Standard Practice for Dosimetry in Electron Beam and X-ray Facility for Radiation Processing of Food & Allied Products

Department of Atomic Energy
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Table of Contents

FOREWORD

Radiation processing has become a well-accepted technology in global market with uses ranging from sterilization of medical devices to polymer cross-linking and preservation of food & agricultural produce. The technology of food processing by ionizing radiation is more than 100 years old and used commercially for irradiation of variety of foods to achieve the desired results such as microbial decontamination, sprout inhibition, insect disinfestation, delay in ripening of perishable fruits, phytosanitary treatment etc. Globally, the food irradiation is accomplished by isotope based radiation source (Co-60) or machine based radiation source. The electron beam radiation processing facility uses electron accelerator to generate radiation. The E-beam technology is gaining more popularity due to its inherently safe and environment friendly nature. The radiation from the accelerator can be switched ON/OFF as per the requirement in contrary to the isotope source, which continuously emits the radiation.

As per Gazette Notification of Government of India, G.S.R 158, June 24, 2012, Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012 following radiation sources are permitted for food irradiation

a) Gamma radiation.

b) Electron beam from a machine operated at or below ten million electron volts.

c) X-Rays generated from a machine operated at or below seven and half million electron volts

Before the irradiation facility is used for commercial irradiation of food products, it is essential to characterize the facility to accurately and reproducibly deliver radiation doses over the range of operational parameters for which it has been designed. The processing quality and product release require development of the process, qualifying it repeatedly through dosimetry, and then replicating the qualified process on product batches with effective process controls.

Like Gamma Radiation Processing Facilities (GRAPF), electron beam based facilities are required to obtain licence from AERB under Atomic Energy (Radiation Protection) Rules 2004 and subsequently licence for processing of food and allied products from DAE under Atomic Energy (Radiation Processing of Food and Allied Products) Rules 2012. The present document titled **"Standard Practice for Dosimetry in Electron Beam and X-ray Facility for Radiation Processing of Food & Allied Products"** has been prepared for qualification of a radiation processing facility based on electron accelerator. Guidance from various international standards pertaining to qualification of accelerator based radiation processing facilities (ISO/ASTM 51649:2015(E), ISO/ASTM 51608:2015(E) and ISO 14470: 2011) has been taken in preparing the document and various terms and quantities are defined to provide a precise interpretation.

The document includes three stage qualification and validation process: Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). Installation Qualification (IQ) is carried out to generate documentary evidence to establish that the irradiation equipment and any ancillary items have been supplied and installed in accordance with their specifications. Operational Qualification (OQ) is carried out to characterize the performance of the irradiation equipment including conveyor system with respect to reproducibility of the dose delivered to the product. Performance

Qualification (PQ) tests are carried out in actual product with the objective of establishing all the process parameters to deliver specified dose to the process load.

Experts from Industrial Accelerators Division, RRCAT prepared the first draft of this document. It has been reviewed by experts from BRIT, BARC and Advisory cum monitoring Committee for Utilization of Industrial Accelerators and Other Technologies of RRCAT. Further, the document has been vetted by Dose Verification Committee (DVC), BARC and approved for further publication by DAE for the benefit of applicants using radiation processing technology for food using electron accelerator.

RRCAT wishes to thank all individuals and organizations who have prepared and reviewed the draft document and helped in its finalization. The list of experts who have participated in preparation of this document, along with their affiliation and e-mail is included for information.

1. Introduction

Electron accelerator based irradiation facilities are used for radiation processing of food and allied products. Radiation processing is primarily carried out to achieve certain technological benefits. For food and agricultural commodities the technological objectives include, controlling physiological changes, insect disinfestation, and microbial decontamination. This document describes the process qualification requirements for an electron beam irradiation facility used both in electron beam and X-ray modes. It is essential to establish the base line data for evaluating the ability of the facility to accurately and reproducibly deliver radiation doses over a range of operational parameters for which a facility has been designed. The "electron beam irradiation facility*"* (herein after called facility*)* shall be used for irradiation of the above mentioned products, packaged or in bulk, for the technologic purposes listed above. As a first step, specifications of the accelerator and the conveyor systems associated with dose delivery are to be recorded and documented. Installation of the equipment in line with the specifications and the capability of the facility to deliver the required doses are to be tested through a series of qualification tests. These include:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

The procedures recommended by various international standards organizations [1-9] for qualification have been consulted in the preparation of this document.

2. Scope

This document entitled "Standard practice for dosimetry in an electron beam irradiation facility for radiation processing of food and allied products using electron beam and X-ray modes" describes the standard practice to be followed for the commissioning and the re-commissioning dosimetry of radiation processing facilities operated both in electron and X-ray modes for irradiation of food and allied products at electron energies between 300 keV and 10 MeV. The irradiation of food and allied products shall be carried out in accordance with the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012 [20] using the following machine based sources:

a) Electrons beams from a machine operated at or below 10 MeV.

b) X-rays generated from a machine operated at or below 7.5 MeV
(The target material tantalum or gold shall be used for machine sources at energies not exceeding 7.5 MeV and tungsten also can be used for machine sources at energies not exceeding 5.0 MeV)

A typical block diagram of an electron beam (EB) facility is given in Fig. 1.

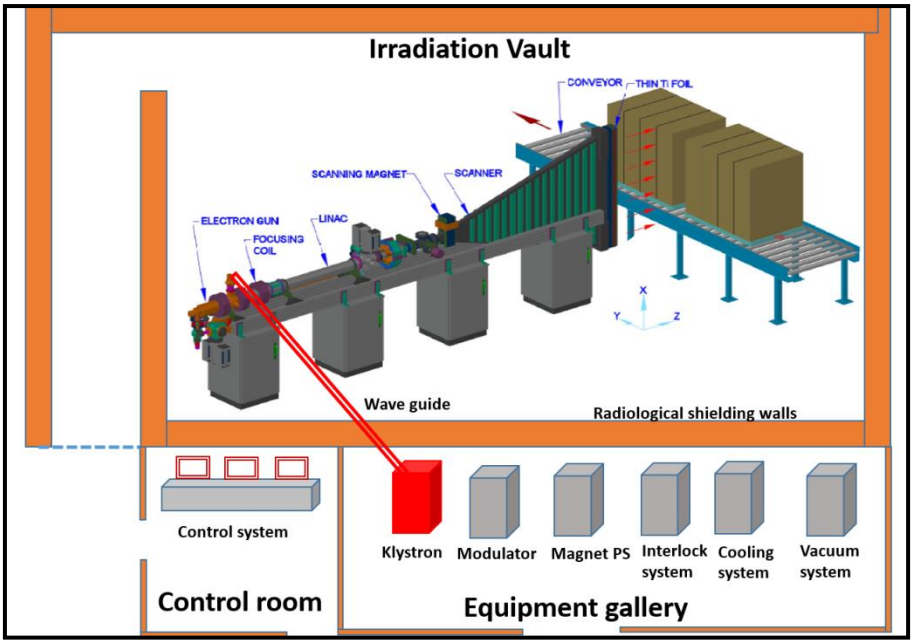


Fig. 1: Typical block diagram of electron accelerator facility

3. Definitions

3.1. **Absorbed Dose (D) -**Quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram (1 Gy = 1 J/kg) of energy. Absorbed dose is sometimes simply referred to as dose. The mathematical relationship is the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is mean incremental energy imparted by ionizing radiation to the matter of incremental mass dm

$$D = \frac{d\bar{\varepsilon}}{dm}$$

3.2. **Average beam current-** Time-averaged electron beam current. For pulsed accelerator, the averaging is done over a time duration covering a number of pulses [Fig. 2]

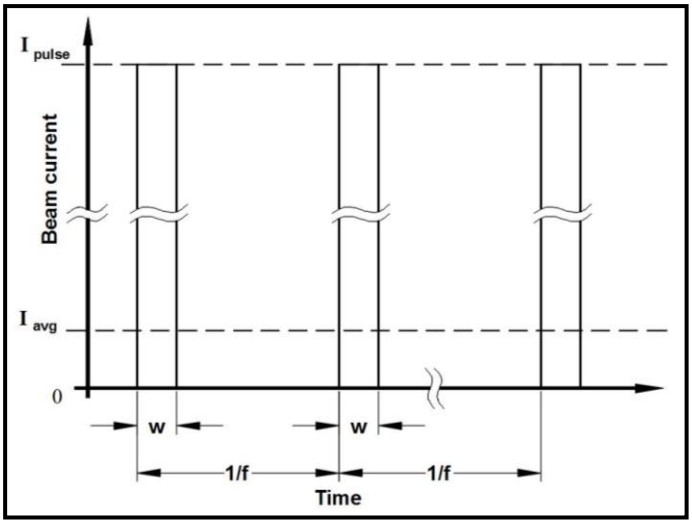


Fig. 2: Pulse beam current (I_{pulse}), average beam current (I_{avg}), pulse width (w) and pulse rate (f) for a pulsed accelerator.

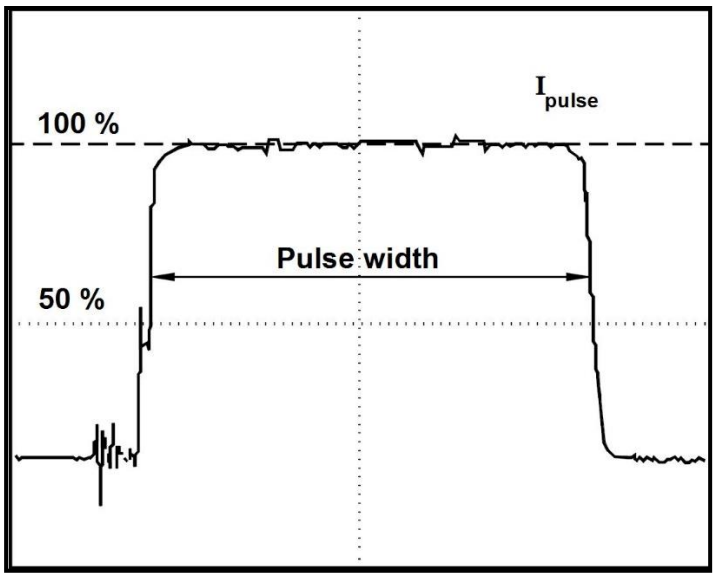
3.3. **Electron beam energy-** Kinetic energy of the accelerated electrons in the beam. Electron volt (eV) is often used as the unit for electron beam energy where 1 eV = 1.602 x 10^{-19}J. In radiation processing, where beams with a broad electron energy spectrum are frequently used, the terms *most probable energy* (E_p) and *average energy* (E_a) are common. They are linked to the *practical electron range* R_p and *half-value depth* R_{50} by empirical equations

3.4. **Electron energy spectrum-** Particle fluence distribution of electrons as a function of energy

3.5. **Beam power-** Product of the average electron beam energy and the average beam current

3.6. **Duty cycle-** Defined for pulse accelerator as the fraction of time the beam is effectively ON. Duty cycle is the product of the pulse width (w) in seconds and the pulse rate (f) in pulses per second.

3.7. **Pulse width (*w*) -** Defined for pulse accelerator as the time interval between two points on the leading and trailing edges of the pulse current waveform where the current is 50 % of its peak value. Pulse widths are of the order of µs. A typical pulse current waveform is depicted in Fig.3



Horizontal axis: Time, typically in µs; Vertical axis: Pulse beam current, typically in mA

Fig. 3: Typical pulse current waveform in a linear accelerator.

3.8. **Electron beam range-** Penetration distance in a specific, totally absorbing material along the beam axis of the electrons incident on the material

3.9. **Pulse repetition rate (PRR) -** Defined for pulse accelerator as the pulse repetition frequency in hertz, or pulses per second

3.10. **Beam spot-** Shape of the un-scanned electron beam incident on the reference plane

3.11. **Scanned beam-** Electron beam that is swept back and forth with a varying magnetic field. This is most commonly done along one dimension (beam width), although two-dimensional

scanning (beam width and length) may be used with high-current electron beams to avoid overheating the beam exit window of the accelerator or product under the scan horn

3.12. **Scan frequency-**Number of complete scanning cycles per second

3.13. **Scan uniformity-** Degree of uniformity of the dose measured along the scan direction

3.14. **Beam length-** Dimension of the irradiation zone along the direction of product movement at a specified distance from the accelerator window [Figs. 4(a), 4(b),5]. Beam length is therefore perpendicular to beam width and to the electron beam axis. In case of a product that is stationary during irradiation, 'beam length' and 'beam width' may be interchangeable

3.15. **Beam width (W) -** Dimension of the irradiation zone perpendicular to the direction of product movement at a specified distance from the accelerator window [Figs. 4(a), 4(b), 5]

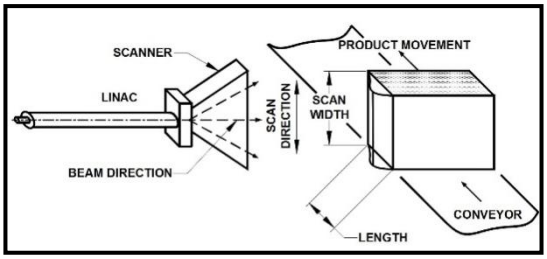


Fig. 4 (a): Diagram showing beam length and beam width for a scanned beam of horizontal electron accelerator using a conveyor system

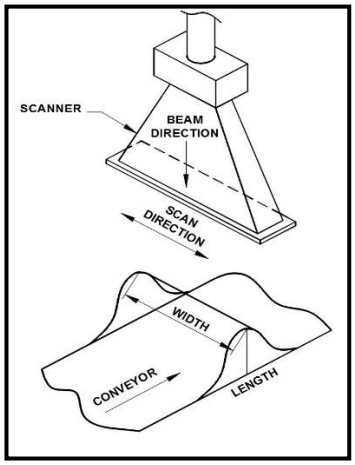


Fig. 4 (b): Diagram showing beam length and beam width for a scanned beam of vertical electron accelerator using a conveyor system

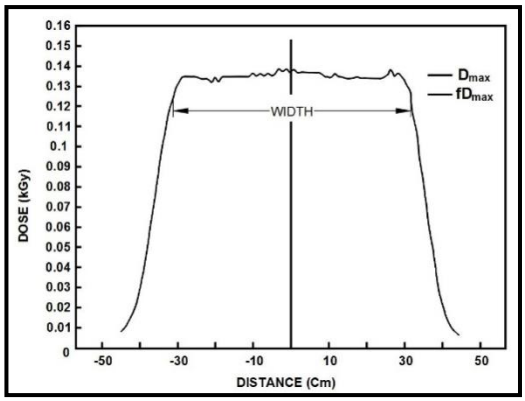
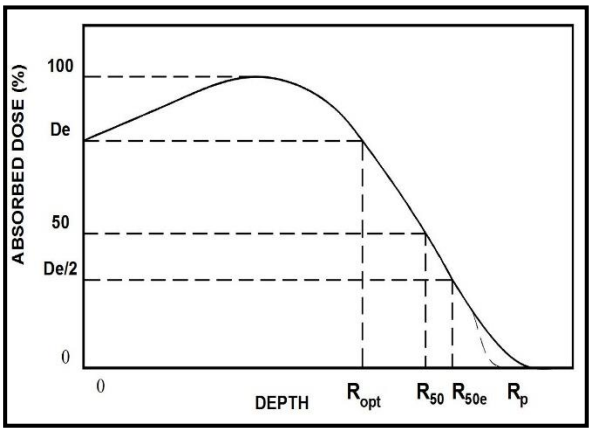


Fig. 5: Example of electron-beam dose distribution along the scan direction, where the beam width is specified at a defined fractional level f of the average maximum dose D_{max}

3.16. **Depth-dose distribution-** Variation of absorbed dose with depth from the incident surface of a material exposed to a given radiation [Fig. 6]

3.17. **Optimum thickness (R_{opt}) -**Depth in homogeneous material at which the absorbed dose equals its dose value at the entrance surface of the material [Fig. 6]

3.18. **Practical electron range (R_p) -**Depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the extrapolated X-ray background **[**Fig. **6]**. Penetration can be measured from experimental depth-dose distributions in a given material. Other forms of electron range are found in the dosimetry literature, for example, extrapolated range derived from depth- dose data and the continuous-slowing-down-approximation range. Electron range is usually expressed in terms of mass per unit area ($kg \cdot m^{-2}$), but sometimes in terms of thickness (m) for a specified material



D_e: Dose at entrance surface; R_{opt}: Depth at which dose at descending part of curve equals D_e; R_{50}: Depth at which dose has decreased to 50 % of its maximum value; R_{50e}: Depth at which dose has decreased to 50 % of D_e; R_p:Depth where extrapolated straight line of descending curve meets depth axis

Fig. 6: A typical depth-dose distribution for an electron beam in a homogeneous material

3.19. **Extrapolated electron range (R_{ex}) -**Depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution meets the depth axis

3.20. **Half-entrance depth (R_{50e}) -** Depth in homogeneous material at which the absorbed dose has decreased to 50 % of its dose value at the entrance surface of the material [Fig. 6]

3.21. **Half value depth (R_{50}) -** Depth in homogeneous material at which the absorbed dose has decreased to 50 % of its maximum dose value [Fig. 6]

3.22. **Dose uniformity ratio (DUR) -** Ratio of the maximum to the minimum absorbed dose within the irradiated product. This concept is also referred to as the max/min dose ratio

3.23. **Installation qualification (IQ) –** Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications

3.24. **Operational qualification (OQ) –** Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.25. **Performance qualification (PQ) -** Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria

3.26. **Beam characterization (BC) -**Determination of beam characteristics which includes measurement of electron beam energy, average beam current or pulse current, pulse repetition rate, scan width and scan uniformity

3.27. **X-ray convertor (Target for X-ray) -**A metallic device used to generate X-ray beam on bombardment of electron beam. Tantalum or gold shall be used as target material for treatment of food and agricultural products at energy less than 7.5 MeV

3.28. **Process load-**Volume of material with a specified product loading configuration irradiated as a single entity

3.29. **Reference material (Phantom material)-** Homogeneous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as scan uniformity, depth-dose distribution, and reproducibility of dose delivery

3.30. **Reference plane-** Selected plane in the radiation zone that is perpendicular to the electron beam axis

3.31. **Standardized depth (z) -** Thickness of the absorbing material expressed as the mass per unit area, which is equal to the product of depth in the material (t) and density (ρ)

3.32. **Routine monitoring position-** Position where absorbed dose is monitored during routine processing to ensure that the product is receiving the absorbed dose specified for the process

This position may be a location of minimum or maximum dose in the process load or it may be an alternate convenient (sometime called reference dose position) location in, on or near the process load where the relationship of the dose at this position with the minimum and maximum dose has been established.

3.33. **Commissioning/ re-commissioning dosimetry-** To characterize the distribution, magnitude, and reproducibility of absorbed dose in a homogeneous material and to relate these parameters with operating conditions. The commissioning/ re-commissioning dosimetry is to be carried out under the conditions given in Table- 1.1 and Table- 1.2

Table 1.1 — Conditions for qualification for installation and/ or for carrying out changes for operating in electron mode

Facility parameter for installation or change	Installation qualification	Operational qualification			
	Installation testing and equipment documentation	Operational testing	Equipment calibration	Facility dose mapping	Type of dose measurement
Accelerator mechanical alignment	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Steering or focusing magnet systems	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Bending magnet systems	✓		✓	✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Beam current monitoring system	✓		✓	✓	Scan uniformity in the direction of product travel
Scanning magnet system	✓		✓	✓	Scan uniformity in the direction of product travel
Conveyor speed monitoring and/or control circuitry	✓		✓	✓	Scan uniformity in the direction of product travel Process interruption testing
Conveyor system motors, belts, and gearing	✓	✓			

Table 1.2 — Conditions for qualification for installation and or for carrying out changes for operating in X-ray mode

Facility parameter for installation or change	Installation qualification	Operational qualification			
	Installation testing and equipment documentation	Operational testing	Equipment calibration	Facility dose mapping	Type of dose mapping
Accelerator mechanical alignment	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Steering or focusing magnet systems	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Bending magnet systems	✓		✓	✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Beam current monitoring system	✓		✓	✓	Scan uniformity in the direction of product travel
Scanning magnet system	✓		✓	✓	Scan uniformity in the direction of beam scan
Conveyor speed monitoring and/or control circuitry	✓		✓	✓	Scan uniformity in the direction of product travel Process interruption testing
Conveyor system motors, belts and gearing	✓	✓			
Product container redesign	✓	✓		✓	Scan uniformity in the direction of product travel Depth-dose in the direction of product travel

Removal or relocation of conveyor inside irradiation cell	✓	✓		✓	Scan uniformity in the direction of product travel Depth-dose in the direction of product travel
Redesign that affects the source-to-product distance	✓	✓		✓	Scan uniformity in the direction of product travel Scan uniformity in the direction of beam scan Depth-dose in the direction of product travel
Changes to type of electron beam radiation safety monitoring devices	✓	✓			
Replacement, redesign, or realignment of the X-ray target	✓	✓		✓	Scan uniformity in the direction of beam scan and beam travel. Scan uniformity in the direction of product travel. Depth-dose in direction of beam travel.

4. **Facility information**

4.1.	Name and address of the facility	:	
4.2.	Type of accelerator	:	……
4.3.	Beam direction	:	Horizontal or Vertical beam
4.4.	Mode of operation	:	
	a) Electron mode	:	Energy: …… Beam power: ……..
	b) X-ray mode	:	Energy: …… Beam power: ……..
4.5.	Irradiation mode	:	Continuous conveyor, batch, or bulk flow
4.6.	Irradiation pathway	:	Single sided or double sided
4.7.	Product box size	:	
4.8.	Nature of product to be irradiated (declaration to be provided by user regarding the elemental composition of material to be irradiated	:	Metallic/ non-metallic / both
4.9.	Density and bulk density of the material intended to be processed	:	Density …… Bulk density ……
4.10.	Facility ID number allotted by AERB	:	

5. Requirements for dosimetry

5.1. Dosimetry laboratory

The facility shall have a dosimetry laboratory for dose measurement. The laboratory shall have suitable provisions for ventilation, and control of humidity and temperature.

5.2. Dosimetry system [Ref. 10-19]

The dosimetry system shall consist of suitable dosimeter with appropriate readout system for dosimeter response measurement and computation of absorbed dose (Annex-5).

5.3. Selection and procurement of dosimetry system

A proper dosimetry system shall be selected from those listed in Annex-5, based on the required dose range for the product to be irradiated at the facility. Employer shall obtain adequate number of dosimeters (routine/process dosimeters) from an approved manufacturer/supplier, along with calibration graph or a mathematical relationship to convert the dosimeter reading/response into dose. The dosimetry system shall have a valid traceability certificate issued by any International Standard Laboratory (NIST/NPL or equivalent) or National Standard Laboratory (NSL), Radiation Standards Section, RSSD, BARC, Mumbai hereafter referred to as RSSD, BARC. It is also necessary to check the date of manufacturing, date of expiry for the particular batch of dosimeters. The dosimetry system shall comply with the ASTM /ISO standard or other established national/international standard.

Other than the established dosimeters accepted internationally, other dosimeters for which the traceability is established can also be used. Additionally, a proper build up should be provided in X-ray irradiation as recommended in ASTM standards/manufacturer. It is required to establish a routine dosimeter (in-house) before proceeding for the dosimetry exercises.

5.4. Computation of dose

Suitable software/calibration chart supplied by the manufacturer or generated in-house) shall be used for computation of absorbed dose or the dosimeter shall be calibrated by the manufacturer.

5.5. Reporting of absorbed dose

Absorbed dose shall be computed and reported at 25^{o}C by applying appropriate correction for irradiation temperature and dose measuring temperature.

5.6. Trained staff

Dosimetry shall be carried out by trained dosimetry staff or the operator that has undergone certification course with approved syllabus prescribed by AERB for plant operators or the radiation safety officer of the facility.

6. Dose inter-comparison with National Standard Laboratory (NSL)

6.1. Dose inter-comparison

Irradiation facility shall carry out dose inter-comparison exercise for the dosimeter batch intended to be used for plant commissioning/ re-commissioning dosimetry with National Standard Laboratory (NSL) RSSD, BARC, Modular Laboratory, Trombay, Mumbai-400085). The purpose of this exercise is to ensure i) traceability of dose measurements to NSL, ii) the competence of an irradiation facility to measure absorbed dose, and iii) the preparedness of the facility for dosimetry.

6.2. Procedure

a) Irradiation facility shall send 20 Nos. of un-irradiated dosimeters from a dosimeter batch to NSL for dose inter-comparison.

b) NSL will irradiate these dosimeters to minimum three different known doses within the dose range of the dosimeter. Delivery of pre-determined doses will be achieved by controlling the time of irradiation in a calibrated Gamma chamber having known "dose delivery rate". After the dose delivery the dosimeters will be returned to the facility.

c) The facility shall carry out evaluation of irradiated dosimeters and send the dose measurement results to NSL.

d) NSL will compare the dose values measured by the facility with those delivered by NSL. NSL will send the results to the concerned facility. The agreement between these values shall be within ± 5 % (1σ) [26]. If the dose values differ by more than ± 5% (1σ), the dose inter-comparison exercise shall be repeated with new set of dosimeters.

7. Dosimetry

7.1. Selection of material for preparation of dummy and dosimetry boxes

It is preferable to use the actual product for dosimetry. In case, the actual product is not available, a material having comparable bulk density and homogeneous nature similar to the intended for product processing shall be used as reference (phantom) material for IQ and OQ. Reference (phantom) materials such as corrugated card board, rice husk, saw dust or mixture of rice husk and saw dust, dry raisins or other products consisting of low atomic weight elements such as C, H, O, N shall be used. The density of reference (phantom) material shall be within ± 10 % of the actual product density. A list of some reference (phantom/ dummy) materials is given in Annex-7. It is mandatory to use the actual product in its final packing format for PQ (internal packing arrangement within the box, box size and the box orientation for radiation processing used in PQ shall be the same as that will be used in the final production batches).

7.2. Dummy and dosimetry boxes

Packaging simulating the actual product in terms of outer dimensions and the real density shall be used for preparation of dummy and dosimetry boxes. The dummy boxes are those, which are filled with reference (phantom) material. The dosimetry boxes are those, which are filled with product/reference (phantom) material having dosimeters placed at the designated positions.

7.3. Preparation of dummy boxes

The dummy boxes shall be filled in such a way as to fulfill the requirement of bulk density of the product to be processed during routine irradiation. Weight of each dummy box shall be noted. While selecting a mixture of materials as reference (phantom) material, care shall be taken to see that density of the reference (phantom) material within the packing remains homogenous (as intended) and different components of the mixture do not separate or settle to create different layers of different densities. The number of product/dummy boxes and relative distances between the boxes shall be same as to be used for actual processing (to appropriately include the effects of scattering) before starting the plant commissioning/re-commissioning dosimetry. All typical box positions (like corner boxes, in-between boxes, upper/lower boxes) shall be included in the dosimetry boxes.

7.4. Preparation of dosimetry boxes

Dosimeters shall be affixed at specified positions on cardboard sheets/actual product and placed in the dosimetry boxes for different sets of measurements for the plant commissioning/ re-commissioning dosimetry. Along with dosimeters, humidity and temperature measurement devices also need to be kept since both are critical parameters in dose measurement exercise.

8. Steps to be followed during plant commissioning/re-commissioning dosimetry

Plant commissioning/ re-commissioning dosimetry shall be carried out in the three sets of measurements viz. IQ, OQ, PQ.

8.1. Installation Qualification (IQ)

A written specification of the irradiation equipment and the ancillary equipment used shall be available before starting the IQ tests. Installation qualification (IQ) is carried out to obtain documented evidence that the irradiation equipment and any ancillary items have been supplied and installed in accordance with their specifications. Beam Characterization (BC) tests shall be performed in which the determination and recording of the beam characteristics (electron energy, average beam current/pulse current, scan width and scan uniformity) and conveyor system are included. The procedure is prepared in accordance with ISO/ASTM 51649, ISO/ASTM 51608 and ISO 14470 [Annex-1 (a), (b), (c), (d) and (e)]. The Beam Characterization (BC) procedure is common for IQ, OQ and PQ tests.

8.2. Operation Qualification (OQ)

A written specification of the irradiation equipment and its design performance with respect to the reproducibility of the dose delivery shall be available before starting the OQ tests. Operational qualification (OQ) is carried out to characterize the performance of the irradiation equipment with respect to reproducibility of the dose delivered to the product. Volumetric dose mapping is carried out using an irradiation container filled with homogeneous material to the upper limit of its design specification. Dose mapping exercise shall be carried out in a homogeneous phantom material close to the density of actual product to be radiation processed. Mapping of the absorbed dose distribution by three dimensional grid of dosimeters in the process load (product/dummy material) is carried out to locate the minimum dose (D_{min}) and maximum dose (D_{max}) positions/regions inside the product box. The amount of product/dummy material in

the process load shall be the same (i.e. by volume and density) as is expected to be loaded in the actual process run.

A sufficient number of process loads (minimum 3) of homogeneous density shall be dose mapped to estimate the variability of magnitude and distribution of absorbed dose within process load. During the dose mapping exercise, characteristics of the beam shall be controlled within the limits of facility specifications. The following measurements shall be carried out as per the procedures described in Annex-2 (a), (b), (c), (d) and (e) and the outcome shall be recorded.

a) Conveyor speed vs dose measurement

b) No. of pass vs dose measurement

c) Depth dose profile

d) Dose mapping

e) Process interrupt

If the specifications of the facility are not met during the OQ tests, the specifications shall be revised to include the actual characteristics as determined from the OQ tests.

8.3. **Performance Qualification (PQ)**

A written specification of the irradiation equipment and its design performance with respect to the dose distribution and reproducibility of the dose delivery to the actual process products shall be available before starting the PQ tests. The objective of the performance qualification is to establish all process parameters that will satisfy absorbed dose requirements of the actual material to be processed. The PQ tests include determination and recording of

a) Dose mapping in actual products for identification of minimum and maximum dose positions/regions

b) Routine (or reference) monitoring position (D_{ref})

c) Dimensions and bulk density of the process load

d) Internal packing arrangement and orientation of products within the package

e) Orientation of the product with respect to the material handling system and beam direction

f) Irradiation pathway (single sided/ double sided)

g) Repeatability of dose at D_{max} and D_{min} position

h) Dose uniformity ratio (DUR)

i) Relationship between D_{ref}, D_{max} and D_{min}

PQ will be carried out for fully loaded process load. Repeat of PQ dose mapping is needed if the product (including its internal or external packaging) is changed affecting dose or dose distribution significantly or if OQ measurements show that the irradiation facility characteristics are changed. The rationale for decisions taken shall be documented. Annex -3 (a), (b) describes the procedure for PQ measurements.

9. Dose results

9.1. Determination of dose uniformity ratio (DUR)

The ratio of maximum dose (D_{max}) to minimum dose (D_{min}) is expressed as DUR.

Dose uniformity ratio (DUR) = $\frac{D_{max.}}{D_{min.}}$ …….. [9.1]

9.2. Calculation for dose delivered using dose measurement at reference location

The ratio of D_{min} to D_{ref} is termed as $R_{min.}$ and D_{max} to D_{ref} is termed as $R_{max.}$ which is calculated from dosimetry dose data obtained during PQ. This ratio shall be used to determine the minimum and maximum dose during routine radiation processing.

i. Calculation of reference ratio:

Minimum to reference ratio ($R_{min.}$) = $\frac{D_{min.}}{D_{ref.}}$ …….. [9.2 (a)]

Maximum to reference ratio ($R_{max.}$) = $\frac{D_{max.}}{D_{ref.}}$ …….. [9.2 (b)]

ii. Calculation for delivered dose during routine radiation processing using dose measured at reference location ($D_{ref.}$):

Minimum delivered dose ($D_{min.}$)= $R_{min.} \times D_{ref.}$ …… [9.2 (c)]

Maximum delivered dose ($D_{max.}$)= $R_{max.} \times D_{ref.}$ …… [9.2 (d)]

9.3. Target dose calculation

Target dose shall be calculated for a confidence level of 95% using tolerance factor k given in Annex- 6.

Target minimum dose in kGy = $D_{min} + k \times (S.D.)_1$ …….. [9.3 (a)]

Target maximum dose in kGy = $D_{max} - k \times (S.D.)_2$ …….. [9.3 (b)]

D_{min} and D_{max} values are as per the existing regulatory requirements.

Where $(S.D.)_1$and $(S.D.)_2$ are the standard deviation values for average minimum and average maximum dose respectively obtained from PQ.

9.4. **Ultimate uniformity ratio (UUR):** This can be calculated for a confidence level of 95% using tolerance factor k given in Annex- 6.

Limiting minimum dose in kGy

D_{min}^{lim} = Average minimum dose delivered (D_{min}) - $k \times (S.D.)_1$ …….. [9.4 (a)]

Limiting maximum dose in kGy

D_{max}^{lim}= Average maximum dose delivered (D_{max}) + $k \times (S.D.)_2$ …….. [9.4 (b)]

Ultimate uniformity ratio= $\frac{\text{Limiting maximum dose } (D_{max}^{lim})}{\text{Limiting minimum dose } (D_{min}^{lim})}$……...….. [9.4 (c)]

Where $(S.D.)_1$and $(S.D.)_2$ are the standard deviation values for average minimum and average maximum dose respectively obtained from PQ.

10. **Conveyor speed setting**

Machine parameters are optimized and fixed during PQ. The conveyor speed shall be set/adjusted on the basis of the target minimum dose calculated from the results obtained in the PQ [using equation no. - 9.3 (a)].

*The results of Plant commissioning/ Re-commissioning Dosimetry shall be reported as per the format given in Annex-4***.**

11. Dose verification in product

11.1. Purpose

Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012 [20] require establishing documentary evidence that food processed by the facility has received doses within the recommended technological dose limits. All these measurements shall be traceable to national/international standards through an unbroken chain. Radiation Standards Division (RSSD) of BARC is entrusted with the task of carrying out verification of dosimetry. Hence, it is recommended to carry out dose inter-comparison exercise in the one actual product in given class [20] to be processed using routine process dosimeter of plant and the Transfer Standard Dosimeters supplied by RSSD, BARC as per the written instructions provided below. This exercise is to be carried out by the irradiation facility after commissioning/ re-commissioning dosimetry.

A copy of the results of this exercise shall be part of the dosimetry report to be submitted for obtaining Food Processing Licence from the DAE.

11.2. Steps to be carried out for dose verification

a) The facility shall utilize the transfer standard dosimeters supplied by RSSD, BARC or any other organization accredited for the purpose of carrying out process validation dosimetry.

b) The facility shall obtain at least 30 numbers of transfer standard dosimeters.

c) The facility shall perform the dose distribution measurement using the transfer standard dosimeters along with dosimeter from the same batch which were used for carrying out dose inter-comparison.

d) The dose distribution measurement shall be performed in at least one product box, using minimum three different symmetric planes perpendicular to beam central axis.

e) The number of dosimeters to be placed per plane shall be at least nine and distributed symmetrically in 3 rows and 3 columns with at least 2 to 3 cm margin from edges of the plane. At each point routine dosimeter (which were used for carrying out dose inter-comparison exercise) and reference dosimeter shall be placed side by side (i.e. adjacent to each other). This arrangement produces a 27 point three dimensional grid for dose mapping in the product box to ascertain the position and value of D_{min} and D_{max}. Rest three dosimeters shall be placed at reference dose position.

f) The facility shall evaluate its dosimeters (routine dosimeter) as well as transfer standard dosimeters and send their results to RSSD, BARC along with irradiated transfer standard dosimeters of RSSD, BARC.

g) RSSD, BARC will measure the transfer standard dosimeters and compare these results with facility measured dose values and communicate the results and recommendations to the concerned authority. The agreement in the dose values of the facility (Applicant) and RSSD shall be within ± 10 % (1σ).[25]

h) The position of D_{min} and D_{max} quoted by the facility shall be match to RSSD results.

12. **Flow chart for plant commissioning/ recommissioning dosimetry**

Commissioning/ modification / recommissioning of accelerator systems

|

IQ

(For beam current, PRR, beam energy, product surface scan width and uniformity)

|

Placement of dosimeters on cardboard sheets/phantom material for dosimetry

|

OQ

(For establishment of relationship between conveyor speed and number of passes)

|

Preparation of dummy boxes (homogeneous material)
(For, depth dose mapping)

|

Preparation of dummy boxes (homogeneous material)
(For volumetric dose mapping, identification of minimum and maximum dose positions)

|

PQ

Preparation of dosimetry boxes with actual process load

(For dose mapping in actual product, statistical evaluation of D_{min}, D_{max}, D_{ref} , and dose uniformity ratio and ultimate dose uniformity ratio)

|

Setting of cycle time/ speed/no. of passes
(For product processing)

****

Annex-1 Installation Qualification- Beam Characterization

Beam Characterization (BC) -Determination and record the characteristics of beam (electron energy, average beam current, scan width and scan uniformity) and conveyor system, prepared in accordance with ISO ASTM 51649, ISO ASTM 51608 and ISO 14470 standards.

The characteristics of beam parameters will be measured as per the protocol/procedure described in following forms-

S. No.	**Name of form**	**Purpose**	**Annex detail**
1.	Form-1/BC/ Beam current measurement	To measure peak pulse current at different time interval	Annex- 1 (a)
2.	Form-2/BC / PRR measurement (*applicable for pulsed accelerator*)	To measure pulse repetition rate	Annex- 1 (b)
3.	Form-3/BC / Beam energy measurement	To measure electron beam energy	Annex- 1 (c)
4.	Form-4/BC / Scan uniformity measurement	To measure scan uniformity	Annex- 1 (d)
5.	Form-5/BC / Conveyor speed measurement	To measure speed of box in front of scanner	Annex- 1 (e)

Form-1/BC/Beam current measurement

An online beam current measuring system such as Faraday cup/ACCT/DCCT (current sensor device), or suitable beam current measuring system deployed by manufacturer shall be used to measure beam current (peak pulse current in case of pulsed accelerator and average DC current for DC accelerator). Fig.-7shows a typical trace of pulse peak current from RF Linac. The value for peak current/average current shall be recorded at different time interval in following table to find out the average peak beam current (for RF accelerator) or average current for DC accelerator.

Beam current measurement data

Date of measurement :

Beam energy :

Gun emission current :

Klystron HV (applicable for pulsed accelerator) :

Forward RF Power (applicable for pulsed accelerator) :

PRR (applicable for pulsed accelerator) :

Scanning current :

Time interval	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**T10**	**Average**
Faraday cup/ACCT/ DCCT data											

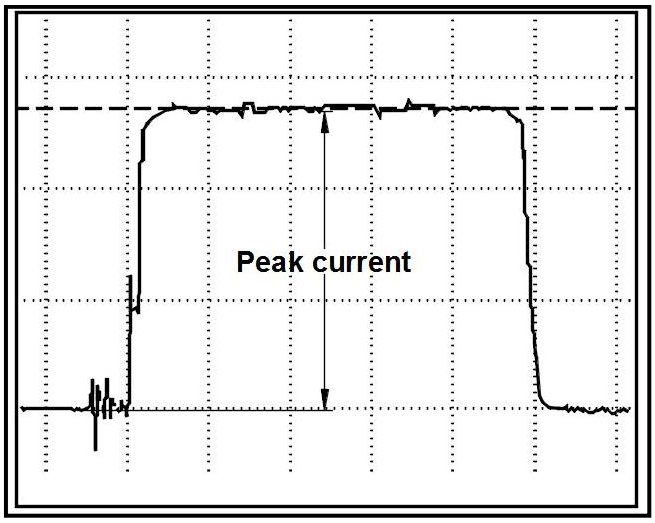


Fig. 7: Typical beam current profile of pulsed RF LINAC

Form-2/BC/ PRR measurement *(applicable for pulsed accelerator)*

In case of RF Linac, current sensor with fast data acquisition system such as DSO or other device shall be used to measure the beam pulse repetition rate. Record the data in following table at different time intervals

Pulse repetition rate measurement data

Date of measurement :

Beam energy :

Beam current :

Gun emission current :

Klystron HV :

Forward RF Power :

Scanning current :

Time interval	**T1**	**T2**	**T3**	**T4**	**T5**	**Average**
Master trigger set value (Hz)						
Measured values (Hz)						

Form-3/BC/ Beam energy measurement

Penetration of the electron beam in a homogeneous material is nearly proportional to their initial energy. This relationship between the energy and penetration is used to determine the energy of the electron beam. Beam energy measurement shall be performed in accordance with ISO/ASTM 51649:2015 (E), using Aluminum stack/wedge [Fig. 8 (a), (b)] and radiochromic films. The most probable energy (E_p, in MeV) of the incident electron beam shall be determined from the practical range (R_p, in cm) derived from the depth dose profile using following empirical relation. The experiment shall be repeated at least three times to obtain statistically stable value for energy.

$$E_p = 0.423 + 4.69R_p + 0.0532 \times R_p^2$$ **(ISO/ASTM 51649:2015 (E)-A4.14)**

The machine operating parameter shall be recorded and documented.

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Conveyor speed	:
Nos. of passes	:

Beam energy measurement data

S. No.	Parameter	Value
1	Measured practical range	
2	Most probable energy	

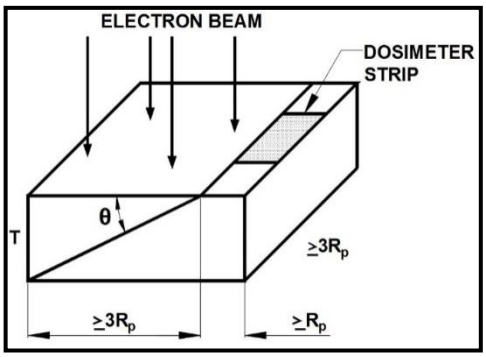


Fig. 8 (a)- Typical Aluminium wedge (wedge angle ~Θ 15°)for measurement of electron beam energy

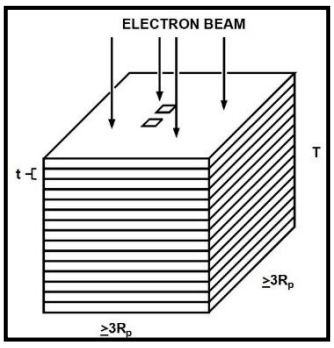


Fig. 8 (b)- Typical Aluminium stack for measurement of electron beam energy

Form-4/BC/ Scan uniformity measurement

Dose distribution along the scan direction is measured by placing strips of dosimeter film or arrays of single dosimeters in the scan direction. Using arrays of single dosimeters, more dosimeters shall be placed in zones of expected high dose gradients (such as at the extremes of scan), and less where dose distribution is expected to be uniform. The dosimeter array or long strips shall be mounted on a fixture with homogeneous backing material. The dosimeter fixture is irradiated by passing it through the electron beam using a known set of operating parameters. The center line of the dosimeter array shall correspond to the expected center line of the beam width. The overall width of the dosimeter array shall be large enough to compensate for any possible differences in centering. Dose values shall be plotted as a function of measurement location. Beam width and the variation of the measured dose along the scan direction (scan uniformity) are determined. Beam width is the distance between the points along the dose profile which are at a defined fractional level (90%) from the maximum dose region in the profile [Fig. 9 (a), (b)].

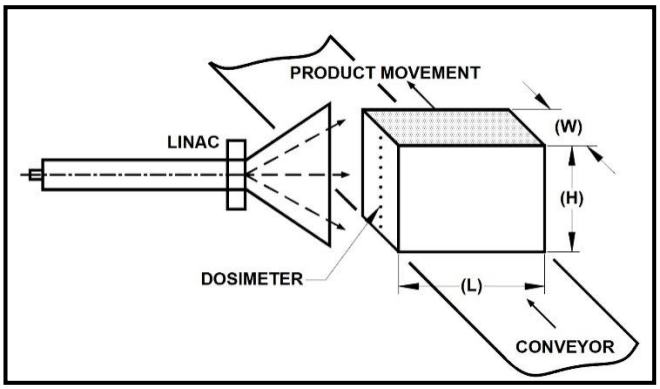


Fig. 9 (a): Placement of dosimeter for scan uniformity measurement

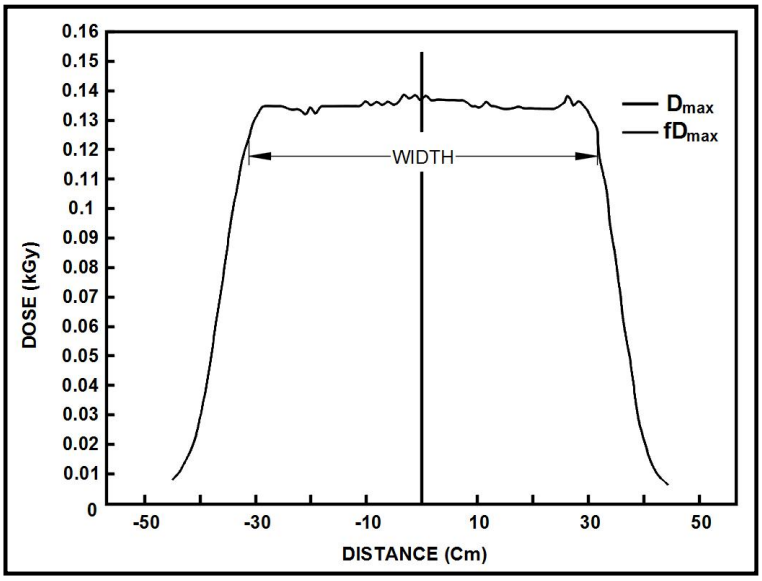


Fig. 9 (b): Typical profile of electron-beam dose distribution along the scan direction for scan width and uniformity measurement

Date of measurement :

Beam energy :

Beam current :

Gun emission current :

PRR (applicable for pulsed accelerator) :

Klystron HV (applicable for pulsed accelerator) :

Forward RF Power (applicable for pulsed accelerator) :

Scanning current :

Scan frequency/ cycle time :

Conveyor speed :

Nos. of passes :

Results of Measurement

S. No	Parameter	Value
1.	Scan current	
2.	Scan frequency/ cycle time	
3.	Scan width	
4.	Surface uniformity	

Form-5/BC/ Conveyor speed measurement

Load full batch of process load on the product trays (1 m long) placed over conveyor. Mark a reference pointer on fixed rail of conveyor in front of scanner. Run the conveyor at different set speeds (in operating range) and measure the travel time taken by each tray (1 m length) in crossing the reference pointer. Calculate the average speed and compare with set speed value.

Set speed (m/min)	**Travel time for 1 m length (s)**								**Ave. speed (m/min)**

Annex-2 Operational Qualification

S. No.	Name of form	Purpose	Annex detail
1.	Form-6/OQ/Conveyor speed vs dose measurement	To measure surface dose as function of conveyor speed	Annex- 2 (a)
2.	Form-7/OQ/No of pass vs dose measurement	To measure surface dose as function of number of passes at constant conveyor speed	Annex- 2 (b)
3.	Form-8/OQ/Depth dose profile measurement	To measure depth dose profile in homogeneous phantom of equivalent density	Annex- 2 (c)
4.	Form-9/OQ/Dose mapping	3-Dimensional volumetric dose distribution in homogeneous phantom	Annex- 2 (d)
5.	Form-10/OQ/ Process interrupt	To determine effect of process interruption	Annex- 2 (e)

Form-6/OQ/ Conveyor speed vs dose measurement

Prepare a dosimetry box by placing dosimeters (triplicate) at center of front face of the box filled with homogeneous phantom material [Fig.-10]. Load the full batch of product including the dosimetry box on conveyor. Operate the linac at harmonized operating parameters and run conveyor at preset speed to expose the dosimeters. Note down machine parameters. Repeat the experiment over the operating range of the conveyor and record the data in following table. Generate the plot (1/conveyor speed) vs Dose

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Nos. of passes	:
Box dimension and weight	:
Product density	:

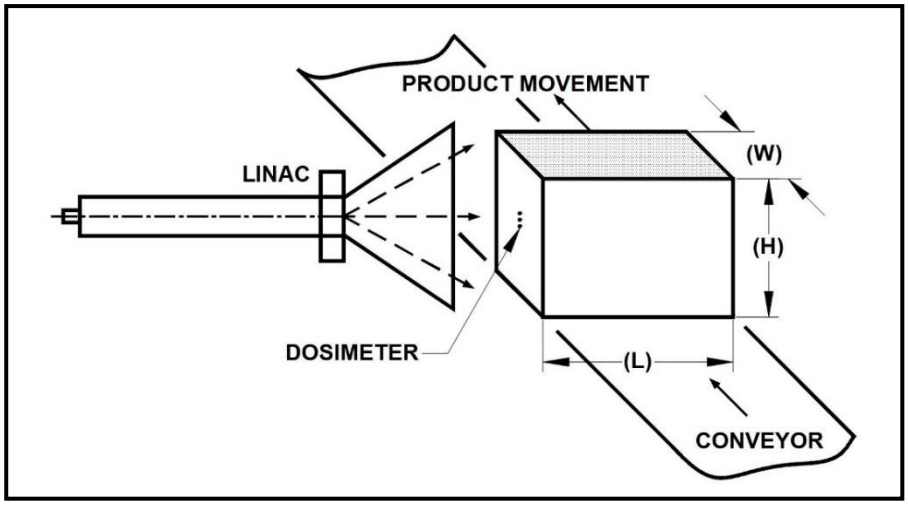


Fig. 10 :Typical drawing for placement of dosimeters

S. No.	**Set conveyor speed (m/min)**	**Nos. of passes** ***(typical)***	**Dose per pass (kGy)**
1.	1.0	1	
2.	1.5	2	
3.	2.0	2	
4.	3.0	4	
5.	4.0	4	

Form-7/OQ/ No. of pass vs dose measurement

Prepare a dosimetry box by placing dosimeters (triplicate) at centre of front face of the box filled with homogeneous phantom material [Fig. - 11]. Load the full batch of product including the dosimetry box on conveyor. Operate the linac at harmonized operating parameters and run conveyor at preset speed to expose the dosimeters. Note down machine parameters. Repeat the experiment for different Nos of passes at constant speed. Record the data in following table. Generate the plot between numbers of passes vs Dose

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Nos. of passes	:
Box dimension and weight	:
Product density	:

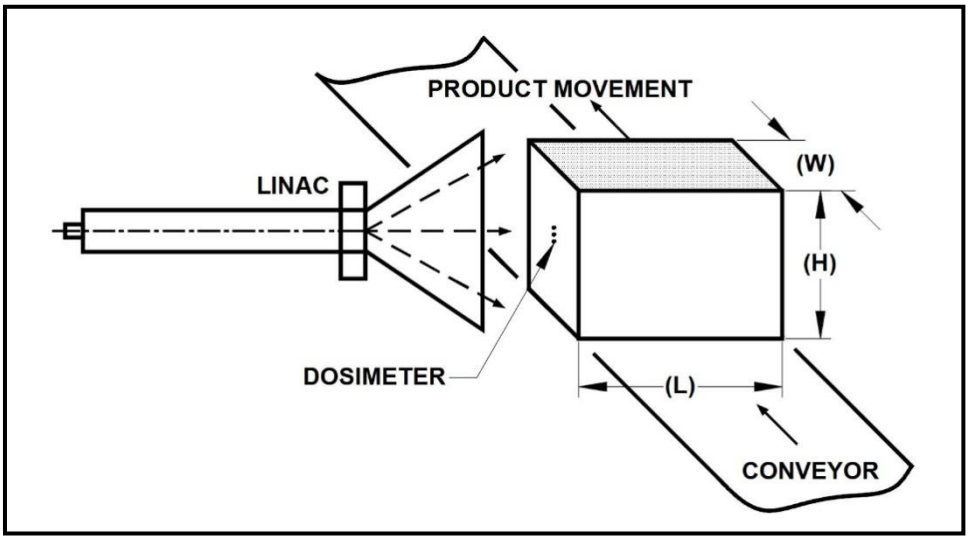


Fig. 11: Typical drawing for placement of dosimeters

Annex-2 (b)

S. No.	**Set conveyor speed (m/min)**	**No of passes** ***(typical)***	**Integrated dose (kGy)**
1.	2	1	
		2	
		4	
		6	
2.	3	1	
		2	
		4	
		6	

Form-8/OQ/ Depth dose profile measurement

Prepare a dosimetry box by placing dosimeters along the central axis of the box (at equal spacing along beam penetration direction). Fill the product box with homogeneous phantom material having density equivalent to the product to be radiation processed as shown in [Fig. -12]. Load the dosimetry box with two identical boxes placed side by side on the conveyor tray. Box central line shall pass through the central axis of beam. Operate the linac at harmonized operating parameters and run conveyor at preset speed to expose the dosimeters at adequate measurable dose. Note down machine parameters. Record the data and generate the dose profile as function of depth.

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Conveyor speed	:
Nos. of passes	:
Box dimension and weight	:
Product density	:

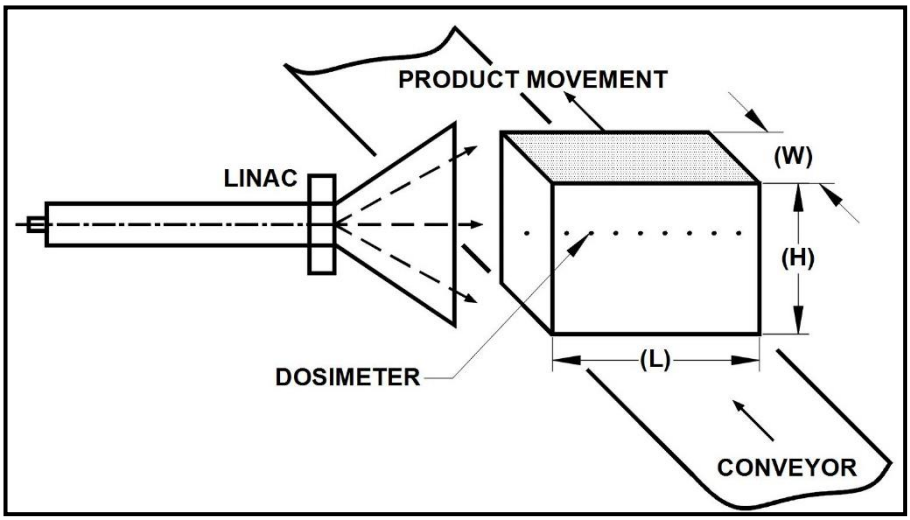


Fig. 12: Typical drawing for placement of dosimeters for depth dose measurment

S. No	Depth (cm)	Dose (kGy)
1.		
2.		
3.		

Form-9/OQ/Dose mapping

This set of measurement shall be carried out to determine absorbed dose distribution inside entire volume of the box filled with homogenous material to determine minimum and maximum dose position/region. Phantom material shall have density equivalent to product density. A full batch load shall be prepared by filling all the boxes with phantom material. Two boxes marked with Dosimetry Box-1 and Dosimetry Box-2 are chosen for dosimetry purpose. Each dosimetry box shall be divided into three to five planes depending on the depth of the product box. Example shown in Fig. 13, in which the product box is divided into five planes. Individually numbered dosimeters in pair shall be placed at nine locations (leaving a margin of 20-30 mm from corners) in each of five vertical planes as shown in Fig.13 (Total 90 dosimeters). The dosimetry boxes shall be placed on conveyor in such a way that the sufficient number of boxes precedes/ follows the dosimeter box. Note down machine parameters and run the conveyor at constant speed to deliver adequate measurable dose from both sides (front and back).

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Conveyor speed	:
Nos. of passes	:
Box dimension and weight	:
Product density	:

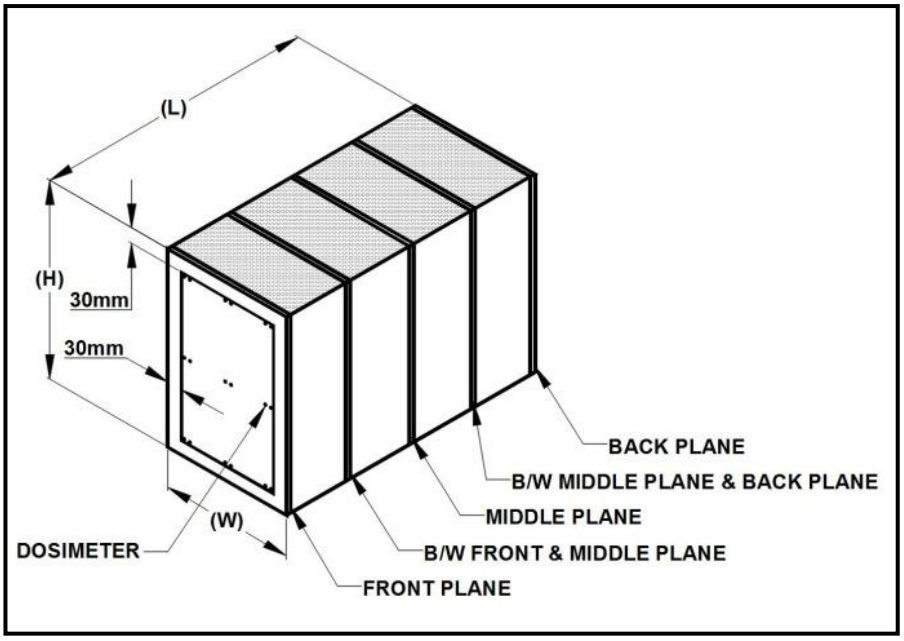


Fig.- 13: Placement of dosimeters in different vertical planes filled with phantom dummy material

After irradiation dosimeters are measures and data recorded in Table 2 and position of minimum and maximum dose are identified.

Table-2: Absorbed dose (kGy) in five vertical planes

Dosimeter position	Front plane	B/W front & middle plane	Middle plane	B/W middle & back plane	Back plane
1					
2					
3					
4					
5					
6					
7					
8					
9					
Average					
S.D. ±					
C. V. (%)					

Minimum dose position/region: -
Maximum dose position/region: -

Form-10/OQ/Process interrupt

The irradiation process may get interrupted for a number of reasons, either due to fault in the electron accelerator or in the conveyor system. Faults in the ancillary systems (for example, cooling, or ventilation system) can also lead to the interruption of the irradiation process.

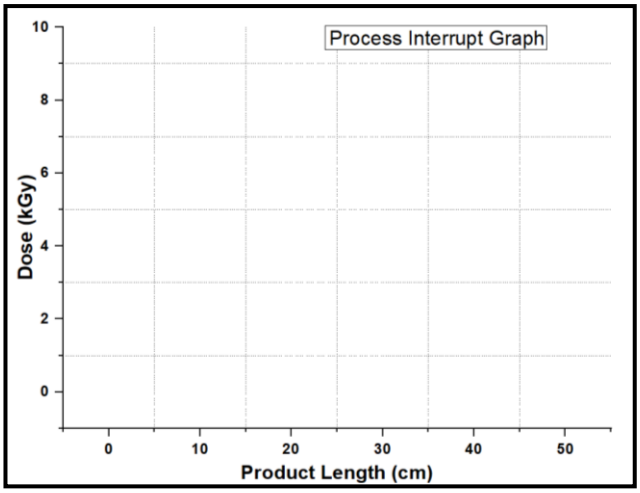
The effect of a process interruption on delivered dose shall be assessed, so that necessary actions is taken.

Procedure: In order to measure dose variations as a consequence of process interruption, an array of dosimeters or a strip of dosimeter film shall be placed on the surface of product box (at centre position) filled with reference (phantom) material along the direction of product movement. During irradiation, the process shall be interrupted (by interrupting the LINAC or by stopping the conveyor in two separate steps) intensely and subsequently, the operation at already set parameter shall be resumed to continue further irradiation.

The irradiated dosimeters shall be measured and plotted for dose as a function of product length (in the direction of product movement). Analysis of dosimetry results shall involve comparison of normal and interrupted dose variability at the location of interruption.

Process interruption testing shall be conducted for conditions that might be expected to have maximum effect on dose to product. This may imply testing at, for example, maximum conveyor speed, maximum process load mass or testing for multiple interruptions. If as a result of process interrupt and resumption the dose crosses the set range values, the product box shall be treated as nonconforming.

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Conveyor speed	:
Nos. of passes	:
Box dimension and weight	:
Product density	:
Duration of Interruption	:



S. No.	Conveyor speed (m/min.)	Number of process interruption introduced intensely	Dose variation in uninterrupted processing along the product length	Dose variation in interrupted processing along the product length
1.				
Average				
S.D. ±				
C.V. (%)				

Annex-3 Performance Qualification

S. No.	Name of form	Purpose	Annex detail
1.	Form-11/PQ/ Dose mapping in actual product	3-Dimensional volumetric dose distribution in product and identification of D_{min} and D_{max} point	Annex- 3 (a)
2.	Form-12/PQ/DUR and reference point dose	Determine DUR and establish relation of minimum dose / maximum dose to reference point dose	Annex- 3 (b)

Form-11/PQ/ Dose mapping in actual product

This set of measurement shall carried out to determine absorbed dose distribution inside the box filled with actual material to determine minimum and maximum dose position/region. Three boxes marked with Dosimetry Box-1, Dosimetry Box-2 and Dosimetry Box-3 filled with actual material shall be taken for dosimetry purpose. Each dosimetry box shall be divided into three to five planes depending on the depth of the product box. Example shown in Fig. 14, in which the product box is divided into five planes. Individually numbered dosimeters in pair are placed at nine locations in each of five verticals (Total 90 dosimeters). A full batch load shall be prepared by filling all other boxes with equivalent density phantom material. The dosimetry boxes shall be placed on conveyor in such a way that the sufficient number of boxes precedes follows the dosimeter box. Note down machine parameters and run the conveyor at constant speed to deliver adequate measurable dose from both sides (front and back).

Date of measurement	:
Beam energy	:
Beam current	:
Gun emission current	:
PRR (applicable for pulsed accelerator)	:
Klystron HV (applicable for pulsed accelerator)	:
Forward RF Power (applicable for pulsed accelerator)	:
Scanning current	:
Foil to surface distance	:
Conveyor speed	:
Nos. of passes	:
Box dimension and weight	:
Product density	:

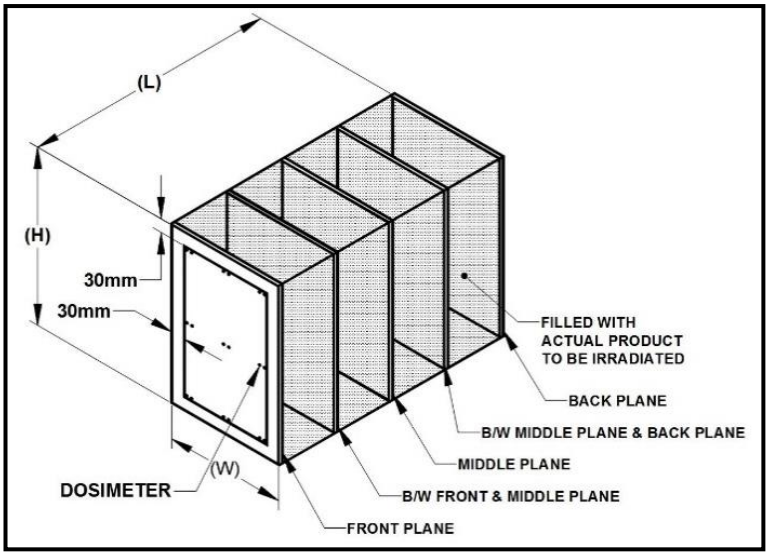


Fig.- 14: Typical arrangement of dosimeters in different planes filled with actual product

After irradiation dosimeters are evaluated and data shall be recorded in Table 3 and position of minimum and maximum dose are identified.

Table-3Absorbed dose (kGy) in five vertical planes

Dosimeter position	**Front plane**	**B/W front & middle plane**	**Middle plane**	**B/W middle & back plane**	**Back plane**
1					
2					
3					
4					
5					
6					
7					
8					
9					
Average					
S.D. ±					
C.V. (%)					

Minimum dose position/region: -
Maximum dose position/region: -

Form-12/PQ/DUR and dose at reference point

This set of measurement shall be carried out for statistical evaluation of minimum and maximum dose, dose uniformity ratio/over dose ratio, ultimate uniformity ratio, conveyor speed and number of passes for target dose and relationship between dose at reference, minimum and maximum dose positions/regions. Eight boxes marked with Dosimetry Box-1 to Dosimetry Box-8 filled with actual material shall be taken for dosimetry purpose. Individually numbered dosimeters (in triplicate) shall be placed at minimum, maximum and reference dose positions of dosimetry boxes. A full batch load shall be prepared by filling all other boxes with equivalent density phantom material. The dosimetry boxes shall be placed on conveyor in such a way that the sufficient number of boxes precedes follows the dosimeter box. Note down machine parameters and run the conveyor at constant speed to deliver adequate measurable dose from both sides (front and back).

Date of measurement :

Beam energy :

Beam current :

Gun emission current :

PRR (applicable for pulsed accelerator) :

Klystron HV (applicable for pulsed accelerator) :

Forward RF Power (applicable for pulsed accelerator) :

Scanning current :

Foil to surface distance :

Conveyor speed :

Nos. of passes :

Box dimension and weight :

Product density :

Cycle time (in minutes) :

Interruption duration, if any :

Irradiation temperature :

Dose measuring temperature :

Result of PQ experiments:

Dosimeter box no.	**Dose at D_{min} position**	**Dose at D_{max} position**	**Dose at reference position, D_{ref}**
PQ-1			
PQ -2			
PQ -3			
PQ -4			
PQ -5			
PQ -6			

PQ -7			
PQ -8			
Average dose			
S.D. ±	$(S.D.)_1$	$(S.D.)_2$	
C. V. (%)			

(Each reading is an average of thee dosimeters readings)

a) **Dose uniformity ratio (DUR):**

Dose uniformity ratio (DUR) = $\frac{\text{Average maximum dose } (D_{max.})}{\text{Average minimum dose } (D_{min.})}$

b) **Calculation for dose delivered using dose measurement at reference location:**

i. Calculation of Reference Ratio:

Minimum to reference ratio $(R_{min.}) = \frac{D_{min.}}{D_{ref.}}$

Maximum to reference ratio $(R_{max.}) = \frac{D_{max.}}{D_{ref.}}$

ii. Calculation for delivered dose during routine radiation processing using dose measured at reference location ($D_{ref.}$):

Minimum delivered dose $(D_{min.}) = R_{min.} \times D_{ref.}$

Maximum delivered dose $(D_{max.}) = R_{max.} \times D_{ref.}$

c) **Target dose calculation:** This can be calculated for a confidence level of ≥ 95% using tolerance factor k given in Annex- 6.

Target minimum dose in kGy = $D_{min} + k \times (S.D.)_1$

Target maximum dose in kGy = $D_{max} - k \times (S.D.)_2$

D_{min} and D_{max} values are as per the existing regulatory requirements.

Where $(S.D.)_1$and $(S.D.)_2$ are the standard deviation values for average minimum and average maximum dose respectively obtained from PQ.

d) Ultimate uniformity ratio (UUR): This can be calculated for a confidence level of ≥ 95% using tolerance factor k given in Annex- 6.

Limiting minimum dose in kGy

D_{min}^{lim} = Average minimum dose (D_{min}) - $k \times (S.D.)_1$

Limiting maximum dose in kGy

D_{max}^{lim} = Average maximum dose (D_{max}) + k × $(S.D.)_2$

Ultimate uniformity ratio= $\frac{\text{Limiting maximum dose } (D_{max}^{lim})}{\text{Limiting minimum dose } (D_{min}^{lim})}$

Where $(S.D.)_1$and $(S.D.)_2$ are the standard deviation values for average minimum and average maximum dose respectively obtained from PQ.

Annex-4: Report on Plant Commissioning/Re-Commissioning Dosimetry

for

Name and complete address of the facility

(Date, Month & Year)

Name and address of the organization performing plant commissioning/re-commissioning dosimetry

Annex-4

Date: dd/mm/yyyy

DOSIMETRY REPORT

1.	**Facility Details**		
1.1.	Name of the facility	:	
1.2.	ID No. allotted by AERB	:	
1.3.	Type of facility- (Horizontal mount/ Vertical mount LINAC)	:	
1.4.	Mode of Operation (Electron/X-ray)	:	
1.5.	Electron beam parameters	:	*Write NA where not applicable*
	i. Electron beam energy (MeV)	:	
	ii. Peak beam current (mA)	:	
	iii. Average beam power (kW)	:	
	iv. Pulse repetition rate (Hz)	:	
	v. Pulse width (μsec)	:	
	vi. Scan width (cm)	:	
	vii. Scanning frequency/Scan time	:	
1.6.	Conveyor system (Roller/Slit/ Other)	:	
1.7.	Product processing (Batch/Continuous)	:	
1.8.	Number of carriers/carrier plates	:	
1.9.	Number of boxes on each carrier/ carrier plate	:	
1.10.	Window foil to box surface distance (cm)	:	
1.11.	In case of X-ray mode, X-ray target to product distance (cm)	:	
2.	**Phantom box/ Product box details**		
2.1.	Phantom/ Product Box size- (l x h x w) in cm (O.D.)	:	
2.2.	Material of construction of phantom/product box	:	
2.3.	Type of product/ phantom material (Homogeneous/ non-homogeneous)	:	

2.4.	Product distribution inside the box		
2.5.	Phantom/dummy material (if blended give ratio) & thickness (mm)	:	
2.6.	Weight of filled phantom/product box (kg)	:	
2.7.	Volume of the phantom/product box (cc)	:	
2.8.	Bulk density (g/cc)	:	

3. Purpose

3.1.	Name of the product to be processed	:	
3.2.	Purpose of Irradiation	:	

4. Dosimetry system employed

4.1.	Dosimeters used	:	
4.2.	Dosimeter size	:	
4.3.	Dose range	:	
4.4.	Batch number and date of expiry	:	
4.5.	Buildup detail, if used- a) Material b) Thickness (mm)	:	
4.6.	Dose readout system used	:	
4.7.	Traceability	:	Give details of inter-comparison carried out with RSSD, BARC

5. Results

5.1.	**Installation Qualification results**	**:**	
5.1.1	Beam Characterization (BC) results		Provide detailed measurement data as per Annex- 1 (a) (b) (c) (d) (e)
a)	Measured beam energy (most probable energy)- MeV	:	…. ± ….
b)	Measured beam peak current/ average DC current - mA	:	…. ± ….

c) Measured PRR- Hz : …. ± ….

d) Measured scan width- cm : …. ± ….

e) Measured scan uniformity- cm : …. ± ….

f) Measured conveyor speed range- m/min. :

5.2. **Operational Qualification results** : Provide detailed measurement data as per Annex- 2 (a) (b) (c) (d) (e)

a) Conveyor speed vs dose :

b) No. of pass vs dose measurement :

c) Depth dose profile :

d) Dose mapping:

i) Minimum Dose position/region :

ii) Maximum Dose position/ region :

e) Process interrupt dose variation : …. ± ….

5.3. **Performance Qualification results** : Provide detailed measurement data as per Annex- 3 (a) (b)

a) Dose uniformity ratio :

b) Average minimum dose to average reference dose ratio :

c) Average maximum dose to average reference dose ratio :

6. Remarks :

6.1. To deliver minimum dose of …….. kGy in electron mode/ X-ray mode to the …… (product name) {bulk density …… g/cc}, Following parameters shall be set.

a) Electron beam energy-

b) Electron beam current- (Peak current- for RF accelerator and average DC current- for DC accelerator

c) Pulse repetition rate (applicable for pulsed accelerator)-

d) Pulse width (applicable for pulsed accelerator) -

e) Scanning magnet current

f) Scanning magnet frequency/Scan cycle time-

g) Conveyor speed-

h) Orientation of product inside the box-

Name & Signature

Name of the persons participated in dosimetry
Facility representatives
i)
ii)

To: Facility in Charge,
…….
……..

Annex-5: Dosimetry systems for plant commissioning/ re-commissioning dosimetry

Dosimeter	**Mode**	**Readout system**	**Usable absorbed dose Range in Gy**	**ASTM No**
Radiochromic Film	Electron/ X-ray	Spectrophotometer	1- 1.5 $\times 10^5$	51275
Polymethyl methacrylate	X-ray	Spectrophotometer	10^2- 1.5 $\times 10^5$	51276
Radiochromic Optical wave guide	X-ray	Spectrophotometer	1-10^5	51310
Dichromate	X-ray	Spectrophotometer	2 $\times 10^3$- 5 $\times 10^4$	51401
Ethanol chlorobenzene solution	X-ray	Spectrophotometer, colour titration, high frequency conductivity	10 - 2 x10^5	51538
Alanine	Electron/ X-ray	Electron Paramagnetic Resonance spectrometer	1 - 10^5	51607
Calorimetric	Electron	Calorimeter	10^2- 5 $\times 10^4$	51631
Cellulose tri acetate	Electron/ X-ray	Spectrophotometer	5$\times 10^3$ - 3 $\times 10^5$	51650
Fricke solution	X-ray	UV spectrophotometer	20- 4 $\times 10^2$	51026
Ceric-Cerous Sulfate	X-ray	Potentiometry	5 $\times 10^2$- 5 $\times 10^4$	51205

Note: Relevant ASTM practice shall be followed for use of dosimetry system

Annex-6: Factor K for one sided Normal tolerance Limits

	100 γ=90%			100 γ=95%			100 γ=99%		
	100(1-α)			100(1-α)			100(1-α)		
n	90%	95%	99%	90%	95%	99%	90%	95%	99%
2	NA	NA	NA	20.58	26.26	37.09	103	131.4	185.6
3	4.258	5.31	7.34	6.156	7.656	10.55	14	17.17	23.9
4	3.187	3.957	5.437	4.162	5.144	7.042	7.38	9.083	12.39
5	2.742	3.4	4.666	3.407	4.203	5.741	5.362	6.578	8.939
6	2.494	3.091	4.242	3.006	3.708	5.062	4.411	5.406	7.335
7	2.333	2.894	3.972	2.756	3.4	4.642	3.856	4.728	6.412
8	2.219	2.755	3.783	2.582	3.187	4.354	3.497	4.285	5.812
9	2.133	2.649	3.641	2.454	3.031	4.143	3.241	3.972	5.389
10	2.065	2.568	3.532	2.355	2.911	3.981	3.048	3.738	5.074
11	2.012	2.503	3.444	2.275	2.815	3.852	2.898	3.556	4.829
12	1.966	2.448	3.371	2.21	2.736	3.747	2.773	3.41	4.633
13	1.928	2.403	3.31	2.155	2.671	3.659	2.677	3.29	4.472
14	1.895	2.363	3.257	2.109	2.615	3.585	2.593	3.189	4.337
15	1.866	2.329	3.212	2.068	2.566	3.52	2.522	3.102	4.222
16	1.842	2.299	3.172	2.033	2.524	3.464	2.46	3.028	4.123
17	1.82	2.272	3.136	2.002	2.486	3.414	2.405	2.963	4.037
18	1.8	2.249	3.106	1.974	2.453	3.37	2.357	2.905	3.96
19	1.781	2.228	3.078	1.949	2.423	3.331	2.314	2.854	3.892
20	1.765	2.208	3.052	1.926	2.396	3.295	2.276	2.808	3.832
21	1.75	2.19	3.028	1.905	2.371	3.262	2.241	2.768	3.776
22	1.736	2.174	3.007	1.887	2.35	3.233	2.208	2.729	3.727
23	1.724	2.159	2.987	1.869	2.329	3.206	2.179	2.693	3.68
24	1.712	2.145	2.969	1.853	2.309	3.181	2.154	2.663	3.638
25	1.702	2.132	2.952	1.838	2.292	3.158	2.129	2.633	3.601
30	1.657	2.08	2.884	1.777	2.22	3.064	2.03	2.516	3.447
35	1.623	2.041	2.833	1.732	2.167	2.995	1.957	2.43	3.334

n = number of readings
100γ is the confidence level in %,
100(1-α) is the percentage of population below (or above) tolerance limits

Annex-7: List of Reference (phantom/ dummy) Material for Dosimetry Purpose

Sr. No.	Bulk Density (g/cc)	Simulated Product
1	0.15 - 0.2	Cardboard sheets, rice husk, saw dust, wooden chips, ground nut shell,
2	0.3-0.5	Raisins, rice bran powder, coir,
3	0.5 -0.6	Ragi flour, flour of various cereals, betel nut powder, poha powder
4	0.7-0.8	Bajra seeds and its flour

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