/PUC (3)/DoP (4))	Name of Packing House Facility	Date/ Time of Receipt	Quantity/ No of Packages Delivered After treatment	Date/ Time of Delivery	Transport by	Fees received	Rejection if, any	Sign. of Plant In-charge

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2.1. Scope:

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

2.2. Definition of terms:

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

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

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

2.2.1. 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

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

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

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

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

2.3. Responsibility & Authority:

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

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

2.4. Specific equipments:

2.4.1. Illuminated magnifier

2.4.2. Compound microscope

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2.5. Activity:

- 2.5.1. 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 page numbered and calico-bound.
- 2.5.2. 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 (#2) for inspection (The sampling of each lot is as per addenda of Irradiation Operation Work Plan).
- 2.5.3. The officer of Dte of PPQS jointly with inspector of APHIS will check thoroughly the sampled cartons at the inspection room (# 21) 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.
- 2.5.4. The officer of Dte of PPQS (NPPO) will take following action if any pest or disease detected during inspection.
- 2.5.4.1. In case of non-target quarantine pest presence, the number of infested articles is recorded. The entire lot is refused for treatment and rejected for phytosanitary certification. The results of action taken are intimated to PPA, Dte of PPQS (NPPO) and inspector of APHIS.

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2.5.4.2. If multiple interceptions of non-target quarantine pests are encountered from a specific packing house facility and /or a production area, the officer of Dte of PPQS will immediately suspend further exports from that packing house and/or production area and investigate the case further to implement measures to reduce their presence. He will intimate the action taken to PPA, Dte of PPQS (NPPO) and inspector of APHIS

2.5.4.3. If no non-target quarantine pest detected, the officer of Dte of PPQS will grant permission for treatment of consignment and intimate the in-charge of the treatment facility.

2.5.5. 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.

2.6. References

- 2.6.1. Irradiation Operational Work Plan
- 2.6.2. Export Inspection Manual (PQ 15)

2.7. Records

- 2.7.1. Record of Export Inspection Application (Approved/Rejected)
- 2.7.2. Export Inspection Register

2.8. Annexes

- 2.8.1. Format of Export Inspection Application (Annex-1)
- 2.8.2. Format of Export Inspection Register (Annex-2)

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2.8.1. Export Inspection Application Format (Annex-1): P 4/6 &5/6

To _____ _____ (Name & Designation of PQ Officer)	For PQ Office use: Receipt No. : Date of Receipt:	Registration No.: Date of Regn. :
I/We, the exporter/the authorized agent of the exporter, herewith submit an application for inspection/disinfection/ disinfection and issue of Phytosanitary Certificate for export of the goods described hereunder:		
Name & address of Exporter	Name & address of Importer	For PQ Office
Commodity Name (Common/Botanical name)/Variety	Quantity (Wt./Vol.)	Export status: <input type="checkbox"/> Prohibited <input type="checkbox"/> Restricted <input type="checkbox"/> Canalised <input type="checkbox"/> Unrestricted
No. of pieces/packages/containers	Distinguishing marks (Product Identification Number):	Documents verified: <input type="checkbox"/> Import Permit <input type="checkbox"/> Export License
Nature of package material	Means of conveyance	<input type="checkbox"/> Letter of Credit/ Contract/ Agreement <input type="checkbox"/> Invoice/ packing list
Country/Place of origin	Port of loading	<input type="checkbox"/> Shipping/ Airway Bill
Country of export	Port of unloading	<input type="checkbox"/> Others
Date & place of inspection	Invoice/Shipping/Airway Bill No. & date	_____ (specify) N.B.: Tick appropriate box
Value of commodity (Rs.)	Purpose of Export Sowing/Planting/Consumption	Date: _____ Sign. of PQO

Declaration

- (1) I/We the exporter/ the authorized agent of the exporter, on behalf of M/s. _____ declare that the information furnished on this form, to the best of knowledge and belief is true, correct and complete in every respect.
- (2) I/We shall pay any fees prescribed for inspection/fumigation/treatment of the consignment and any other charges towards issue of Phytosanitary/fumigation/treatment certificate.
- (3) I/We shall carry out the instructions given by the Plant Protection Adviser to the Govt. of India or any Officer duly authorized by him in this behalf in connection with inspection/fumigation/treatment of the consignment and issue of Phytosanitary Certificate.
- (4) I/We shall provide any relevant information and related documents connected with export of consignment and issue of Phytosanitary Certificate.

Date: _____

Seal

(Name/ Sign. of Applicant)

N.B. (1) Application should be submitted by the Exporter/his authorized agent in duplicate duly filled and complete.

(2) Duplicate copy to be returned to the exporter/his authorized agent after endorsing the quarantine order and receipt of payment.

FOR PLANT QUARANTINE USE:

Assessment of fees:

Commodity	Wt.(Kg)/No. of pieces	Particulars of fees in Rs.
	TOTAL	

Received Rs. _____ (_____) by a DD No _____
dated. _____ drawn on _____

(Bank/branch)

Date: _____

Assessed by

Received by

(Sign of staff)

(Sign. of Officer of Dte of PPQS)

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Annex-2

Export Inspection Register

1. Export Inspection Reg. No./ Date:
2. Plant Product(Common/Botanical Name)/Variety:
3. Quantity/No of Packages:
4. Product Identification Number:

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(PHC (2)/PUC (2)/DoP (4))
5. Place of Origin:
6. Port of loading:
7. Means of Conveyance:
8. Exporting Country/Foreign port of shipment:
9. Name of Exporter/Packing House Facility:
10. Registration Number of Packing House Facility
11. Number of Packages Sampled & fruits inspected:
12. Results of inspection:
 - (a) Any pest or disease detected: Yes/No
If 'yes' Common/Botanical Name of Pest detected:
 - (b) In the case of Non-target Quarantine pest presence, the number of infested articles detected
 - (c) Results of inspection are made known to the inspector of APHIS: Yes/No
13. Remarks Recommendations, if any:
14. Inspected by (Name, Designation & Signature):
15. Particular of Treatment given & evidence thereof:
16. Particulars of Phytosanitary Certificate issued (No/Date of issue):
17. Issuing Authority (Name, Designation & Signature):

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3.1. Scope:

From the storage of packaged articles in untreated article storage area (#2) to the movement of articles for loading in product boxes on conveyor.

3.2. Definition of terms:

3.3. Responsibility & Authority:

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

3.4. Activity:

3.4.1. Prior to storage of packages in untreated article storage area, Plant In-charge/quality control 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.

3.4.2. Plant In-charge/Quality control 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.

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

3.4.4. Plant In-charge/Quality control 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 9 digit Product Identification Number (Packing House Code (PHC-2 digits), Production Unit Code (PUC-3 digits), and Date of Packing (DoP-4 digits)) assigned by the packing house registered with APEDA and packing material conforms to US-FDA requirements.

3.5. References:

Irradiation Operational Work Plan

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4.1. Scope:

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

4.2. Definition of terms:

- 4.2.1. **BARC:** Bhabha Atomic Research Institute
- 4.2.2. **D^{max}:** The localized maximum absorbed dose within the process load [ISPM No. 18, 2003]
- 4.2.3. **D^{min}:** The localized minimum absorbed dose within the process load [ISPM No. 18, 2003]
- 4.2.4. **Dosimetrist:** A trained personnel responsible for carrying out dose mapping and dosimetry.
- 4.2.5. **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]
- 4.2.6. **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]
- 4.2.5. **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]
- 4.2.4. **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)
- 4.2.5. **Irradiation:** Treatment with any type of ionizing radiation [ISPM No.18, 2003]
- 4.2.6. **Process load:** A volume of material with a specified loading configuration and treated as a single entity [ISPM No. 18, 2003]
- 4.2.6. **Programme articles:** Refer to S-1
- 4.2.7. **RADURA:** internationally recognized symbol used to indicate when a food product has been irradiated
- 4.2.8. **TLD:** Thermo-Luminescence Dosimeter

4.3. Responsibility & Authority:

- 4.3.1. **Dosimetrist** is responsible for dose mapping of product box and routine dosimetry.
- 4.3.2. **Plant Operator** is responsible for carrying out treatment operations at the irradiation facility
- 4.3.3. **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.

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4.3.4. **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.

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

4.4. Specific equipment:

4.4.1. Radiation Monitor

4.5. Activity:

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

4.5.2. Plant In-charge/Quality control officer at the facility will ensure that only 30 packages of mangoes, each having dimensions of 370 X275 X 90 mm, carrying mangoes and weighing maximum 3.5 kgs, are loaded into each product box. The total number of product boxes at any one time of treatment will not exceed 49.

4.5.3. At the start of treatment process, the dosimetrist will map the product box geometry to determine D^{min} and D^{max} positions as per procedure specified in Section-11.

4.5.4. Dosimetrist will place dosimeters at D^{min} and D^{max} 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).

4.5.5. 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 (# 5) 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.

4.5.6. 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.

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- 4.5.7. Before start up of process, plant operator will conduct a search operation starting from control room (# 10) to the inside of irradiation cell (# 3) 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.
- 4.5.8. Plant operator will register each step of irradiation process through the computer-controlled microprocessor located at the control room (# 10), 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.
- 4.5.9. Radiological safety officer will closely monitor the radiation levels at all delineated areas that may be exposed to radiation above ambient levels (# 4). It is mandatory that all persons while working inside the irradiation plant will wear 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.
- 4.5.10. At the end of irradiation process, dosimetrist will retrieve the exposed dosimeters that are kept at D^{\min} and D^{\max} positions inside the product box 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 (#11) as per the procedure specified in Section-12. If the absorbed doses fall outside of the acceptable limits, dosimetrist will intimate the Plant In-charge/quality control 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.
- 4.5.11. At the end of irradiation treatment of each lot, Plant In-charge/Quality control officer will firmly affix the RADURA labels on the irradiated packages of mangoes (programme articles). Also verify that the label contains the unique Treatment Identification Number (assigned to each lot), Name of Irradiation Facility, Treatment Facility Code (assigned by the Dte of PPQS, IMO A (NPPO)), Dosage/Exposure Period, Product treated and Treatment Date/Time.

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4.5.12. The Plant In-charge/Quality Control Officer will enter the data in a serially page numbered treatment register (Annex-1), which is calico-bound and issue a treatment certificate (Annex-2) to each treated lot.

4.6. References:

4.6.1. Irradiation Operational Work Plan

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

4.7. Records:

4.7. 1. Record of Treatment Register

4.7.2. Record of Dose Mapping

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

4.8. Annexes:

4.8.1. Format of Treatment Register (Annex-1)

4.8.2. Format of Treatment Certificate (Annex-2)

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Annex-1
Treatment Record

Name of Treatment Facility	
Treatment Facility Code (assigned by NPPO)	
Treatment Identification Number	
Name of Packing House Facility	
Plant Product (Common/Botanical Name)/variety	
Quantity (in MTs)/No of Packages	
Product Identification Number (PHC (2)/PUC (3)/DoP (4))	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Purpose of Treatment	
Target Pest	
Target Dose (Gy)	
Date/Start Time/End Time of Treatment	
Absorbed Dose (Gy) measured	D^{min} : _____
	D^{max} : _____
	Average Dose : _____
Remarks, if any:	
Name/Signature of Plant Operator	
Name/Signature of Plant In-charge/Quality Control Officer	

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Section-4 (Rev.1.1)	Irradiation of articles	Page 6 of 6

Annex-2

Treatment Facility Code: _____	_____ _____ (Name & Address of Treatment Facility)	Treatment Identification Number: _____
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Irradiation Treatment Certificate

This is to certify that the plant products described here under have undergone irradiation treatment at this facility at the specified dosage indicated below as verified by the dosimetry and is in compliance with the requirements of Irradiation Operational Work Plan.

Date: _____
 Place: _____ (Signature/Name/Designation of Authorized Person)

Name of Packing House Facility											
Name of Commodity/ Variety											
Quantity (in metric tones)/No of Packages											
Product Identification Number (PHC (2)/PUC (3)/DoP (4))	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>										
Purpose of Treatment											
Target Regulated Pest (s)											
Source of Radiation											
Target Dose (Gy)											
Absorbed Dose (Gy) Measured	D ^{min} : _____ D ^{max} : _____										
Date of Treatment											

Document Approved Date: _____	Approved by: _____ (NPPO)
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Standard Operating Procedures- Name of the facility		
Section-5 (Rev.1)	Post-treatment storage	Page 1 of 3

5.1. Scope:

From receipt of treated article at the treated article storage area (#7) to delivery of treated product at loading/shipping area (# 8).

5.2. Definition of terms:

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

5.3. Responsibility & Authority:

5.3.1. Plant In-charge/Quality control 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.

5.4. Activity:

5.4.1. Plant In-charge/Quality control 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.

5.4.2. Plant In-charge/Quality control officer will ensure that the treated articles stored in treated article storage area are covered with polythene shrink wrap or with net wrapping to prevent reinfestation until moved for delivery at the loading area of the facility.

5.4.3. Plant In-charge/Quality control 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 (#7) is a secured area, which is distinct and physically separated from the untreated articles storage area (#2) by a insect-proof screened partition (#6)

5.4.3. 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.

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Standard Operating Procedures- Name of the facility		
Section-5 (Rev.1)	Post-treatment storage	Page 2 of 3

5.5. References:

5.5.1. Irradiation Operational Work Plan

5.6. Records:

5.6.1. Export inspection Register

5.6.2. Copy of Phytosanitary Certificate issued


5.6.3. Copy of PPQ Form 203 issued

5.7. Annexes

5.7.1. Format of Phytosanitary Certificate (Annex-1)

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Annex-1 (P 3/3)

 सत्यमेव जयते	Government of India MINISTRY OF AGRICULTURE Department of Agriculture & Cooperation Directorate of Plant Protection Quarantine & Storage		PSC No
	PHYTOSANITARY CERTIFICATE		E Reg No. Date:
1. From: Plant Protection Organisation of <u>INDIA</u>		2.To: Plant Protection Organisation of <u>USA</u>	
Description of Consignment			
3. Name and address of exporter		4. Declared name and address of consignee	
5. Declared means of conveyance		6. Place of origin	7. Declared point of entry
8. Distinguishing marks		9. Number and description of packages	
10. Name of produce/ Botanical name of plants		11. Quantity declared	
This is to certify that the plants or plant products described above have been inspected according to appropriate procedures and are considered to be free from quarantine pests and practically free from the injurious pests and that they are considered to conform to the current phytosanitary regulations at the importing country			
Disinfestation and/ or Disinfection Treatment			
12. Date _____		13. Temperature: _____	
14. Duration: _____		15. Chemical (active ingredient) _____	
15. Treatment _____		16. Concentration _____	
17. Additional information: _____			
18. Additional declarations:			
19. Place of issue: _____		Stamp of Organization	Name:
20. Date of issue : _____			_____
21. Code No : _____			(Signature & Stamp of authorized officer)

N.B: No financial liability with respect to this certificate shall attach to the Dte of Plant Protection, Quarantine & Storage or to any of its officers or representatives.

Standard Operating Procedures- Name of the facility		
Section-6	Loading and shipping of treated article	Page 1 of 1

6.1. Scope:

From delivery of treated articles at the loading and shipping area (# 8) of the treatment facility to shipping of programmed articles to the port in sealed container/closed conveyance

6.2. Definition of terms:

6.3. Responsibility & Authority:

6.3.1. **Plant In-charge** is responsible for delivery of treated article to the exporter/representative of packing house facility at the loading port of the treatment facility.

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

6.4. Activity:

6.4.1. Plant In-charge will supervise and permit the delivery of treated articles at the loading area of the facility and after verifying the documents in respect of each shipment

6.4.2. 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.

6.4.3. At the end of loading, Plant In-charge will affix the seals on the doors of closed container or the conveyance and issue a gate pass for security clearance

6.4.4. Initially the shipments are planned by direct flight from Mumbai to Los Angeles, New York, St Fransisco and subsequently may be extended to other ports.

6.5. References

6.5.1. Irradiation Operation Work Plan

6.6. Records

6.6.1. Product log book

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Standard Operating Procedures- Name of the facility		
Section-7 (Rev.1)	Pest exclusion and trapping	Page 1 of 2

7.1. Scope:

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

7.2. Definition of terms

7.2.1. Pest exclusion: is to exclude the pest

7.2.2. Trapping: Trapping fruit flies using pheromone traps

7.3. Responsibility & Authority

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

7.4. Specific Equipment

7.4.1. Fruit fly traps with lures (methyl euginol or cue lure)

7.5. Activity

7.5.1. 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 (#2) and treated article storage area (#7).

7.5.2. The officer of Dte of PPQS jointly with the inspector of APHIS will carry out routine inspection of facility and testing to ensure that insect-proof conditions are maintained at the facility to exclude hitch hiking pests.

7.5.3. 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 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.

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Standard Operating Procedures- Name of the facility		
Section-7 (Rev.1)	Pest Exclusion & Trapping	Page 2 of 2

7.5.4. 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.

7.6. References:

7.6.1. Irradiation Operation Work Plan

7.7. Records:

7.7.1. Record of Pest Control Measures

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	(NPPO)

Standard Operating Procedures- Name of the facility		
Section-8 (Rev.1)	Handling of rejected articles	Page 1 of 2

8.1. Scope:

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

8.2. Definition of terms:

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

8.3. Responsibility & Authority:

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

8.4. Activity:

8.4.1. At the beginning quality control officer will physically check the articles received at untreated article storage area (# 2).

8.4.1.1. If less than 1% packages found damaged, the same are segregated and marked “Rejected” on the cartons. The rejected cartons are removed to the rejected articles storage area (# 9) for disposal.

8.4.1.2. If more than 1% packages are found damaged in a single instance the entire lot will be rejected for treatment and rejected lot is immediately removed to rejected article storage area for disposal. The exporter or packing house facility is asked to remove the rejected lot from the facility and further notified to undertake mitigating measures to prevent damage.

8.4.1.3. 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 are temporarily suspended and the APEDA is notified to investigate the case to ensure corrective measures are implemented.

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Standard Operating Procedures- Name of the facility		
Section-8 (Rev.1)	Handling of rejected articles.	Page 2 of 2

- 8.4.2. If any articles found damaged during treatment or handling or articles that do not pass treatment, the Plant In-charge/quality control officer will segregate and mark “Rejected” on the cartons. The rejected articles are immediately removed to rejected article storage area for disposal.
- 8.4.3. Plant In-charge/Quality control officer will ensure the prompt removal of any rotten/over ripened fruits from the facility, treat and dispose the same on the same day by burying in a pit covered with six inches deep soil.
- 8.4.4. The fruit waste collected from the laboratory during inspection or debris collected from fallen fruits at the conveyor is bagged, treated and removed from the facility on the same day and the floor is immediately moped and disinfected.
- 8.4.5. The details of rejected articles are recorded in the product log book maintained at the facility at the end of each working day.

8.5. References

- 8.5.1. Irradiation Operation Work Plan

8.6. Records

- 8.6.1. Product log book

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Standard Operating Procedures- Name of the facility		
Section-9	Facility cleaning and sanitation	Page 1 of 1

9.1. Scope:

Procedures related to general cleanliness and sanitation at the facility.

9.2. Definition of terms

9.3. Responsibility & Authority

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

9.4. Activity:

9.4.1. The floors are swept and mopped twice a day using disinfectant solution such as Lysol.

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

9.4.3. The conveyor places and interior of irradiation cell are cleaned/de-dusted at the end of each process load.

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

9.5. References

9.5.1. House keeping manual

9.6. Records

9.6.1. Record of House Keeping

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Standard Operating Procedures- Name of the facility		
Section-10 (Rev.1)	Management of treatment documents and data	Page 1 of 7

10.1. Scope:

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

10.2. Definition of terms:

- 10.2.1 **Document:** Standards, Procedures, work instructions, references, specifications or regulatory material for the administration of the system.
- 10.2.2 **Data:** Quantified information in documents.
- 10.2.3 **Controlled document:** Documents formally identified. These documents are registered, maintained and their change, as well as, their implementation is regulated.
- 10.2.4 **Procedure:** Document that describes, “who does the job”, “when”, “where”, and “why”.
- 10.2.5 **Work instructions:** Document that identifies the procedures to perform a task or activity.
- 10.2.6 **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.
- 10.2.7 **Master List of Documents:** List that contains information related to documents and includes information such as documents titles, revision number and document codes.
- 10.2.8 **Record:** Document (electronic or print), product or sample statement, which will confirm that a procedure (or part of the procedure) has been carried out.
- 10.2.9 **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.

10.3. Responsibility & Authority:

- 10.3.1. **General Manager** is responsible for management and overall operation, maintenance of the facility.
- 10.3.2. **Plant In-charge** is responsible for the operation and maintenance of plant and good irradiation practices
- 10.3.2. **Quality Control Officer** is responsible for management of treatment documents and data

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Standard Operating Procedures- Name of the facility		
Section-10 (Rev.1)	Management of treatment documents and data	Page 2 of 7

10.4. Activity:

10.4.1. Document Control Procedure

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

10.4.1.1.3. .If it does not exist in the master list of documents, the quality control 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.

10.4.1.1.2. 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.

10.4.1.2. Plant In-charge/Quality control 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.

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

10.4.1.4. Plant In-charge/Quality control 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.

10.4.1.5. Confidential documents are identified by the General Manager and stamped and are handled by authorized persons identified through the work instructions

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10.4.1.6. Plant In-charge/Quality control 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.

10.4.2. Record Control Procedure

10.4.2.1. The Plant In-charge/Quality control 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.

10.4.2.2. 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 and electronically in the PC and also back-ups in the form of CDs (write-protected). The electronic records are protected by an encrypted password and the officer of Dte of PPQS or the inspector of USDA-APHIS given permission to access the data

10.4.2.3. 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.

10.4.2.4. Plant In-charge/Quality control 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.

10.5. References:

Irradiation Operational Work Plan

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10.6. Records

10.6.1. Master list of controlled documents

10.7. Annexes

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

10.7.2. Document change application (Annex-2)

10.7.3. Master List of Records (Annex-3)

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**Annex-2
Document Change Application**

Change Requested By	Application Date:	
Document Title		
Change Requested		
Reason		
Recommendation (Select One)		
<input type="checkbox"/> Reject (Reason)		
<input type="checkbox"/> Accept with Changes (Explain)		
<input type="checkbox"/> Accept		
If Accepted	Suggested Date	Valid Since
Revision		

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Standard Operating Procedures- Name of the facility

Section-10 (Rev.1)

Management of treatment documents and data

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Annex-3

Master List of Records

Record Title	Code Number	Date Of Disposal	Disposal Authorized By	Disposal Made By	Period Of Retention	Method Of Disposal	Comments

Document Approved Date:_____

Approved by:_____

(NPPO)

Standard Operating Procedures- Name of the facility		
Section-11 (Rev.1)	Dose mapping	Page 1 of 4

11.1. 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.

11.2. Definition of terms:

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

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

11.2.3. **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]

11.2.4. **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]

11.2.5. **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]

11.3. Responsibility & Authority:

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

11.4. Activity:

11.4.1. 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 Ceric-Cerous Sulphate (3 mM) and potentiometer is used as a read out system (ISO/ASTM 51205: 2002 (E), which is calibrated by using Fricke Reference standard E 1026-04 and spectrometer read out system

11.4.2. Dosimetrist will always ensures to run the facility with a load of dummy material to simulate the product density for at least 24 h to see if any interruption occurs during a blank run before the actual run for dosimetry, to ensure smooth functioning of the facility during the actual run.

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Standard Operating Procedures- Name of the facility		
Section-11(Rev.1)	Dose mapping	Page 2 of 4

- 11.4.3. Dosimetrist will verify the product density to ensure uniform filling out in the product boxes to its designed volume to permit the placement of dosimeter for dose measurement in multiple internal locations.
- 11.4.4. 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.
- 11.4.5. 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.
- 11.4.6. 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.
- 11.4.7. Dosimeters encapsulated in electron build-up caps in duplicate 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.
- 11.4.8. 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).

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- 11.4.9. 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. A minimum and maximum thermometer are placed in the central box to evaluate the average irradiation temperature. At this point of time all the other product carriers of the facility are loaded with the dummy boxes filled with the dummy material.
- 11.4.10. 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.
- 11.4.11. 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 ($n > \text{or} = 3$). 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).
- 11.4.12. 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.

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Section-11(Rev.1)	Dose mapping	Page 4 of 4

- 11.4.13. 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 with a maximum and minimum thermometer to know the average irradiation temperature. 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.
- 11.4.14. 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

11.5. References:

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

11.6. Records:

11.6.1. Record of Dose Mapping

11.6.1. Dosimetry Data

11.7. Annexes:

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Standard Operating Procedures- Name of the facility		
Section-12 (Rev.1)	Dosimetry	Page 1 of 2

12.1. Scope:

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

12.2. Definition of terms:

- 12.2.1. **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 [ISPM No. 18, 2003]
- 12.2.2. **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]
- 12.2.3. **Dosimetrist:** A trained personnel responsible for carrying out dose mapping and dosimetry.
- 12.2.4. **Reference Dosimeter:** Dosimeters used for calibration of routine dosimeters, which are traceable to national and international standards
- 12.2.5. **Routine Dosimeter:** Calibrated Dosimeters that are used in plant commissioning and routine dosimetry studies
- 12.2.6. **Plant Commissioning Dosimetry:** Dosimetry studies that are carried out for commissioning irradiation plant
- 12.2.7. **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.

12.3. Responsibility & Authority:

12.3.1. **Dosimetrist** is responsible for dosimetry

12.4. Specific Equipment:

- 12.4.1. Dosimeters
- 12.4.2. Potentiometer

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Standard Operating Procedures- Name of the facility		
Section-12 (Rev.1)	Dosimetry	Page 2 of 2

12.5. Activity:

12.5.1. Routine dosimetry as well as dose mapping is carried out by Ceric-Cerous Sulphate (3 mM) dosimeters with a potentiometer as a read out system ISO/ASTM 51205: 2002 (E), which is calibrated by using Fricke Reference standard E 1026-04 and spectrometer read out system and which is traceable to national standards established by Dosimetry Section, Radiation Safety Systems Division, Bhabha Atomic Research Centre (BARC) and the international standards established by International Dose Assurance Service (IDAS), International Atomic Energy Agency, under the name "IDAS".

12.5.2. At the beginning, the dosimetrist will verify the dosimeters to ensure that they are serially numbered and batch number for identification before placing in product boxes following the procedures of dose mapping described in Section 11. He will evaluate for their stability against the effects of variables of temperature, light, humidity, storage time and the type and timing of analyses required.

12.5.3. The dosimeters are stored at climate controlled dosimetry lab in a closed and sealed lead box to prevent the decay until their use.

12.5.3. 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.

12.5.4. At the climate controlled dosimetry lab the dosimeters are uncapped and the liquid contents are read by a potentiometer.

12.5.5. Dosimetrist will compute the absorbed dose from the analysis of potentiometer readings, using a standard curved established by using Fricke Reference standard E 1026-04 and spectrometer read out system.

12.5.6. Dosimetrist will use dosimeters for each process load in order to ensure that the programmed articles receive minimum absorbed dosage specified under Irradiation Operation Work Plan

12.6. References:

12.6.1. Irradiation Operation Work Plan

12.7. Records:

12.7.1. Dosimetry Data

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Standard Operating Procedures- Name of the facility		
Section-13	Calibration of Spectrophotometer	Page 1 of 2

13.1. Scope:

From procurement of equipment to regular calibration and maintenance of equipment

13.2. Definition of terms:

13.3. Responsibility & Authority:

13.3.1. **Dosimetrist** is responsible for regular calibration of spectrophotometer and maintenance of calibration records at the facility

13.3.2. **Plant In-charge/Quality control officer** is responsible for entering into annual maintenance contract with the manufacturer/supplier of the spectrophotometer

13.4. Activity:

13.4.1. Dosimetrist will identify and document the test procedure for calibration and level of required accuracy of the measurement

13.4.2. Dosimetrist will calibrate the equipment using the calibration kit provided by the manufacturer following the documented procedure and will record the date of calibration, method followed, observed values and the tolerances allowed as per the manufacture of equipment and deviated results as per Annex-1. For external calibration, he will obtain a certificate of calibration and keep for the record

13.4.3. If the results are within the permissible limits, dosimetrist will affix a suitable calibration label on the equipment.

13.4.4. Dosimetrist will record the details of calibration done in the log book maintained in respect of spectrophotometer

13.5. References:

13.6. Records:

13.6.1. Record of Calibration Report

13.6.2. Log book

13.7. Annexes:

13.7.1. Calibration Record Format (Annex-1)

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Section-13	Calibration of Spectrophotometer	Page 2 of 2

Calibration Record Format (Annex-1)

Name of equipment					
Manufacturer/Supplier					
Identification number					
Tolerance (if applicable)					
Conditions					
Frequency of Calibration					
Method					
Remarks					
	Date	time	condition	adjust	initial
1					
2					
3					
4					
5					
6					
7					
8					

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Standard Operating Procedures- Name of the facility		
Section-14	Verification of conveyor speed or exposure times	Page 1 of 1

14.1. Scope:

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

14.2. Definition of terms:

14.3. Responsibility & Authority:

14.3.1. **Dosimetrist** is responsible for verification of conveyor speed or exposure times (timer or cycle validation) based on dose mapping and dosimetry studies

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

14.4. Activity:

14.4.1. 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.

14.4.2. 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.

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

14.4.4. 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.

14.5. References

14.5. Records

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Standard Operating Procedures- Name of the facility		
Section-15	Staff training	Page 1 of 3

15.1. Scope:

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

15.2. Definition of terms:

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

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

15.3. Responsibility & Authority

15.3.1. **General Manager** is responsible for determining the training needs of personnel and preparing the budget, planning, conducting and evaluating the training program

15.3.2. **Plant In-charge** is responsible for maintaining the training records and evaluation of results of training

15.4. Activity

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

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

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

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

15.4.5. 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).

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Section-15	Staff training	Page 2 of 3

15.4.6. 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

15.4.7. Plant In-charge/Quality control 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.

15.5. References

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

15.5.2. Irradiation Operational Work Plan

15.6. Records

15.6.1. Program of internal and external training needs

15.6.2. Record of workshop schedules

15.6.3. Record of workshops programs

15.6.4. List of human resources

15.6.5. Record of list of participants

15.6.6. Record of evaluation/ certificates

15.7. Annexes

15.7.1. Schedule of Internal/External training workshops (Annex-1)

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