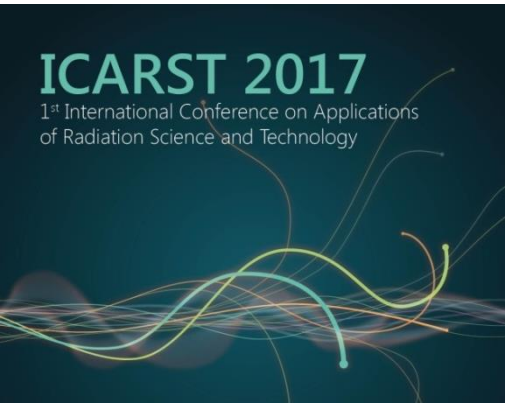

Dosimetry and process control for using low energy electron beams for sterilization or decontamination of surfaces

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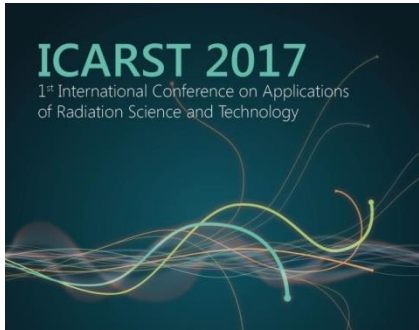
Contents

- Introduction
  - Applications of low energy electrons
- Pharmaceutical filling lines
  - Issues
  - Dosimetry requirements
- Dosimetry with low energy electrons: *D*μ
  - Absorbed dose to water in first micrometer at surface
- Routine process measurements
- Uncertainty budget
- Process limits
- Ongoing developments / improvements



Introduction

- Low energy electron beams are used in different applications, including:
  - Curing / crosslinking of polymers
  - Disinfection / sterilisation of surfaces

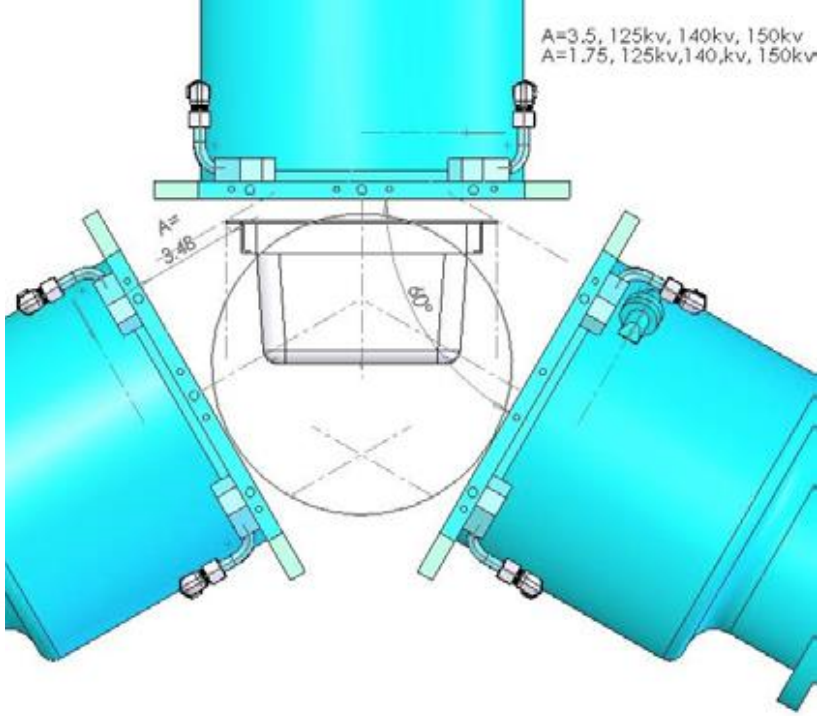
- Pharmaceutical manufacture requires aseptic filling processes
  - Disinfection / sterilisation of the outside of tubs containing syringes of vaccines, for example

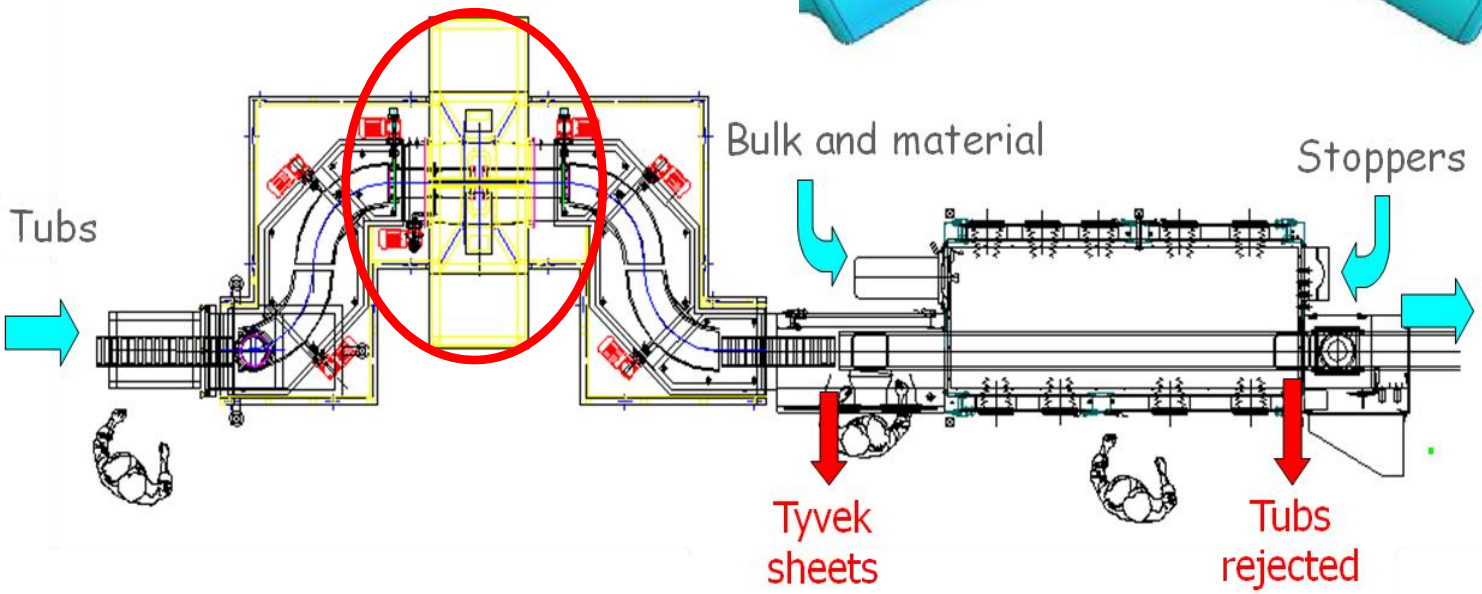
Pharmaceutical tubs

Sterilised with empty syringes, and then filled under aseptic conditions

Pharmaceutical filling line

Pharmaceutical tub filling line

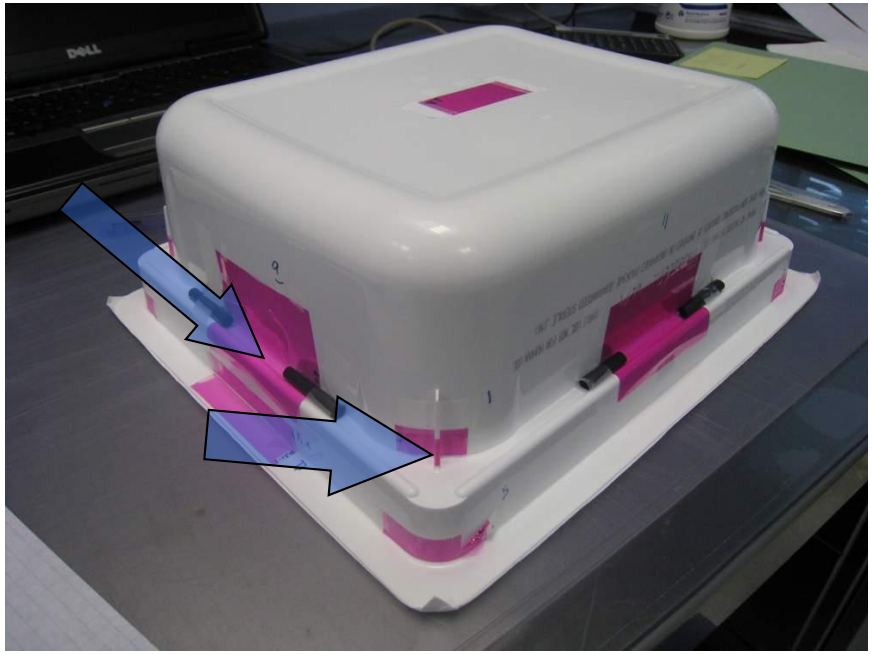




E-Beam tunnel | Working Isolator | Filling isolator

Placement of dosimeters on product

- Think like an electron…!

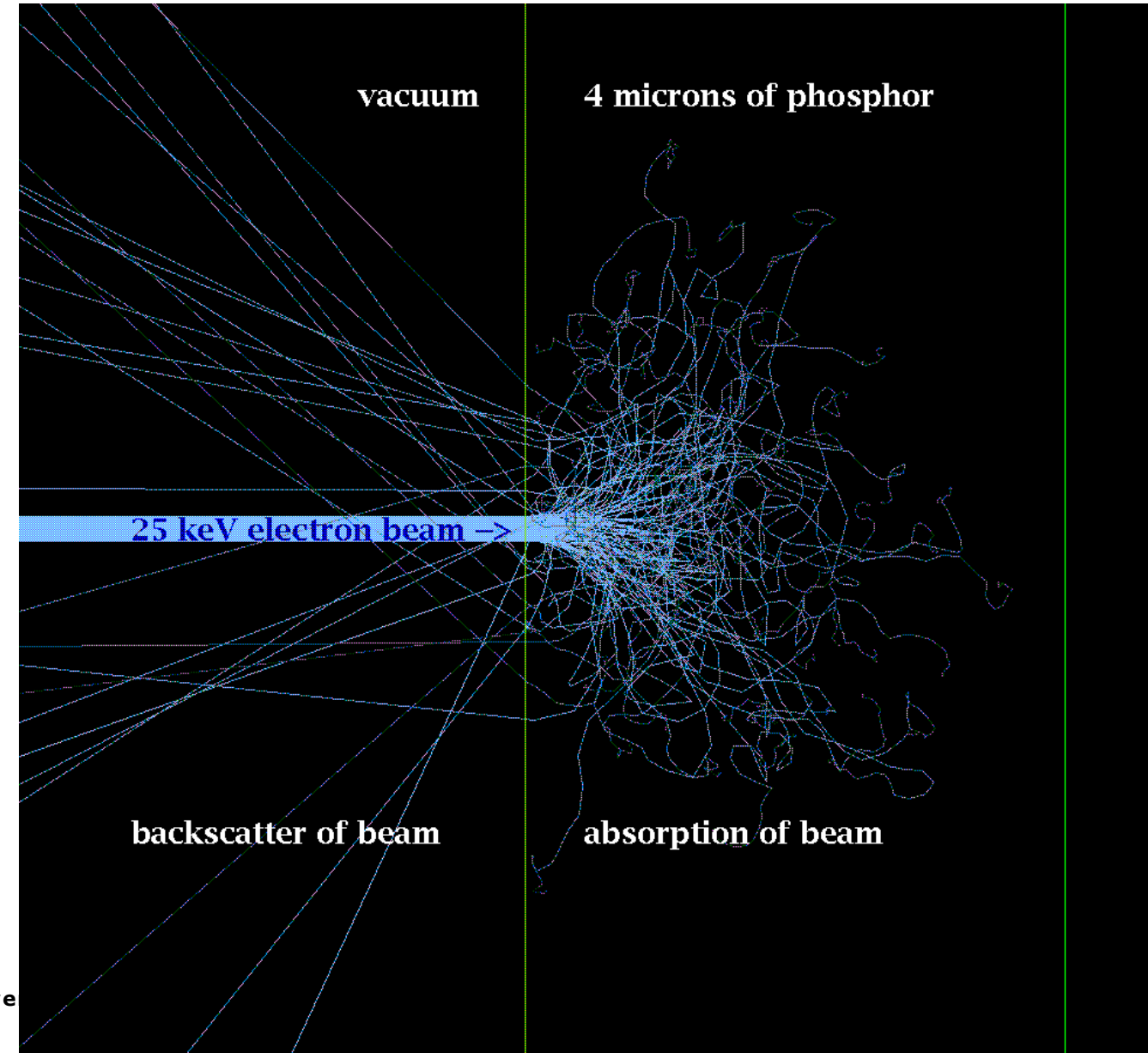


- How do electrons get into those hidden corners?

Electron beams…

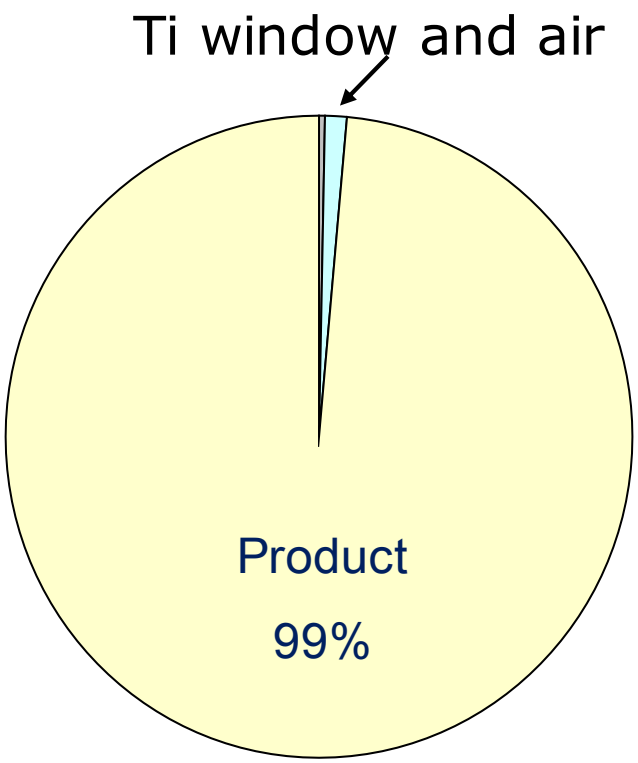
Low energy electrons *scatter* more than high energy electrons

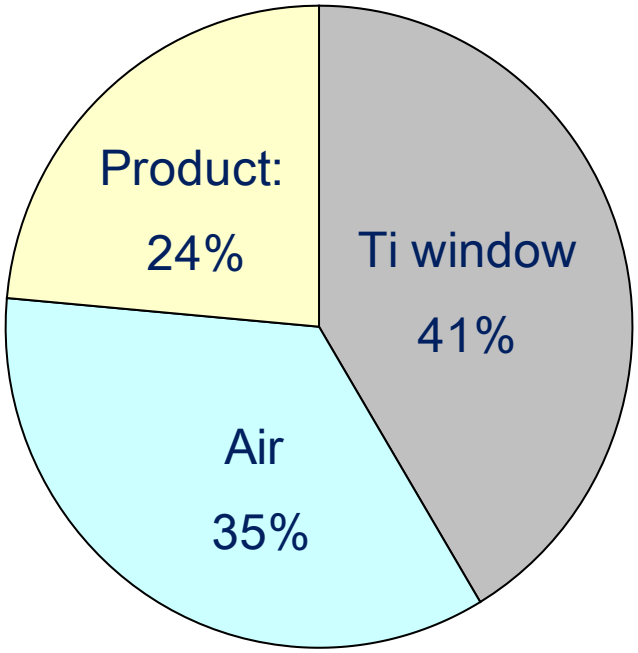
They behave more like a *cloud* as they scatter…



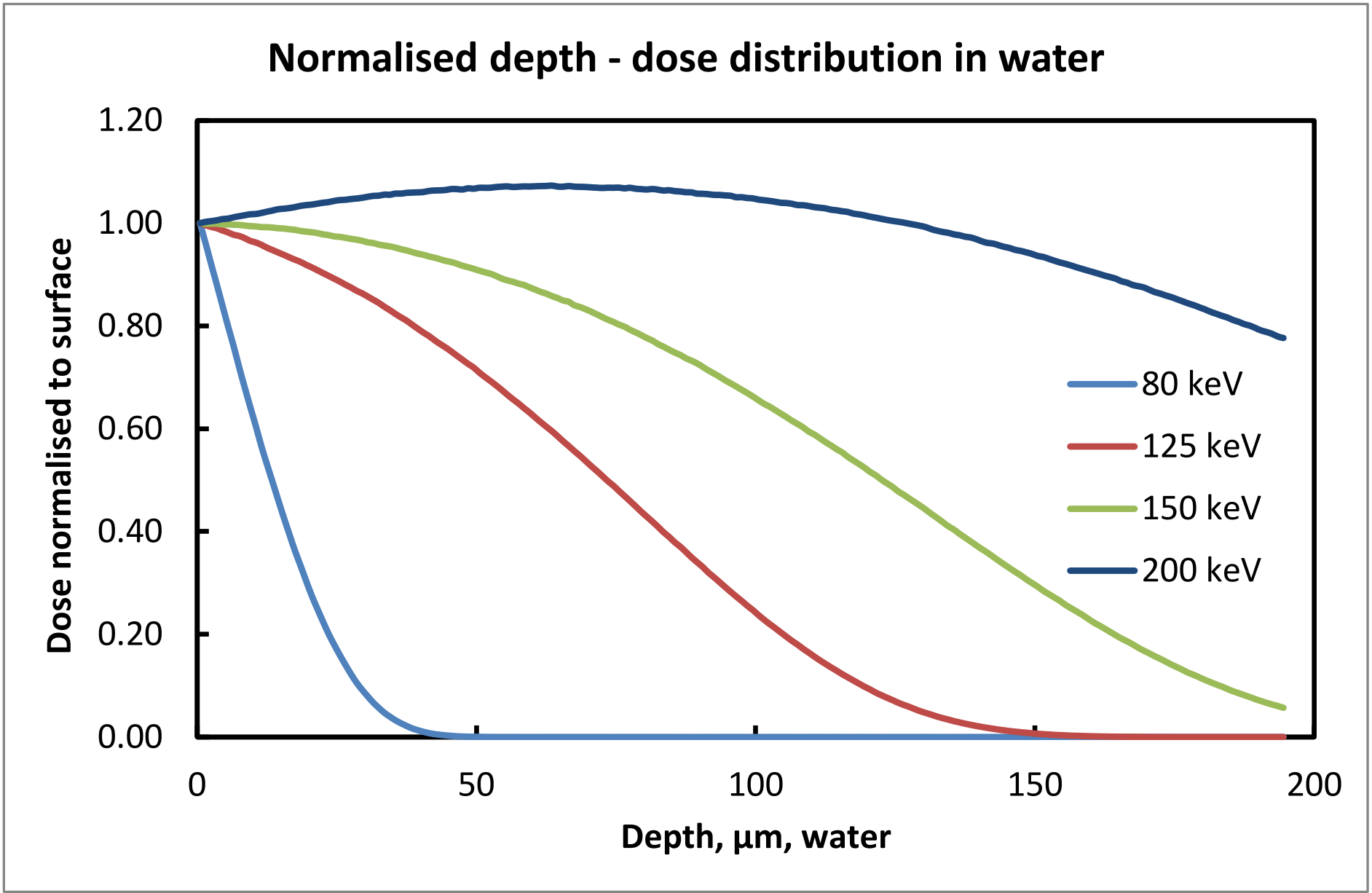
Range of electrons

- 10 MeV electrons:
  - Water: 5 cm
  - Air: 35 m
- 80 keV electrons:
  - Water: 0.14 mm
  - Air: 10 cm

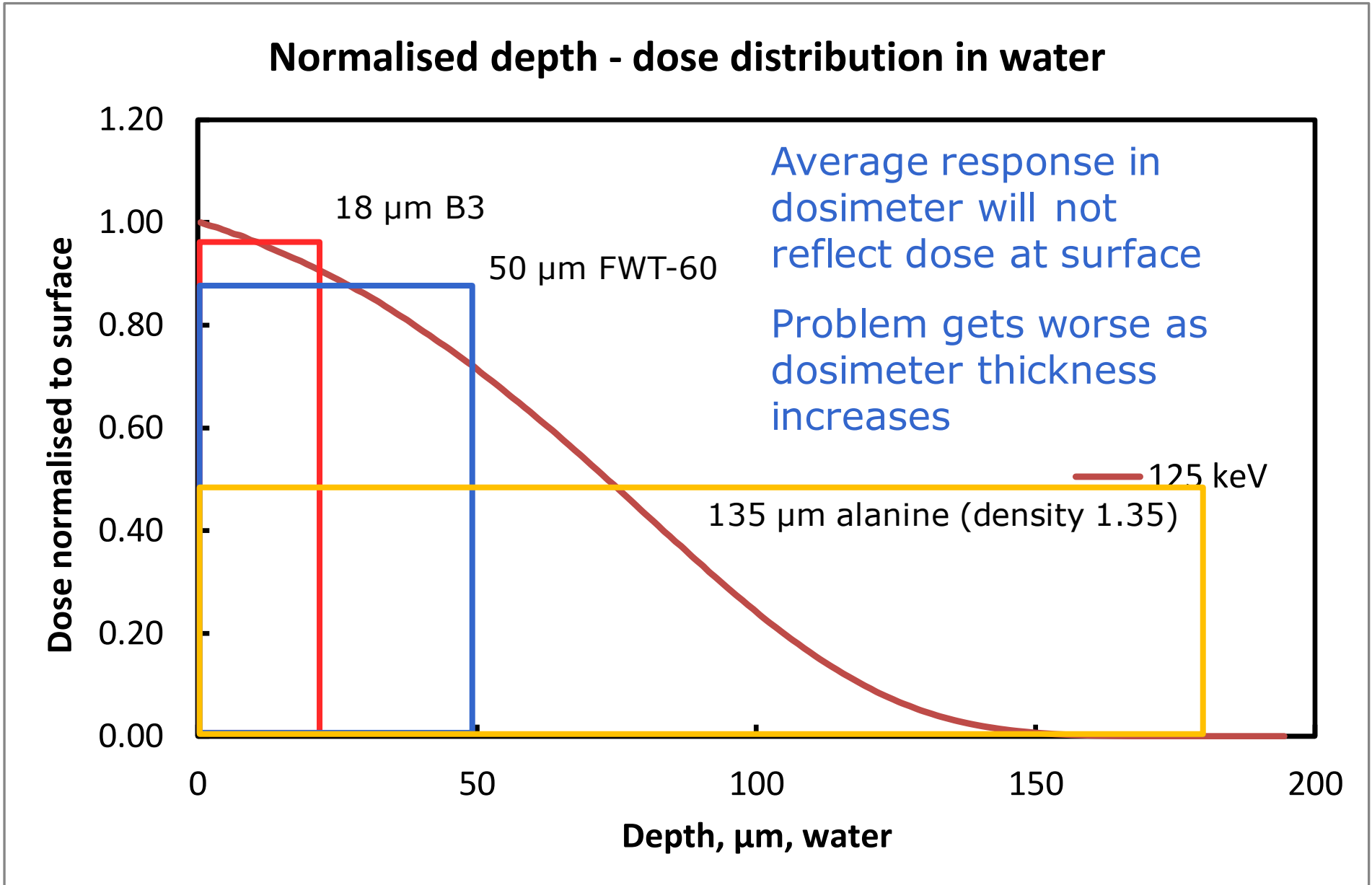




Depth-dose distributions



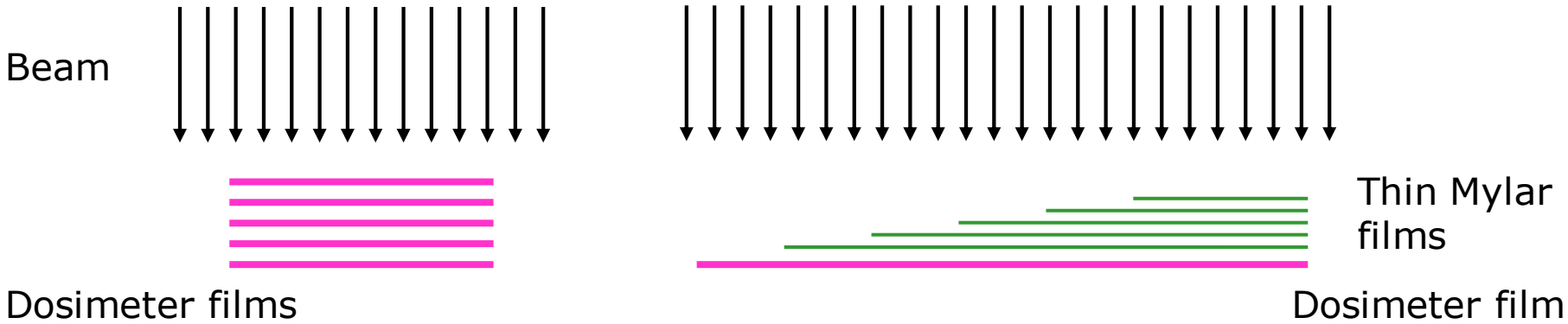
Depth-dose distributions



Measuring the depth-dose distribution

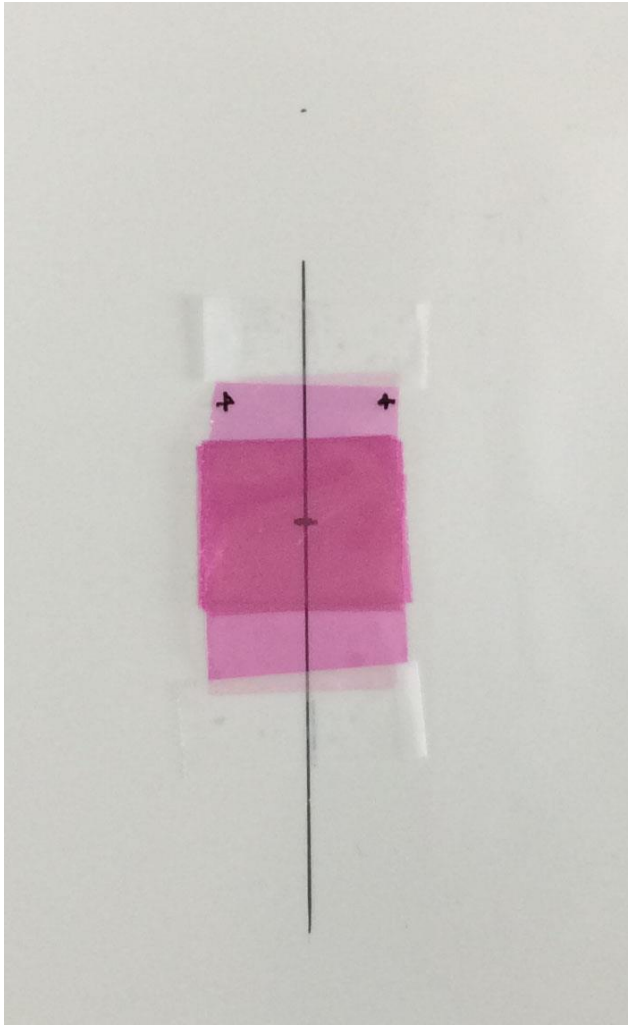
Stack of dosimeter film

Dosimeter film under a stack of e.g. Mylar.



- Enables us to measure *D*μ (absorbed dose in first μm) and relate this to apparent dose measured in reference dosimeters (e.g. alanine, thickness 135 μm)
- *D*μ gives traceability to national standards of absorbed dose via calibration of alanine dosimetry system

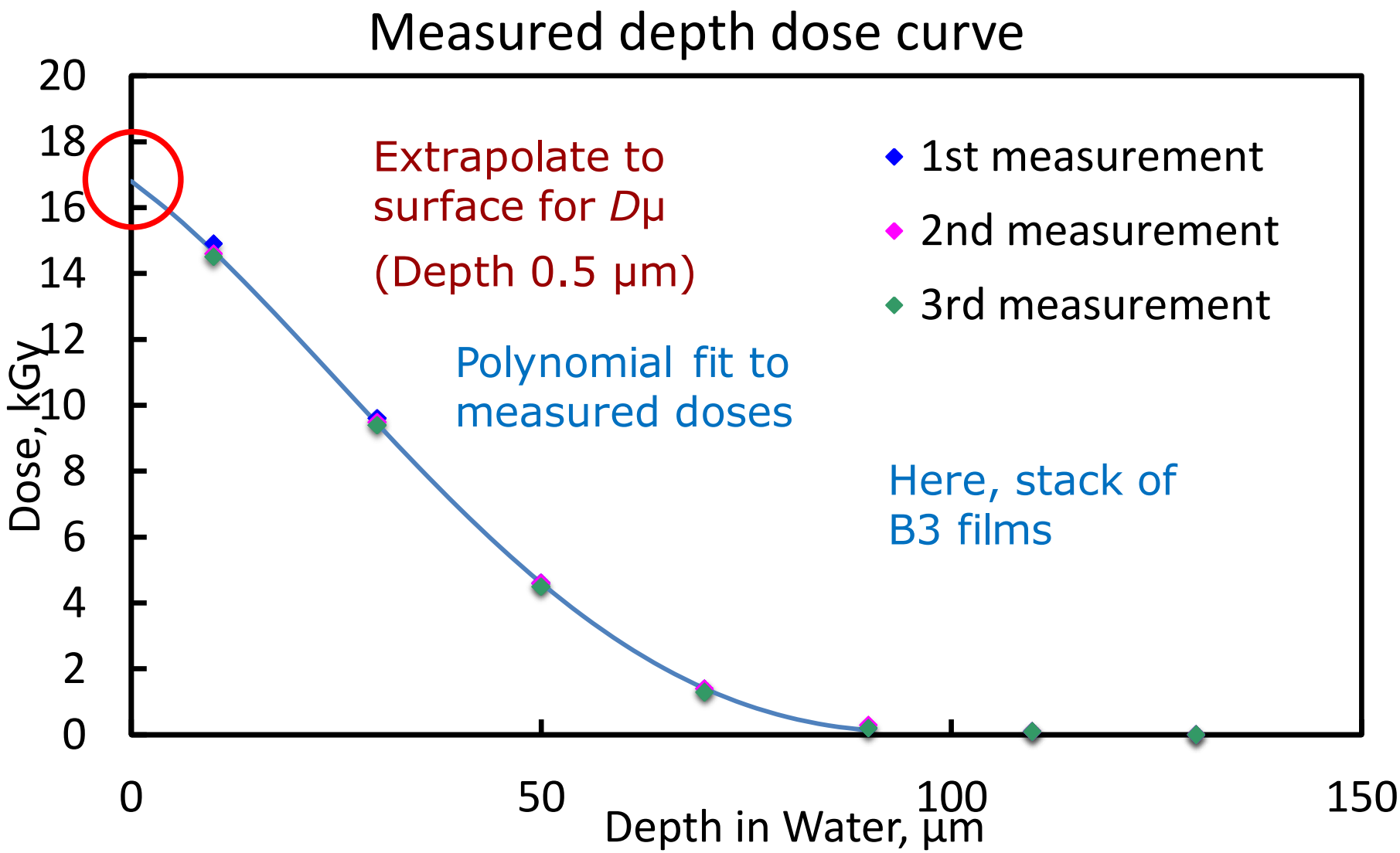
Measuring the depth-dose distribution



Depth-dose stack (here, B3)

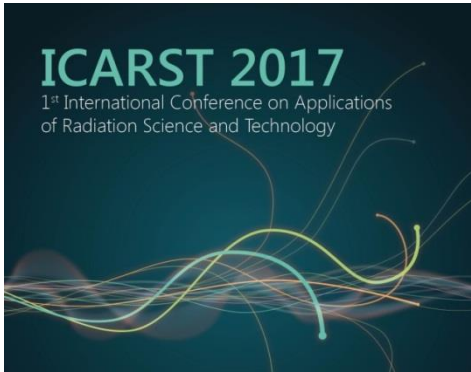
Scan and then analyse using RisøScan

Measuring the depth-dose distribution



Convert to surface dose *D*µ (1)

- Calibration verifications carried out with alanine film dosimeters over several doses
  - Cover the range of doses expected to be used
  - Cover the range of dosimeters to be used



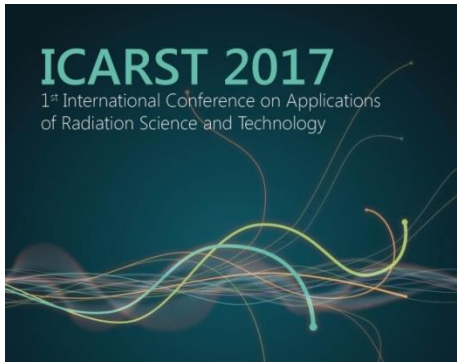
Convert to surface dose *D*µ (2)

- Note: Dose response is *nonlinear for alanine!*
  - At high surface dose, response curve through alanine film is complex
  - Alanine response also changes with temperature
  - Alanine response measured using ESR spectrometer

- For these reasons, these calibrations are carried out by calibration laboratories

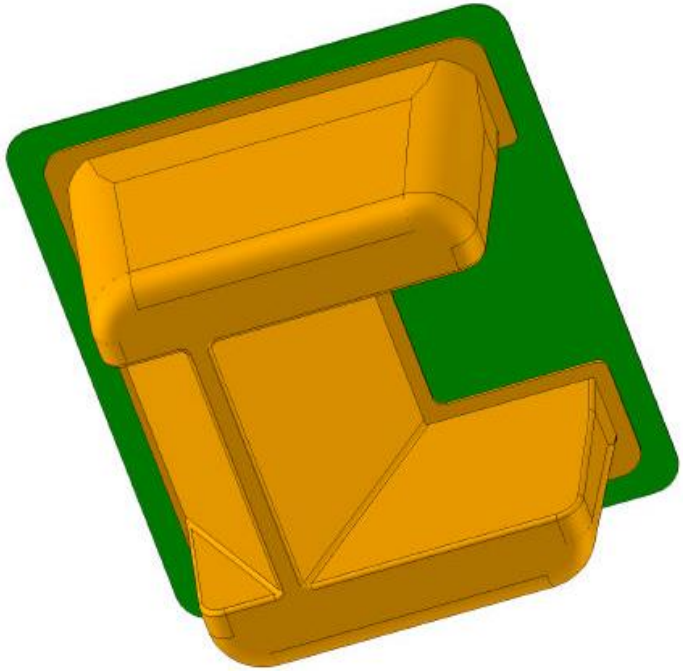
- Enables use of B3 / GEX DoseStix for routine process monitoring of surface treatment

- Uncertainty is currently quite large!



Routine process dosimetry

- Use (e.g.) GEX DoseStix
  - B3 in identified card holder
- Use reference dosimetry tub
  - Maintains distance from emitter to dosimeter, so that dosimeter does not saturate
- Use measured and otherwise identified uncertainty components to set process limits on current and conveyor speed to achieve required doses



Example Uncertainty Budget

Calibration

Reference dosimeter - Alanine film	
Calibration	1.51
Measurement	1.77
Determination of Dμ (at 150 keV)	5.00
Alanine films total uncertainty	5.30

Routine process measurement

Routine dose - DoseStix	
Calibration	5.3
Dosimeter reproducibility	1.0
E-beam facility variability	7.1
Routine dose uncertainty	7.4
Routine dose total uncertainty	9.5

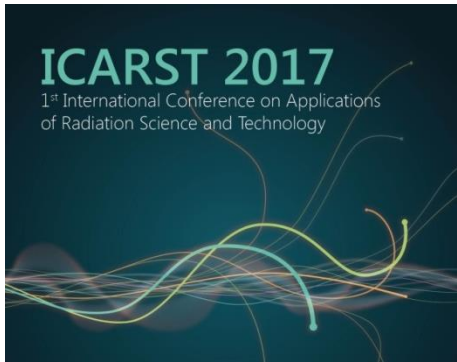
Dose mapping

Dose map - Risø B3 / RisøScan	
Calibration	6.1
Dosimeter reproducibility	2.00
E-beam facility variability	7.1
Minimum dose uncertainty	10.9
Minimum dose total uncertainty	12.5

Dose limits – minimum dose

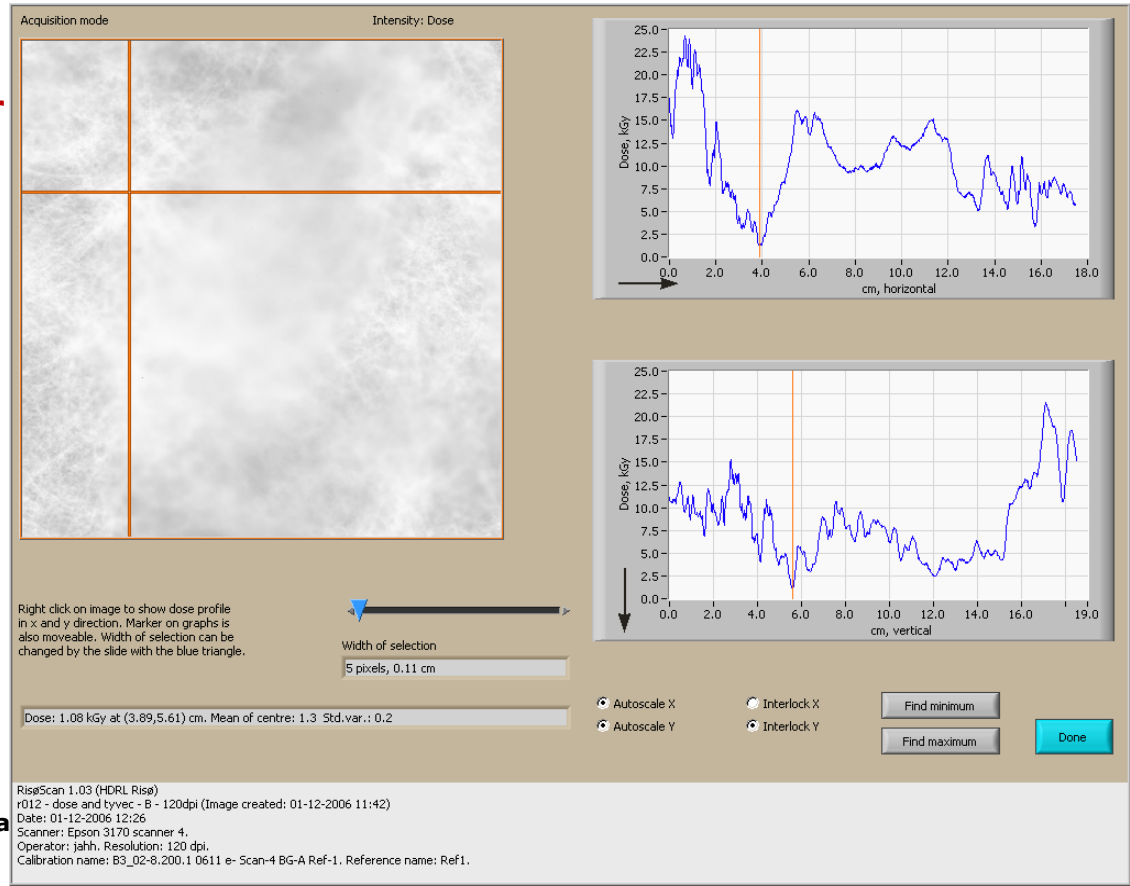
- Sterilisation or disinfection
  - No measurement of bioburden is possible!
  - Device has been sterilised prior to arrival at filling line
  - It is then removed from sterile packaging and placed into filling line machinery

- Acceptance criteria for minimum dose: Usual recommendations:
  - Measured dose at minimum dose locations on the surface of the irradiated tubs must exceed 15 kGy
  - Average minimum dose should exceed 25 kGy



Dose limits

- Acceptance criteria for maximum dose:
  - Most of tub is constructed from polystyrene of about 1mm thickness
  - Maximum dose of significantly above 100 kGy will not cause problems
  - However, dose under Tyvek lid / liner should be below 2 kGy
  - Maximum dose to the top of the Tyvek lid is therefore measured to be below 100 kGy



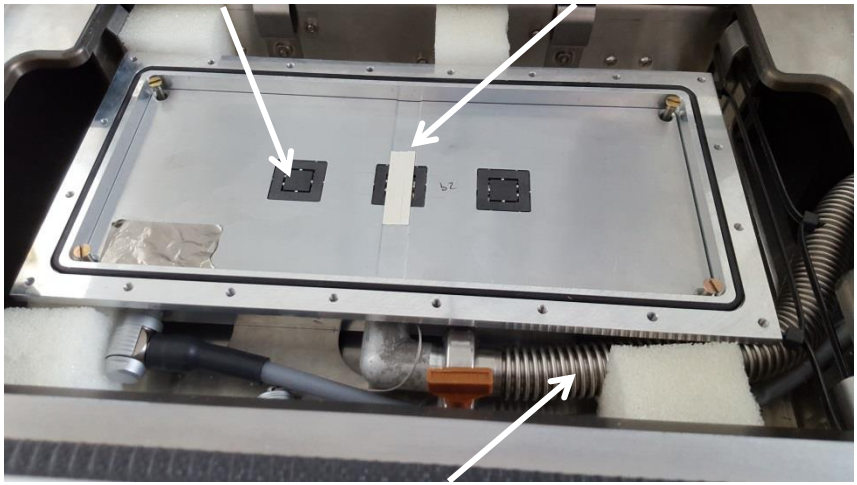
Improvements and developments

- Currently, development is under way with UK National Physical Laboratory (NPL) of a new graphite calorimeter
  - Measure directly energy in graphite from low energy electrons (80 – 200 keV)
  - Relate response in alanine at low energies to response in this calorimeter

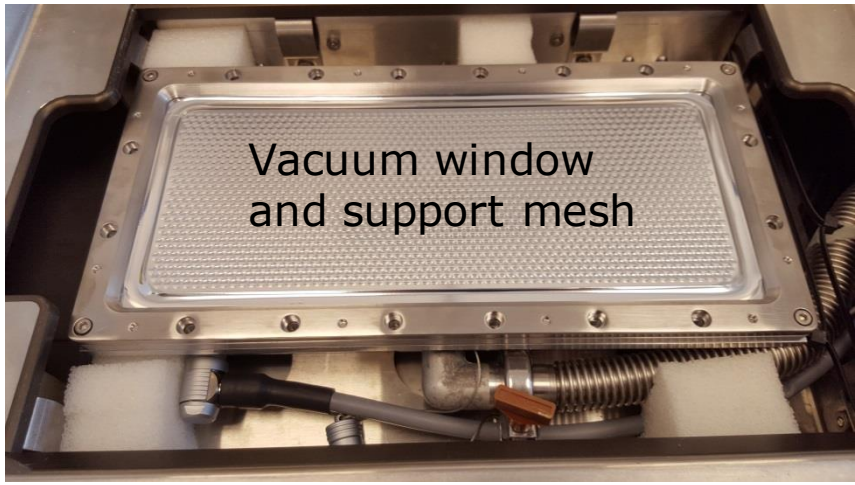
- Significantly reduce the uncertainty in measurement of *D*μ

Graphite calorimeter bodies

Alanine films



Pipe to vacuum pump



Questions?

Risø Courses in 2017: see http://www.nutech.dtu.dk/english/Products-and-Services/Dosimetry/HDRL/HDRL_Courses