Dosimetry

Process Validation

Quality Assurance

Radiation Effect

- Magnitude of radiation effect depends on the quantity of the energy absorbed by the substrate
- Quantity of the energy absorbed is called "dose"
- Essential to determine the dose required for a process

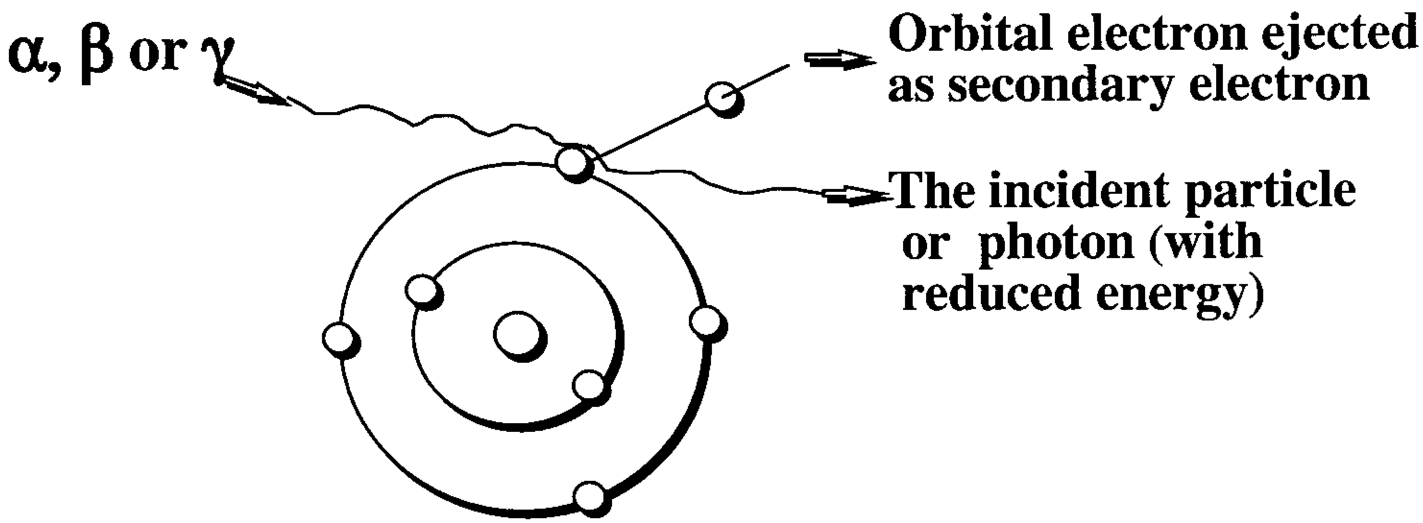
For definitions and details, see ASTM E-170-92, IAEA Technical Report 178 (1977), and Mehta(1988)

Interaction of Ionizing Radiation with Matter

A Simplified Picture

- The energy transfer mechanism involves interactions between the incident particles or photons and orbital electrons of the atomic/molecular constituents of a substrate

Interaction of Ionizing Radiation With Matter



Energy Deposition Event

(for details see Klots in Ausloos, 1968)

- The probability of interaction follows the order, $\alpha > \beta > \gamma$ and hence the order of their penetration in matter
- Energy loss per event, mainly 20-100 eV
- Radiolysis similar to vacuum UV photolysis

Energy Absorption in Mixtures

- Components of a mixture absorb energy in proportion to their respective electron densities (number of orbital electrons per unit weight)
- A reasonable approximation is that the components of a mixture absorb energy in proportion to their weight
    - Biol. System, 75% water, 25% organic
    - Energy absorbed, water ~75%, organic ~25%
- In materials with very different densities, e.g., syringes containing metal parts, the metal would absorb much higher dose and could get quite hot (Zagorski, 1992)

Dose

- Dose can be expressed in erg/g Joules/g, kiloJoules/kg

- The SI unit for dose is the <u>Gray</u> (Gy)

  1 Gray = 1 Joule per kg
  1 kiloGray = 1 kiloJoule/kg

- Rad was the conventional unit for dose

  1 rad = 100 erg/g; 1 Gy = 100 rad
  10 kGy = 1 Mrad

Dose Measurement
Dosimetry

Based on Known Chemical and Physical Effects

1. Primary Standard Dosimetry

- Does not need calibration against another standard dosimeter

- Maintained by many National Laboratories

- Two most common are ionization chambers and calorimeters (accuracy $\pm$ 1%)

- Temperature rise, 2.39×10^{-4} ^{o}C Gy^{-1} in water
  14.06×10^{-4} ^{o}C Gy^{-1} in graphite

Standard Dosimeters

2. Reference Standard Dosimeters (± 1-5%)

- Traceable to a National Primary Standard
- Fricke Dosimeter most commonly used
  $Fe^{2+} \rightarrow Fe^{3+}$, 10-400 Gy
  (ASTM E 1026-32)
- Ceric sulfate, $Ce^{4+} \rightarrow Ce^{3+}$, 10^3 - 10^5 Gy
  (ASTM E 1205-93)
- Potassium dichromate, $Cr^{4+} \rightarrow Cr^{3+}$,
  10^3 - 10^5 Gy
  (ASTM E 1401-91)
- Alanine, free radical by ESR, 1-10^5 Gy
  (ASTM E 1607-94)

Transfer Dosimetry

3. Transfer Dosimeters (± 5%)

- Stable, rugged, can be transported without loss of signal and reproducibility
- Used for calibration of reference standard dosimeters against a primary standard dosimeter
- Thermoluminescence dosimeters (LiF, CaF_2)
- Radiochromic dye dosimeters
  - Solutions of colourless dye precursors, e.g. cyanides or methoxides of pararosaniline and malachite green as liquids (10-10^4 Gy) or solids (10^2 - 10^6 Gy) (ASTM E 1275-93 and E 1540-93)
  - Radiochromic optical wave guides (ASTM E 1310-89)
- Alanine dosimeter can also be used as a transfer dosimeter

Routine Dosimetry

4. Routine Dosimeters (±10%)

- For routine in-house use for dose mapping, dosimetry, process control and quality assurance

  - Radiochromic dye dosimeters
  - Polymethyl methacrylate (PMMA) dosimeters
    - Clear
    - Dyed

    (ASTM E 1276-93)
  - Lyoluminescence, glutamine ($10\text{-}10^5$ Gy)

Solid State Dosimeters

Dosimeters	Dose Range kGy
Radiochromic Dye Film	
Gafchromic	0.1 - 40
FWT-60	0.5 - 100
B3 (Riso)	5.0 - 100
Cellulose Triacetate Film	5.0 - 300
Alanine (rod and film)	
PMMA	
Gammachrome	0.1 - 3
Amber Perspex	1.0 - 30
Red Perspex	5.0 - 50
Radix	5.0 - 50

Woods and Pikaev, 1994; Kovacs et al., 1992.

Dosimetry in Radiation Processing

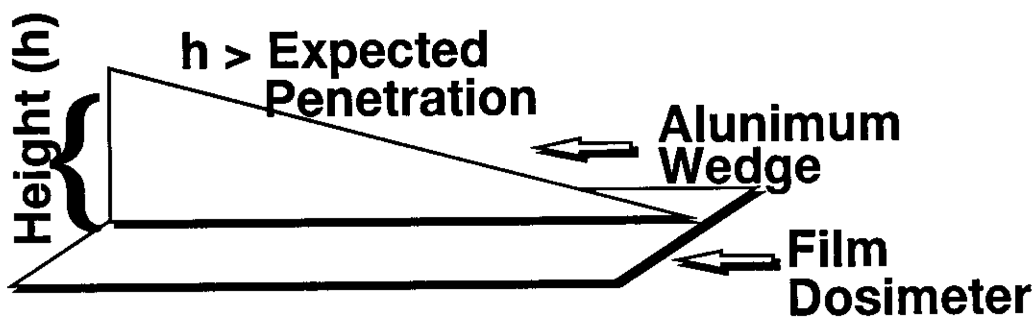
- Dosimetry is very important in various stages of radiation processing
- Stages in Radiation Processing

	e^-	γ
1. Characterization of the Irradiator		
- Energy	yes	yes
- Beam profile	yes	yes
- Nominal dose	yes	yes
- Dose uniformity and scan width	yes	yes
2. Validation of the irradiation process		
- Effect of irradiation on product	yes	yes
- Determination of process dose	yes	yes
- Process qualification	yes	yes
3. Process control during production	yes	yes

Kovacs et al., 1992

Characterization of the Irradiator

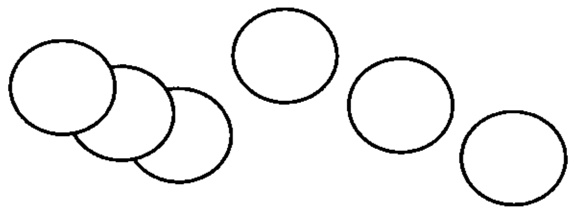
	Source:	e^-	γ
• Determine depth/dose curves wih a wedge		Yes	Yes

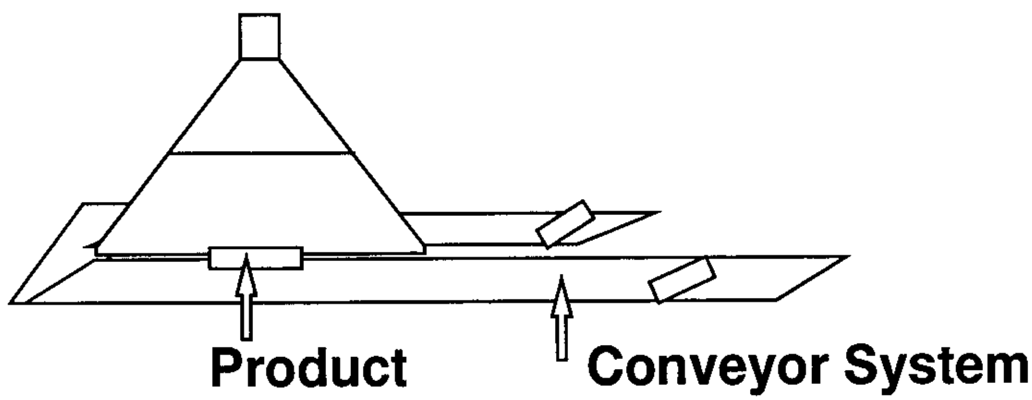


• Determine dose profile	Yes	Yes

Characterization of the Irradiator

	Source:	e^-	γ
• Determine Dose Profile	Scan	Yes	Yes
• Determine Nominal Dose Received by Product		Yes	Yes





Process Validation

- The Objective is to Establish Well Documented Evidence that the Irradiation Process Will Reliably and Reproducibly Achieve the Desired Effect

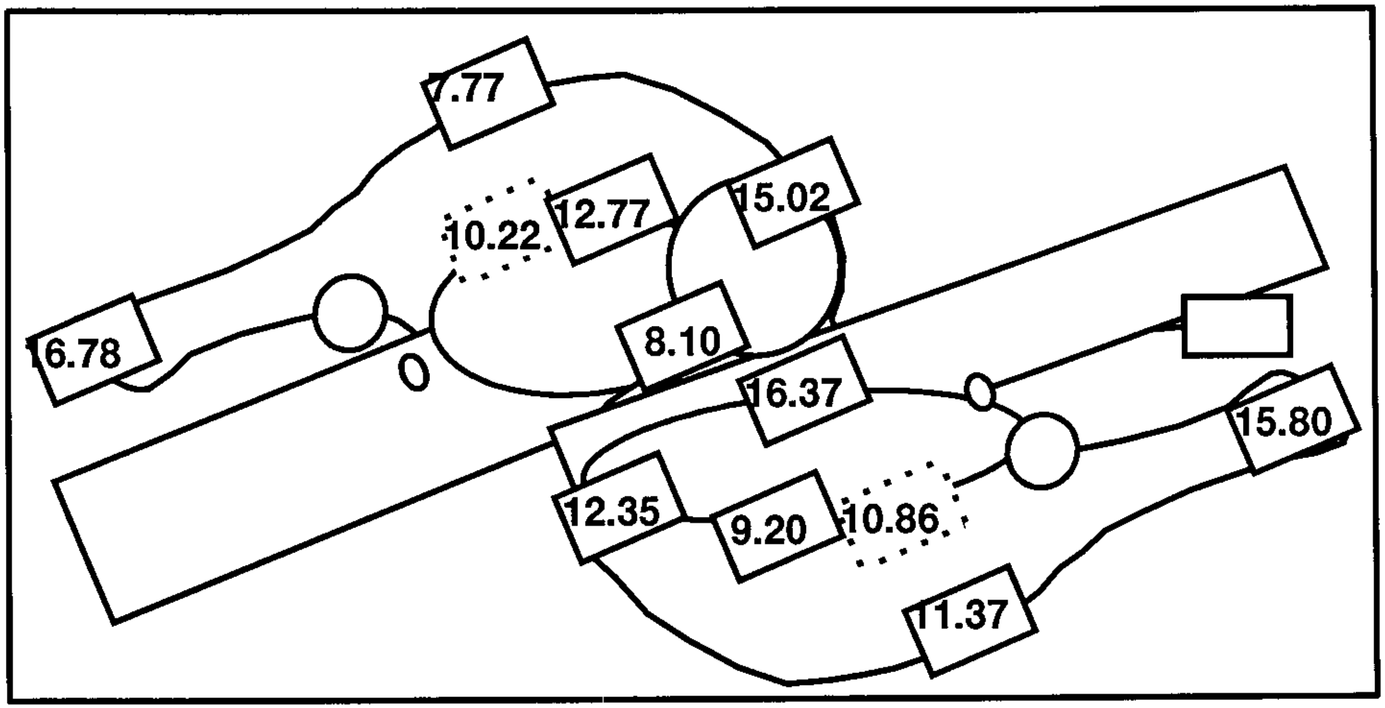
- Selected dose for the process is an extremely important parameter; therefore dosimetry plays a key role in process validation

Mehta (1992)

Validation of an Irradiation Process

	e^-	γ
• **Process Dose** Determine the required minimum (D_{min}) and maximum (D_{max}) doses	yes	yes
• **Materials compatibility** Determine the acceptability of the materials irradiated to the process dose	yes	yes
• **Process qualification** - Optimization of accelerator (beam current beam energy, pulse rate) and other (conveyor speed, temperature) parameters, including dose mapping, and dose monitoring	yes	yes
- Verify reproducibility of irradiation effect under optimized conditions on selected number (~10) of product units	yes	yes

Dosimetry of Chicken Drumsticks



- ❑ Placement of dosimeters showing dose received in kGy
- ❑ Placement of dosimeter on opposite side of drumstick

Routine Process Control

- Measure absorbed dose at regular intervals (dosimeters on selected boxes, or in between boxes), as decided during process validation
- Monitor key operating parameters (conveyor speed, electron beam current, electron beam energy, electron scan width, γ–source position)
- Keep appropriate detailed records
- Follow GMP (Good Manufacturing Practice) and QA (Quality Assurance) procedures (Mehta et. al., 1991)

Quality Assurance

- Appropriate checks on the quality/specification of the product to be irradiated
- Tracking of each product through the irradiation zone
  - Colour-change labels (ASTM E 1539-93)
- Routine periodic dosimetry at selected position of the product (1 in 100, or suitably selected number)
- Periodic comparison of the routine dosimeter with the reference standard dosimeter
- Periodic comparison of the routine dosimeter with the National standard dosimeter
- Follow post-irradiation procedures decided upon during the product/process development and validation, including reading of the dosimeters

Quality Assurance (contd)

- Monitor and Record, Regularly
  - Electron energy
  - Electron current
  - Electron scan width
  - Electron scan frequency
  - Electron pulse repetition rate
  - Electron pulse width
  - Product conveyor speed
  - Rotation of product for multi-sided irradiation
  - Coupling of dose rate and conveyor speed
  - Irradiator shut down if conveyor stops accidently
  - Position of the γ-source
  - Intended dose and dose received by the product

Conclusions

- Dosimetry plays a key role in product and process development, irradiator and process qualification, and process control

- Good dosimetry expertise and facilities are very important for the success of a radiation processing business