Qualification For Gamma and EB Machine

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Pelatihan Penyegaran Petugas Iradiator

Direktorat Pengembangan Kompetensi BRIN - 2025

PROFILE

- Bimo Saputro

- Sarjana – Fisika Nuklir, Politeknik Teknologi Nuklir Indonesia (STTN-BATAN) 2012-2016
- Magister – Fisika, Universitas Indonesia 2023-2024

- Honda Motor Ltd. 2016-2017
- BATAN 2018-2021
- BRIN 2021-Current

- 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

- 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

1. What do you expect from an operation?

2. Is the Operation related to IQ OQ and PQ?

- Installation Qualification
- Operational Qualification
- Peformance Qualification

HIGHLIGHT AGENDA

1. Installation Qualification

2. Operational Qualification

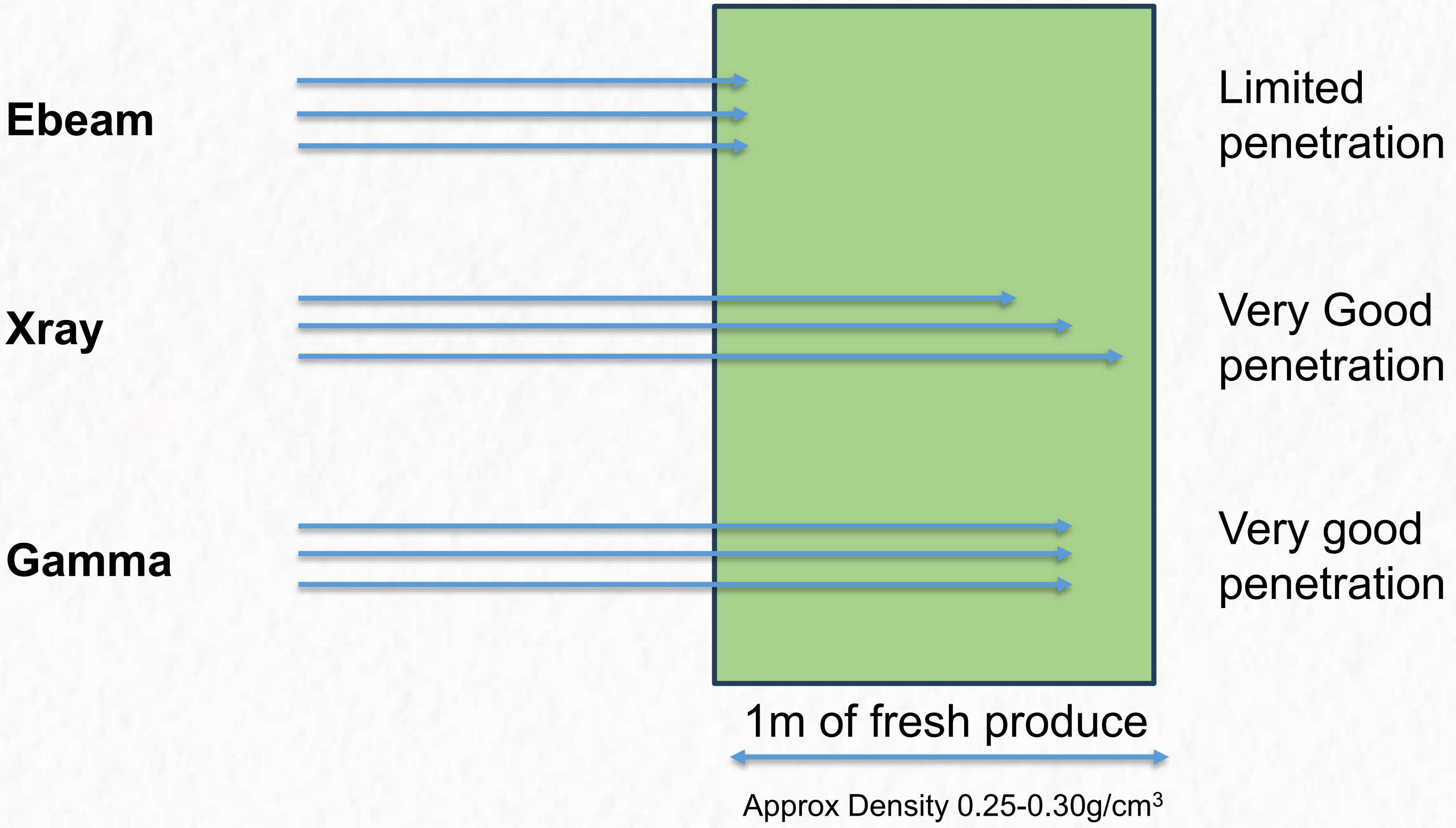
3. Peformance Qualification

4. Process Control

Which modality is more beautiful? Gamma? Xrays? EB?

γ	e⁻	X
^{60}Co (1.17 & 1.33 MeV)	5, 7.5, & 10 MeV	5 & 7.5 MeV
Two photon energies, act like waves	Monoenergetic electrons, act like particles	Bremsstrahlung energies, act like waves
Attenuated	Stopping power	Attenuated

Comparison Technology



Comparison Technology

Feature	eBeam (10 MeV)	Gamma (Co-60)	X-ray (≤7.5 MeV)
Public/Consumer Acceptance	★★★★☆	★★☆☆☆	★★★★☆
Maintenance Requirement	★★☆☆☆	★★★★★	★★☆☆☆
Infrastructure Cost	★★☆☆☆	★★★★☆	★★☆☆☆
Dosimetry Uniformity	★★☆☆☆	★★★★★	★★★★☆
Regulatory Risk	★★★★★	★☆☆☆☆	★★★★★
Speed / Throughput	★★★★★	★★☆☆☆	★★★★☆
Penetration Depth	★☆☆☆☆	★★★★★	★★★★☆

Which modality is more beautiful? ALL TECHNOLOGY ARE BEAUTIFUL!

Gamma Parameters

- Source Energy (MeV)

Coming from type of radioactive. Example Co60 1.17 MeV and 1.33 MeV; Cs137 0.662 MeV

- Dose Rate

Quantity of dose per unit time – Controls the absorb dose of the product

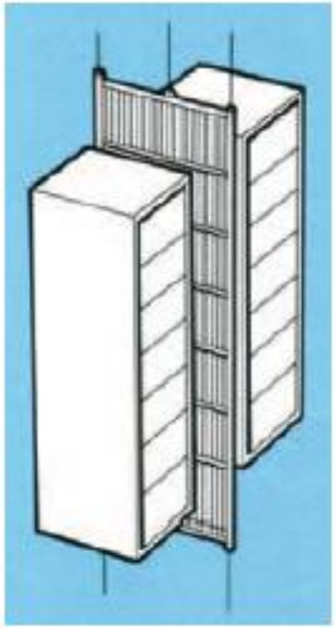
- Time of Irradiation

The relation between dose rate and density products creates the dose rate and consequence the time being exposed to ionising radiations

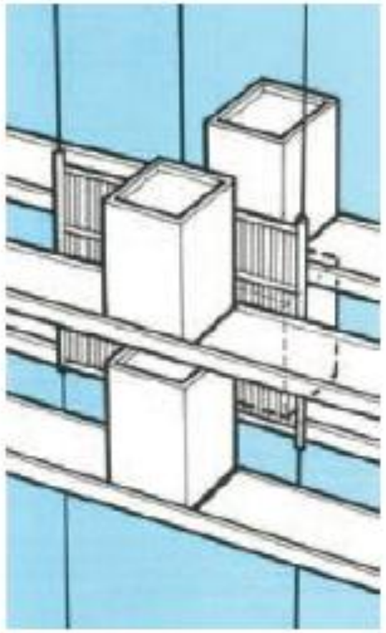
- Carrier Geometry (Tote/ Hanging)

Dimensions of irradiated product to the source (Source overlap/ or product overlap)

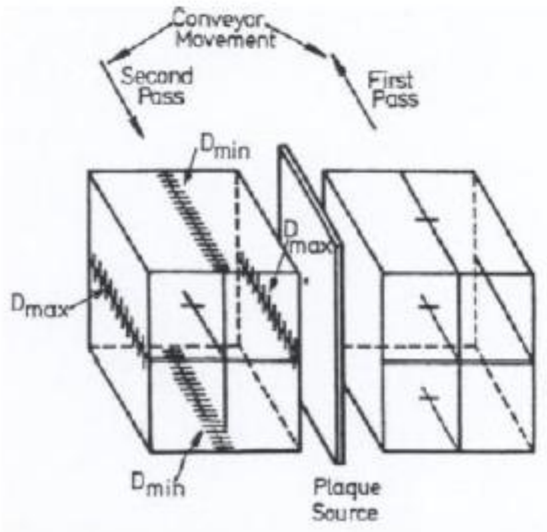
Gamma



Source overlap



Product overlap



Note: Dosimeter placement for OQ dose mapping may depend on source – product arrangement

Gamma

Credit: Iradiator Gamma Merah-Putih

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 µA) 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

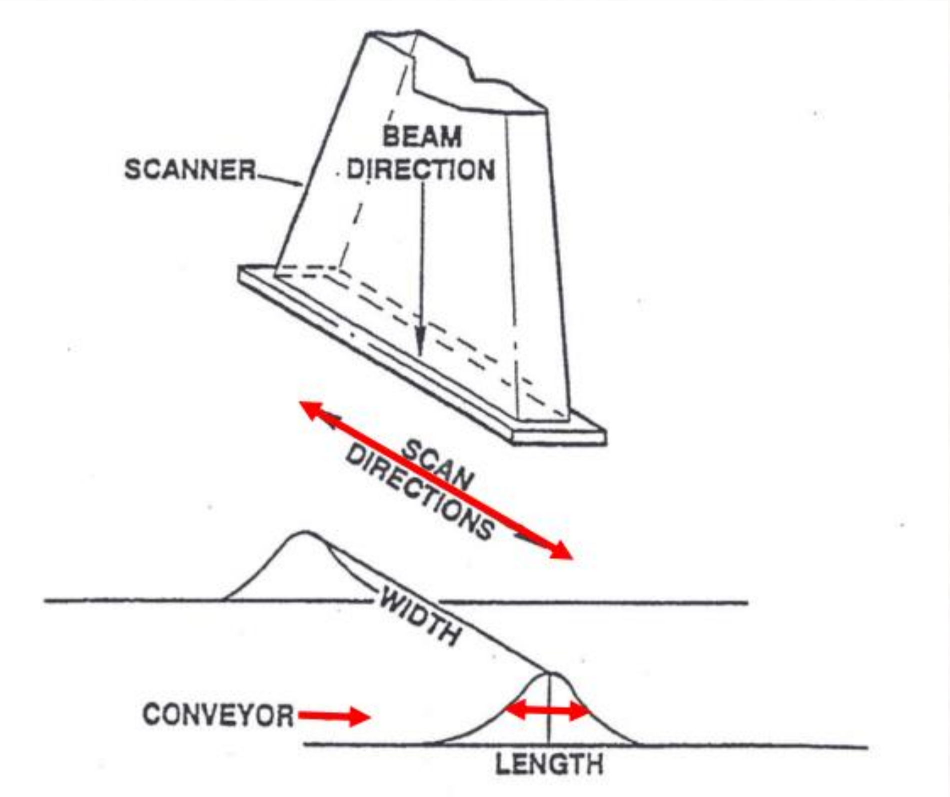
- **Beam Power (kW) kilo Watt**

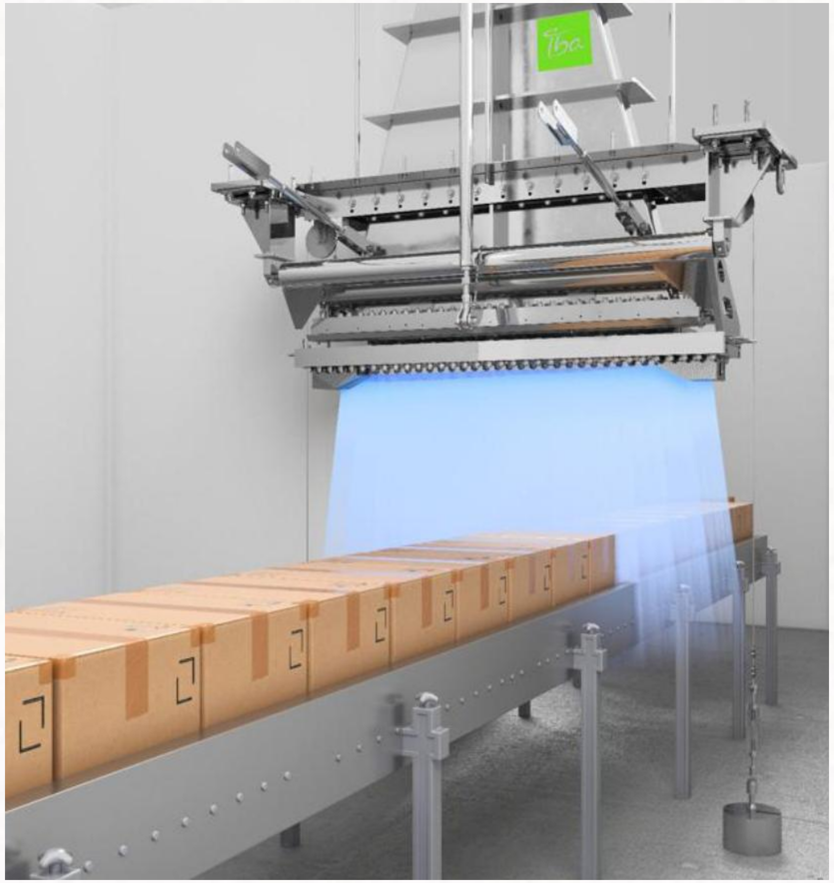
Radiation Power – P = V.I (Example. kW = V (10 MeV) * I (5 mA) = 50 kW – Gives the throughput of irradiation

- **Scanned Lenght (m or cm) meters or centimeters**

Dimensions of irradiation zone to the product movement at a specified distance from the accelelator window

eBeam

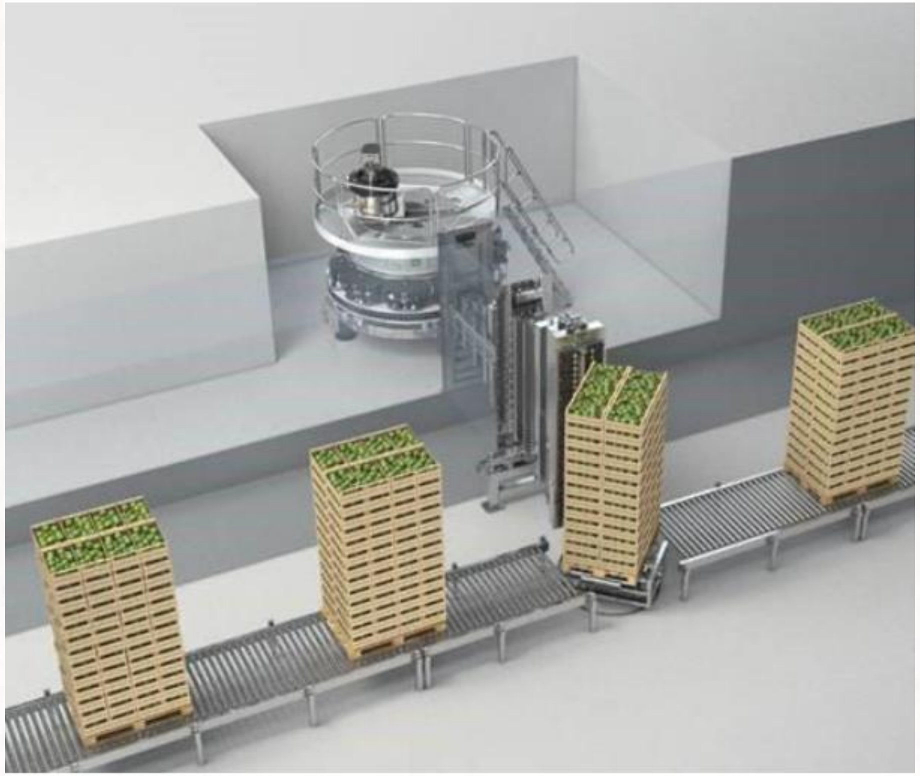




Credit: IBA Industrial

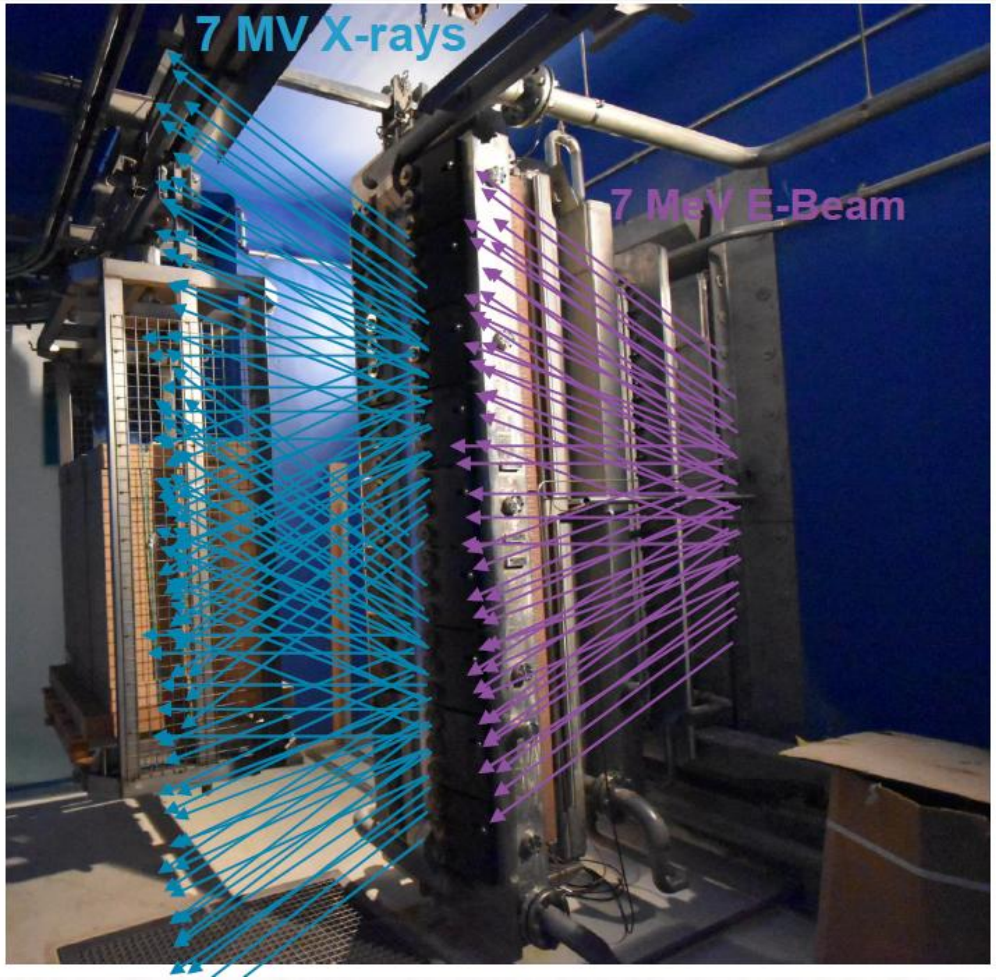
eBeam/Xray

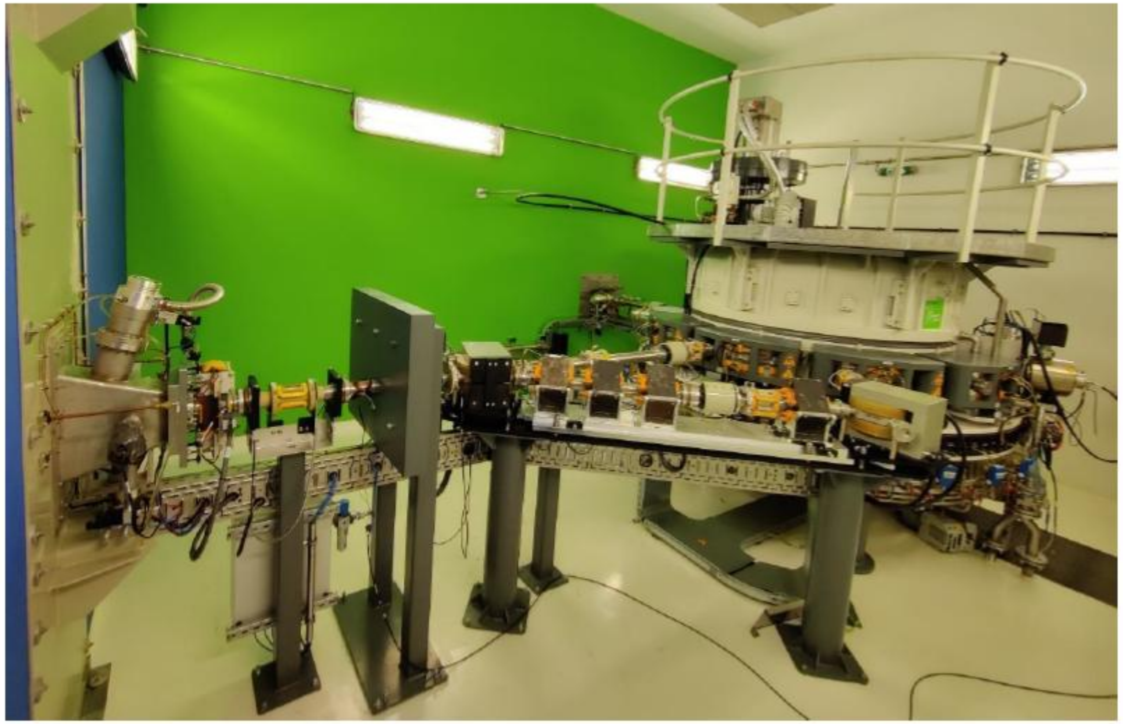
Credit: Steritech Australia



Credit: IBA Industrial

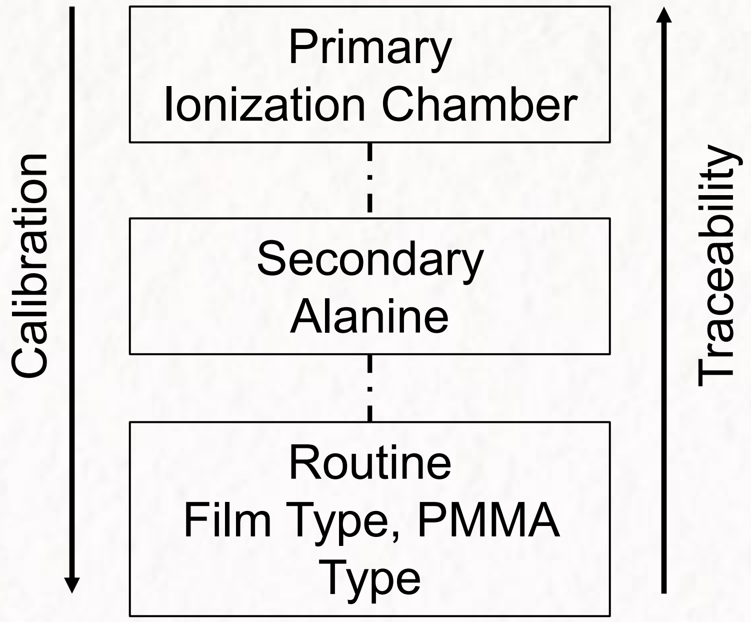
Aerial + IBA Project

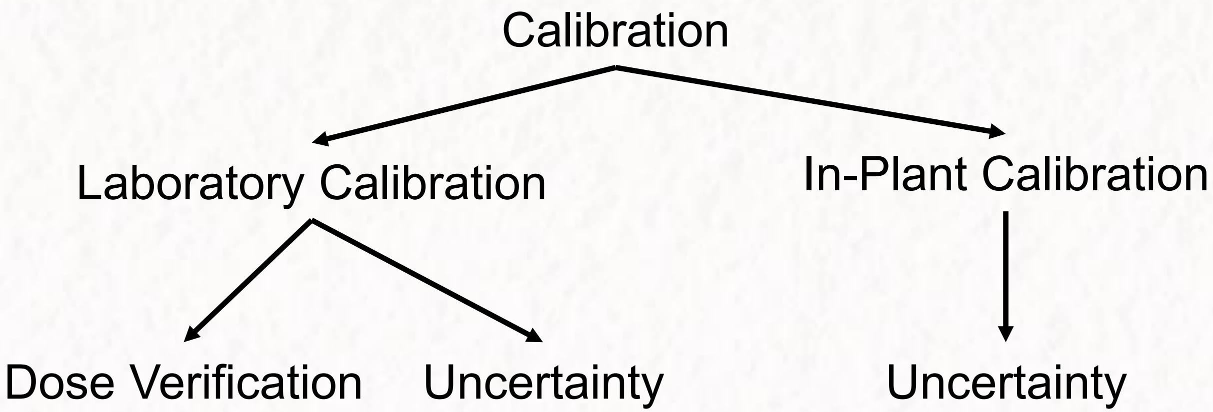




Calibration

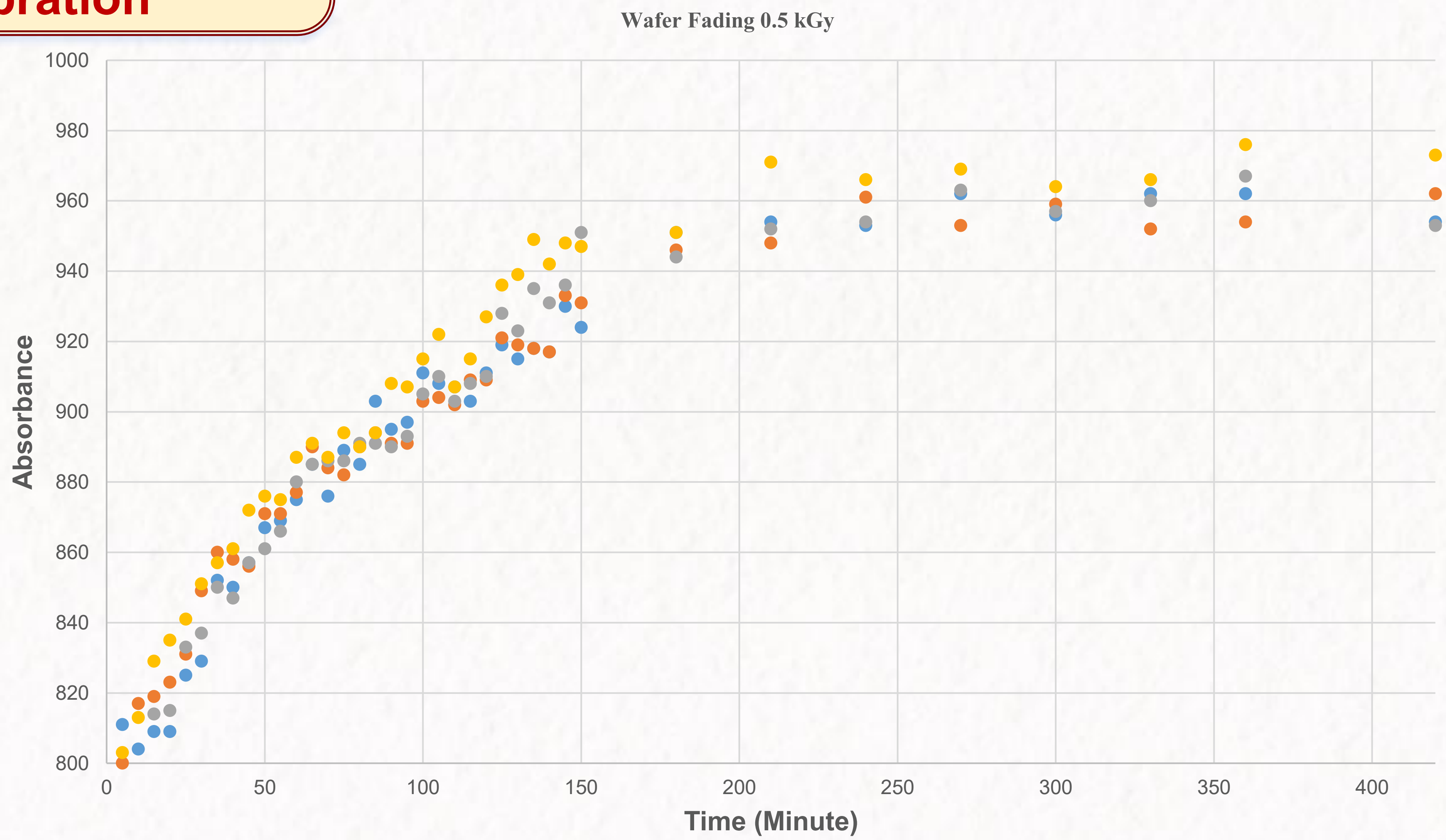
ISO/ASTM 51261:2013
Calibration (3.1.2) Establishes, under specified conditions, the relationship between the value of a quantity by a measurement system or the value through a reference material



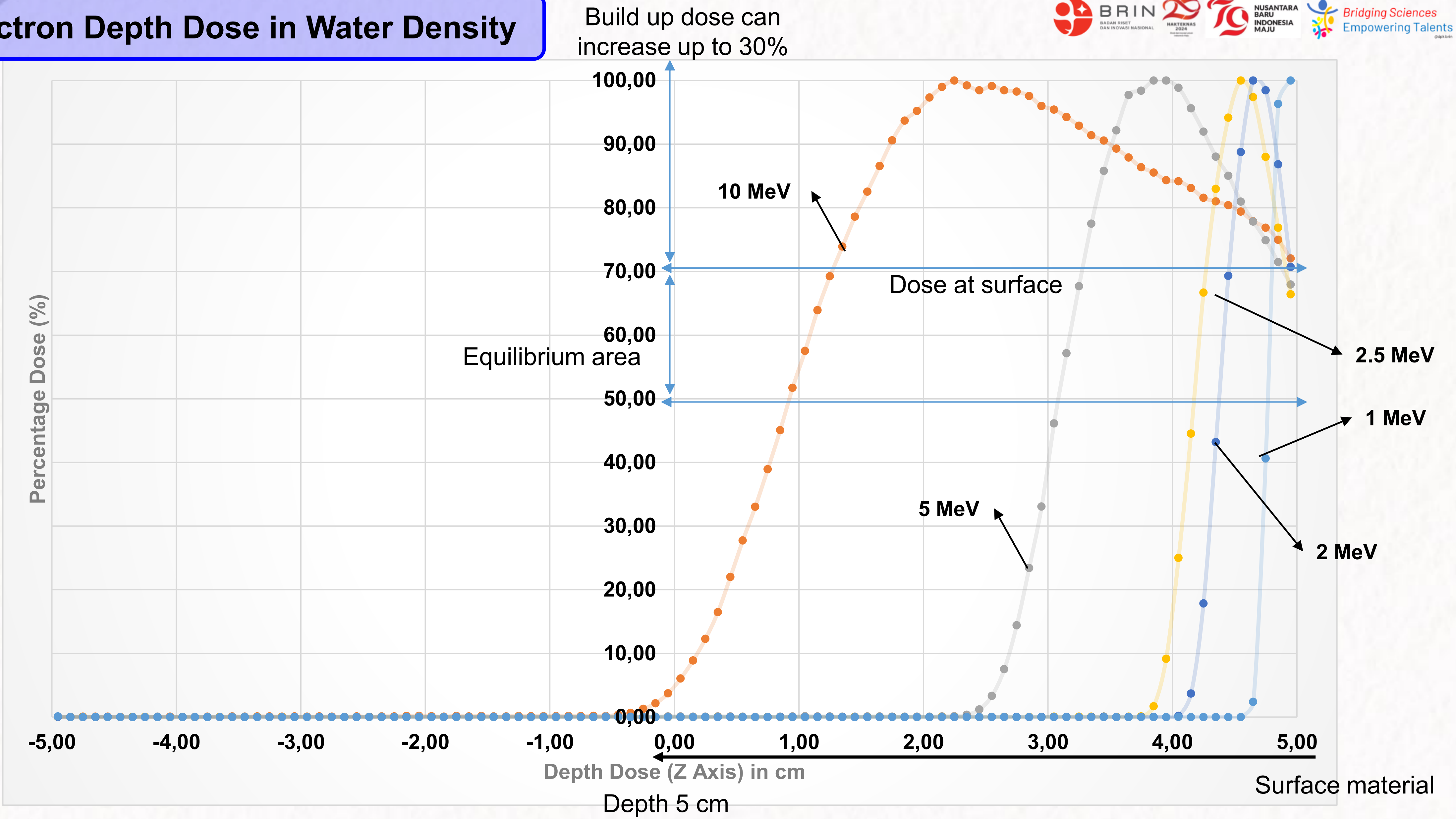


BRIN BADAN RISET DAN INOVASI NASIONAL · HAKTEKNAS 2024 · NUSANTARA BARU INDONESIA MAJU · Bridging Sciences Empowering Talents

Calibration



Electron Depth Dose in Water Density



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

International Standards:

- ISO 14470:2011 Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

and many others …

IQ → OQ → PQ → Monitoring

Installation Qualification
to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications

Operational Qualification
to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for each set of irradiator parameters and process parameters expected to be used for irradiating

Performance Qualification
to determine the appropriate process parameters (including timer setting, conveyor speed, and product-loading configuration) for ensuring that the dose requirements for a particular product can be satisfied

Routine Process monitoring
to demonstrate that the product receives the required absorbed dose by employing proper dosimetric procedures, appropriate statistical controls and adequate documentation

Definitions

- **Installation Qualification**

To demonstrate that irradiator has been supplied and installed in accordance with its specifications

- **Operational Qualification**

To demonstrate that the irradiator, as installed, is capable of operating and delivering appropriate doses within defined acceptance criteria
(characterize the radiation facility)

- **Peformance Qualification**

To determined the appropriated process parameters for ensuring that the dose requirement for a particular can satisfied
(dose distribution in irradiated products)

- **Process Control**

To demonstrate that the product receives the required absorbed dose by employing proper dosimeter procedures, appropriate statistical control, and adequate documentations
(monitor the irradiation process)

Gamma Parameters

- **Source Energy (MeV)**

Coming from type of radioactive. Example Co60 1.17 MeV and 1.33 MeV; Cs137 0.662 MeV

- **Dose Rate**

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- **Time of Irradiation**

The relation between dose rate and density products creates the dose rate and consequence the time being exposed to ionising radiations

- **Carrier Geometry (Tote/ Hanging)**

Dimensions of irradiated product to the source (Source overlap/ or product overlap)

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- **Beam Power (kW) kilo Watt**

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- **Scanned Lenght (m or cm) meters or centimeters**

Dimensions of irradiation zone to the product movement at a specified distance from the accelelator window

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.

A11. TABLE A2 FROM ISO 11137-1

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

Irradiator Change	*Installation Qualification*	*Operational Qualification*			
	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					

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

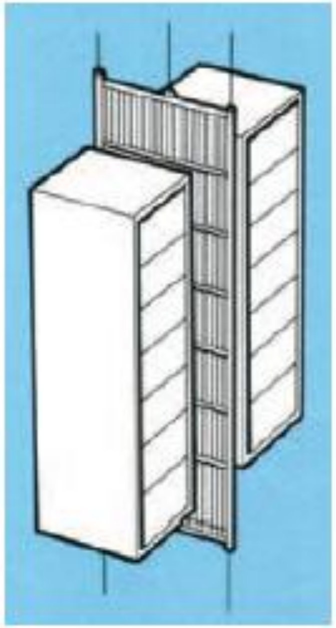
9.2.5 OQ dose mapping shall be carried out on a sufficient number of irradiation containers to allow determination of the distribution and variability of dose between containers.

4 Quality Management System Elements

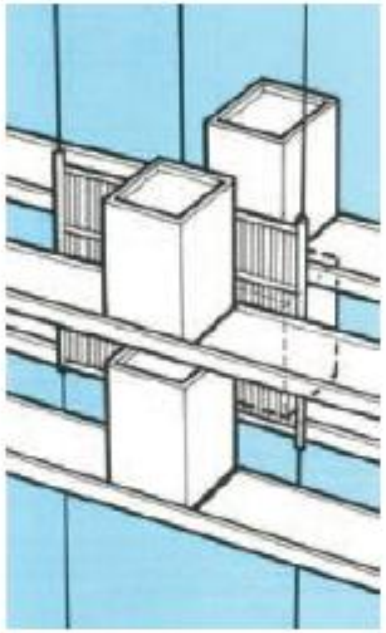
4.3 Product realization

4.3.4 Dosimetry used in the development, validation and routine control of the sterilization process **shall have** measurement traceability to national or international standards and **shall have** a known level of uncertainty.

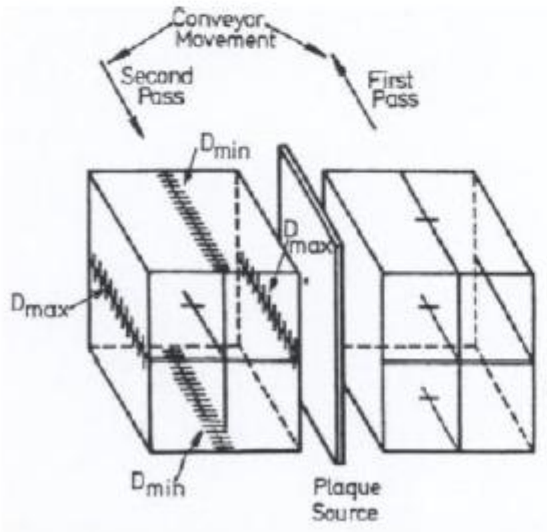
Gamma



Source overlap

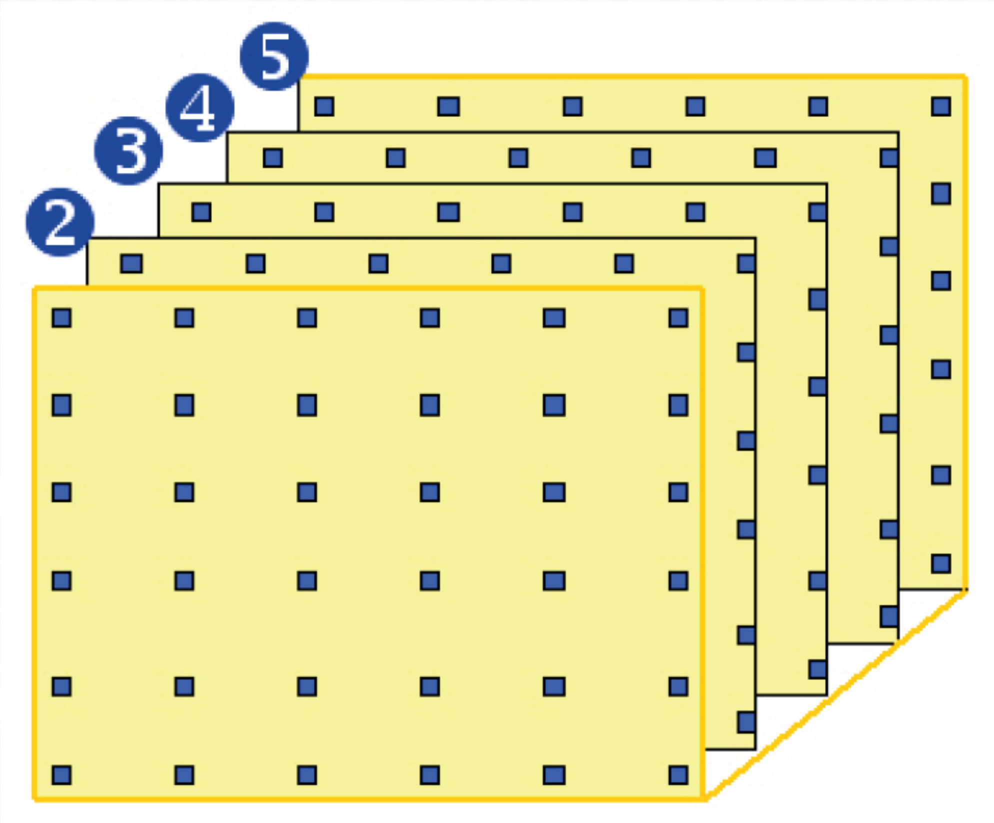


Product overlap

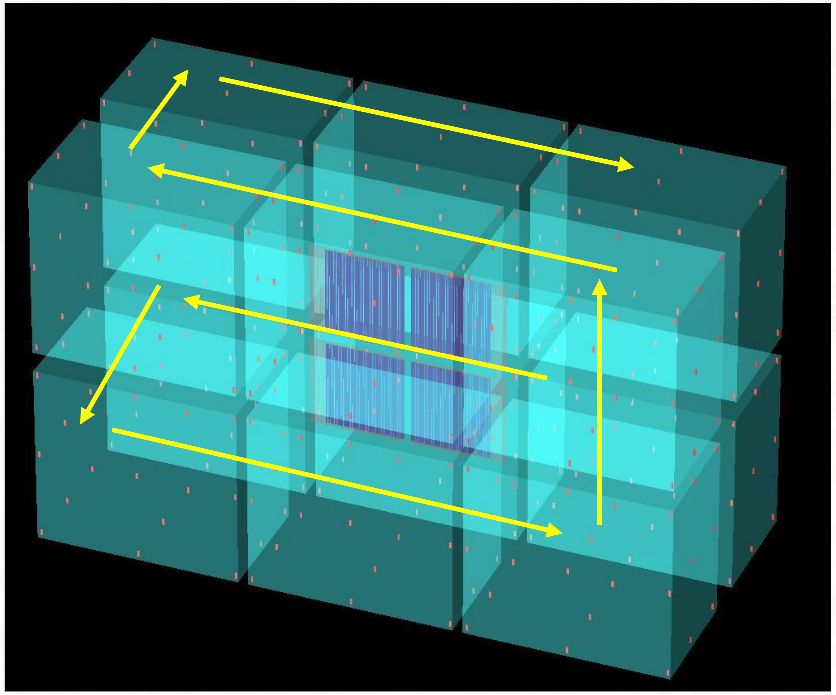


Note: Dosimeter placement for OQ dose mapping may depend on source – product arrangement

Gamma



The number of dosimeter depends on the characteristic of irradiator.



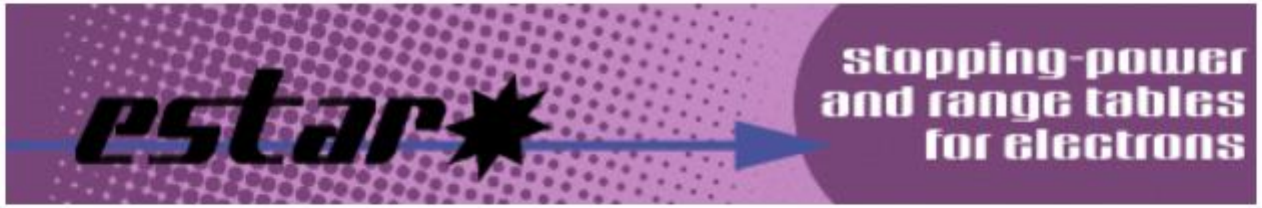
eBeam

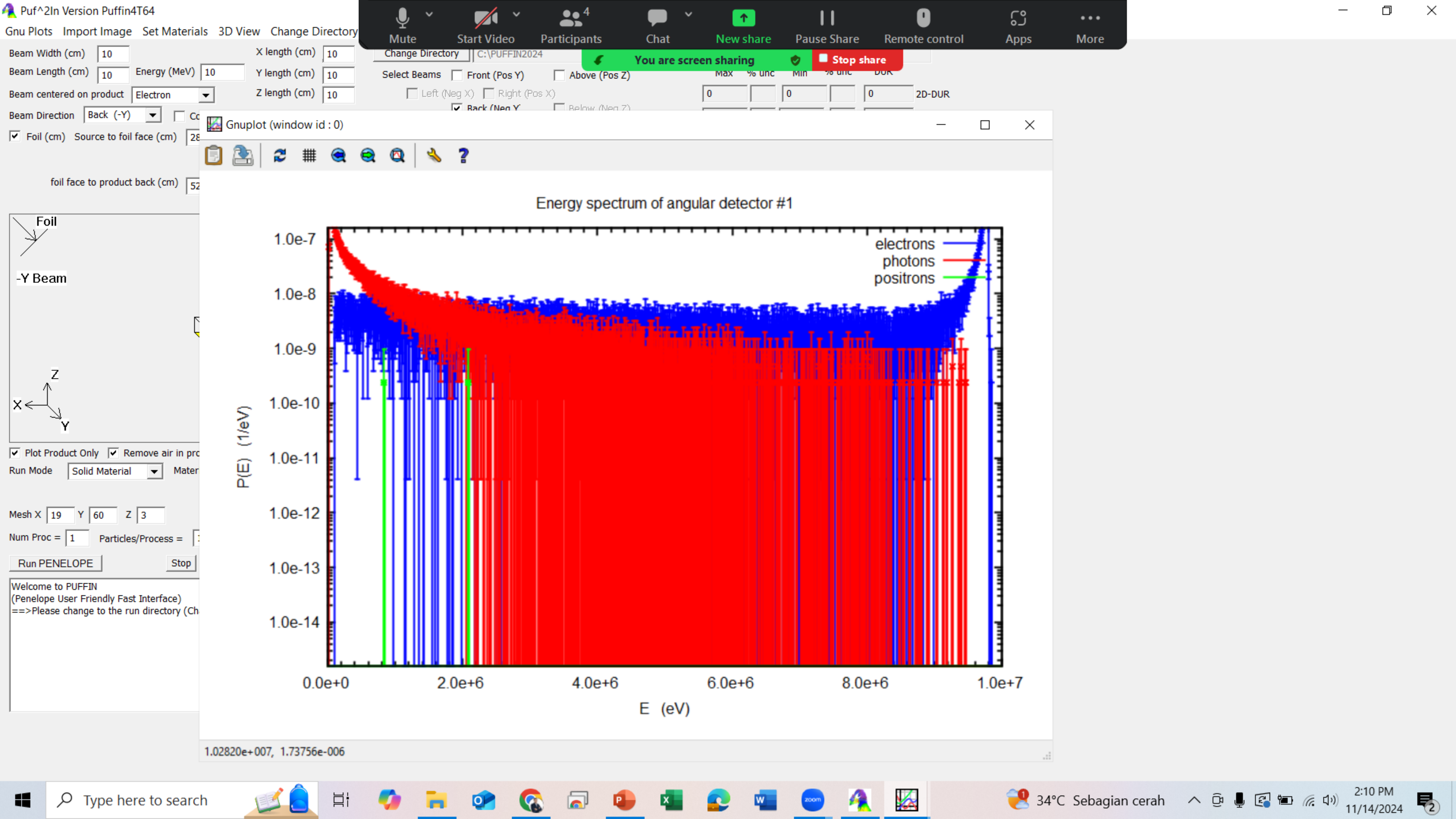
- ❖ Determination of operating parameters

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

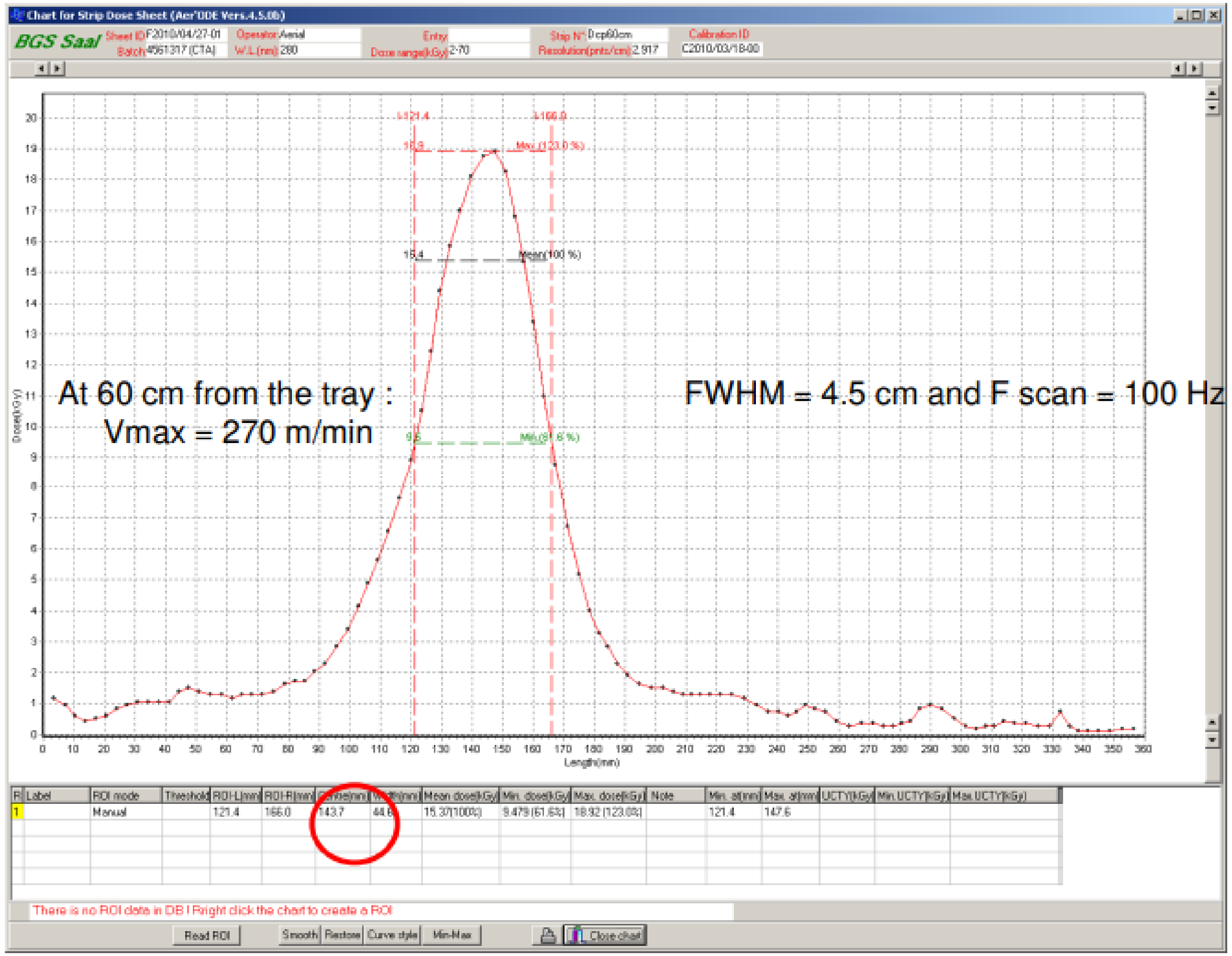
$$\text{Dose at Surface} = \frac{\text{Beam current } (\mu\text{A}) \times \text{Stopping Power Collision } (\mathbf{MeV}\,\frac{\mathbf{cm^2}}{\mathbf{g}})}{\text{Scan Witdh (cm)} \times \text{Conveyor Velocity } (\frac{\text{cm}}{\text{s}})}$$

- Energy = 10 MeV
- Stopping power collision pada 10 MeV water density = 1.968 MeV cm^2/g
- https://physics.nist.gov/PhysRefData/Star/Text/ESTAR.html




Puf^2In Version Puffin4T64
Gnu Plots
Import Image
Set Materials
3D View
Change Directory
Mute
Start Video
Participants
Chat
New share
Pause Share
Remote control
Apps
More
You are screen sharing
Stop share
Beam Width (cm)
10
Beam Length (cm)
10
Energy (MeV)
10
Beam centered on product
Electron
Beam Direction
Back (-Y)
Foil (cm)
Source to foil face (cm)
foil face to product back (cm)
X length (cm)
10
Y length (cm)
10
Z length (cm)
10
Change Directory
C:\PUFFIN2024
Select Beams
Front (Pos Y)
Above (Pos Z)
Left (Neg X)
Right (Pos X)
Back (Neg Y
Below (Neg Z)
2D-DUR
Gnuplot (window id : 0)
Foil
-Y Beam
Z
X
Y
Plot Product Only
Remove air in pro
Run Mode
Solid Material
Mesh X
19
Y
60
Z
3
Num Proc =
1
Particles/Process =
Run PENELOPE
Stop
Welcome to PUFFIN
(Penelope User Friendly Fast Interface)
==>Please change to the run directory (Ch
Energy spectrum of angular detector #1
electrons
photons
positrons
1.0e-7
1.0e-8
1.0e-9
1.0e-10
1.0e-11
1.0e-12
1.0e-13
1.0e-14
P(E) (1/eV)
0.0e+0
2.0e+6
4.0e+6
6.0e+6
8.0e+6
1.0e+7
E (eV)
1.02820e+007, 1.73756e-006
Type here to search
34°C Sebagian cerah
2:10 PM
11/14/2024

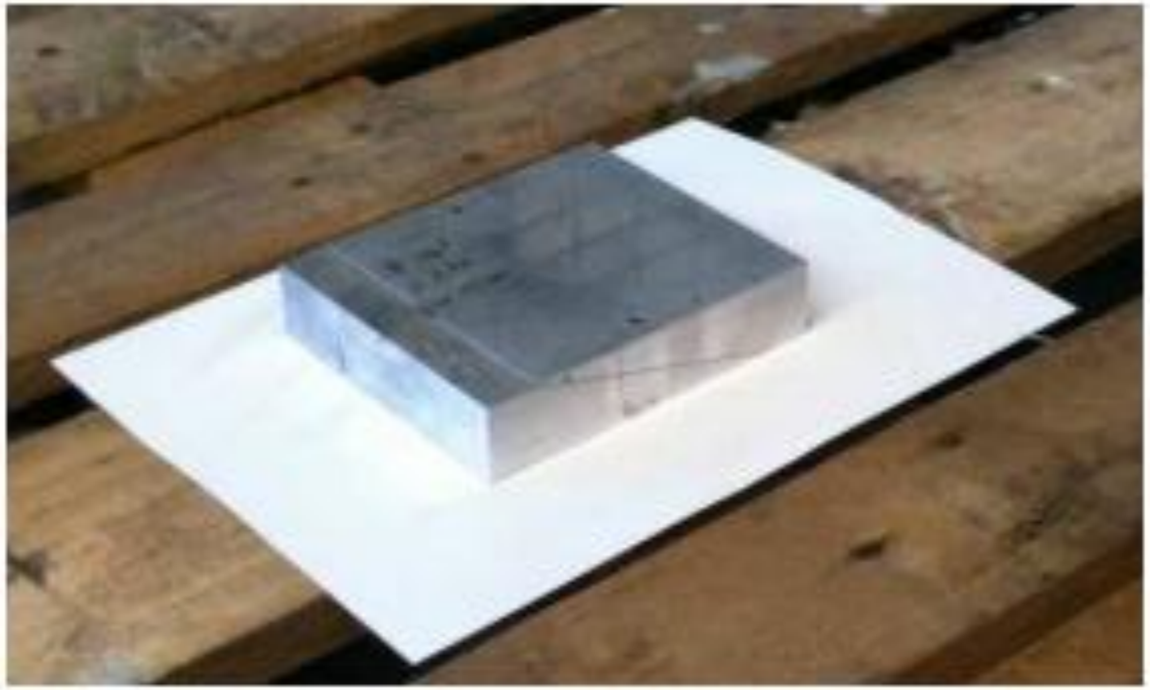
eBeam



At 60 cm from the tray :
Vmax = 270 m/min

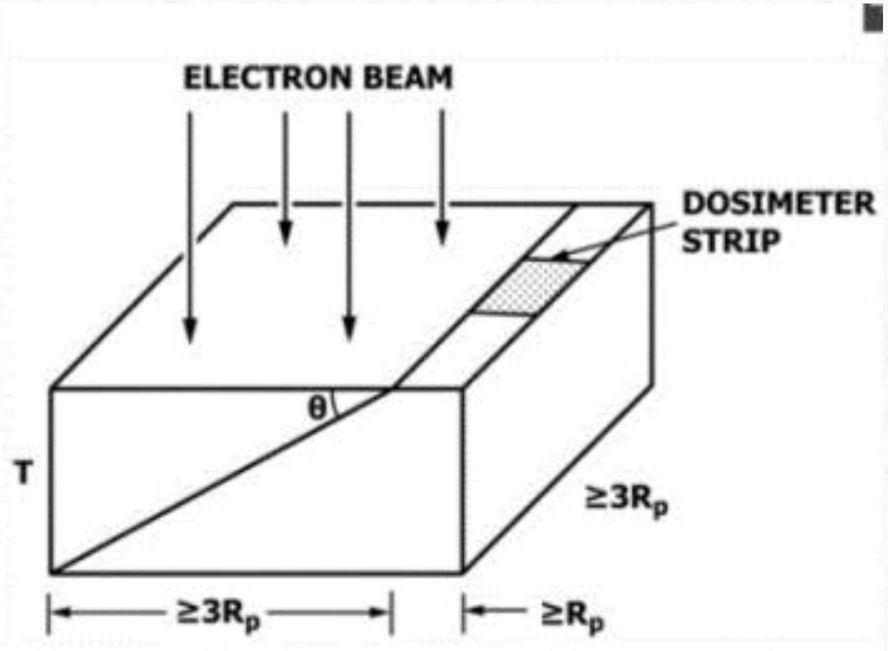
FWHM = 4.5 cm and F scan = 100 Hz

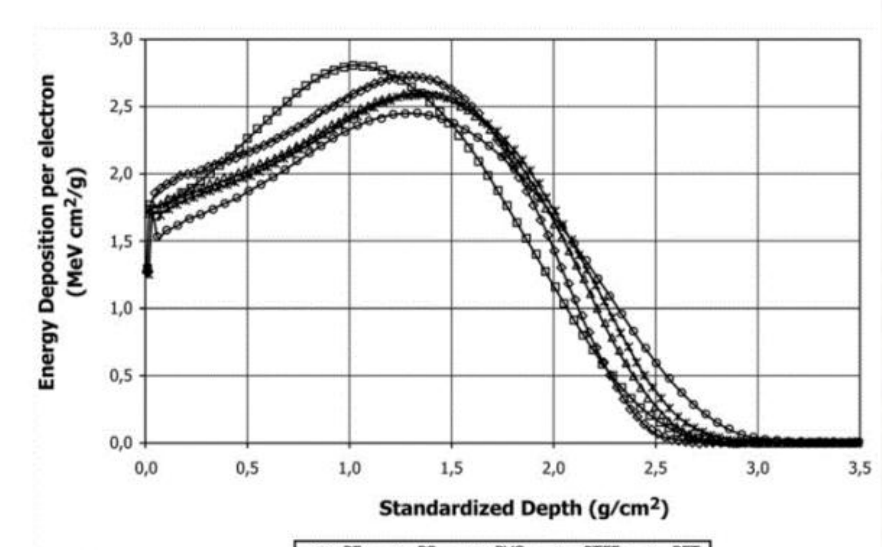
eBeam

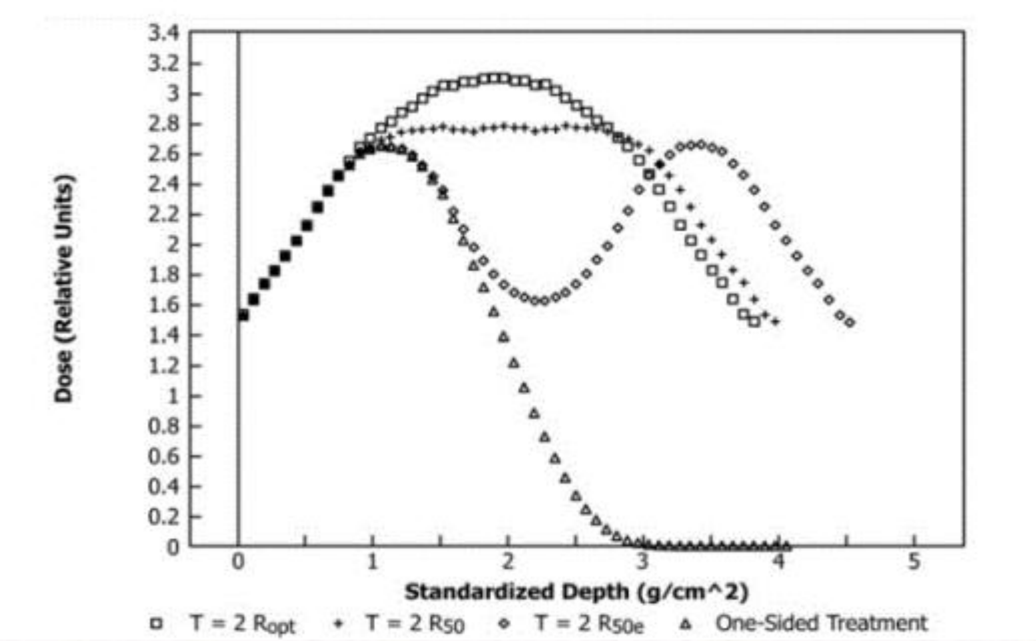


Density : 2.73 g/cm^3
Angle : 16 °

eBeam


ELECTRON BEAM
DOSIMETER STRIP
θ
T
≥3Rp
≥3Rp
≥Rp


Energy Deposition per electron (MeV cm²/g)
Standardized Depth (g/cm²)
3,0
2,5
2,0
1,5
1,0
0,5
0,0
0,0
0,5
1,0
1,5
2,0
2,5
3,0
3,5

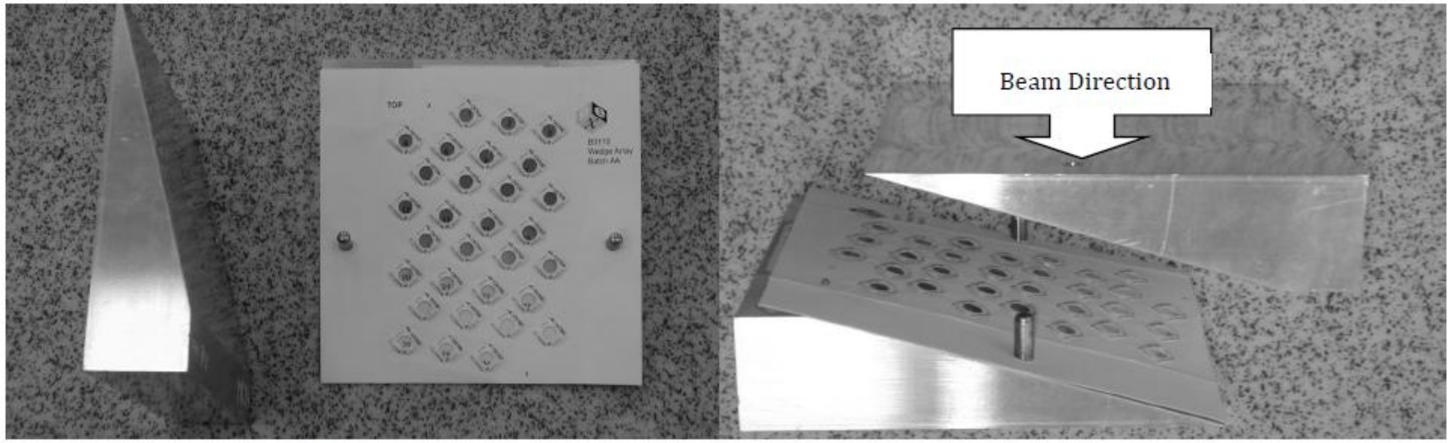

Dose (Relative Units)
Standardized Depth (g/cm^2)
T = 2 Ropt
T = 2 R50
T = 2 R50e
One-Sided Treatment

eBeam

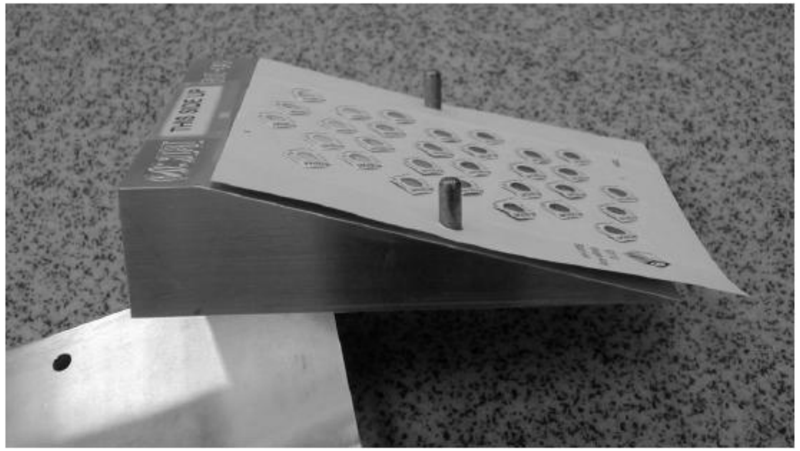
SPECIFICATIONS

Nominal Product Dimensions	Packaging Dimensions	Product Weight
12cm (L) x 14cm (W) x 2.9cm (H) ± 0.1mm	8.5” x 5” x 1.25” / 22.9cm x 15.2cm x 5.1cm	4.0 lbs. / 1.81 kg

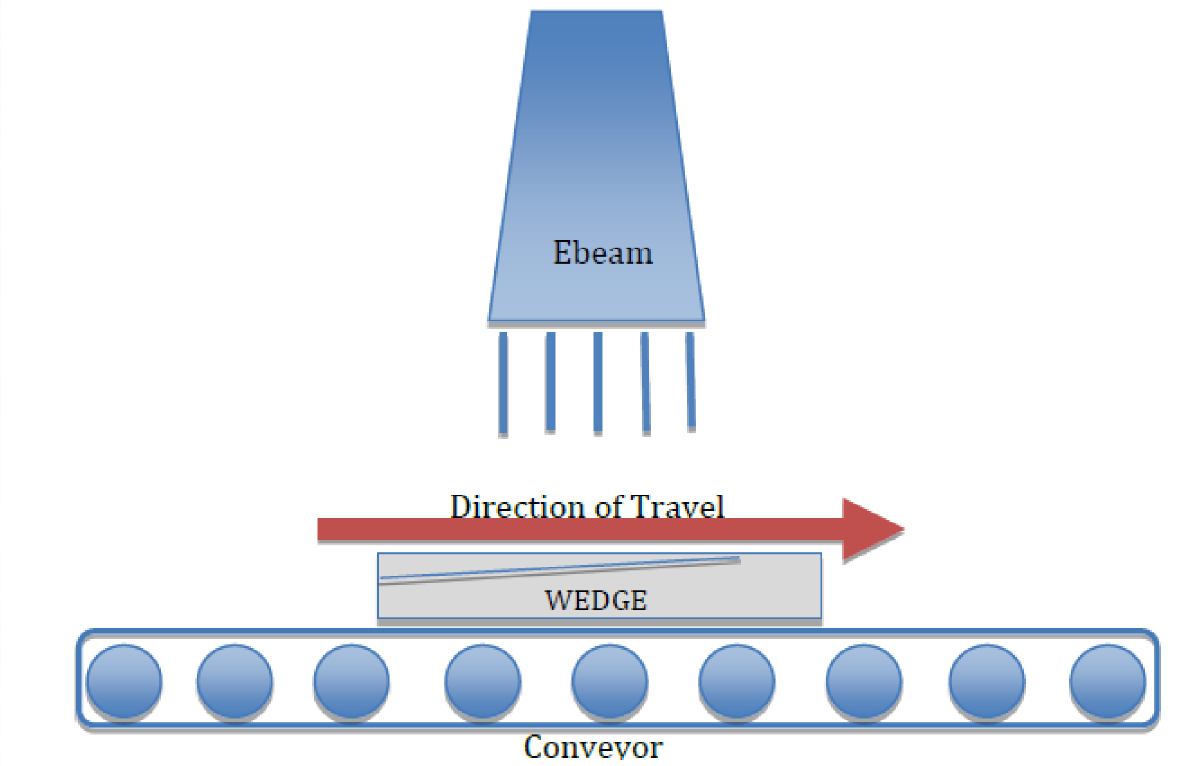
Material:	Aluminum
Color:	Silver (natural)
Printing:	Engraved serial number denoting A (top) and B (bottom) halves of the wedge.
Angle:	16.0° ± 0.3°
Energy Range:	Using strip film: approximately 2 MeV to 20 MeV Using arrays of B3 WINdose dosimeters: 4 MeV to 12 MeV
Precision (MeV):	Precision of the measured energy will depend on the precision of the electron beam system, but experience confirms that the user should expect ± 0.3 MeV or better.

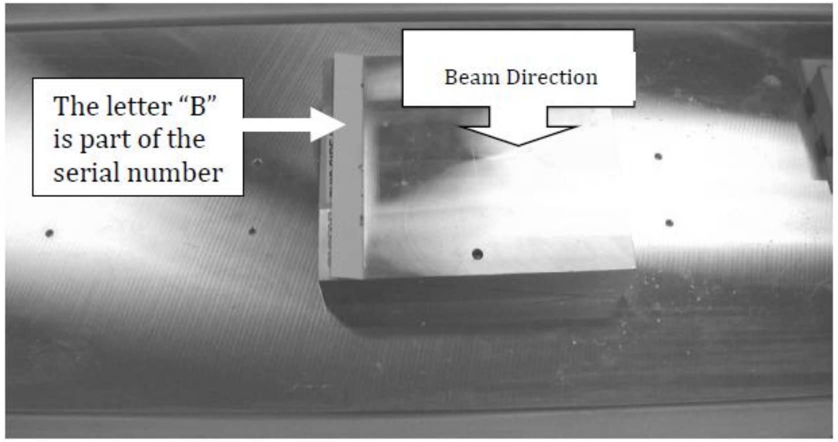


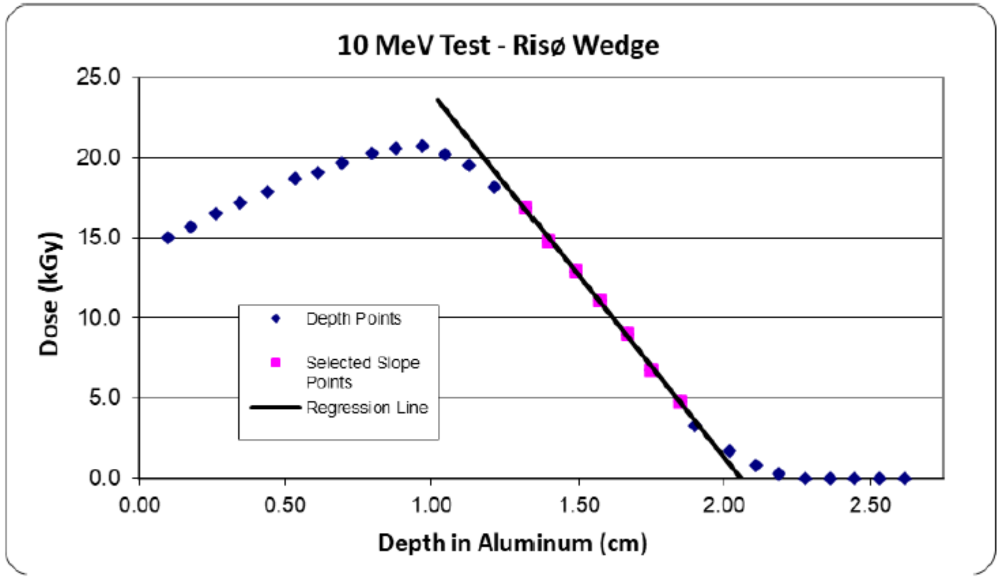
Top view Side view



eBeam







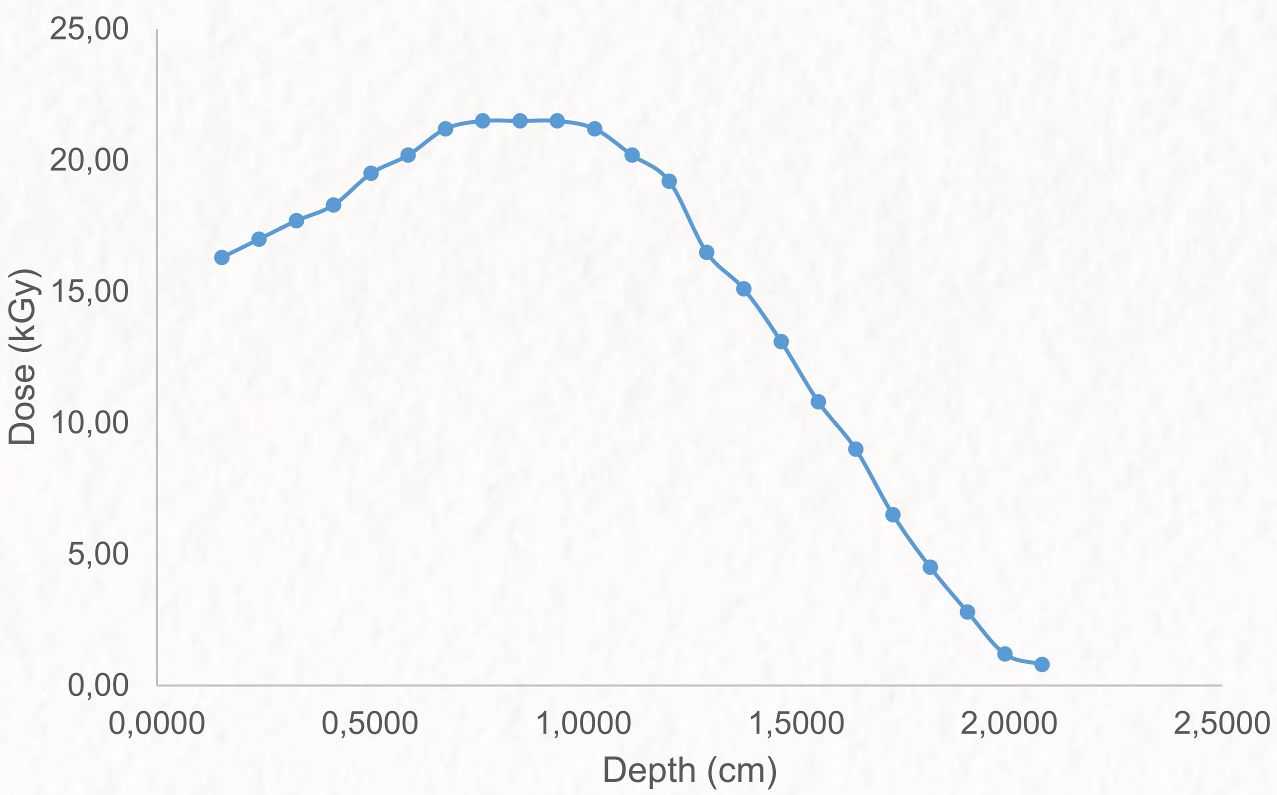
10 MeV Test using an array of B3 dosimeters at increasing depth in the P4701 Risø Aluminum Wedge

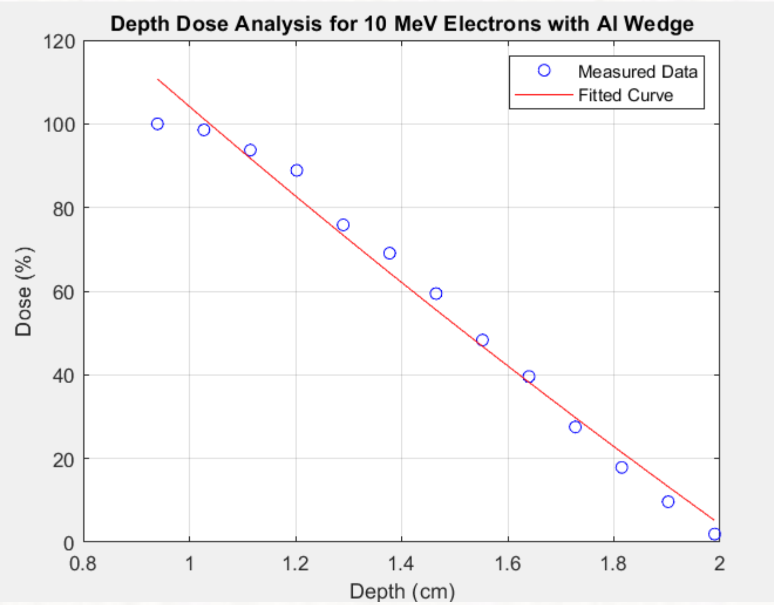
eBeam

RECORD SHEET OF DOSIMETERS				
Sample:	Energy		Irradiation Date:05/12/2024	
irradiation dose: 15 kGy			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	
Dosimeter	Dosimeter	Dosimeter	Irradiated	Dose
Position	Number	ID Number	Absorbance (Ai)	(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 Position	Dosimeter Number	Dosimeter ID Number	Irradiated Absorbance (Ai)	Dose (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

eBeam



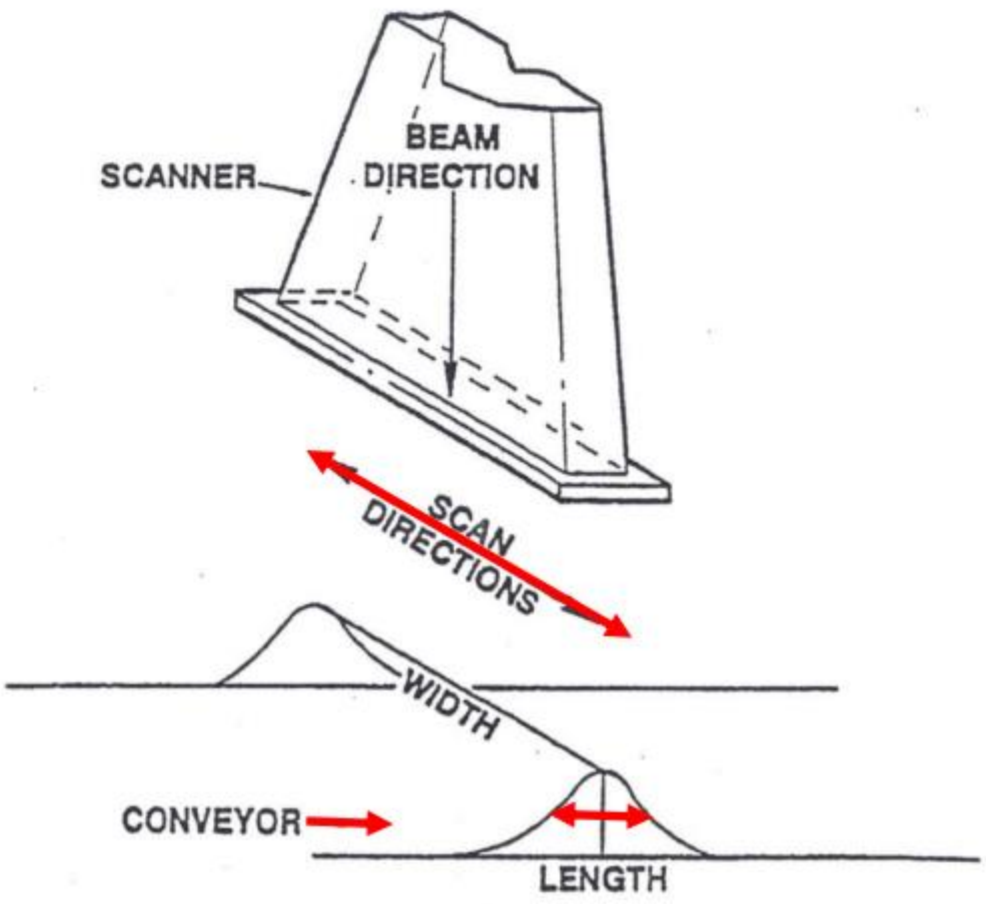


Ep = 0.20 + 5.09 * Rp

Ea = 6.2 * R50

- 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

eBeam



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

eBeam

Conveyor speed control

First part of tray (before the beam stop)		Second part of tray (after the beam stop)	
Duration s	Calculated speed m/min	Duration s	Calculated speed m/min
2,98	5,03	3,13	4,79
3,04	4,93	2,94	5,10
3,12	4,81	2,94	5,10
2,99	5,02	3,07	4,89
3,08	4,87	3,13	4,79
2,85	5,26	3,03	4,95
3,03	4,95	2,98	5,03
3,07	4,89	3,05	4,92
3,02	4,97	3,02	4,97
3,02	4,97	3,03	4,95
2,98	5,03	3,09	4,85
3,09	4,85		
Average	4,97	Average	4,94
Standard dev.	0,12	Standard dev.	0,11
CV%	2,4%	CV%	2,2%

→ no significant difference in speed between the conveyors located before and after the beam stop

eBeam

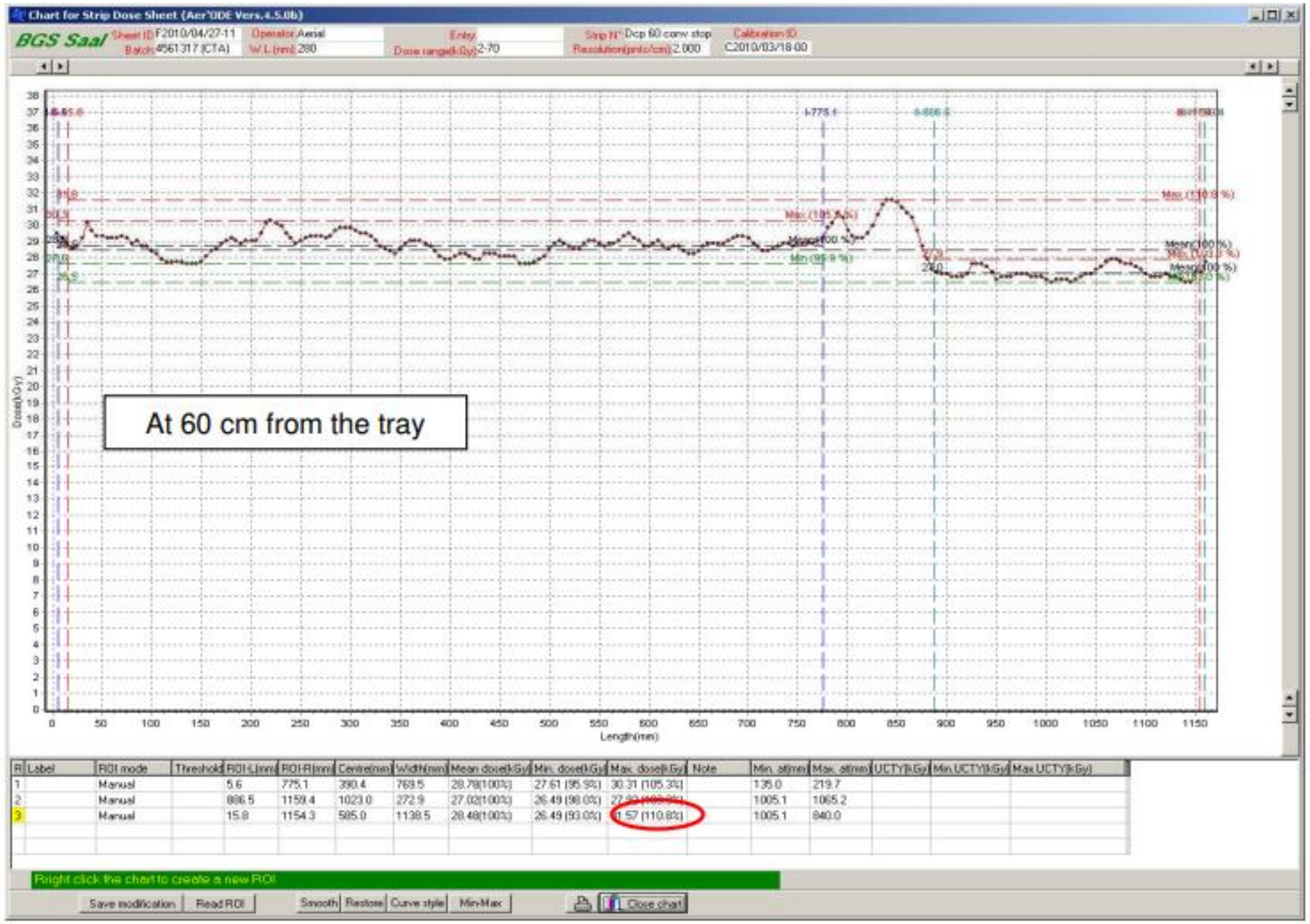
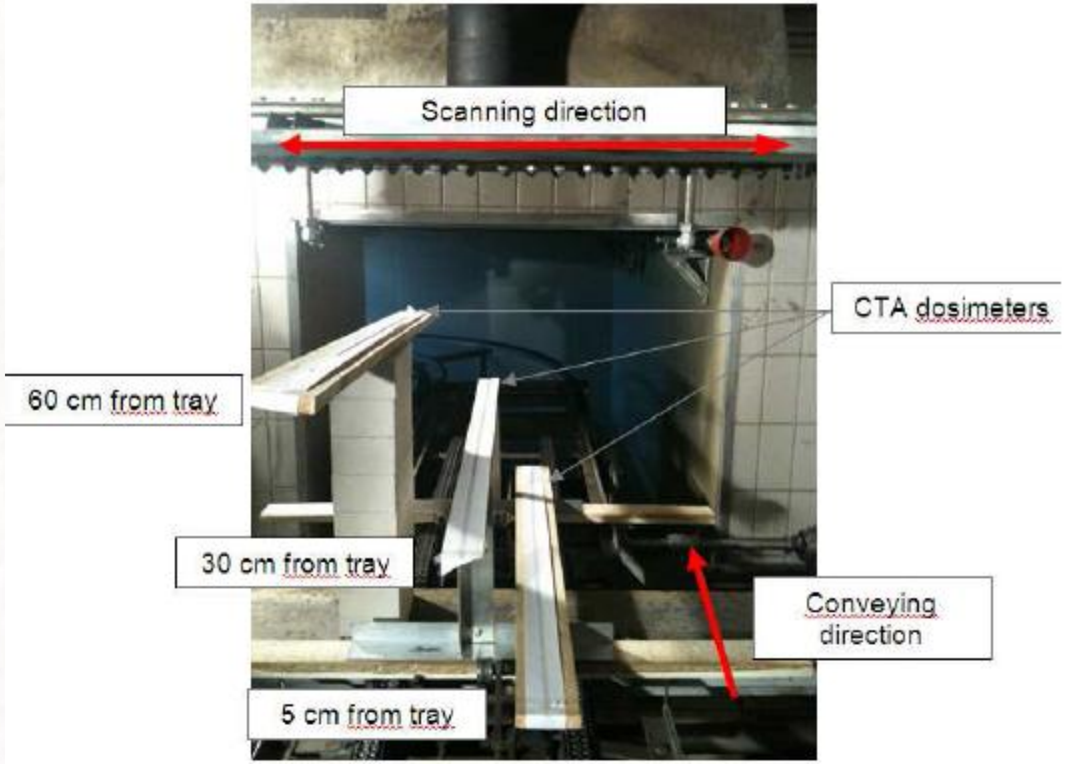
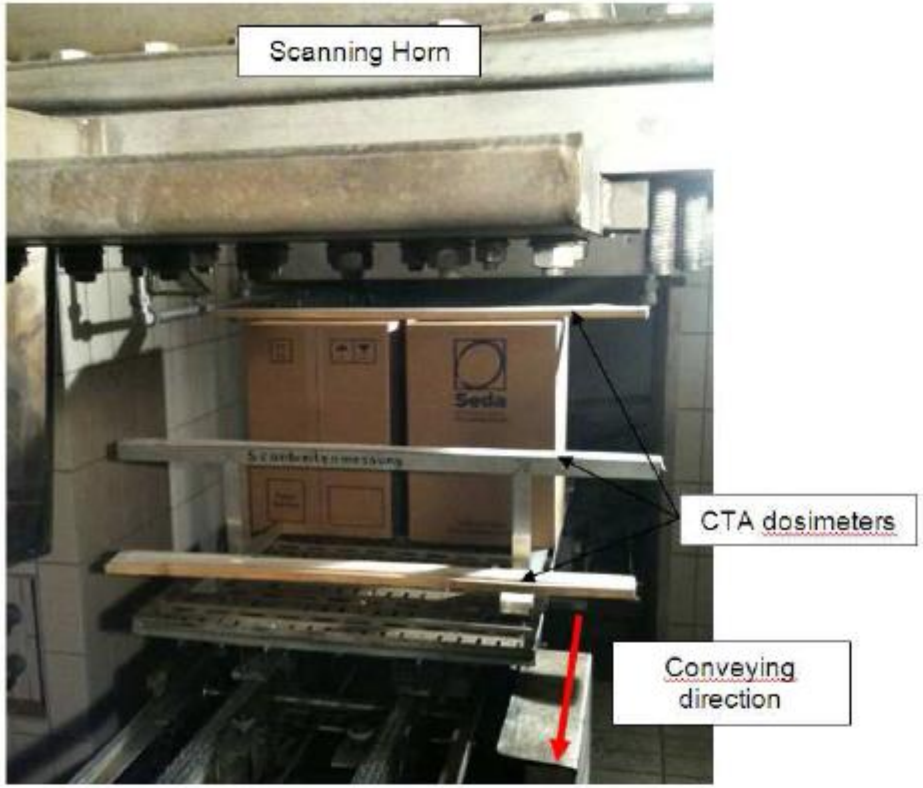
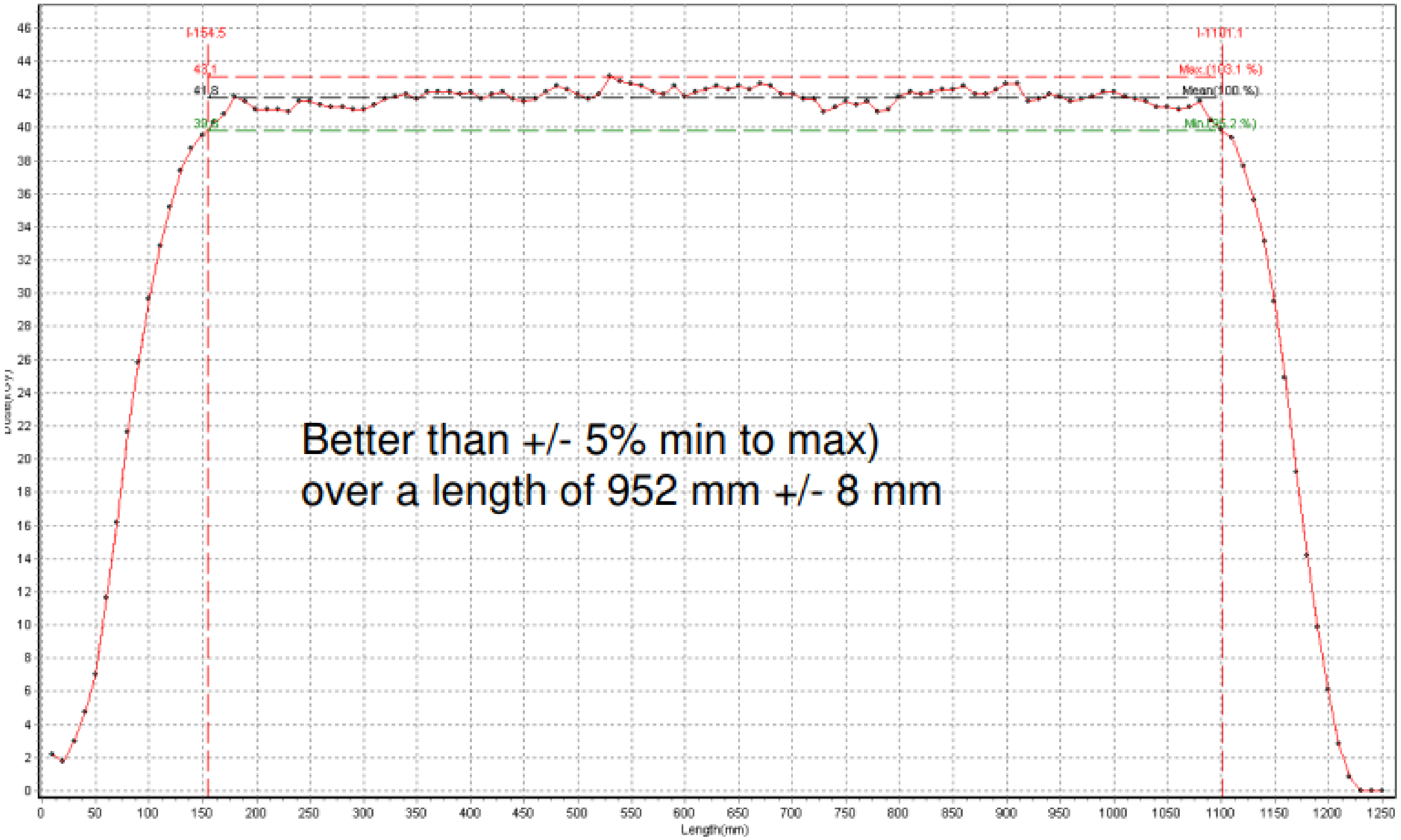


Chart for Strip Dose Sheet
BGS Saal
At 60 cm from the tray
Length(mm)
Right click the chart to create a new ROI
Save modification
Read ROI
Smooth
Restore
Curve style
Min-Max
Close chart


Scanning direction
CTA dosimeters
60 cm from tray
30 cm from tray
Conveying direction
5 cm from tray


Scanning Horn
CTA dosimeters
Conveying direction

eBeam


Better than +/- 5% min to max)
over a length of 952 mm +/- 8 mm
Max (103.1 %)
Mean(100 %)
43.1
41.8
Length(mm)

3 Peformance Qualification

Peformance 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

Peformance Qualification

9.3.1 Concerns dose mapping of real product

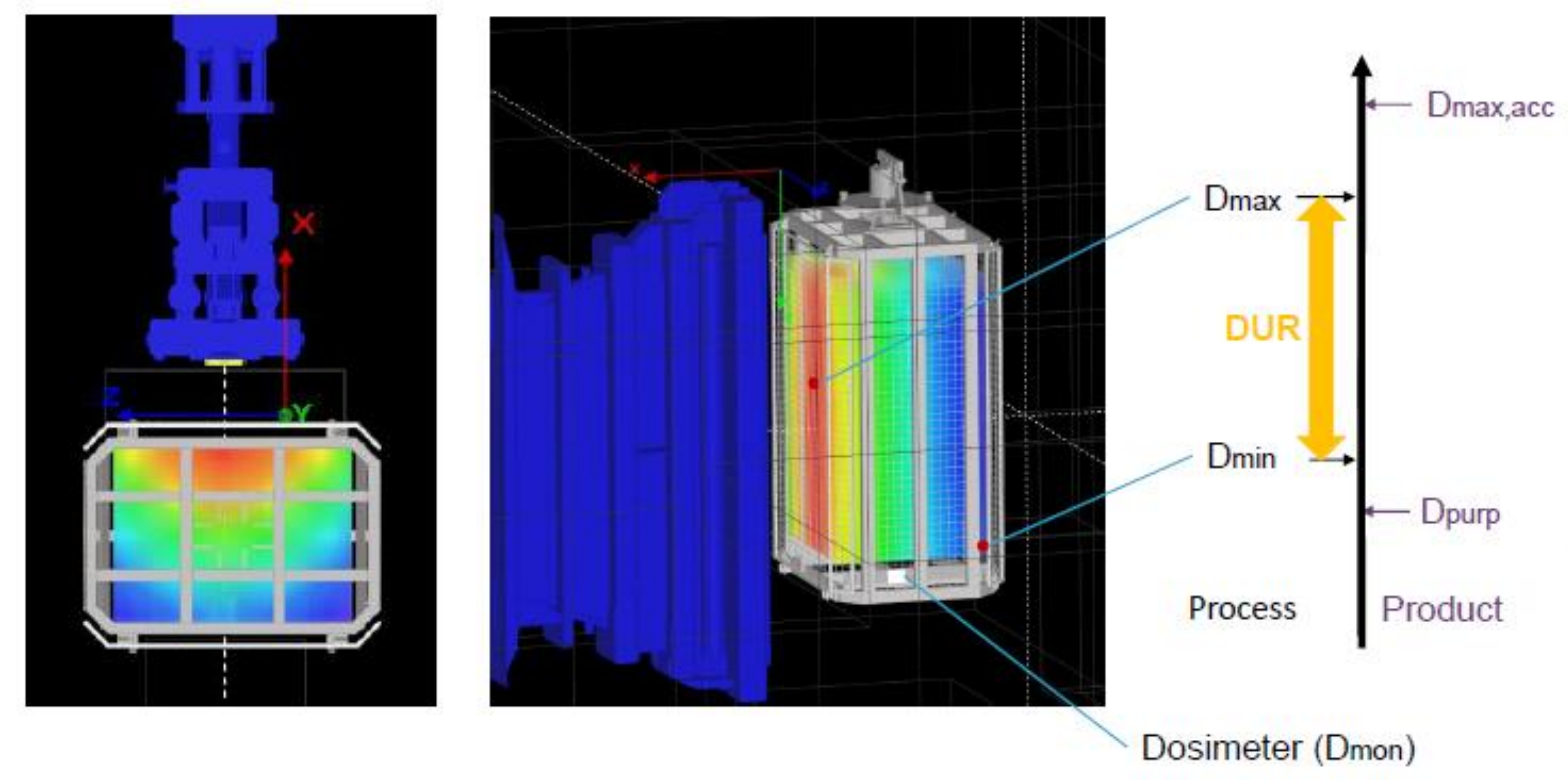
to identify the location and magnitude of minimum and maximum doses

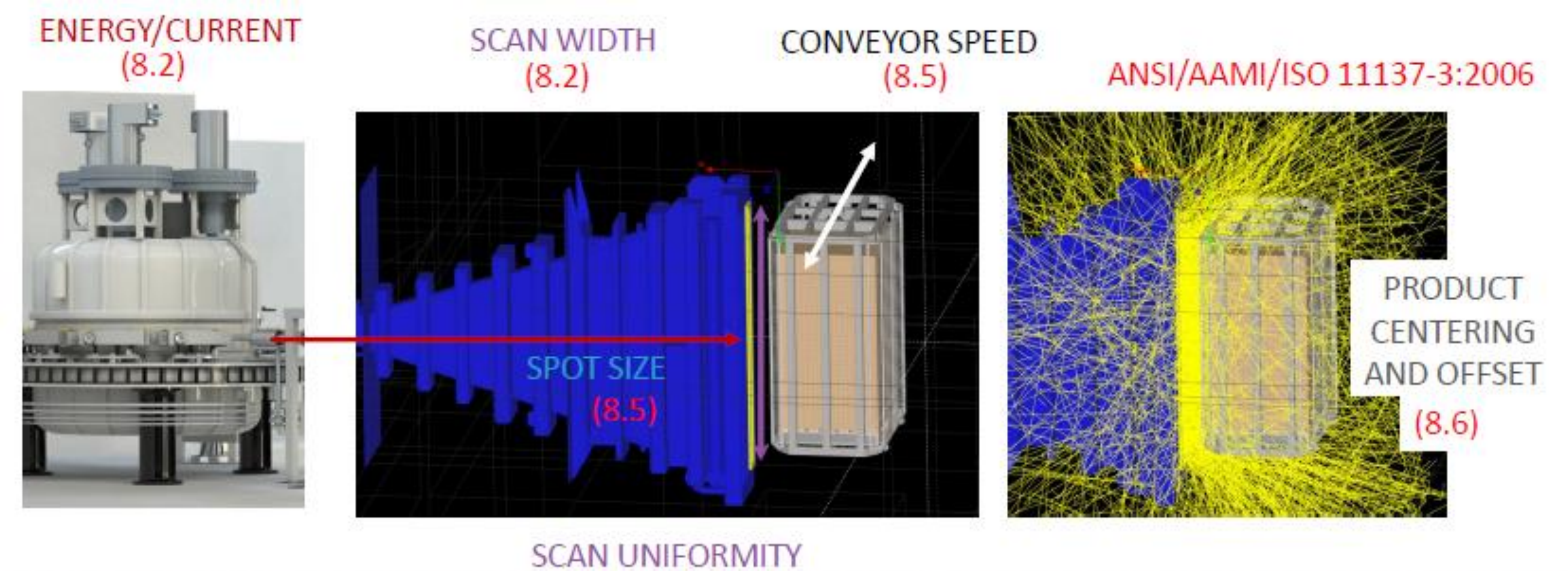
And

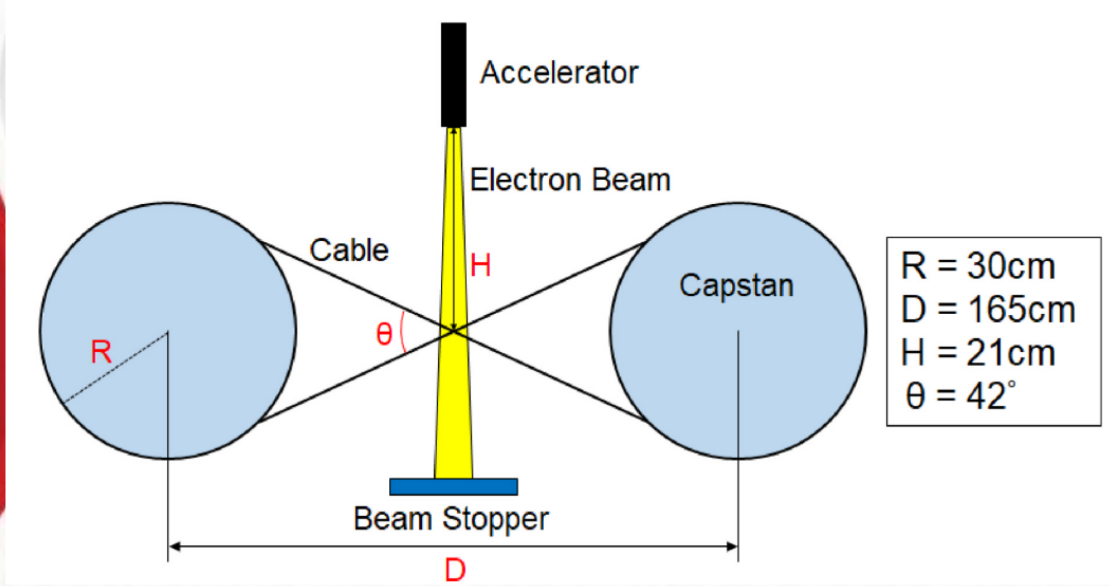
to determine the relationship between the min and max doses and the routine monitoring dose

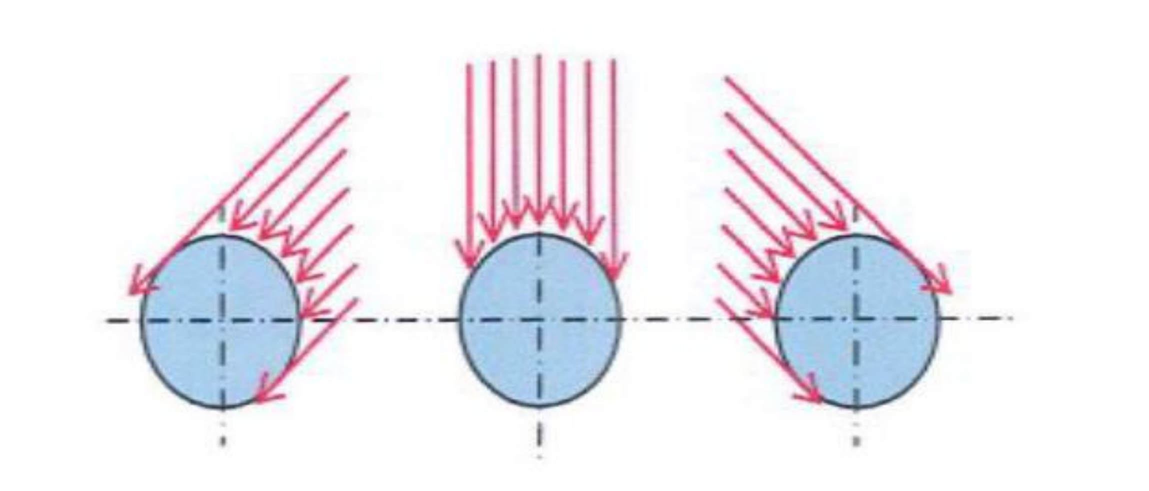
$$D_{min} \geq D_{Ster}$$
$$D_{max} \leq D_{max,acc}$$

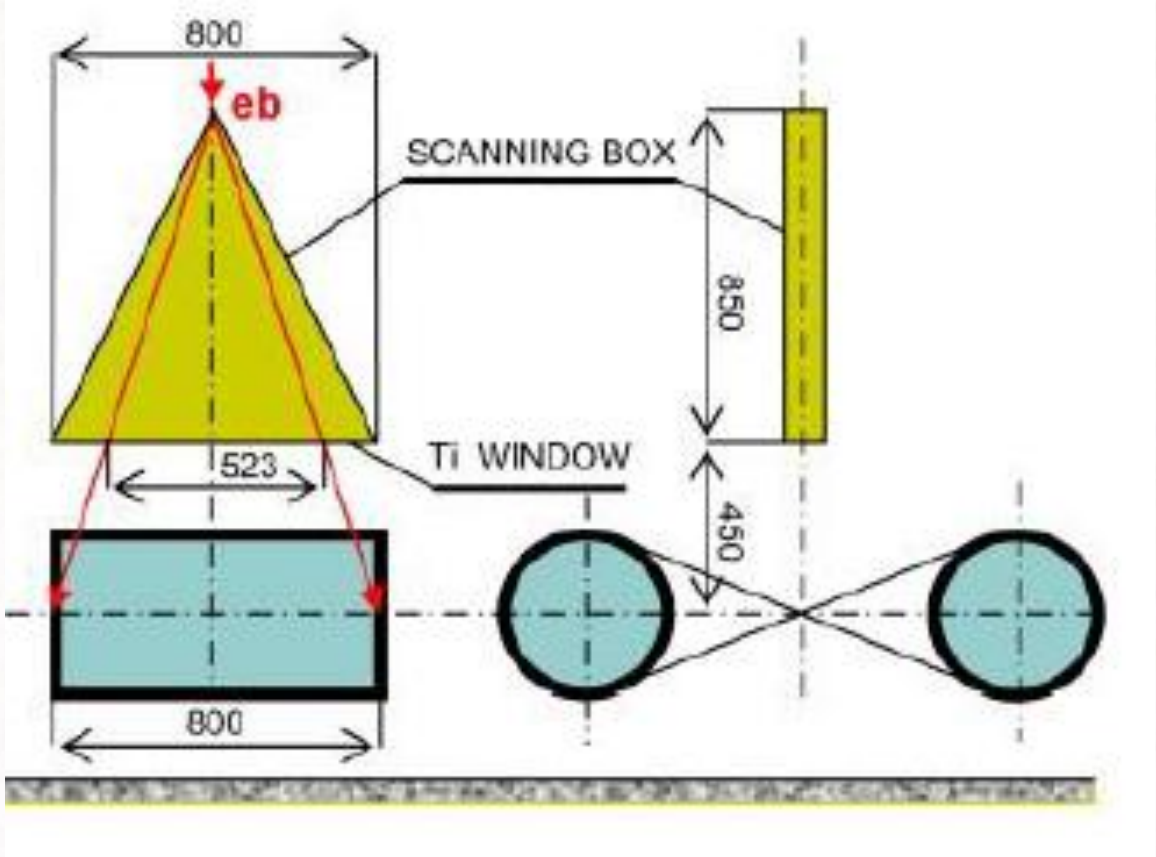
Dmindetermined by sterilization requirements
Dmaxdetermined by radiation-induced changes in product


Dmax,acc
Dmax
DUR
Dmin
Dpurp
Process
Product
Dosimeter (Dmon)


ENERGY/CURRENT
(8.2)
SCAN WIDTH
(8.2)
CONVEYOR SPEED
(8.5)
ANSI/AAMI/ISO 11137-3:2006
SPOT SIZE
(8.5)
PRODUCT
CENTERING
AND OFFSET
(8.6)
SCAN UNIFORMITY


Accelerator
Electron Beam
Cable
H
θ
R
Capstan
Beam Stopper
D
R = 30cm
D = 165cm
H = 21cm
θ = 42˚




800
eb
SCANNING BOX
850
523
Ti WINDOW
450
800

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 ^{o}C - temperature rise 2.63 ^{o}C/kGy

polyethylene 2.30J/g ^{o}C – temperature rise 0.43 ^{o}C/kGy.

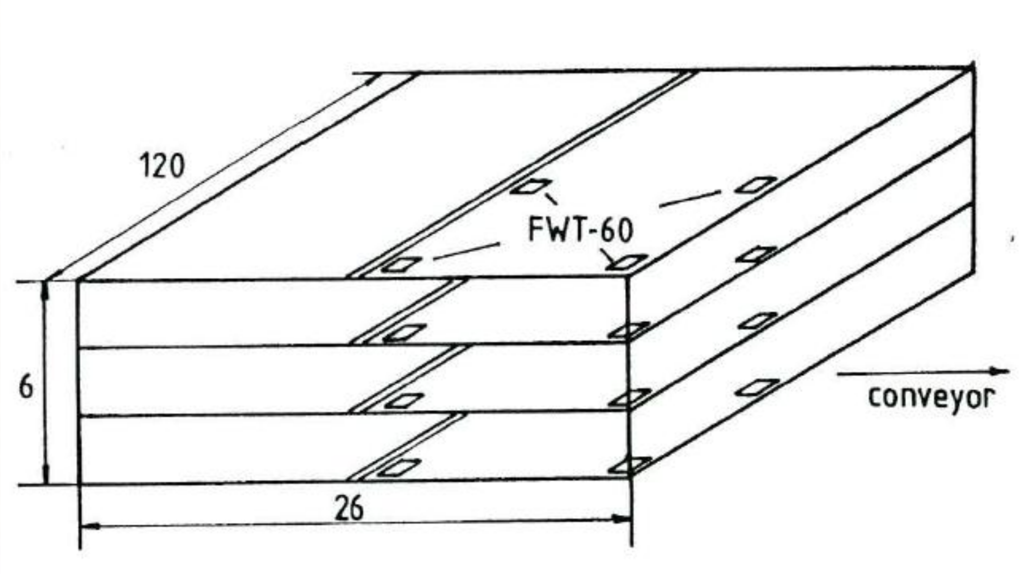
4 Process Control

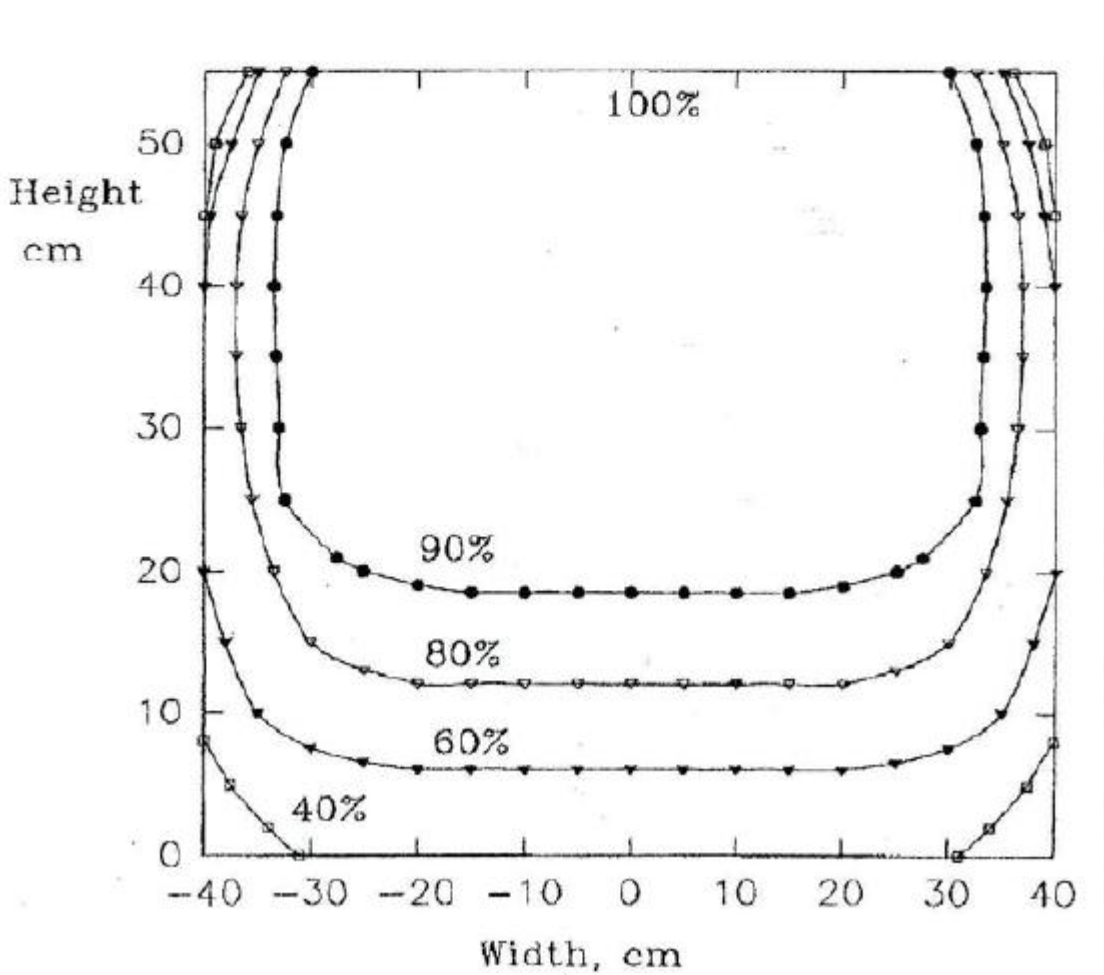
Process Control

General requirements of dose mapping:

1. over a range of operating parameters covering the operational limits;
2. density within ther ange of use(more is better);
3. at least three irradiation containers to be dose mapped;
4. to place dosimeters in a three dimensional array including surface;
5. mathematical modelling to optimize the positioning of dosimeters;
6. to establish the effect of process interruption on the dose;
7. to determine relationships between characteristics of the beam, the conveyor speed and the magnitud eof dose at a defined location

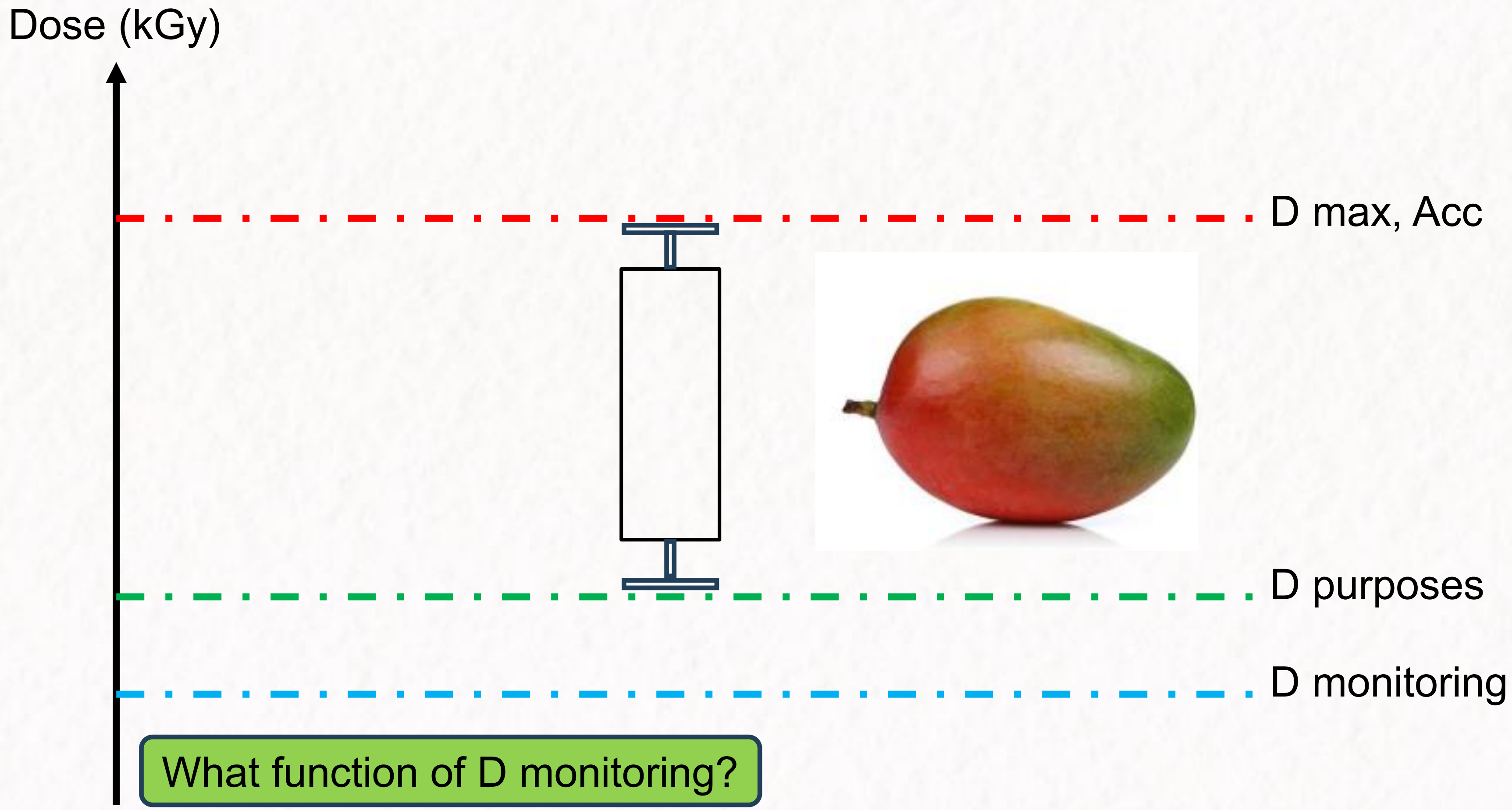
Process Control





Key point: Higher density, lower penetrations

Process Control



Process Control

Experimental
- GEX Windose B3 and alanine were used for dose mapping
- 10 MeV E-Beam double sided irradiation along the Z axis
- Dosimeters placed at suspected minimum and maximum dose zones

Organized box
- DUR (alanine)= 1.55
- DUR (B3) = 1.57

Monte Carlo

Organized box
- DUR = 1.67

Unorganized box
- DUR (alanine) = 1.76
- DUR (B3) = 1.79

Monte Carlo

Unorganized box
- DUR = 1.88

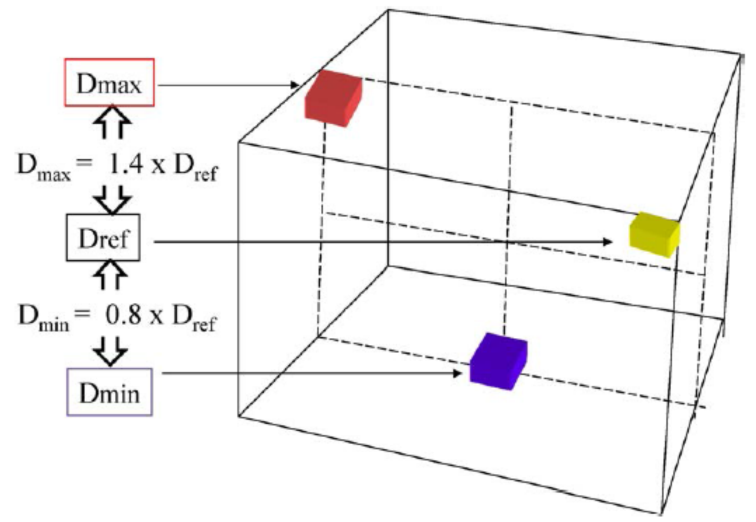
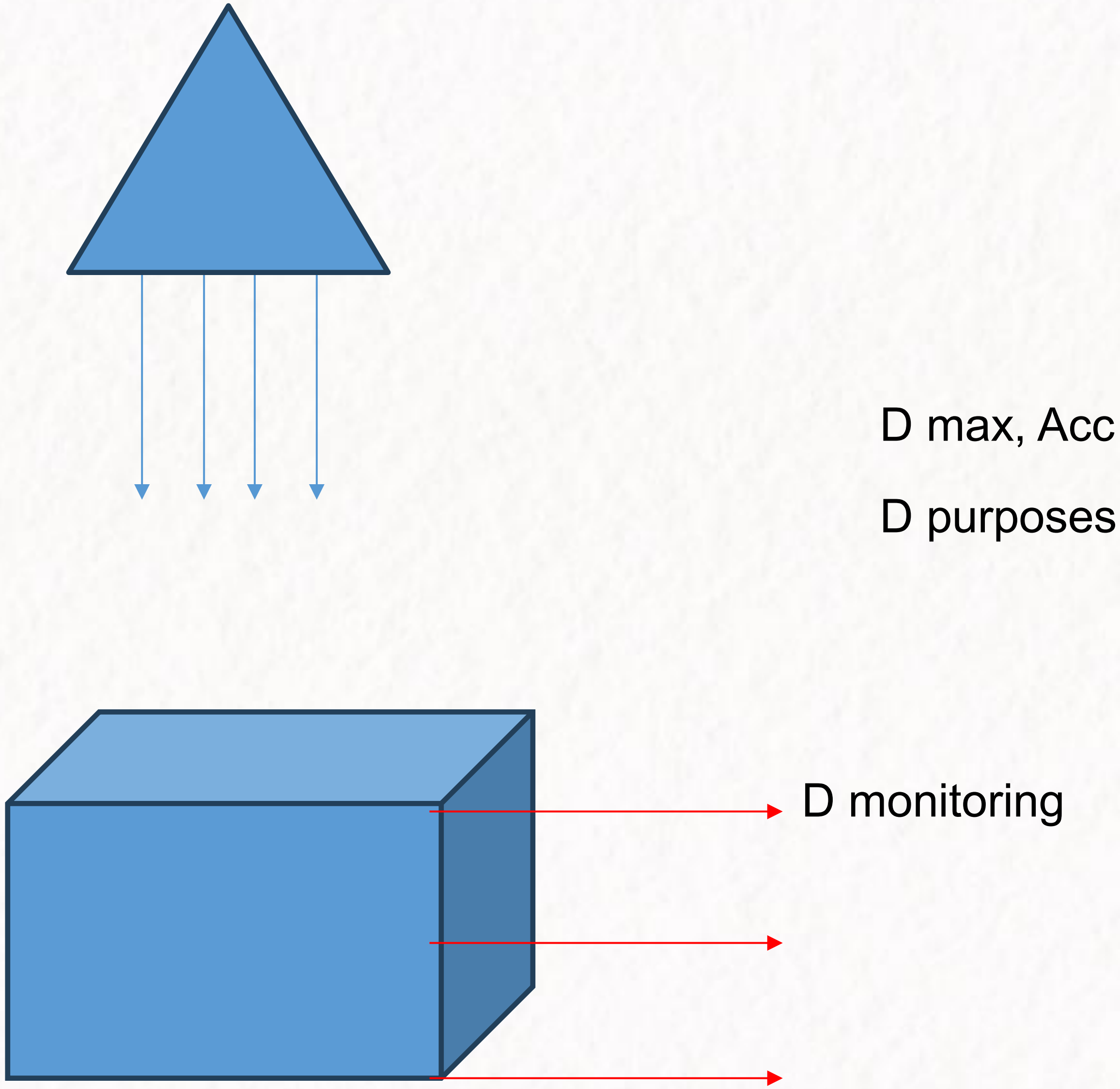


FIG. 17. Relationship between minimum and maximum doses and the dose in the reference position.



Terima Kasih

THANK YOU

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