Florent KUNTZ

Tools and requirements for food irradiation process control

Outline

- Reference documents (code of practice, standards, guides, …)
- Why is dosimetry that important?
- Dosimetry journey for satisfactory food irradiation processing
- IQ/OQ/PQ and process monitoring
- Selection of dosimetry tools
- Conclusion

Outline

CODEX ALIMENTARIUS

World Health Organization

Food and Agriculture Organization of the United Nations

ISO

Reference documents:

- CODEX GENERAL STANDARD FOR IRRADIATED FOODS CODEX STAN 106-1983, REV.1-2003
- INTERNATIONAL CODE OF PRACTICE FOR RADIATION PROCESSING OF FOOD (CAC/RCP 19-1979)
- 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

Outline

Reference documents:

- F1355-19 Standard Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment
- F1356-16 Standard Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms
- F1640-16 Standard Guide for Selection and Use of Contact Materials for Foods to Be Irradiated
- F1736-09(2016) Standard Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms
- F1885-18 Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

Outline

Reference documents:

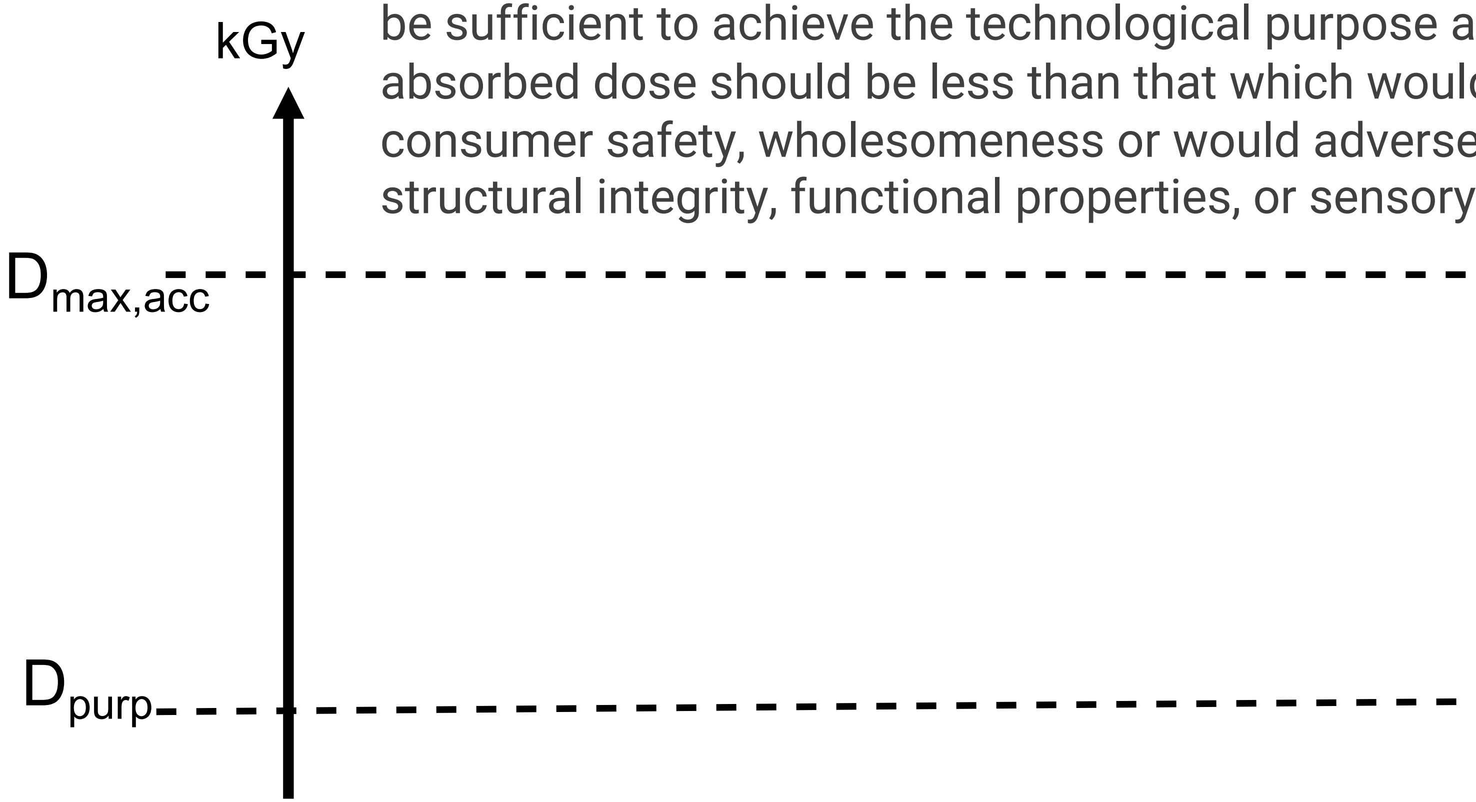
- ISO/ASTM51608-15 Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV
- ISO/ASTM51649-15 Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV
- ISO/ASTM51702-13 Standard Practice for Dosimetry in a Gamma Facility for Radiation Processing

- ANSI/AAMI/ ISO 11137-1:2006/(R)2010 & A1:2013 Requirements for a sterilization process
- ANSI/AAMI/ISO 11137-3:2017 Guidance on dosimetric aspects
- ISO/TS 11137-4:2020 Guidance on process control

Why is dosimetry that important?

Product / technological purpose

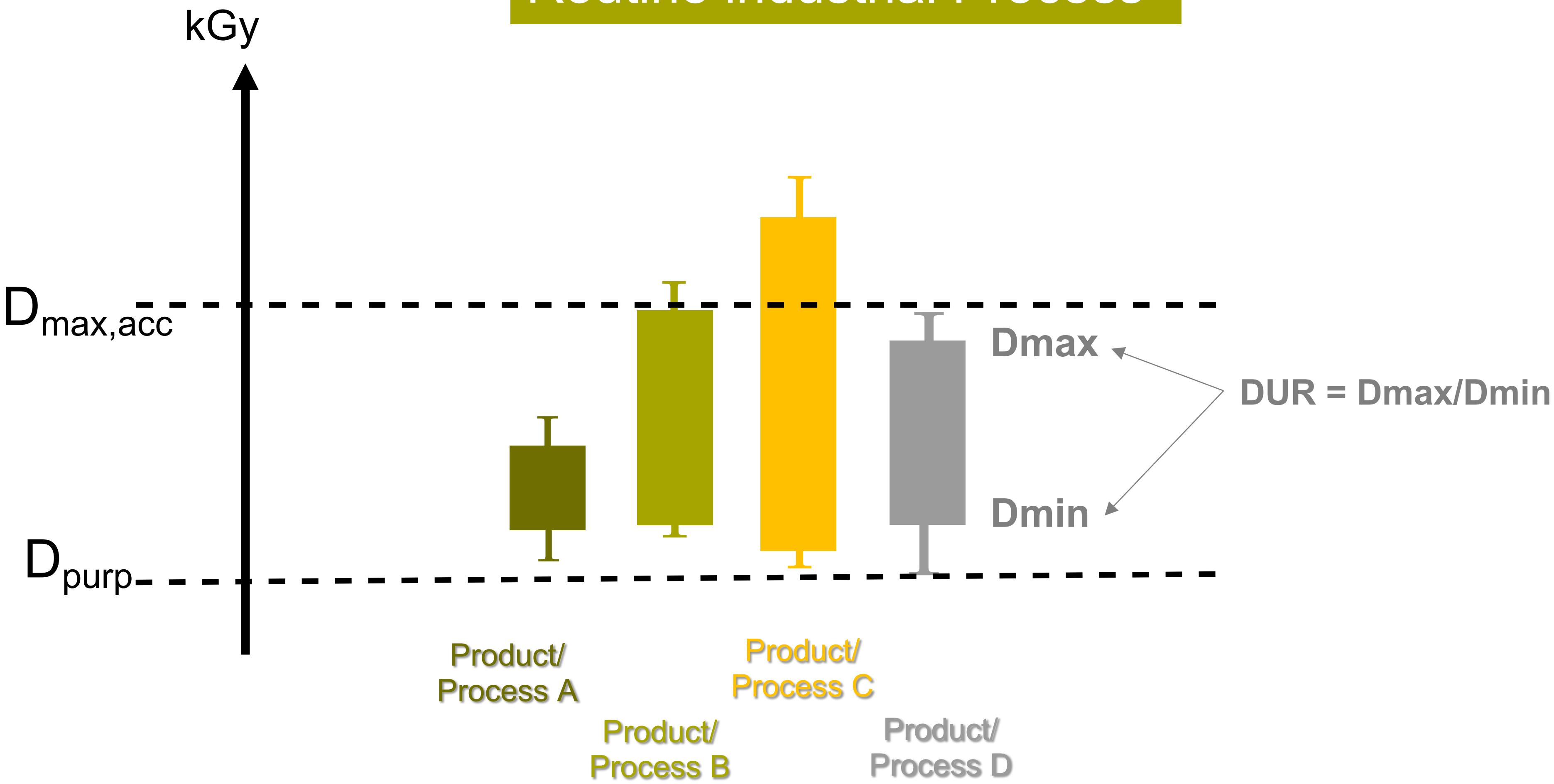
CODEX GENERAL REQUIREMENTS FOR THE PROCESS (2.2)
For the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes.



Why is dosimetry that important?

Product / technological purpose

Routine industrial Process

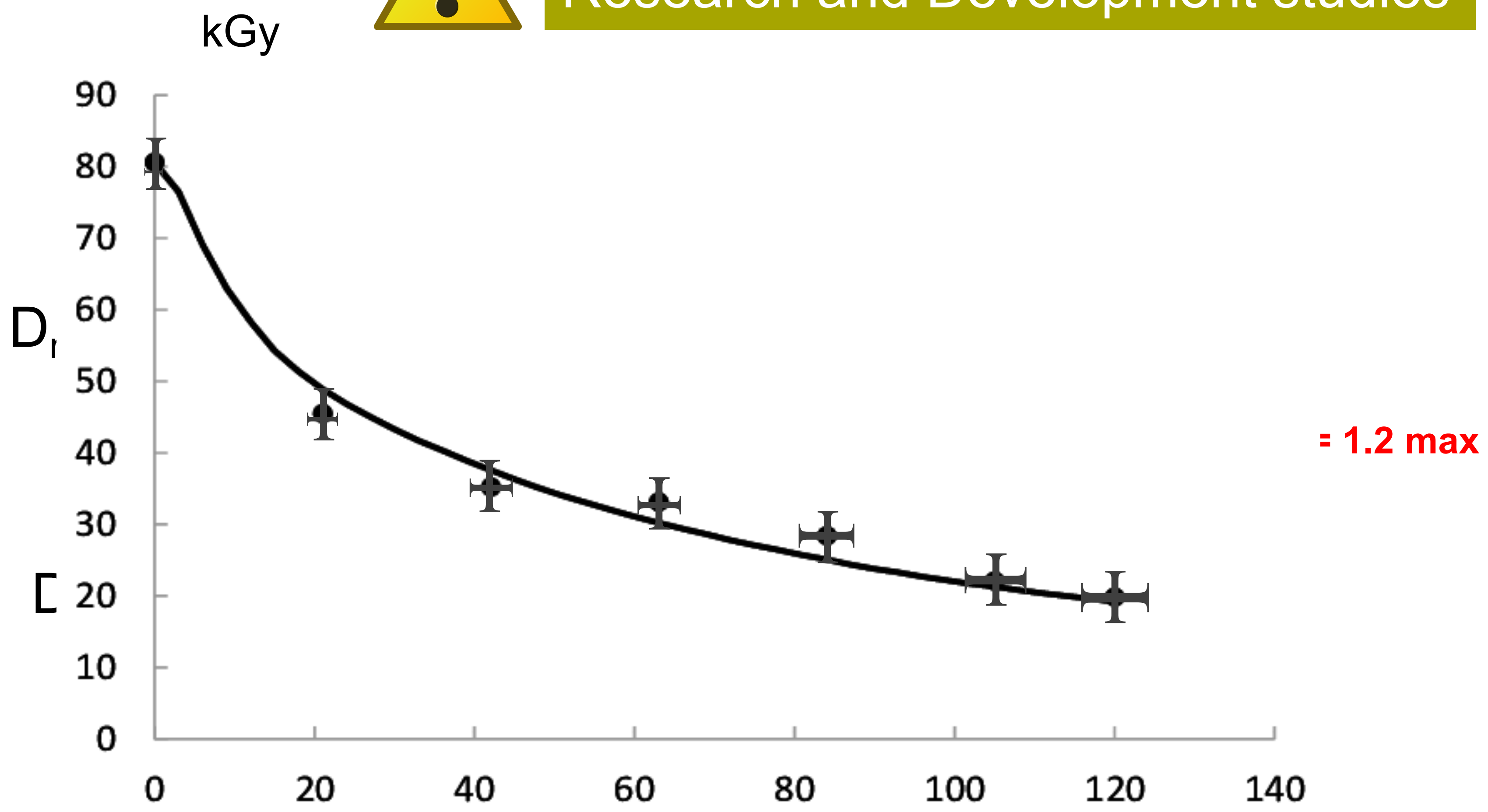


→ Make sure that the product, the process is adapted … and monitor the process

Why is dosimetry that important?

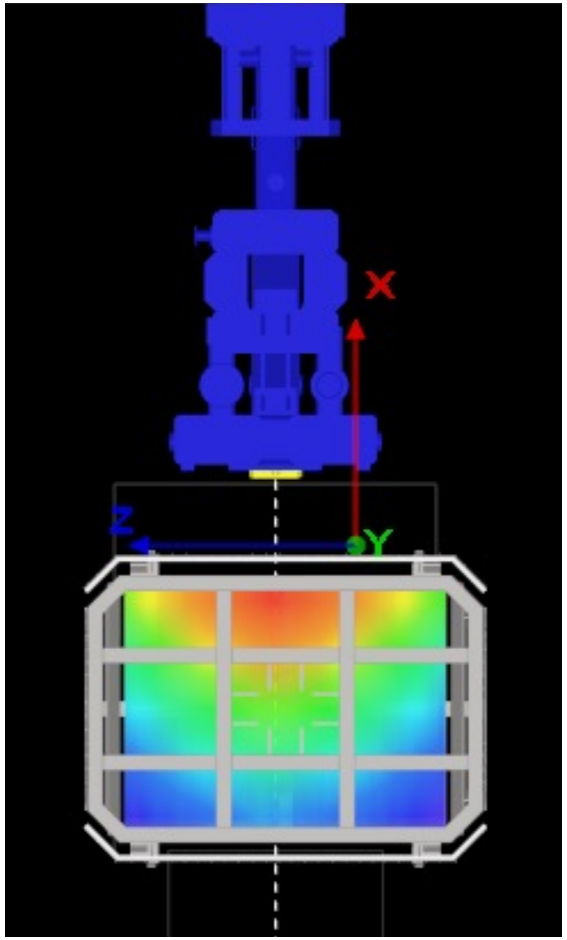
Product / technological purpose

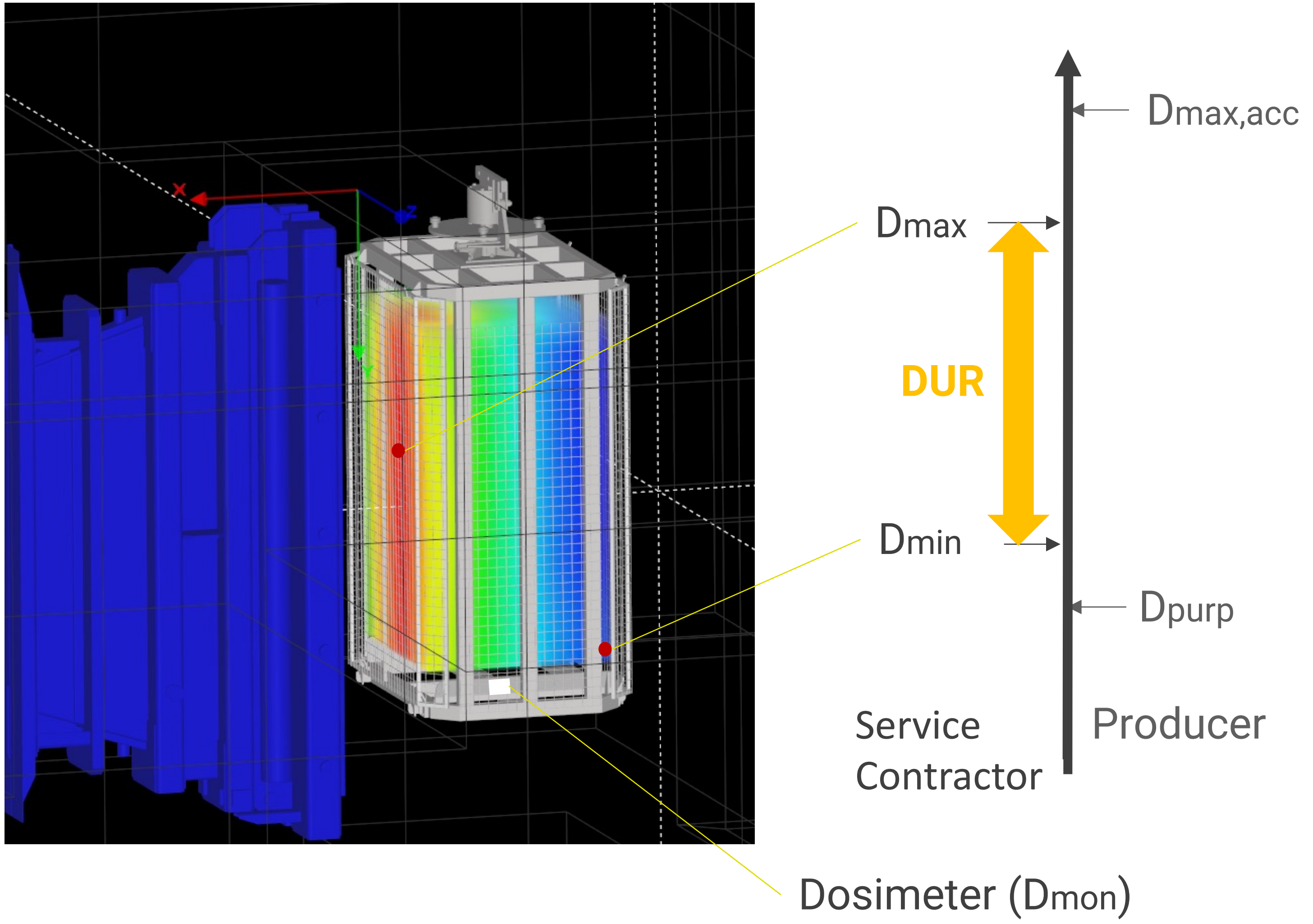
Research and Development studies



→ Make sure that the product, the process is adapted … and monitor the process

Why is dosimetry that important?





Dosimetry journey for satisfactory food irradiation processing

From ISO 14470:2011

About dosimetry ... Section 8

- Dosimetry shall be performed to characterize the radiation facility in operational qualification (OQ).
- Dosimetry shall be performed to measure dose distribution in irradiated products in performance qualification (PQ).
- Routine dosimetry shall be performed during product processing to monitor the irradiation process.

→ Usually, no dosimetry needed in IQ

Dosimetry journey for satisfactory food irradiation processing

From ISO 14470:2011 or ISO 11137-1

About Validation ... Section 9

- Installation Qualification
  - To demonstrate that the irradiator has been supplied and installed in accordance with its specifications
    - Source activity, Ebeam current, Energy, Scan width, Scan Uniformity, Conveyor, softwares, …
- Operational Qualification
  - To demonstrate that the irradiator, as installed, is capable of operating and delivering appropriate doses within defined acceptance criteria
    - Establish baseline data → evaluating effectiveness, predictability, reproducibility, …

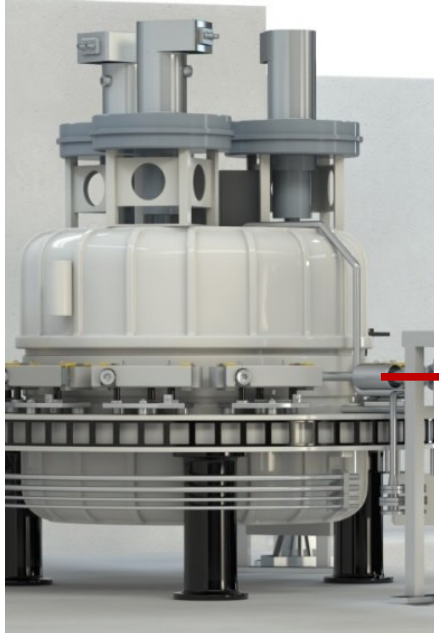
Description of an X-ray process

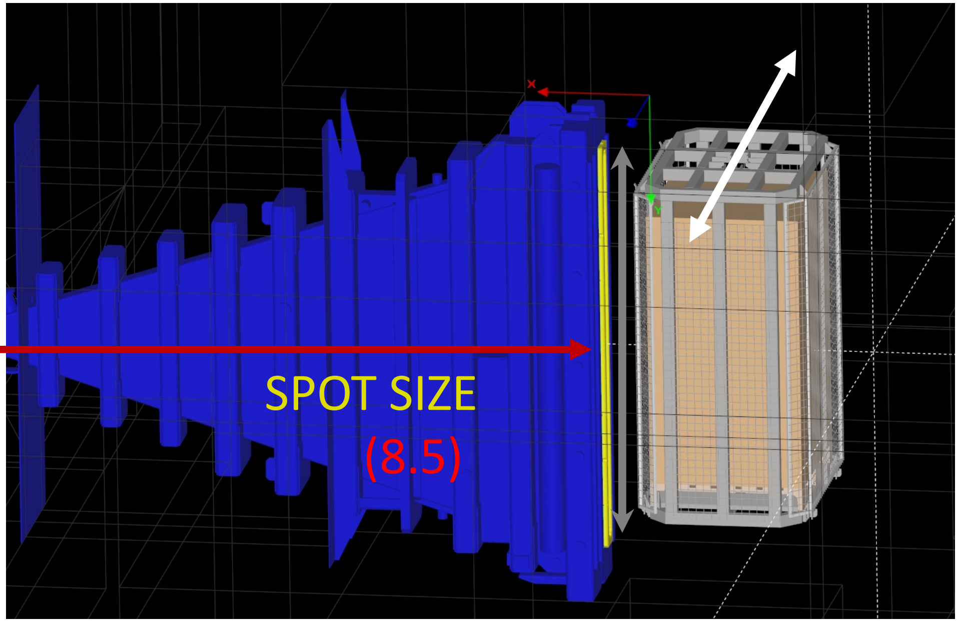
ANSI/AAMI/ISO 11137-3:2006

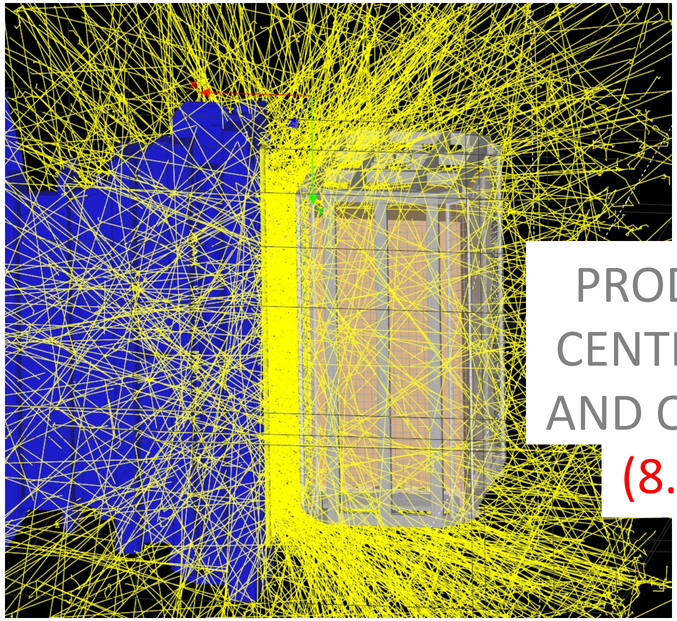
ENERGY/CURRENT (8.2)

SCAN WIDTH (8.2)

CONVEYOR SPEED (8.5)







PRODUCT CENTERING AND OFFSET (8.6)

SCAN UNIFORMITY

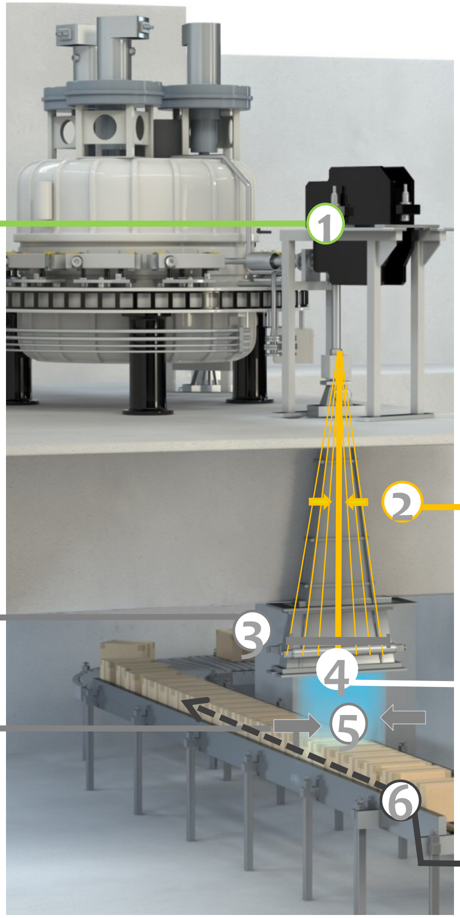
PARALLELISM* (8.5)

* optional

Description of a standard process (E Beam)

ANSI/AAMI/ISO 11137-3:2006

ENERGY/CURRENT (8.2)



SPOT SIZE (8.5)

SCAN WIDTH (8.2)

SCAN UNIFORMITY
PARALLELISM* (8.2)

PRODUCT CENTERING (8.6)

CONVEYOR SPEED (8.5)

* optional

Operational Qualification

Homogeneous material (various densities)

ANSI/AAMI/ISO 11137-3:2006
ISO/ASTM 51649:2005
ISO/ASTM51608-2015
ASTM E2303-2011

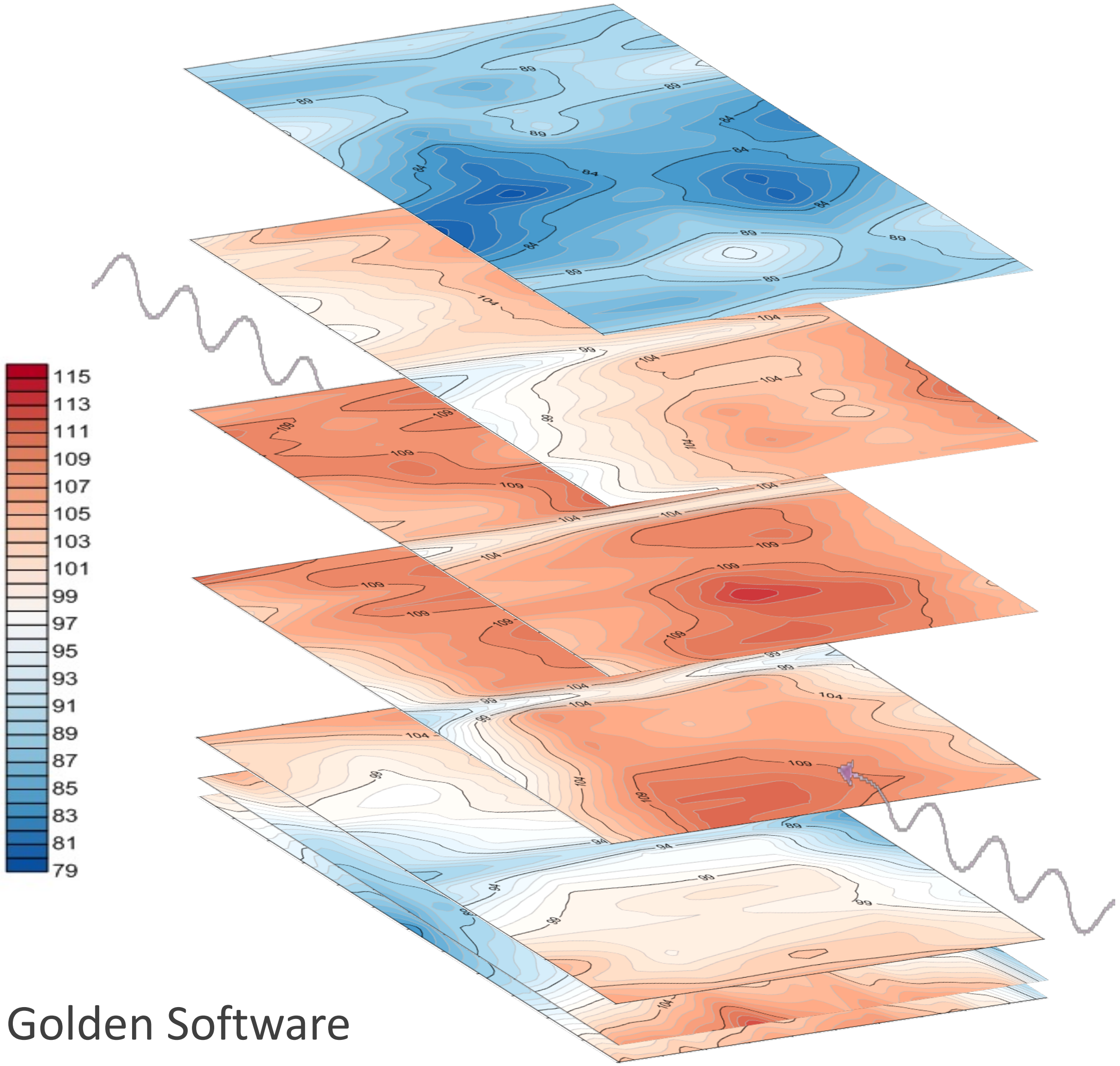
- Dose distribution
  - At product surface (9.3.4)
  - Inside material (side effect, material effect) (9.3.4, 9.3.8)
  - Impact of distance between product and scanner (9.3.5)
- Absorbed dose as function of conveyor speed, beam current, scan width, …(9.3.5)
- Dose variability / reproducibility (9.3.5)
- Process interruption/Restart for both conveyor and electron/X-ray beam (9.3.6)

OQ example 7 MV X Ray plant

- Medium density product (0.15 g/cm^3)

Rockwool

DUR = 1.27



Surfer ® Golden Software

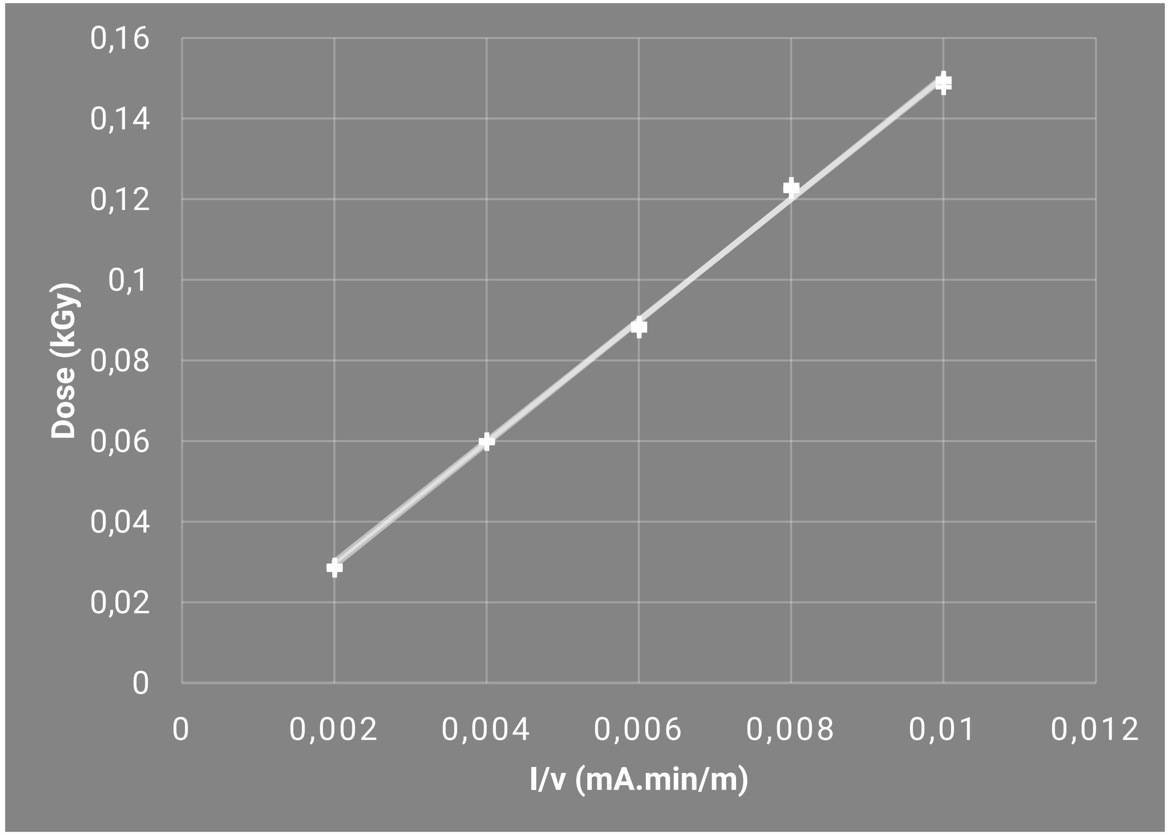
OQ example 7 MV X Ray plant

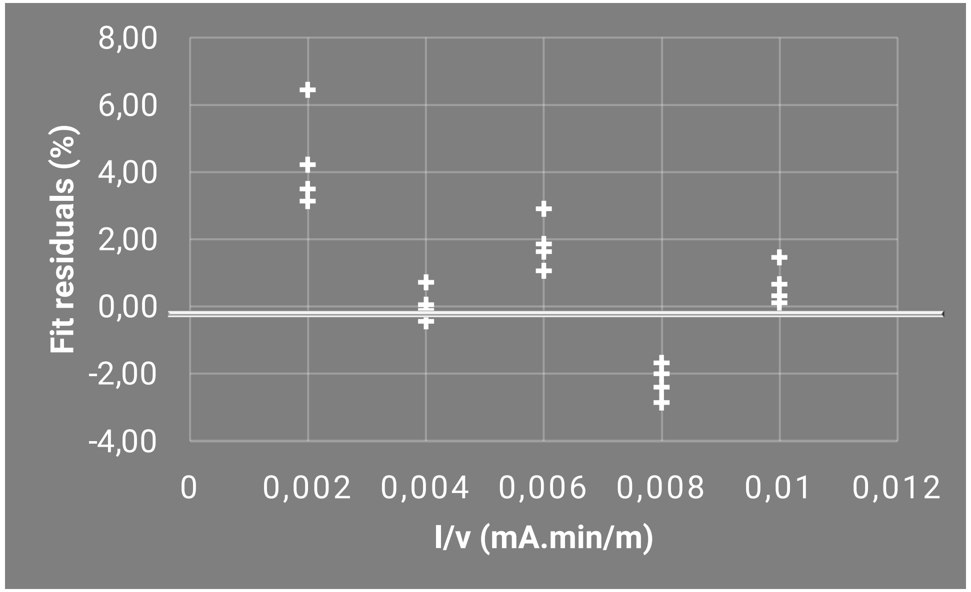
Homogeneous density Material	DUR 0.46 g/cm^3	DUR 0.15 g/cm^3	Min Dose zone	Max dose zone
7 MV X Radiation	2.04	1.27	Top layer middle	Front surface

→ Repetitions of dose distribution will assess variability

OQ example 10 MeV EBeam

Absorbed dose as function of Ebeam plant parameters: conveyor speed, beam current, scan width, …





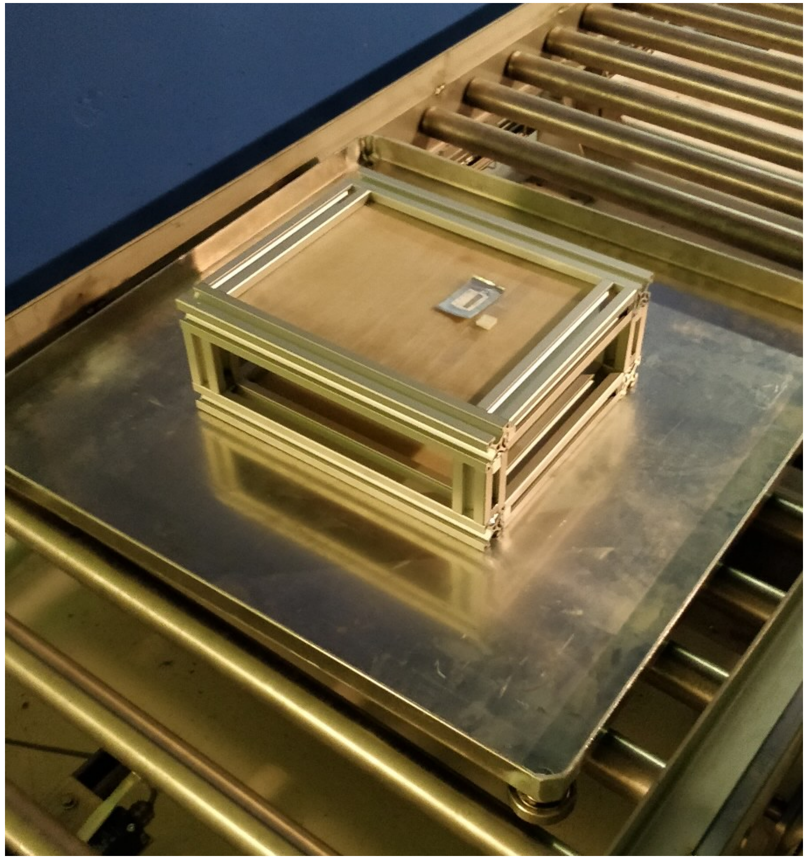
→ Predictability and reproducibility (variability) of process

OQ example 10 MeV EBeam

Dose Monitoring Device (DMD)

- 4 alanine on surface
- 4 alanine on bottom

Pellet id	D bottom [kGy]	D surface [kGy]	D (bottom/surface)
1	48.52	37.03	1.31
2	49.91	37.26	1.34
3	48.57	37.63	1.29
4	47.60	37.28	1.28
5	48.50	36.75	1.32
Average [kGy]	48.62	37.19	1.31
CV[%]	1.7	0.9	1.9



Dosimetry journey for satisfactory food irradiation processing

From ISO 14470:2011 or ISO 11137-1

About Validation ... Section 9

- Performance Qualification

Dosimetry is used in PQ to determine the appropriate process parameters (timer setting, conveyor speed, Beam current, SW ... and product loading configuration) for ensuring that the dose requirements for a particular product can be satisfied.

Outputs of PQ

PQ results are irradiation plant specific !

For a given product, product load and a given process

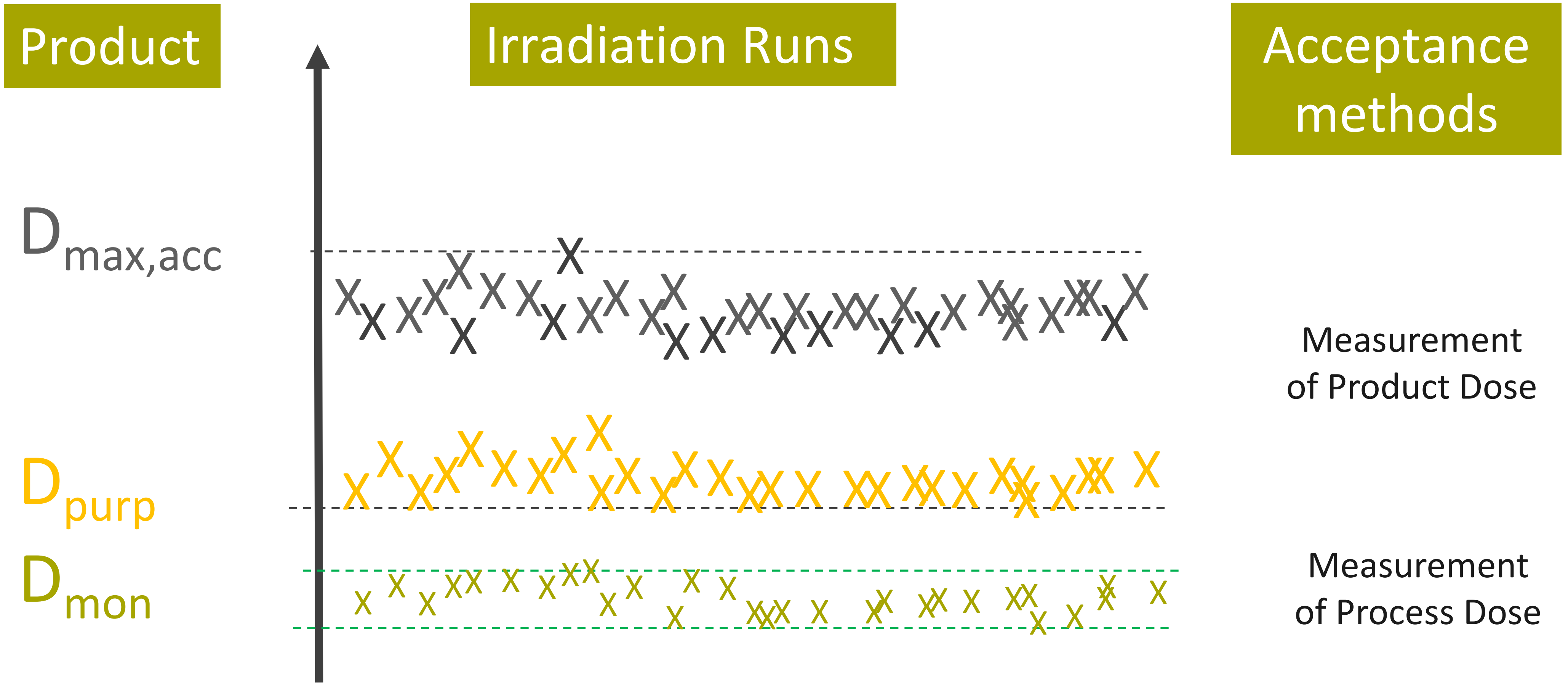
- D_{max}, D_{min}
- Mapping variability → Process variability $\sigma_{process}$
- Location of monitoring dosimeter
- Relationship between D_{purp}, $D_{max,acc}$, D_{min}, D_{max} and D_{mon}

→ Generate process target dose at monitoring location

→ Calculate the acceptable range of process target dose at routine monitoring location

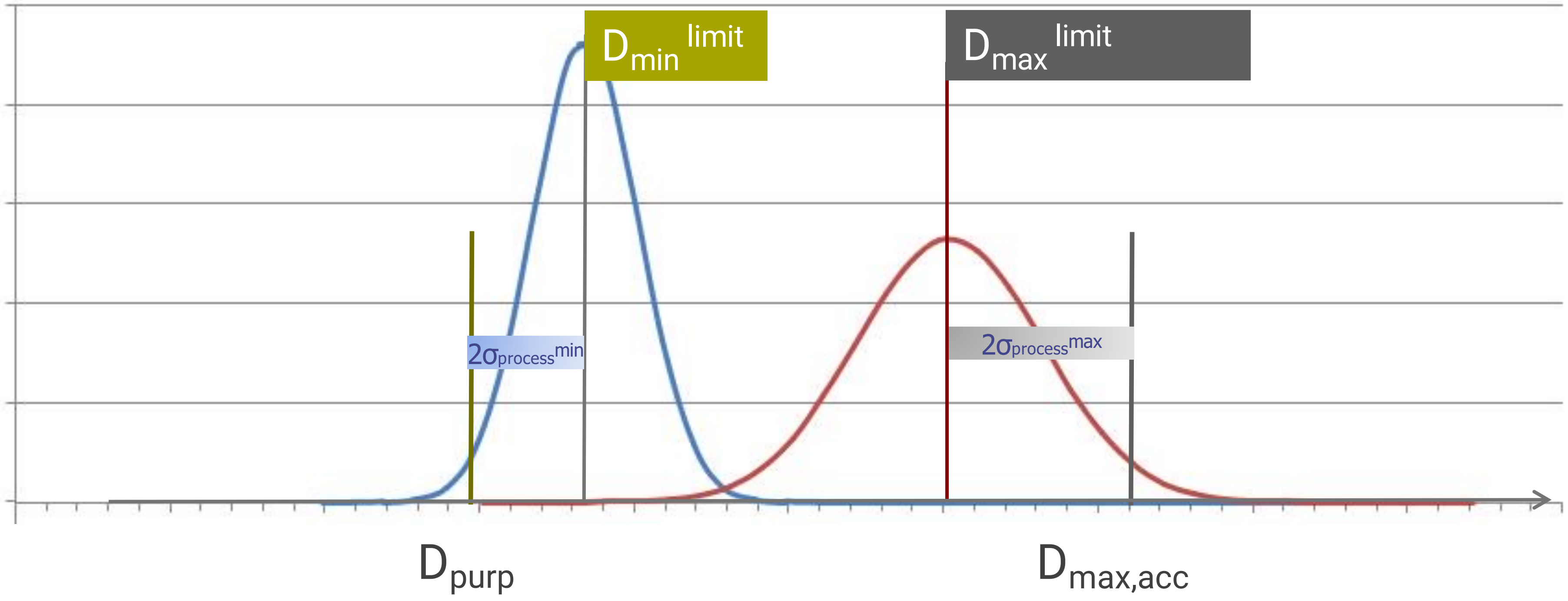
Outputs of PQ

→ Control chart
→ Acceptance methods



Setting the process

- Process to be set with a given 'targetting buffer' (ISO/TS 11137-4)



Guide to PQ dose mapping

- See IBA webinar

  "Product Qualification in E-beam and X-ray – Part 2"

PQ dose mapping examples to come…

- Presented by François, Matthew and Mac

Implications on selection of dosimetry systems

From ISO 144709:2001
About dosimetry ... Section 8

- The selection and use of specific dosimetry systems in a given application shall be justified taking into account the dose range, radiation type, effect of influence quantities, required level of uncertainty and required spatial resolution.

Applications	Dose range
SIT	few 10 Gy
Fruits/vegetables	few 100 Gy
Food decontamination	few kGy
Food Sterilization	few 10 kGy

Implications on selection of dosimetry systems

- Many dosimeters on the market

This is not a dosimeter !

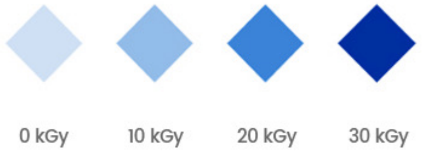
Implications on selection of dosimetry systems

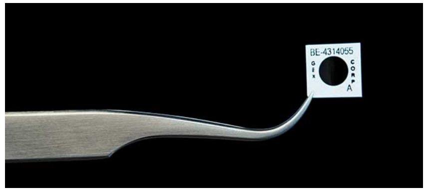
- Many dosimeters on the market
- Few only are adapted to food irradiation process qualification and monitoring…

GafChromic HD V2 10 Gy - 1000 Gy

FWT Optichromics 10 Gy – 10 kGy

CTA 10 kGy – 200 kGy





FWT 60 and GEX B3 film 1 kGy – 80 kGy

Implications on selection of dosimetry systems

- Many dosimeters on the market
- Few only are adapted to food irradiation process qualification and monitoring…

Alanine 1 Gy – 150 kGy covers all application ’s dose ranges

Implications on selection of dosimetry systems

- Calibrated dosimetry system(s) and associated uncertainties

DosASAP Dosimetry equipment

AerEDE EPR Dosimetry equipment

AerODE Optical Dosimetry equipment

Risö Scan equipment

Does it cover all food irradiation applications ?

- No, not all ! Could be easier with better adapted dosimeters …

LEEB decontamination of bulk products (free fall …)

What are the issues ?

Low EBeam penetration depth …

Free fall …

How to perform PQ ?

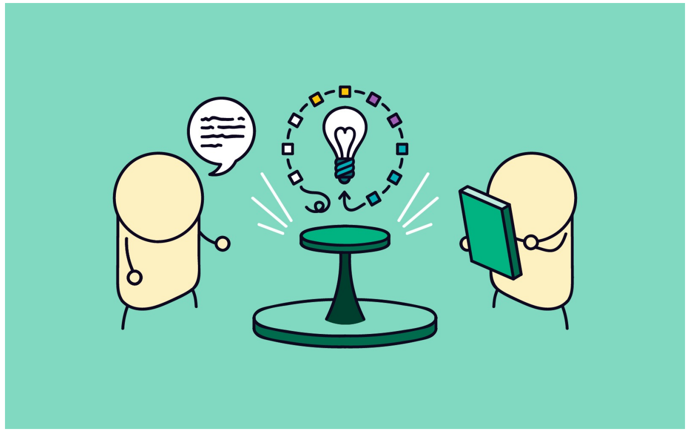
Measure surface and depth dose in products

What about monitoring dosimeter ?

→ Solutions for process qualification and control by Matthew (Bühler AG)

Does it cover all food irradiation applications ?

- No, not all ! Need for additional studies …



LEXray for SIT or phytosanitary applications

What is the issue ?

Dosimeters are not water equivalent at energies lower than 150 keV

Some work has been done on Alanine response

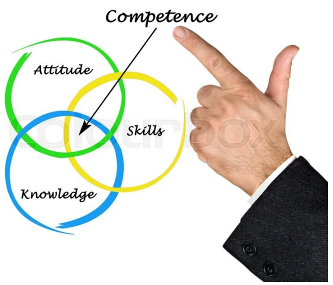
More work needed on thin film dosimeters

Conclusion

- Reference documents for food irradiation
- Qualifications and process control
- Dosimetry tools

→ All the ingredients exist to control the food irradiation process

→ Food processors/producers and irradiation contractors need to work together to establish the process



→ The personnel at an irradiation facility must be competent: appropriate education, training, skills and experience

Thank you !

Florent KUNTZ

Tools and requirements for food irradiation process control

Monte Carlo simulations – High energy

Potential of Monte Carlo simulations. Study of the impact of density and spatial arrangement of products.

François Vander Stappen (IBA)

Product and research program manager
IBA industrial

With a background in electronic engineering and in medical physics, François started working for IBA 12 years ago, in proton therapy. After getting a deep experience on the field, he worked in R&D and led several research programs, aimed at improving the treatment accuracy.

He joined in early 2020 the IBA Industrial business unit in the product management team. He works at developing a research program in collaboration with Aerial, bringing his experience of medical irradiations to the industrial domain.

Monte Carlo simulations – Low Energy

Challenges of simulations of low energy electrons for surface irradiations.

Matthew Murdoch (Bühler Group)

Dr Physicist
Bühler Group

Dr Matthew Murdoch is a Physicist at Buhler Group providing dosimetry and radiation expertise for the LEEB product line. He has 10 years of experience in radiation measurement and Monte Carlo simulations in both academia and industry. Since joining Buhler he has created simulations for both product dosimetry and radiation safety as well as designing dosimetry trials for process control.

[A practical example of X-ray processing]

Phytosanitary X-Ray Processing: Cold Chain, Dose Mapping and Process and Facility Controls.

Macdarragh O'Neill (Steritech)

Process Engineer E-Beam / X-Ray

Macdarragh O'Neill is a Biomedical Engineer who studied at the National University of Ireland, Galway, where he obtained a BEng and a MEngSc in Biomedical Engineering. After starting his career working for a large US multinational in the medical device industry, he then moved to Australia in 2019 where he joined Steritech as Process Engineer for the installation and commissioning of the greenfield X-Ray/E-Beam facility in Melbourne, Australia which was designed and built primarily for phytosanitary irradiation of Fresh Produce. He is now the Process & Compliance Manager for the facility, dealing with all technical and compliance aspects of the irradiation process which also includes accelerator control and troubleshooting, dosimetry modelling, R&D and process innovation.

A practical example of X-ray processing

Phytosanitary X-Ray Processing: Cold Chain, Dose Mapping and Process and Facility Controls.

Barry Cox (Steritech)

General Manager – E-Beam / X-Ray

Barry graduated in 2008 from Dublin City University with a BSc in Biotechnology and a keen interest in R&D, applied technology and technology commercialisation. Starting out in Biopharma process engineering in Ireland, Barry then moved into Industrial Sterilisation working with Gas and Irradiation Technologies. He completed a post graduate in Technology Management in 2011 from University of Galway and moved to join Steritech in Australia the same year. He has spent 10 years in Australia helping companies use industrial sterilisation solutions to solve product contamination and market access problems in a quality and regulatory role and in 2018 he completed a Master of Business Administration from University of Melbourne as he transitioned to his most recent role as General Manager of the new E-Beam / X-Ray facility in Melbourne, leading the commercial start-up, certification and validation from project commissioning through to the first commercial batch of fresh produce processed in January of 2020.

Feedback on dose mappings of fruit pallets

X-ray irradiation of full pallets of fruits. Dose mapping, methodology, and results.

François Vander Stappen (IBA)

Product and research program manager
IBA industrial

With a background in electronic engineering and in medical physics, François started working for IBA 12 years ago, in proton therapy. After getting a deep experience on the field, he worked in R&D and led several research programs, aimed at improving the treatment accuracy.

He joined in early 2020 the IBA Industrial business unit in the product management team. He works at developing a research program in collaboration with Aerial, bringing his experience of medical irradiations to the industrial domain.