

Qualification For Gamma and EB Machine

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Pelatihan Penyegaran Petugas Iradiator

Direktorat Pengembangan Kompetensi BRIN - 2025



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- Sarjana – Fisika Nuklir, Politeknik Teknologi Nuklir Indonesia (STTN-BATAN) 2012-2016
- Magister – Fisika, Universitas Indonesia 2023-2024
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- Honda Motor Ltd. 2016-2017
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- Fellowship on Gamma Radiation Facility at Vinca, Belgrade, Serbia 2019
- Online Training Course by IAEA Expert (Andras Kovacs, Hungary) on Radiation Dosimetry 2020
- Fellowship on Radiation Dosimetry at Aerial CRT, Strasbourg, France 2021
- Scientific Visit on Radiation Processing Technology at KAERI, Jeungup, Korea 2022
- Workshop Accelerating the Adoption of eBeam/X-ray technologies in Asia and the Pacific Daejeon, Korea 2022
- Regional Project on eBeam Application in Asia-Pacific. Daejeon, Korea 2023
- IAEA Research Project on Dosimetry at Aerial CRT Strasbourg, France 2023
- Australian Awards Short Course on Radiation Technology, Melbourne 2025
- Fellowship on Dosimetry for Food Irradiation, National Research Centre Canada, 2025
- Speaker on International Conference on Applications of Radiation Science and Technology at IAEA Vienna, Austria 2022
- Speaker on International Meeting on Radiation Processing IMRP at TINT Bangkok, Thailand 2022
- Speaker on International Meeting on Radiation Processing IMRP at San Jose, Costa Rica 2024
- Speaker on Regional Workshop on eBeam Application at Ho Chi Min, Vietnam 2024
- Speaker on International Conference on Applications of Radiation Science and Technology at IAEA Vienna, Austria 2025
- Speaker on International Food Ionizing Processing Symposium, Chengdu, China 2025
- Speaker on Regional Workshop on eBeam Application at Ho Chi Min, Vietnam 2024
- Technical Expert IAEA for “Preparing Guideline Technical Document Electron Beam Facilities” , Vienna, 2025



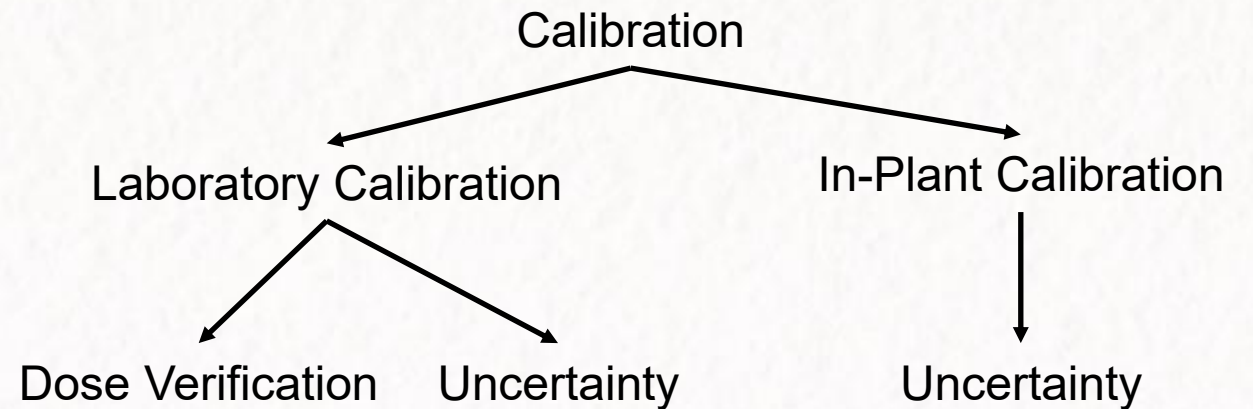
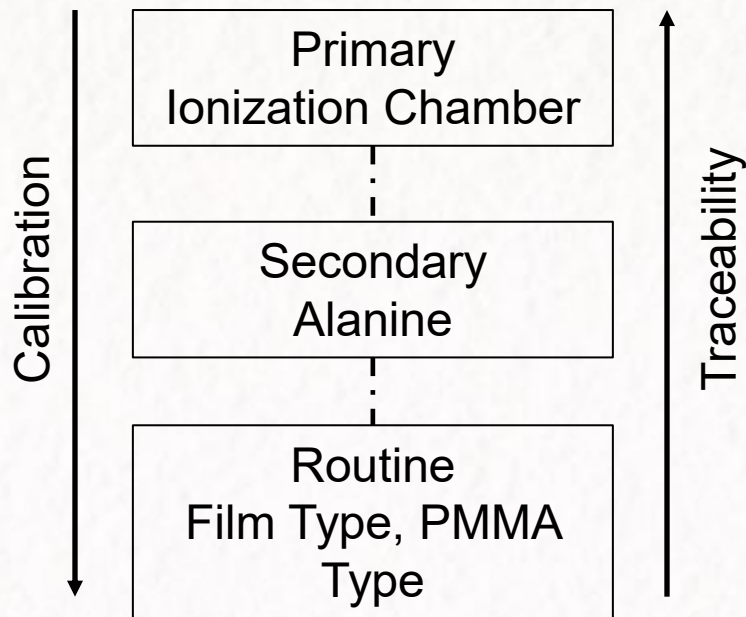
PT. EDS MANUFACTURING INDONESIA
AUTOMOTIVE WIRE DIVISION



Calibration

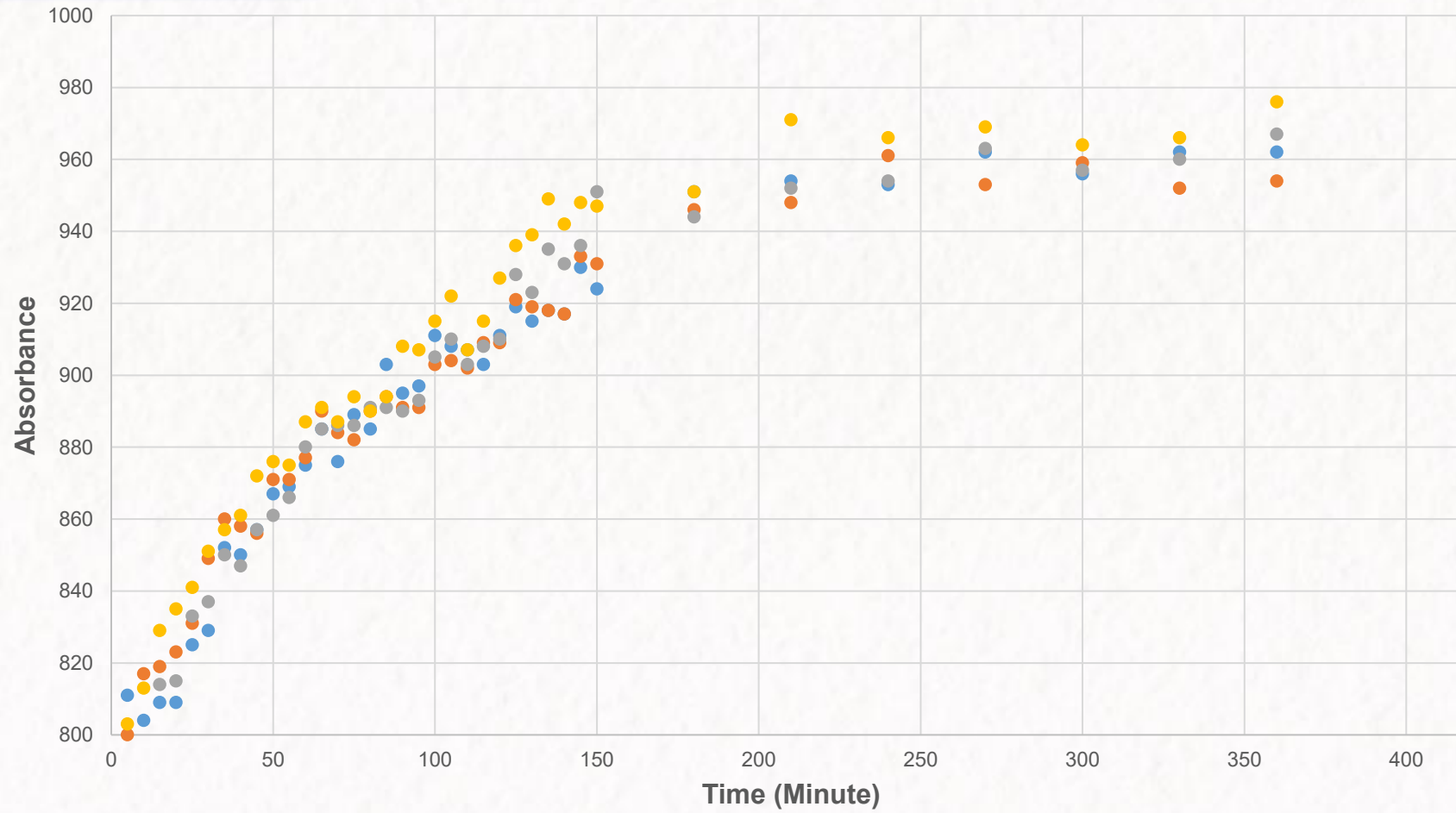
ISO/ASTM 51261:2013

Calibration (3.1.2) Establishes, under specified conditions, the relationship between the value of a quantity by a measurement system or the value through a reference material



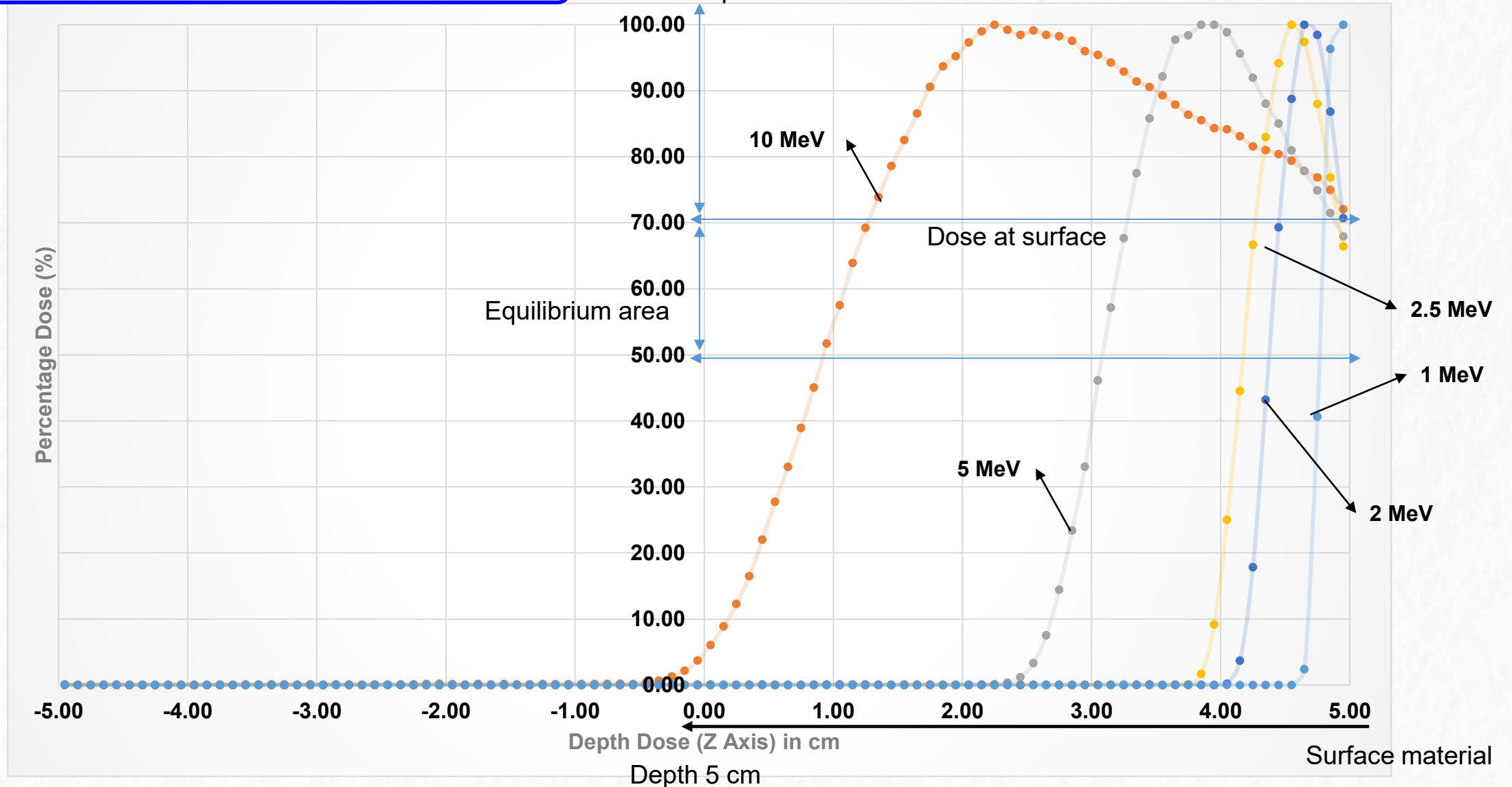
Calibration

Wafer Fading 0.5 kGy



Electron Depth Dose in Water Density

Build up dose can increase up to 30%



10 MeV is about 5 cm in water density

1

Installation Qualification

Definitions

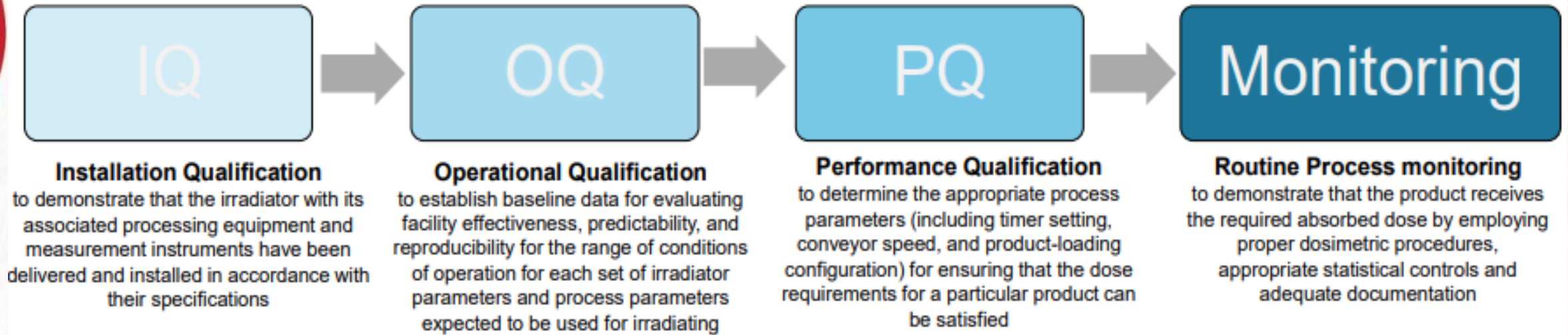
9.1 Installation qualification

3.16 - installation qualification - IQ

process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

Keywords: Whether or not data are “in accordance with their specification” depends on agreement between supplier and user.

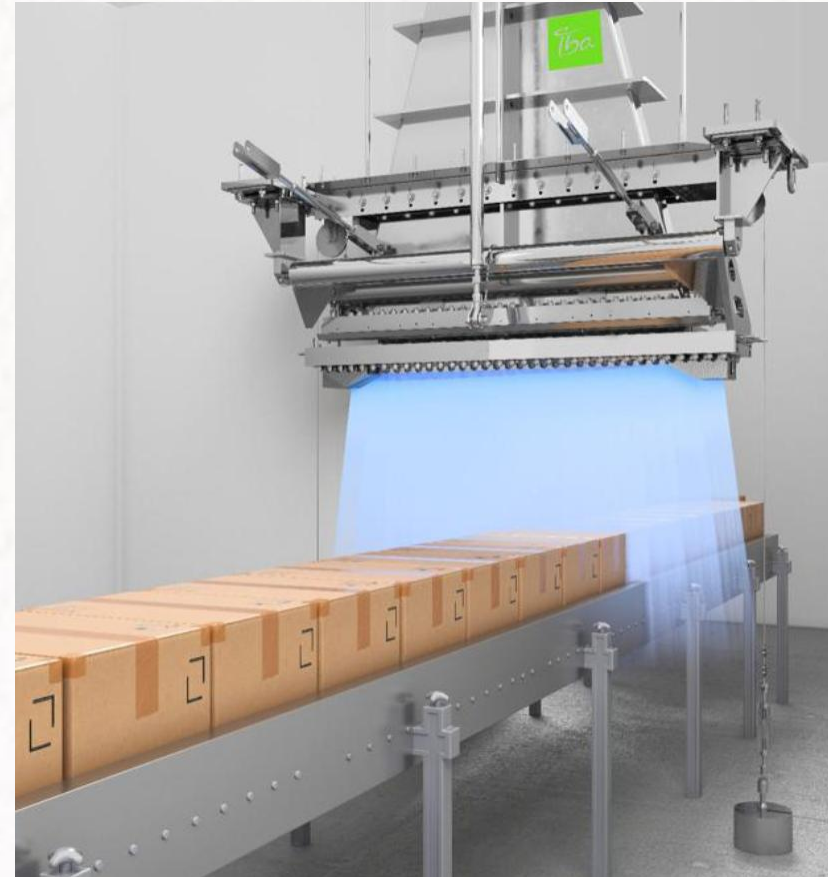
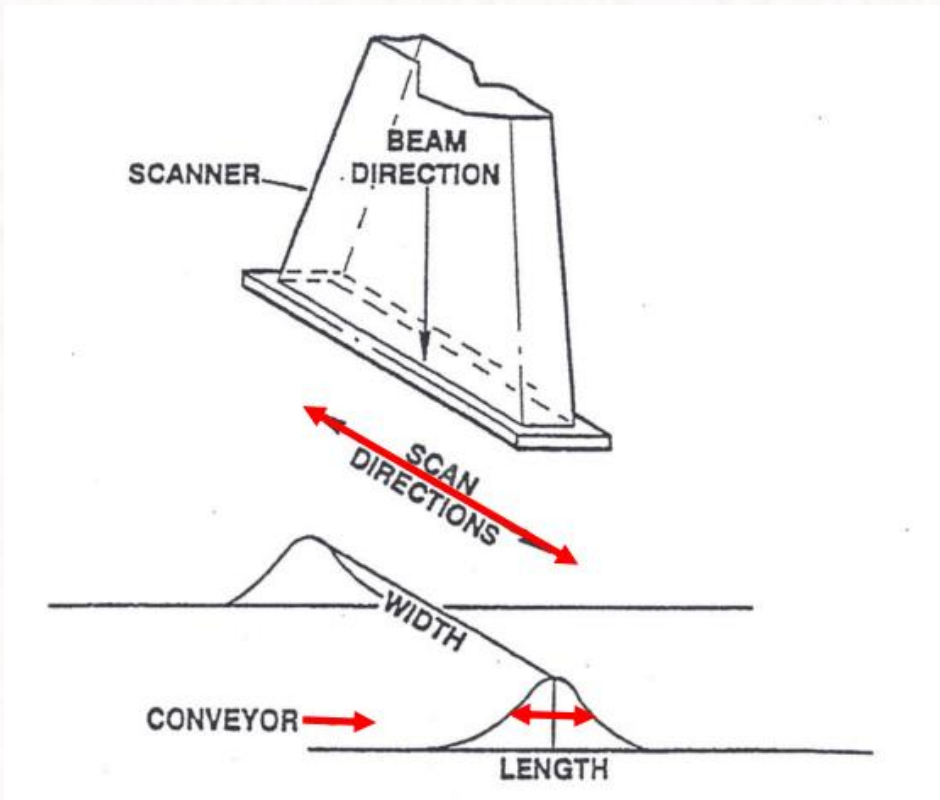
Definitions



EB/ Xrays Parameters

- **Beam Energy (MeV or KeV) Million/ or Kilo Electron Volt**
Energy (speed) of electrons – Controls the penetration of product density
- **Beam Current (mA or μ A) milli/ or micro amperes**
Quantity of electrons produced/ populations of electrons/ electron fluxe – Controls the absorb dose of the product
- **Conveyor Speed/ or Time of Irradiations (m/min) meter per minutes**
The relation between speed and beam creates the dose rate and consequence the time being exposed to ionising radiations
- **Beam Power (kW) kilo Watt**
Radiation Power – $P = V \cdot I$ (Example. kW = V (10 MeV) * I (5 mA) = 50 kW – Gives the throughput of irradiation
- **Scanned Lenght (m or cm) meters or centimeters**
Dimensions of irradiation zone to the product movement at a specified distance from the accelelator window

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Credit: IBA Industrial

2

Operational Qualification

Definitions

9.2 Operational qualification

3.22 Operational qualification - OQ

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

9.2.2 OQ shall be carried out by irradiating appropriate test material to demonstrate the capability of the equipment to deliver the sterilization process that has been defined.

Keywords: Provides baseline data to show consistent operation of the facility

Operational Qualification

12.4.1 Requalification of a sterilization process shall be carried out for defined product and specified equipment; it shall be performed at defined intervals and after the assessment of any change (see 12.5). The extent to which requalification is carried out shall be justified.

12.5.1 Any change in the irradiator which could affect dose or dose distribution shall be assessed. If one or both of these is judged to be affected, then a repeat of part or all of IQ, OQ and/or PQ shall be carried out.

Operational Qualification

9.2 Operational qualification

3.22 Operational qualification - OQ

Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

9.2.2 OQ shall be carried out by irradiating appropriate test material to demonstrate the capability of the equipment to deliver the sterilization process that has been defined. provides baseline data to show consistent operation of the facility

9.2.4 Dose maps must be made with fully loaded irradiation chamber

9.2.5 OQ dose mapping shall be carried out on a sufficient number of irradiation containers to allow determination of the distribution and variability of dose between containers.

TABLE A11.1 Needs for requalification following changes of an electron beam facility

<i>Irradiator Change</i>	<i>Installation Qualification</i>	<i>Operational Qualification</i>			
	Installation Testing & Equipment Documentation	Operational Testing	Equipment Calibration	Irradiator 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.	✓	✓			Scan uniformity in the direction of product travel Process interruption testing
NOTE	OQ dose mapping results may lead to repeat of PQ				

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- ❖ Determination of operating parameters

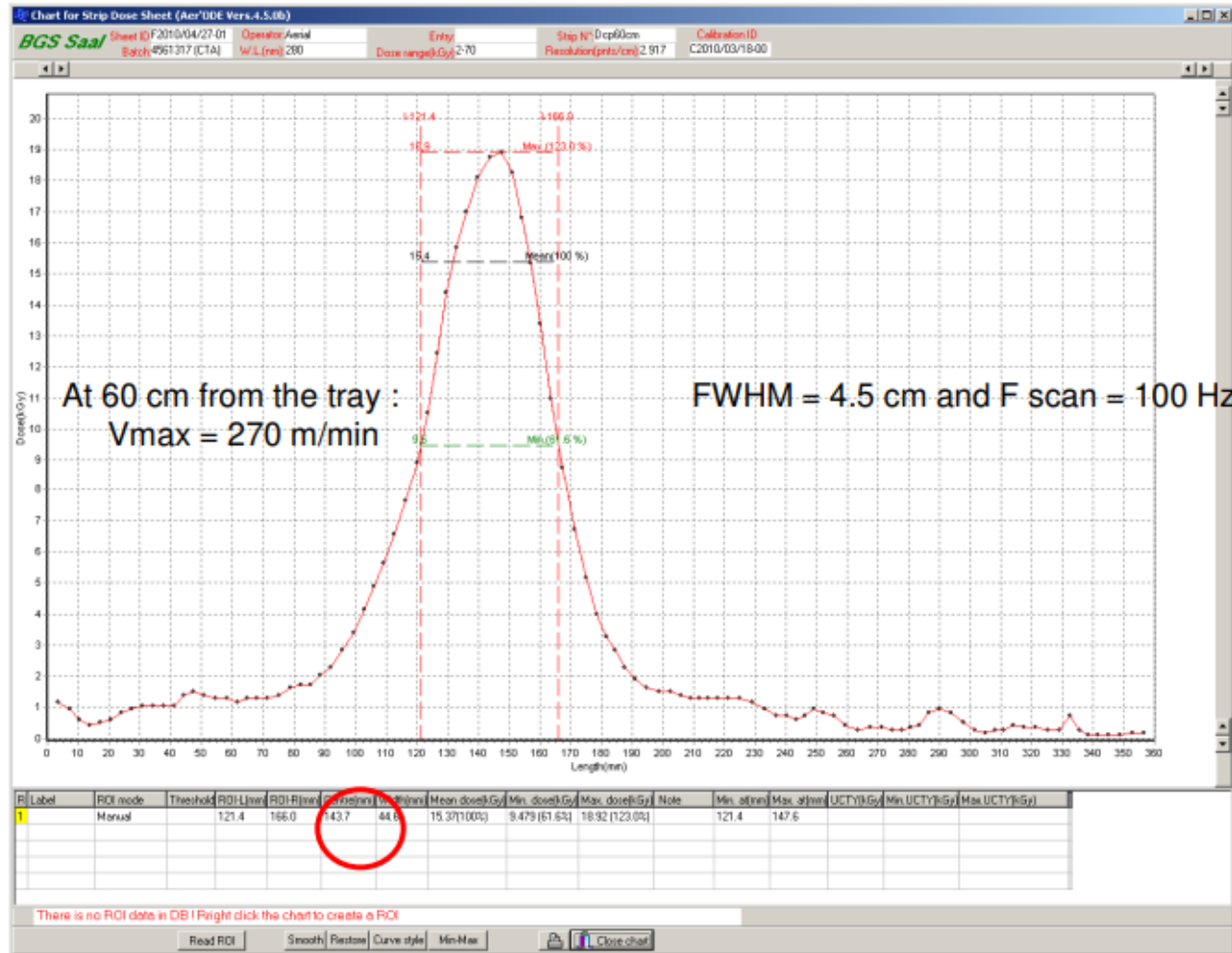
Based on the mathematical equation from NIST, the dose at the material surface can be estimated.

$$\text{Dose at Surface} = \frac{\text{Beam current } (\mu\text{A}) \times \text{Stopping Power Collision } (\text{MeV} \frac{\text{cm}^2}{\text{g}})}{\text{Scan Width (cm)} \times \text{Conveyor Velocity } (\frac{\text{cm}}{\text{s}})}$$

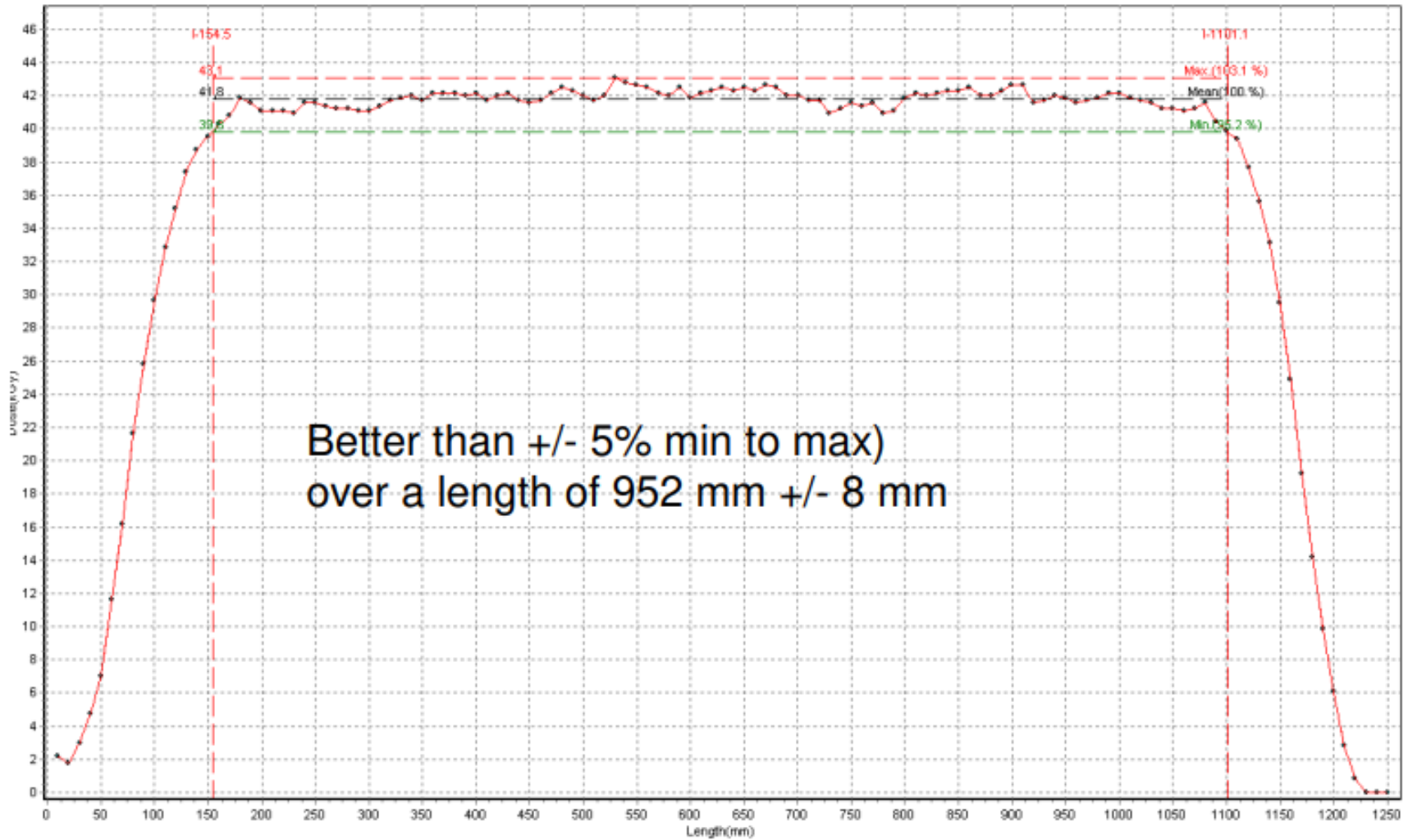
- Energy = 10 MeV
- Stopping power collision pada 10 MeV water density = 1.968 MeV cm²/g
- <https://physics.nist.gov/PhysRefData/Star/Text/ESTAR.html>



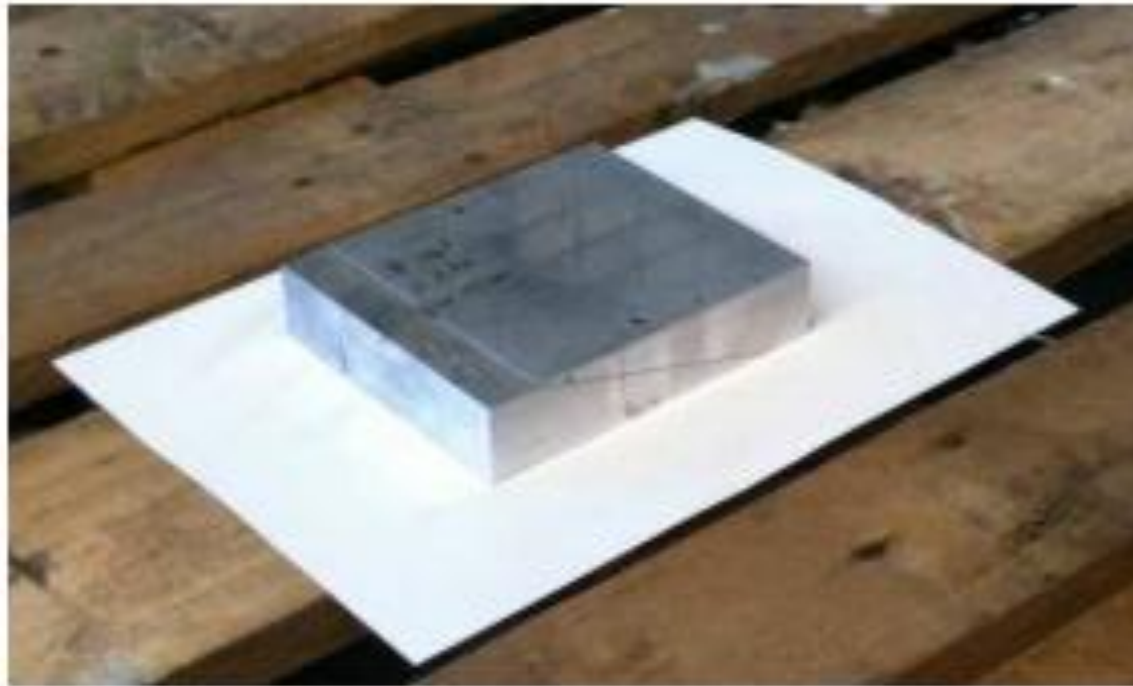
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eBeam



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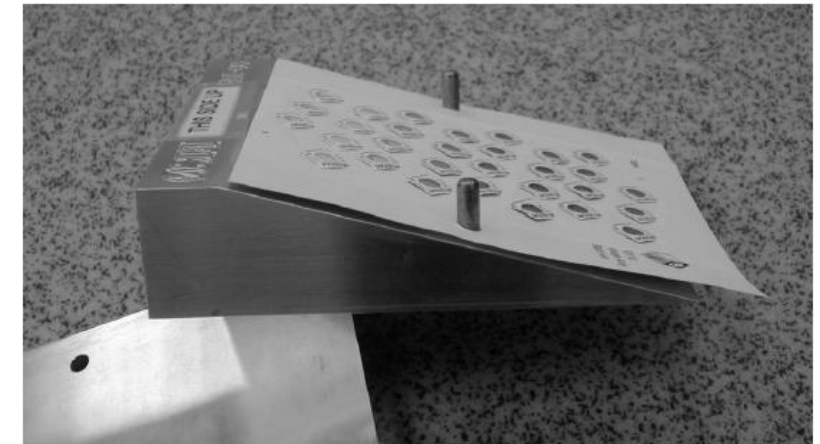
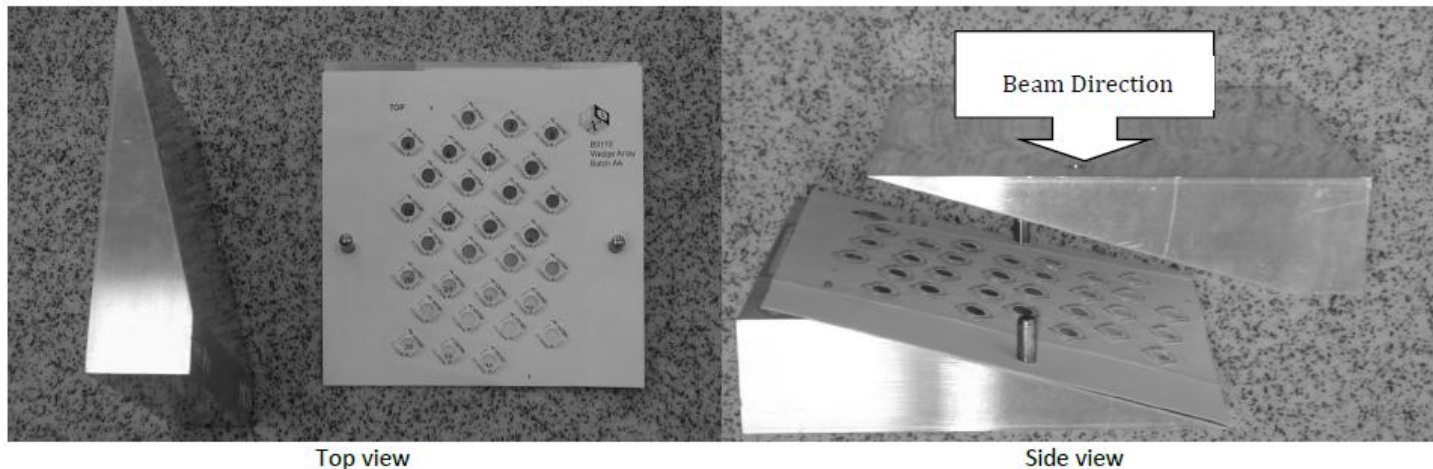


Density : 2.73 g/cm^3
Angle : 16°

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SPECIFICATIONS

Nominal Product Dimensions	Packaging Dimensions	Product Weight
12cm (L) x 14cm (W) x 2.9cm (H) \pm 0.1mm	8.5" x 5" x 1.25" / 22.9cm x 15.2cm x 5.1cm	4.0 lbs. / 1.81 kg
Material:	Aluminum	
Color:	Silver (natural)	
Printing:	Engraved serial number denoting A (top) and B (bottom) halves of the wedge.	
Angle:	16.0° \pm 0.3°	
Energy Range:	Using strip film: approximately 2 MeV to 20 MeV Using arrays of B3 WINDose dosimeters: 4 MeV to 12 MeV	
Precision (MeV):	Precision of the measured energy will depend on the precision of the electron beam system, but experience confirms that the user should expect \pm 0.3 MeV or better.	

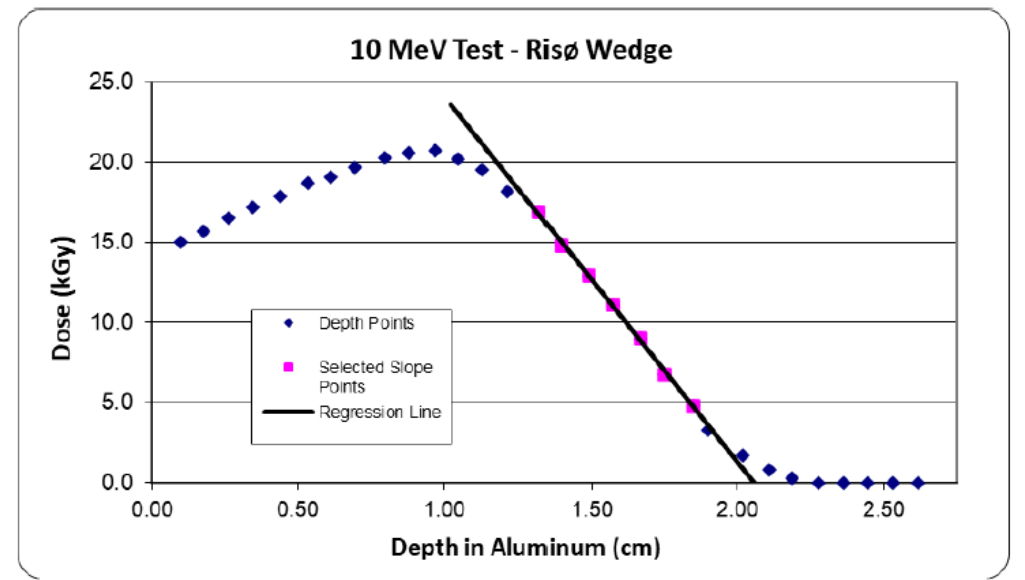
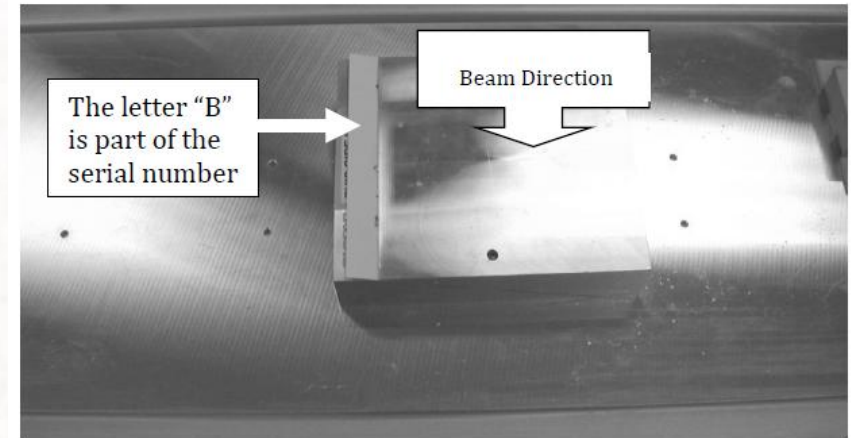
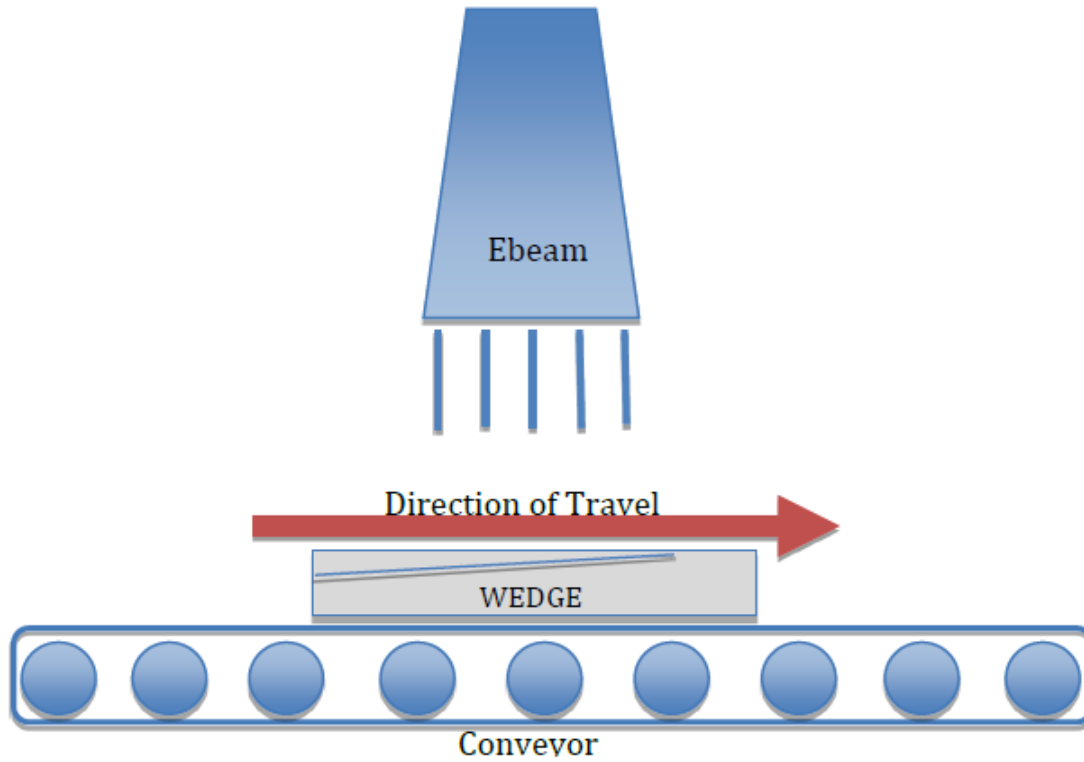


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RECORD SHEET OF DOSIMETERS				
Sample: Energy		Irradiation		
irradiation dose: 15 kGy		Date:05/12/2024		
		Speed of conveyor (m/min): 0.75		
		Scanning width: 50 cm		
Group: 1	F _{syn} : 151 Hz			
Single - slided irradiation				
Dosimetry				
Date:05/12/2024				
Dosimete				
Dosimeter	r	Dosimeter	Irradiated	Dose
Position	Number	ID Number	Absorbance (A _i)	(kGy)
1		3266583A	0.282	16.3
2		3266640A	0.220	17.0
3		3266580B	0.302	17.7
4		3266641A	0.310	18.3
5		3266641B	0.326	19.5
6		3266640B	0.337	20.2
7		3266581A	0.350	21.2
8		3266642B	0.354	21.5
9		3266660B	0.355	21.5
10		3266642A	0.354	21.5

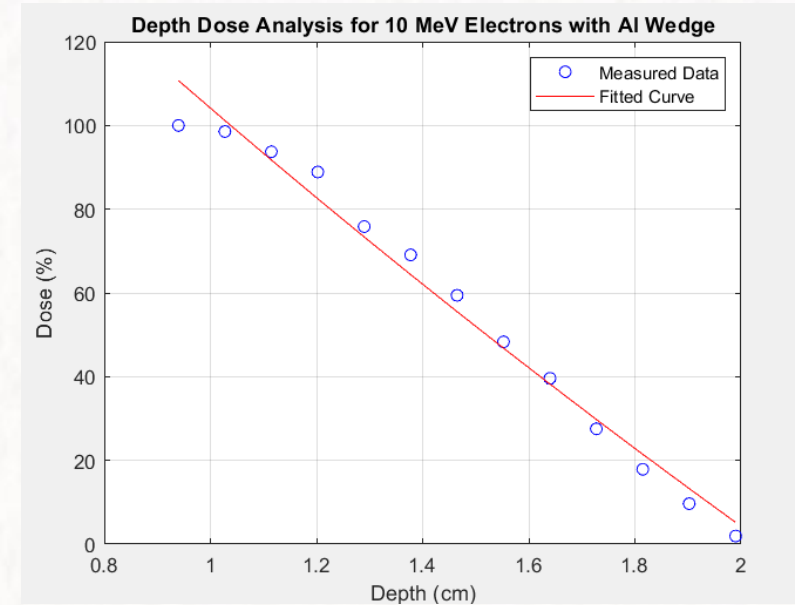
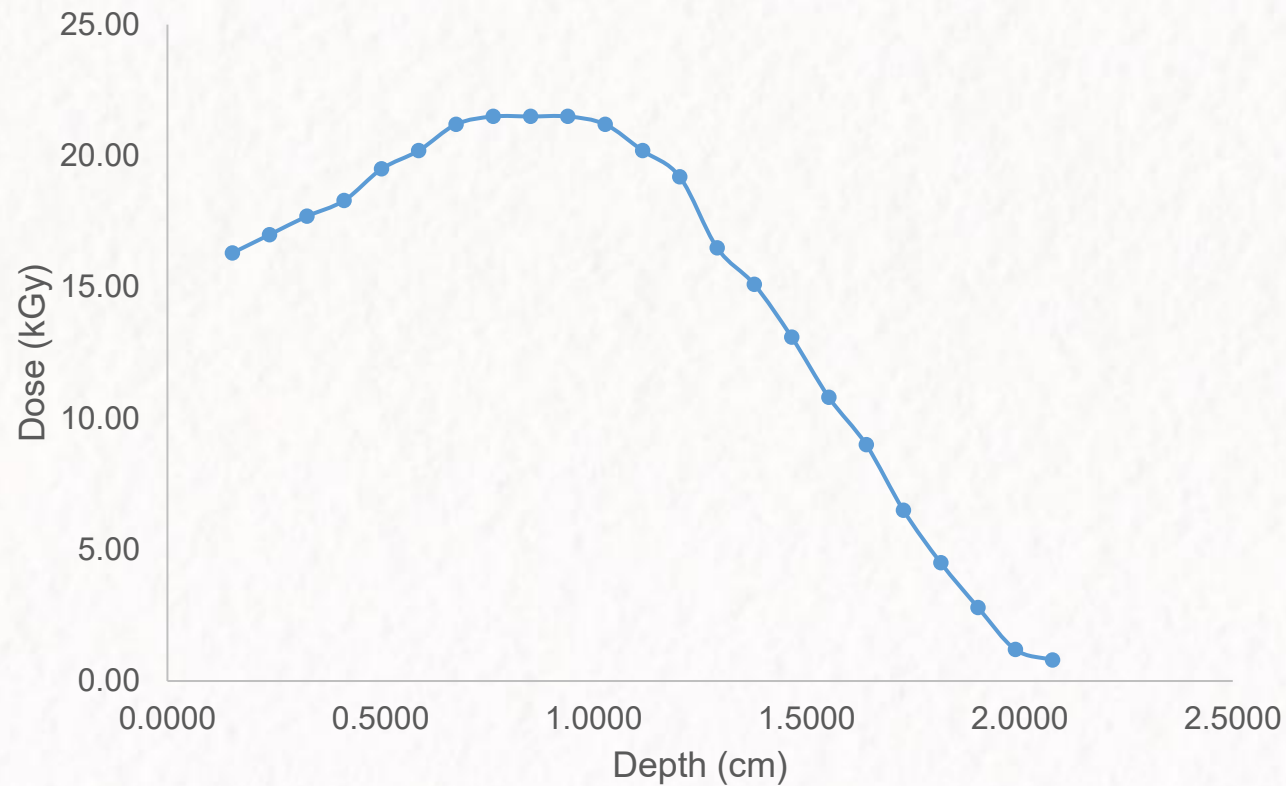
Dosimeter	Dosimeter	Dosimeter	Irradiated	Dose
Position	Number	ID Number	Absorbance (A _i)	(kGy)
11		3266581B	0.350	21.2
12		3266582B	0.337	20.2
13		3266660A	0.322	19.2
14		3266580A	0.285	16.5
15		3266583B	0.265	15.1
16		3266584A	0.237	13.1
17		3266582A	0.204	10.8
18		3266584B	0.177	9.0
19		3266600A	0.142	6.5
20		3266661A	0.112	4.5
21		3266661B	0.088	2.8
22		3266664A	0.069	1.2
23		3266662A	0.059	0.8

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10 MeV Test using an array of B3 dosimeters at increasing depth in the P4701 Risø Aluminum Wedge

eBeam

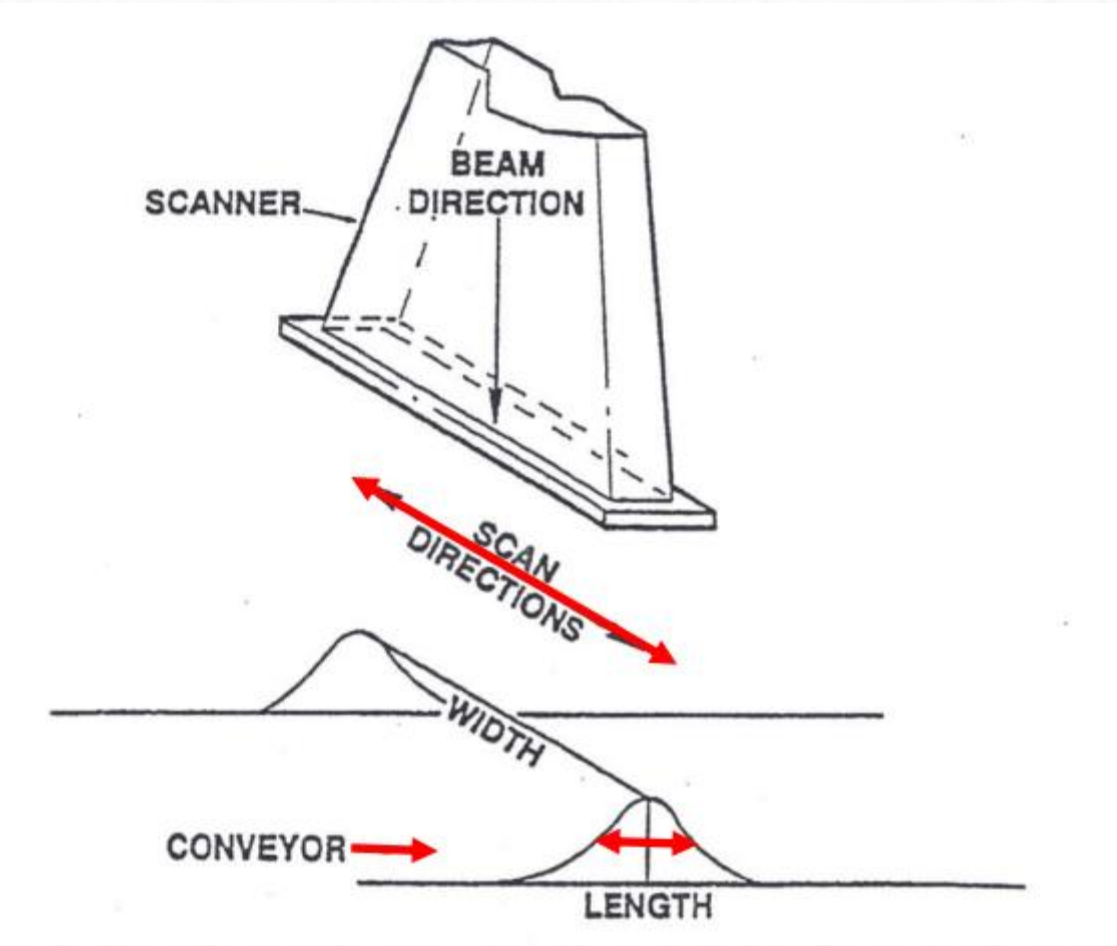


$$E_p = 0.20 + 5.09 * R_p$$

$$E_a = 6.2 * R_{50}$$

- R50 (Depth at 50% dose): 1.54 cm
- Rp (End of penetration): 1.99 cm
- Ep (Energy using Rp): 10.33 MeV
- Ea (Energy using R50): 9.54 MeV

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Speed Conveyor (m/min)		
Conveyor Speed Setting (m/min)	Tachometer Reader (m/min)	Average Speed (m/min)
0.5	0.49	0.495
1	0.99	0.995
1.5	1.48	1.49
2	1.99	1.995
2.5	2.49	2.495
3	2.99	2.995
3.5	3.49	3.495
4	3.98	3.99
4.5	4.5	4.5
5	4.98	4.99
5.5	5.48	5.49
6	5.98	5.99
1.1	1.09	1.095
1.4	1.38	1.39
1.56	1.55	1.555
2.07	2.06	2.065
2.92	2.9	2.91
3.38	3.37	3.375
4.03	4.02	4.025
6.6	6.57	6.585

3

Performance Qualification

Performance Qualification

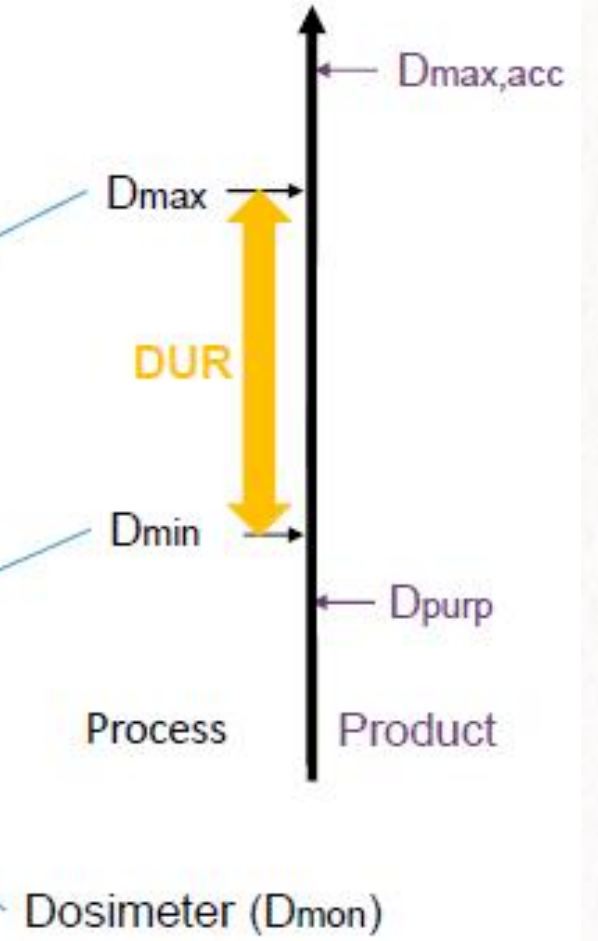
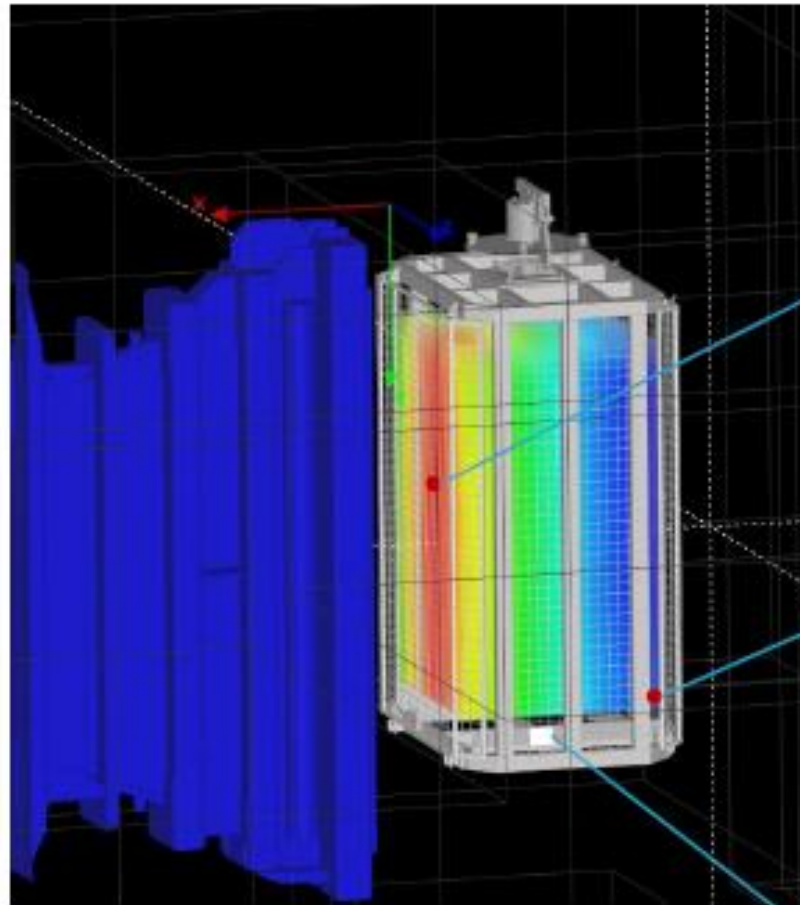
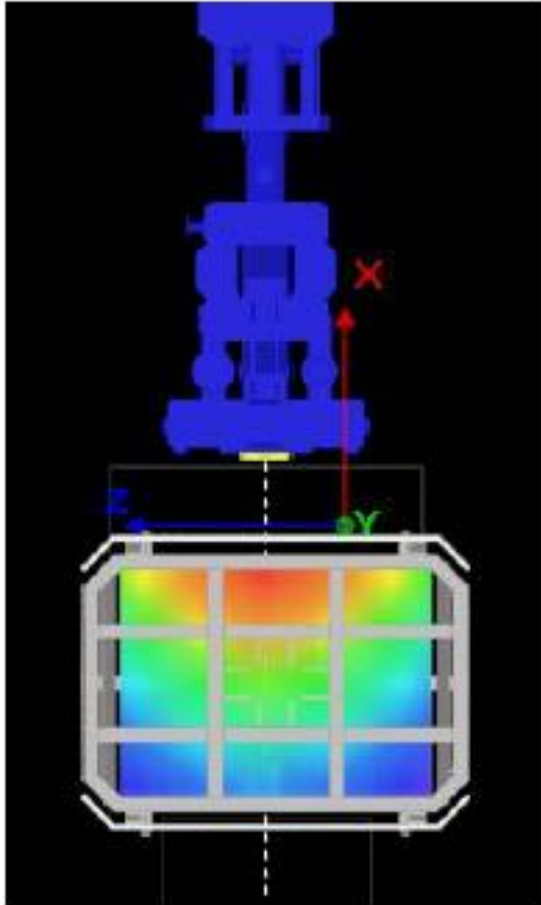
9.3.1 Concerns dose mapping of real product

to identify the location and magnitude of minimum and maximum doses and to determine the relationship between the min and max doses and the routine monitoring dose

It is impossible to measure dose everywhere in/on an irradiated product. Where to measure?

Strategies for dose mapping based on:

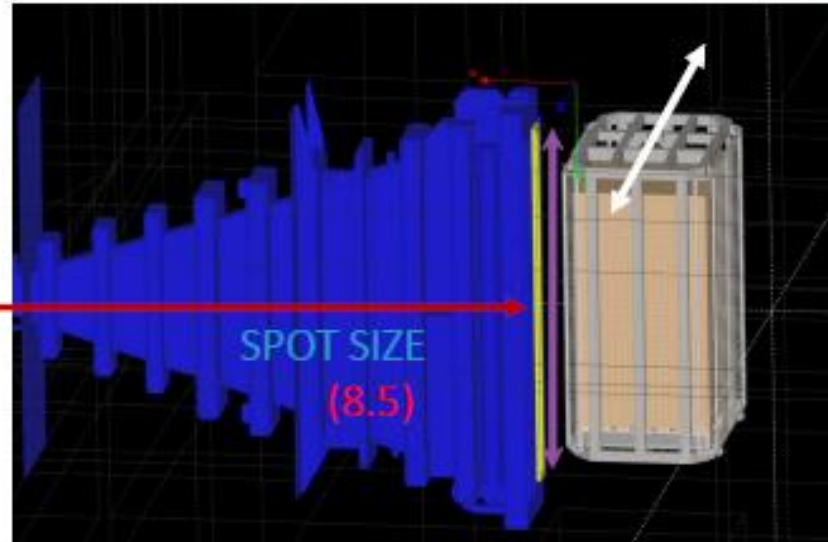
- OQ measurements
- Inhomogeneous product distribution, orientation, voids, interfaces.
- Monte Carlo calculations of dose distributions can help choosing measurement locations and might in the future replace (at least some) measurements



ENERGY/CURRENT
(8.2)

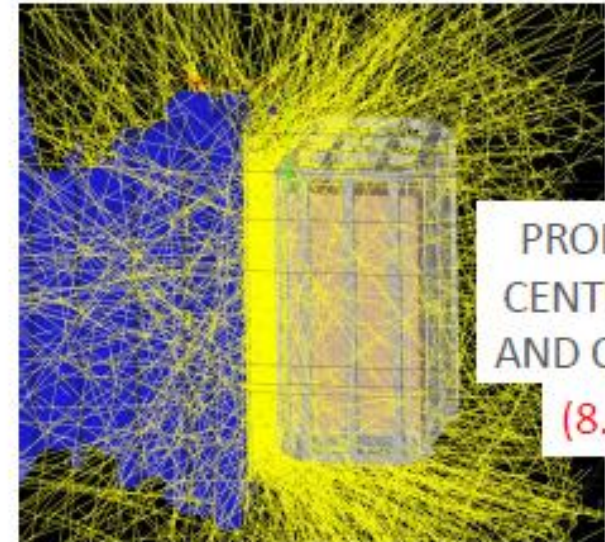


SCAN WIDTH
(8.2)



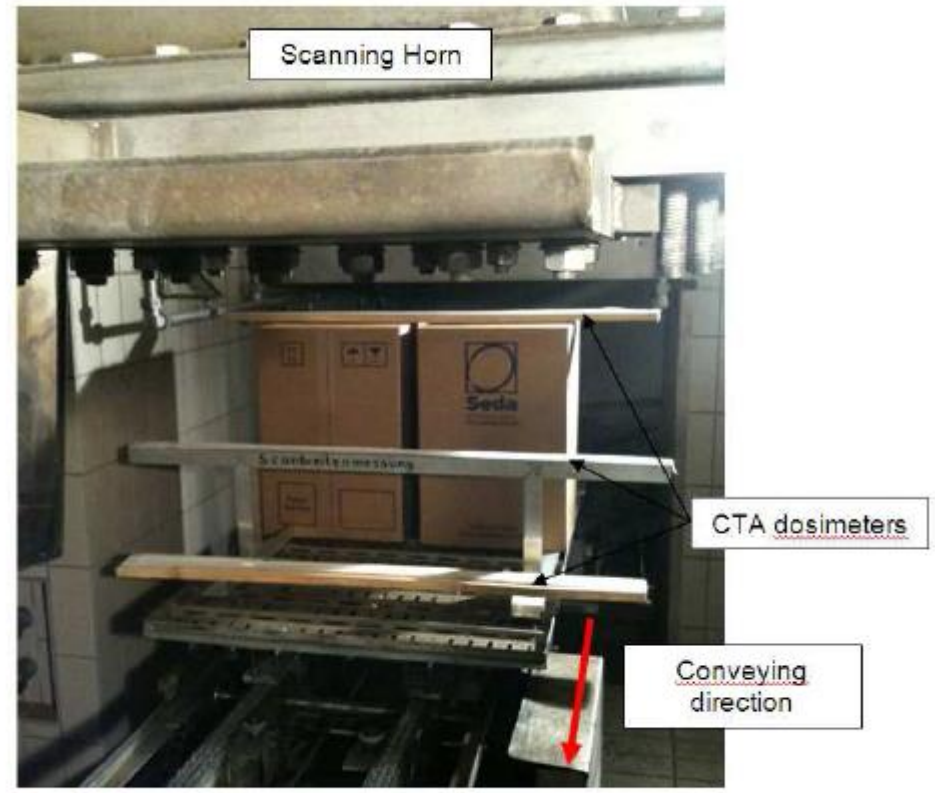
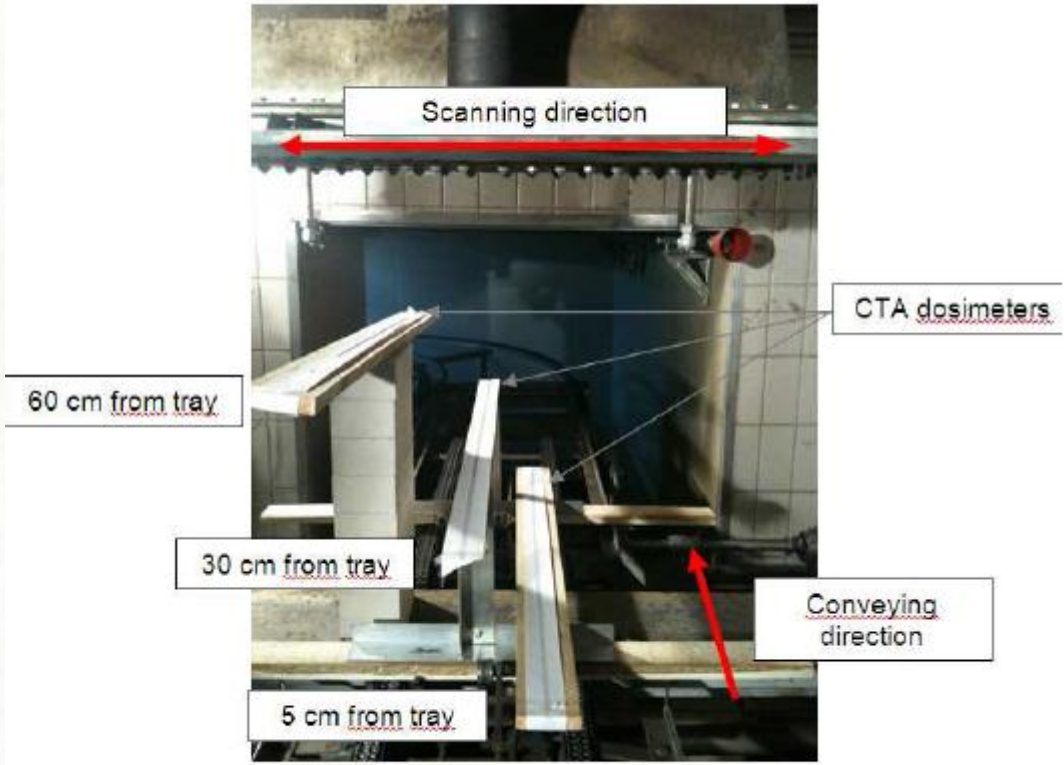
CONVEYOR SPEED
(8.5)

ANSI/AAMI/ISO 11137-3:2006



PRODUCT
CENTERING
AND OFFSET
(8.6)

SCAN UNIFORMITY



Electron energy (MeV)	Av. dose (insulation) (kGy)	Temperature rise (°C)	Av. dose (copper) (kGy)	Temperature rise (°C)
0.5	125	54	14.1	37
1	136	58	48.3	127
1.5	125	54	71.9	189

wire diameter 2.8 mm, insulation thickness 1.3 mm
and copper conductor 1.5 mm

Specific heat:

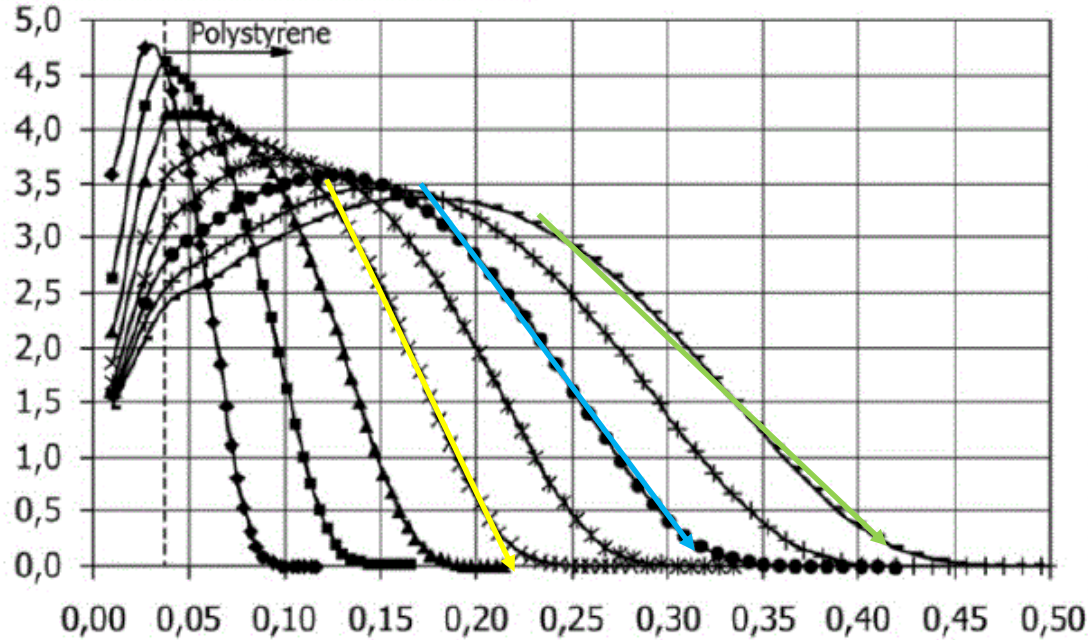
copper 0.38 J/g °C - temperature rise 2.63 °C/kGy

polyethylene 2.30J/g °C – temperature rise 0.43 °C/kGy.



ISO/ASTM 51649:2015(E)

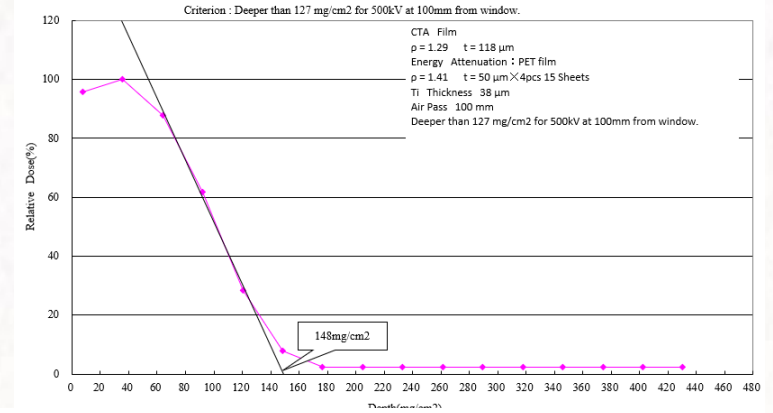
Energy Deposition per electron (MeV cm²/g)



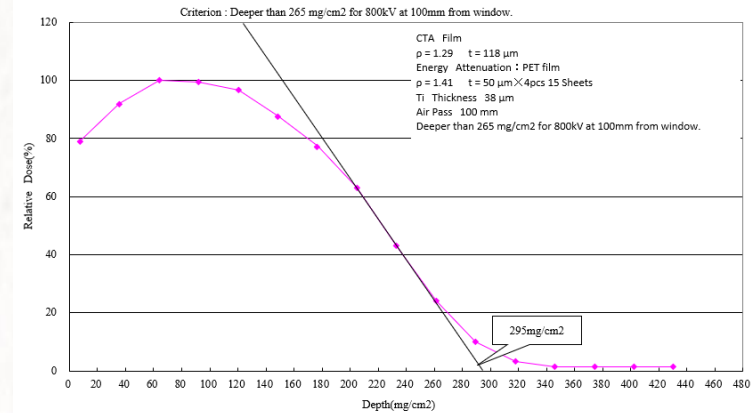
Standardized Depth (g/cm²)

- | | | | |
|-----------|-----------|-----------|------------|
| ◆ 300 keV | ■ 400 keV | ▲ 500 keV | ✕ 600 keV |
| * 700 keV | ● 800 keV | + 900 keV | — 1000 keV |

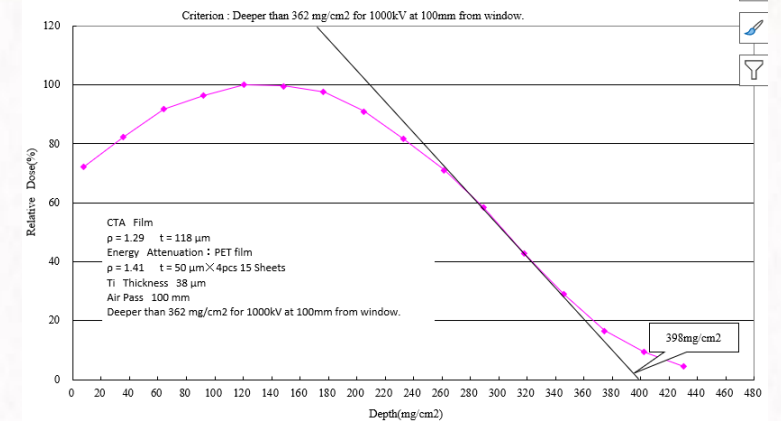
5-1 Dose Penetration Test (500kV)



5-2 Dose Penetration Test (800kV)



5-3 Dose Penetration Test (1000kV)



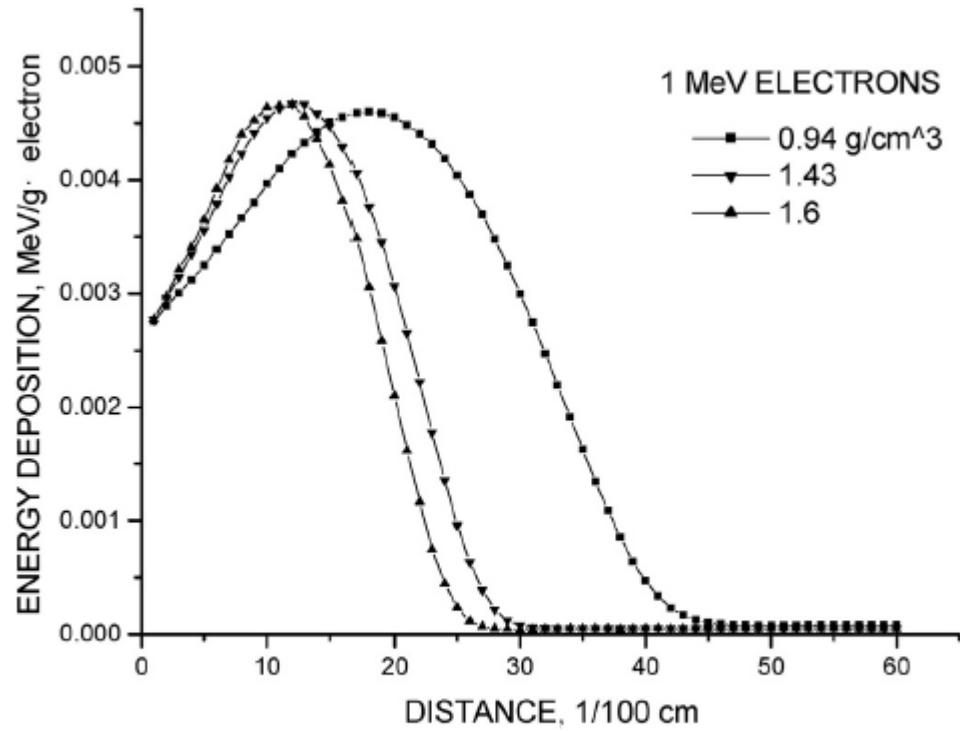
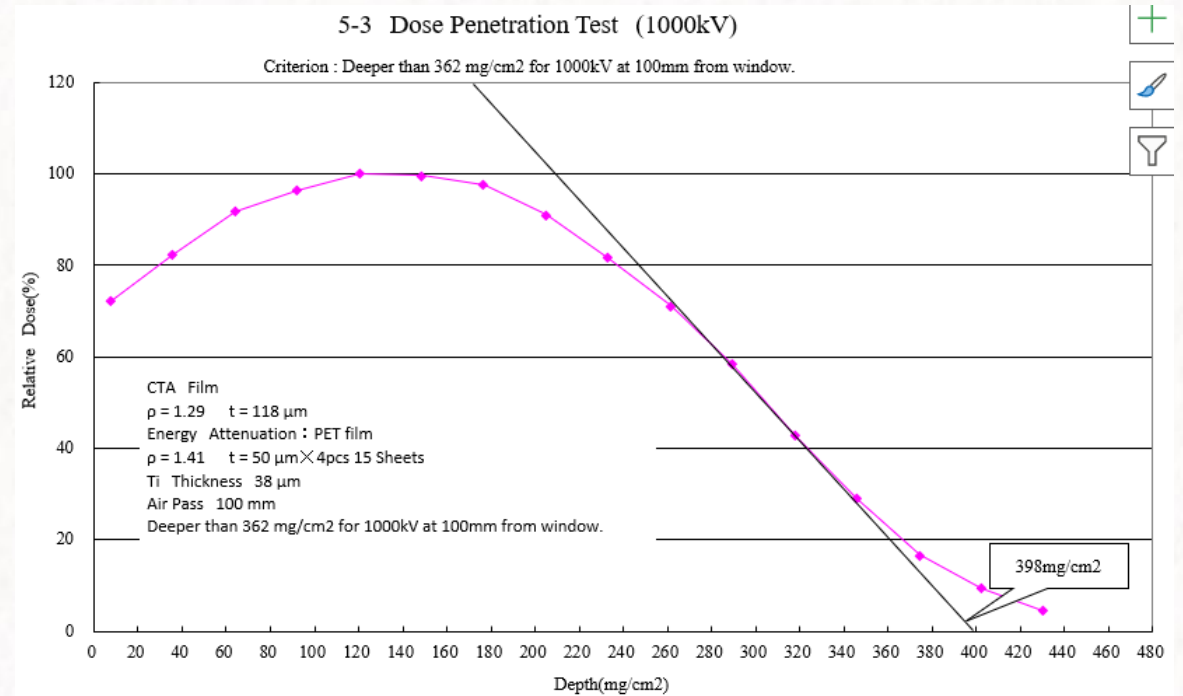
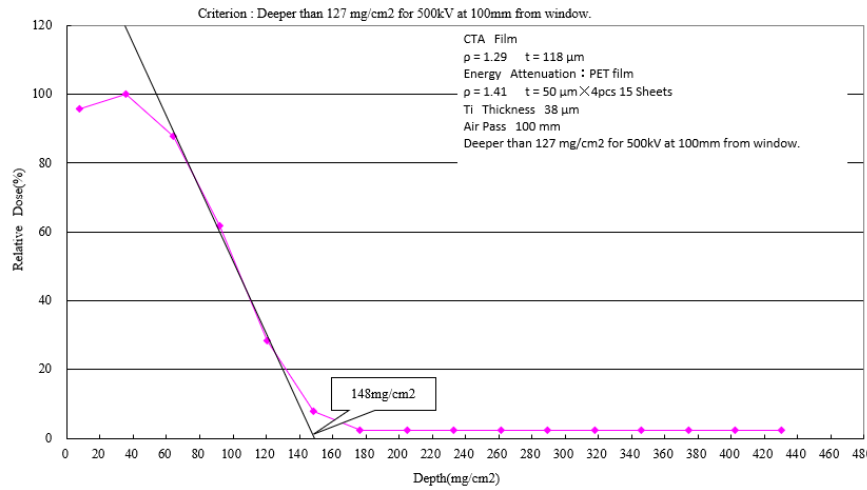


Fig. 4. Relation between energy deposition and density of slab made from polyethylene-based formulation.



5-1 Dose Penetration Test (500kV)



Step 1: Convert 148 mg/cm² into equivalent thickness in polystyrene

Polystyrene density:

$$\rho_{\text{PS}} = 1.05 \text{ g/cm}^3 = 1050 \text{ mg/cm}^3$$

$$R_{\text{poly}} = \frac{148 \text{ mg/cm}^2}{1050 \text{ mg/cm}^3} \approx 0.141 \text{ cm}$$

$$\frac{\text{mg}}{\text{cm}^2} \div \frac{\text{mg}}{\text{cm}^3} = \text{cm}$$

$$\frac{\text{mg/cm}^2}{\text{mg/cm}^3} = \frac{\text{mg}}{\text{cm}^2} \cdot \frac{\text{cm}^3}{\text{mg}} = \text{cm}$$

Step 2: Use practical range equation for polystyrene

$$E = 1.972 \cdot R_p + 0.245 \quad (\text{from ISO/ASTM 51649 for } 0.3\text{--}2.0 \text{ MeV})$$

$$E = 1.972 \cdot 0.141 + 0.245 = 0.278 + 0.245 = \boxed{0.523 \text{ MeV}}$$

Estimated Electron Energy:

$$\boxed{0.52 \text{ MeV (based on CTA depth, adjusted to polystyrene)}}$$

4

ISO/ ASTM Standard

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.



Designation: 51650 – 21^{ε1}

Standard Practice for Use of a Cellulose Triacetate Dosimetry System¹

This standard is issued under the fixed designation 51650; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

^{ε1} NOTE—References to ISO/ASTM standards were editorially updated in December 2024.



Designation: 51275 – 21^{ε1}

Standard Practice for Use of a Radiochromic Film Dosimetry System¹

This standard is issued under the fixed designation 51275; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

^{ε1} NOTE—References to ISO/ASTM standards were editorially updated in December 2024.



TABLE A1.2 Some suppliers of radiochromic film dosimeters

Type	Supplier Address
Far West Technology, Inc.	330 S Kellogg Ave Suite D Goleta, CA 93117 USA
GEX Corporation	7330 South Alton Way Suite 12i Centennial, CO 80112 USA
Ashland LLC	1005 US Highway 202/206 Bridgewater, NJ 08807 USA
Risø High Dose Reference Laboratory	DTU Health Tech Technical University of Denmark DK-4000 Roskilde, Denmark

TABLE A1.1 Basic properties of available radiochromic film dosimeters

Dosimeter Type	Nominal Thickness, μm	Analysis Wavelength, nm	Usable Dose Range, kGy
FWT-60	50	605, 600, or 510	0.5 to 200
B3	18	552 \pm 2	<1.0 to >120
GAFCHROMIC (various models)	Depends on model	Depends on model	Depends on model

Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV¹

This standard is issued under the fixed designation 51818; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

¹ NOTE—Footnote 1 and references to ISO/ASTM standards were editorially updated in December 2024.

6.2.2.1 Dose as Function of Average Beam Current, Beam Width and Conveying Speed—Dose to the product irradiated in an electron beam facility is proportional to average beam current (I), inversely proportional to conveying speed (V), and inversely proportional to beam width (W_b). The last relationship is valid for product that is conveyed through the beam zone perpendicular to the beam width. This is expressed as:

$$D = (K \cdot I) / (V \cdot W_b) \quad (1)$$

where:

- D = absorbed dose (Gy),
- I = average beam current (A),
- V = conveying speed (m s^{-1}),
- W_b = beam width (m), and
- K = slope of the straight line relationship in Eq 1 ($\text{Gy} \cdot \text{m}^2 / (\text{A} \cdot \text{s})$).

NOTE 14—Activities that might affect the OQ status of the irradiation facility include, but are not limited to:

- Replacement of accelerator emitter
- Replacement of accelerator window
- Replacement of window support grid
- Replacement of conveyor parts
- Change in electron energy
- Change in distance of accelerator window to product surface

10. Documentation

10.1 Data and measurement results shall be recorded and stored in accordance with the operator's measurement management system. Data to be recorded and stored include:

10.1.1 Data from initial IQ and from any changes to the irradiation facility.

10.1.2 Data from maintenance of the irradiation facility.

10.1.3 Data from OQ of the irradiation facility.

10.1.4 Data from PQ for products irradiated at the facility.

10.1.5 Process control data.

10.1.6 Calibration data for the dosimetry system(s) used.

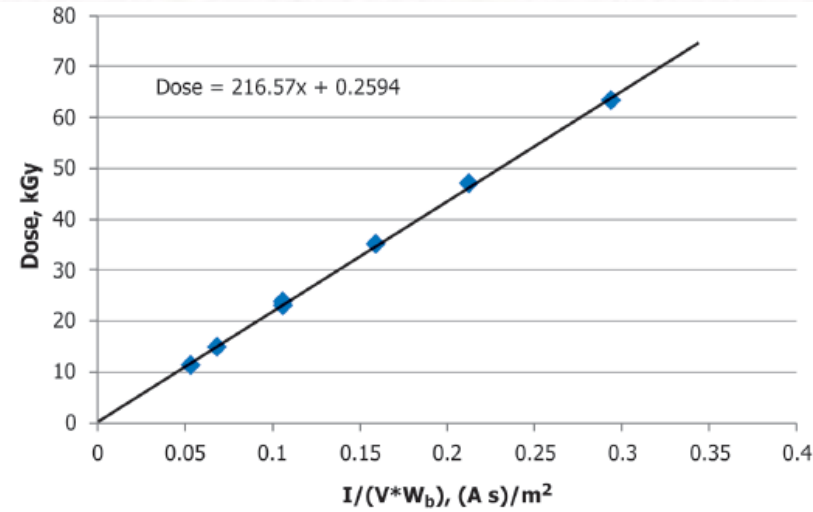
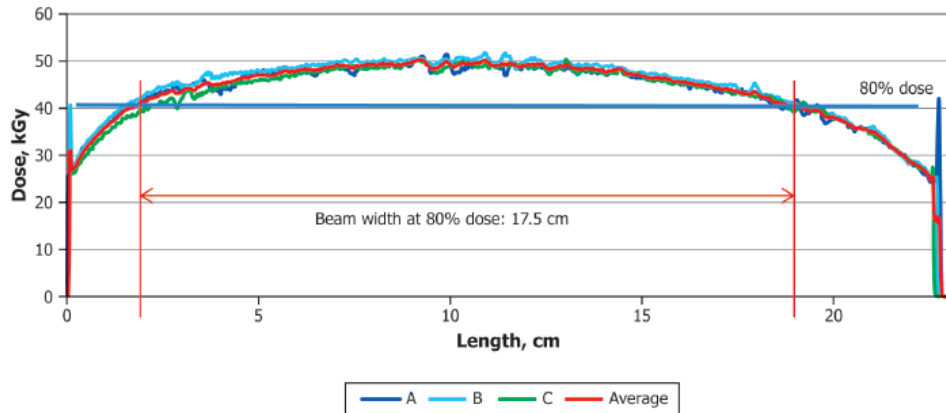
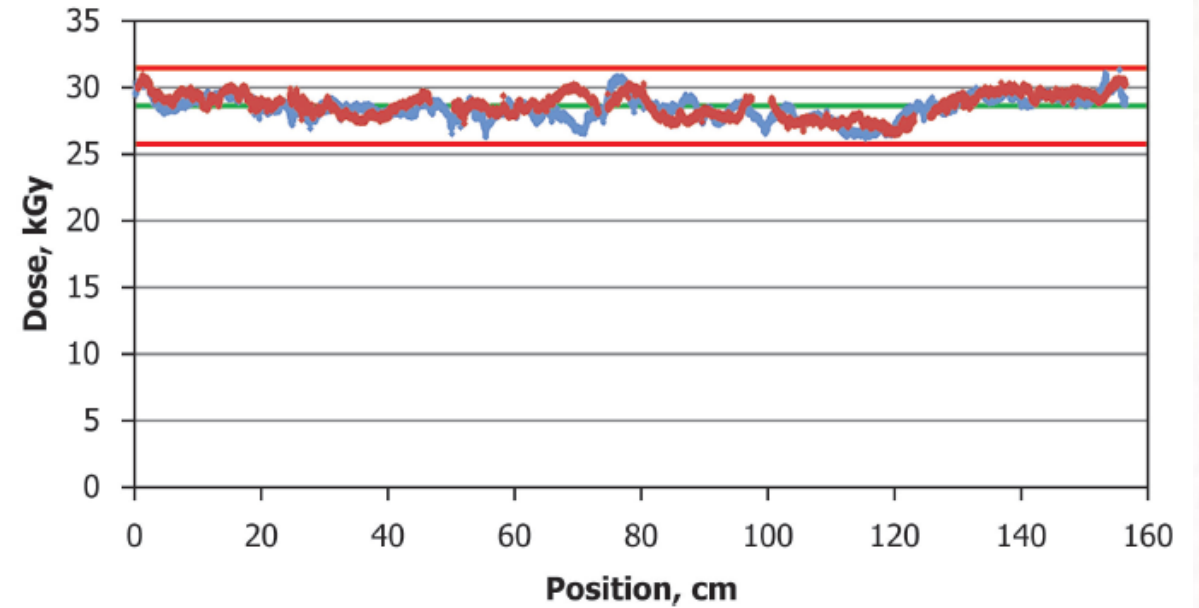


FIG. A1.1 Example of measurement of dose as function of average beam current I , conveying speed V and beam width W_b . Measured at an electron accelerator with beam energy 110 keV.
 $K = 216.57 \text{ (kGy} \cdot \text{m}^2) / (\text{A} \cdot \text{s})$

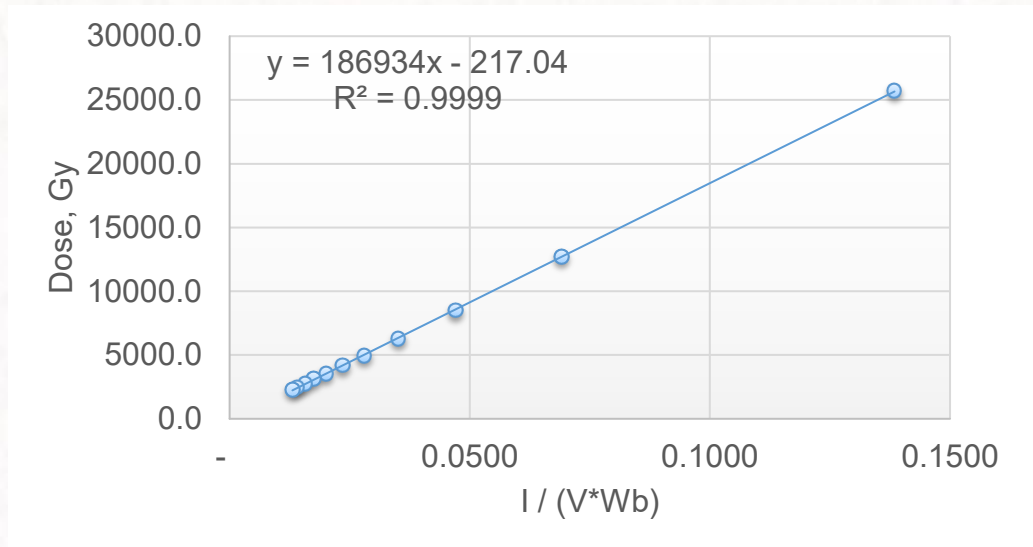
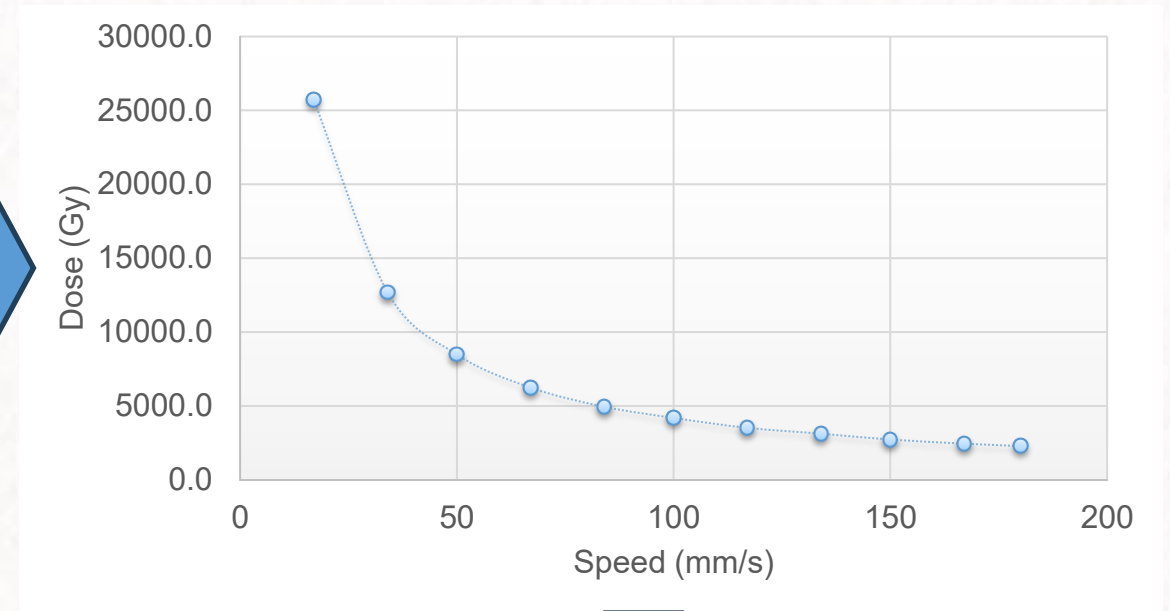


The parameters of the accelerator were:
 Electron energy: 150 keV
 Beam current: 1 mA
 Beam width obtained by elongated electrode (no scanning).
 Beam width was measured to be 17.5 cm at 80 % dose level.

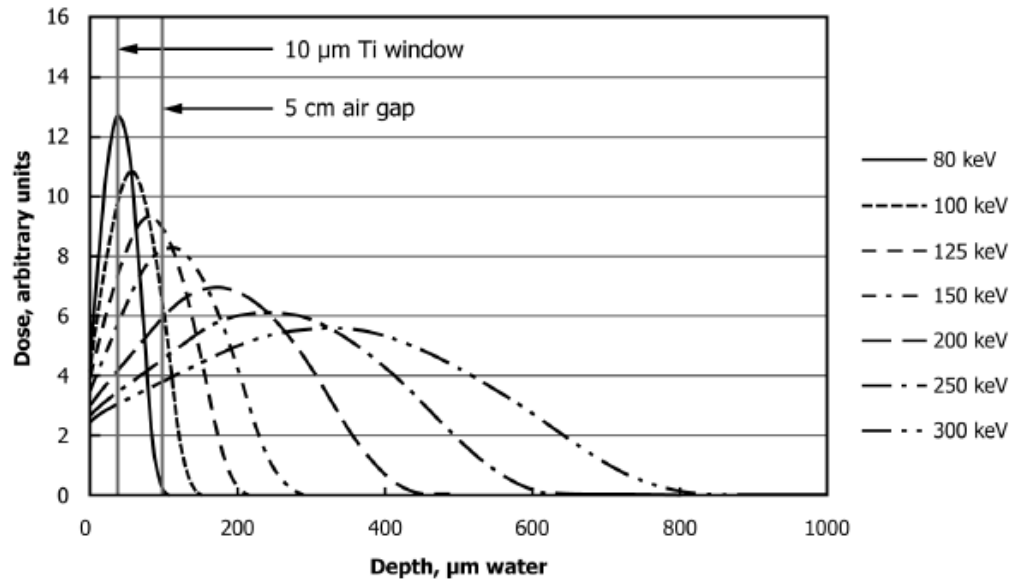
FIG. A1.2 Example of beam width measurement (3 measurements and their average are shown). Beam width was measured on a low-energy accelerator installed in an electron beam tunnel for an aseptic filling line (3)



Speed (mm/s)	Dose (Gray)	std dev	cv
17	25713.0	279.876	1.09%
34	12714.9	136.673	1.07%
50	8492.6	163.078	1.92%
67	6251.2	77.521	1.24%
84	4957.6	53.511	1.08%
100	4202.9	36.702	0.87%
117	3528.6	23.918	0.68%
134	3136.7	52.727	1.68%
150	2738.9	25.169	0.92%
167	2463.0	19.689	0.80%
180	2294.9	12.160	0.53%

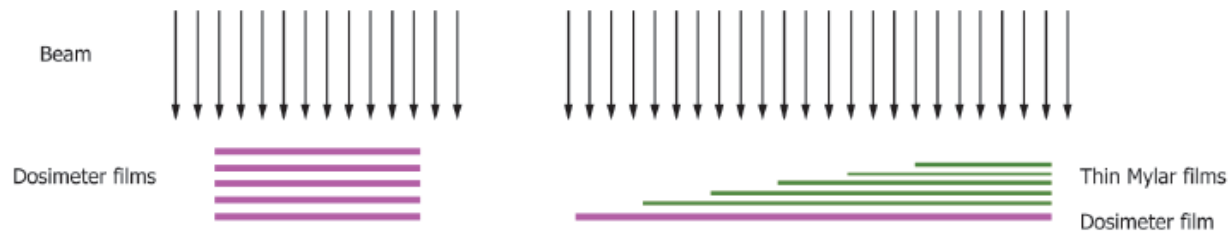


Nomor	I (ampere)	Speed (mm/s)	Wb (m)	I / (V*Wb)	Dose (Gray)
1	0.00193	0.017	0.82	0.1385	25713.0
2	0.00193	0.045	0.82	0.0523	
3	0.00193	0.034	0.82	0.0692	12714.9
4	0.00193	0.050	0.82	0.0471	8492.6
5	0.00193	0.067	0.82	0.0351	6251.2
6	0.00193	0.084	0.82	0.0280	4957.6
7	0.00193	0.100	0.82	0.0235	4202.9
8	0.00193	0.117	0.82	0.0201	3528.6
9	0.00193	0.134	0.82	0.0176	3136.7
10	0.00193	0.150	0.82	0.0157	2738.9
11	0.00193	0.167	0.82	0.0141	2463.0
12	0.00193	0.180	0.82	0.0131	2294.9

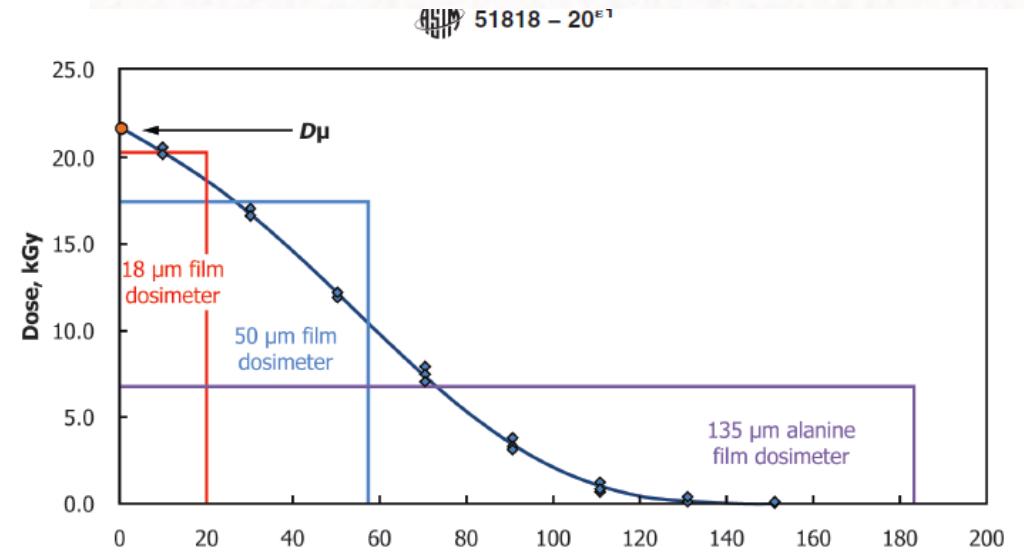


The curves are normalized to electron fluence.
 Monte Carlo code: EGSnrc (5), Cut-off energy 1 keV.
 Examples of beam window and air gap thicknesses are shown.
 A: 10 μm Ti beam window
 B: 5 cm air gap

FIG. A1.5 Calculated depth-dose distribution in water (specific density 1 g cm⁻³)



Left: A stack of thin dosimeter films.
 Right: A dosimeter film under increasing layers of thin plastic (Mylar) films.





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