Irradiation by Ionizing Radiation

Comparison of Ebeam, Xray with Gamma

Low energy electron beams for industrial and environmental applications;
Warsaw, December 8-9, 2016

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Warsaw, December 2016

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The New STERIS Applied Sterilization Technologies

STERIS Isomedix + Synergy AST = **STERIS AST**

- The leading global service supplier with 59 locations in 18 countries
- Multiple sterilization technologies
- Medical device testing laboratories
- Microbiology laboratories in all regions
- Compelling level of business continuity options
- Global capacity and logistical options




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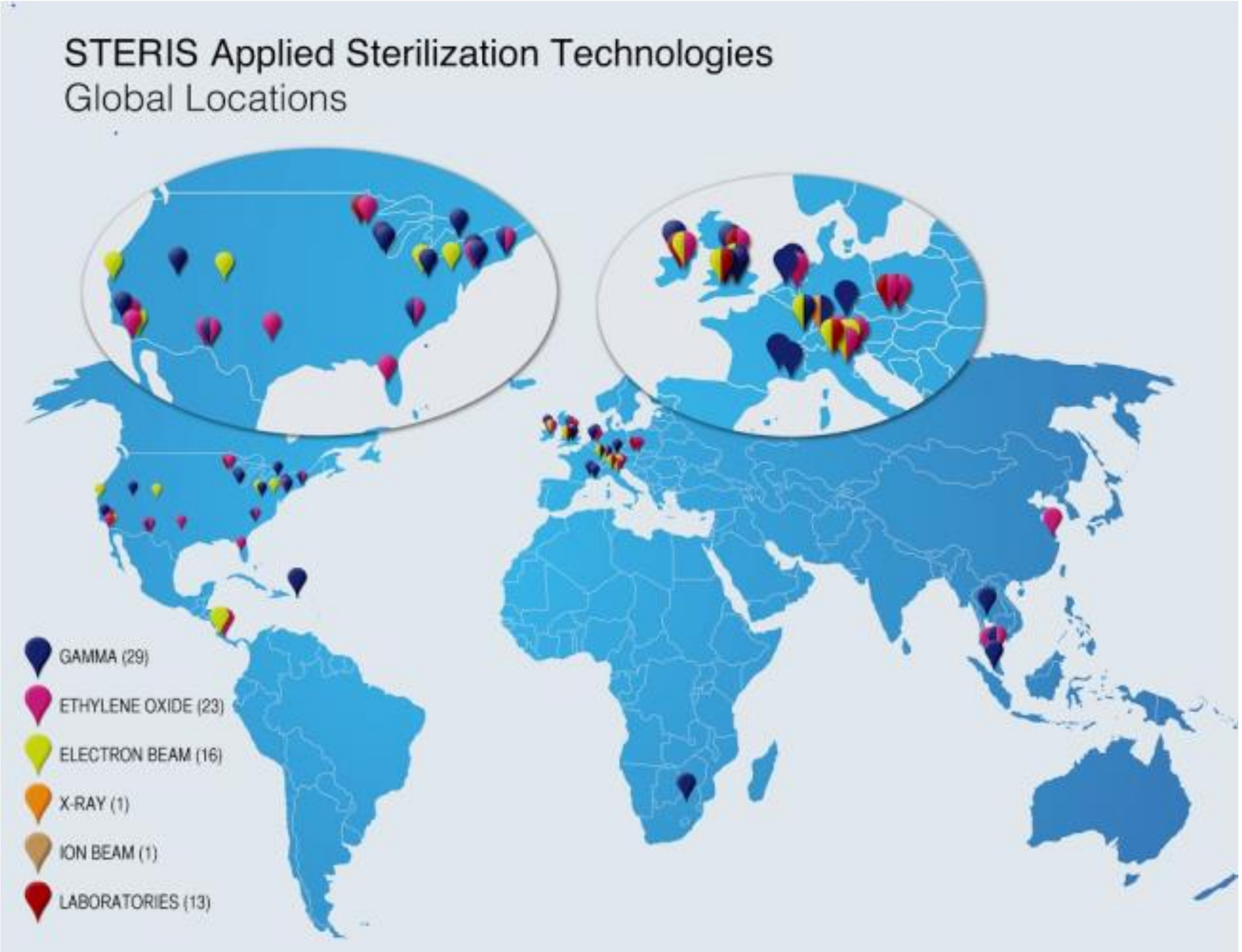
AST & Labs Locations and Technologies



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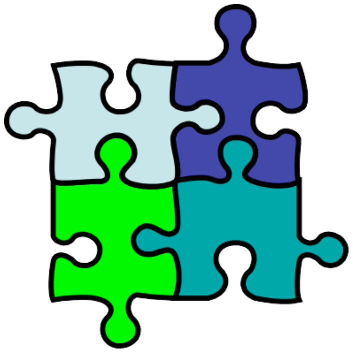
Concepts in Radiation Processing

1. History of Radiation
2. Radiation Technology
   a. Gamma
   b. Electron Beam
   c. X-Ray
   d. Technology Comparison
3. How do we measure an irradiation dose



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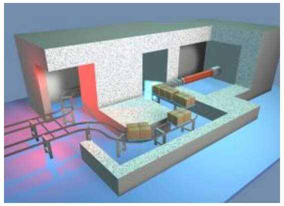
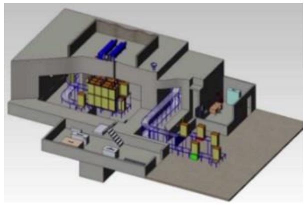
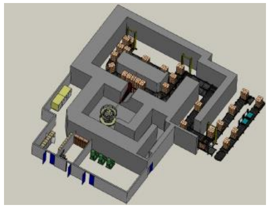
1. History of Radiation

History : Industrial application

1900 **1950** **1963** **2010** **Today**







1950's: First commercial irradiation facility with an electron beam accelerator.

1963: The first gamma irradiator in the US was installed for processing medical devices.

2010: The first X-Ray industrial irradiator globally was installed in Switzerland for processing medical devices.

Current Uses of Irradiation

Many consumer products are sanitized, sterilized or modified by irradiation of the materials

- Reduce contamination levels (consumer goods, animal bedding and feed, food, mold remediation of Archive Materials)
- Increase shelf life (food, spices, seasonings)
- Added assurance
- Crosslinking (wire, cable, hot water tubes, heatshrinkables, film, foam, plastics)
- Materials enhancement (semiconductors, crystals)
- Molecular chain reduction (PTFE, cellulose, wood pulp)
- Sterility required (Medical devices, labware, pharmaceuticals, donor tissue, primary packaging material)

2. Radiation Technology
    a) Introduction
    b) Gamma
    c) Electron Beam
    d) X-Ray
    e) Technology Comparison

Radiation vs. Irradiation What is it?

Radiation

- energy transmitted by waves or a stream or particles (like gamma waves, X-Rays, Electrons, Heat)…
- Generic Term

Irradiation

- the process of exposing a material to ionizing radiation
- Very Specific, refers to energy capable of changing atoms and molecules by creating charged units called ions

energy

process

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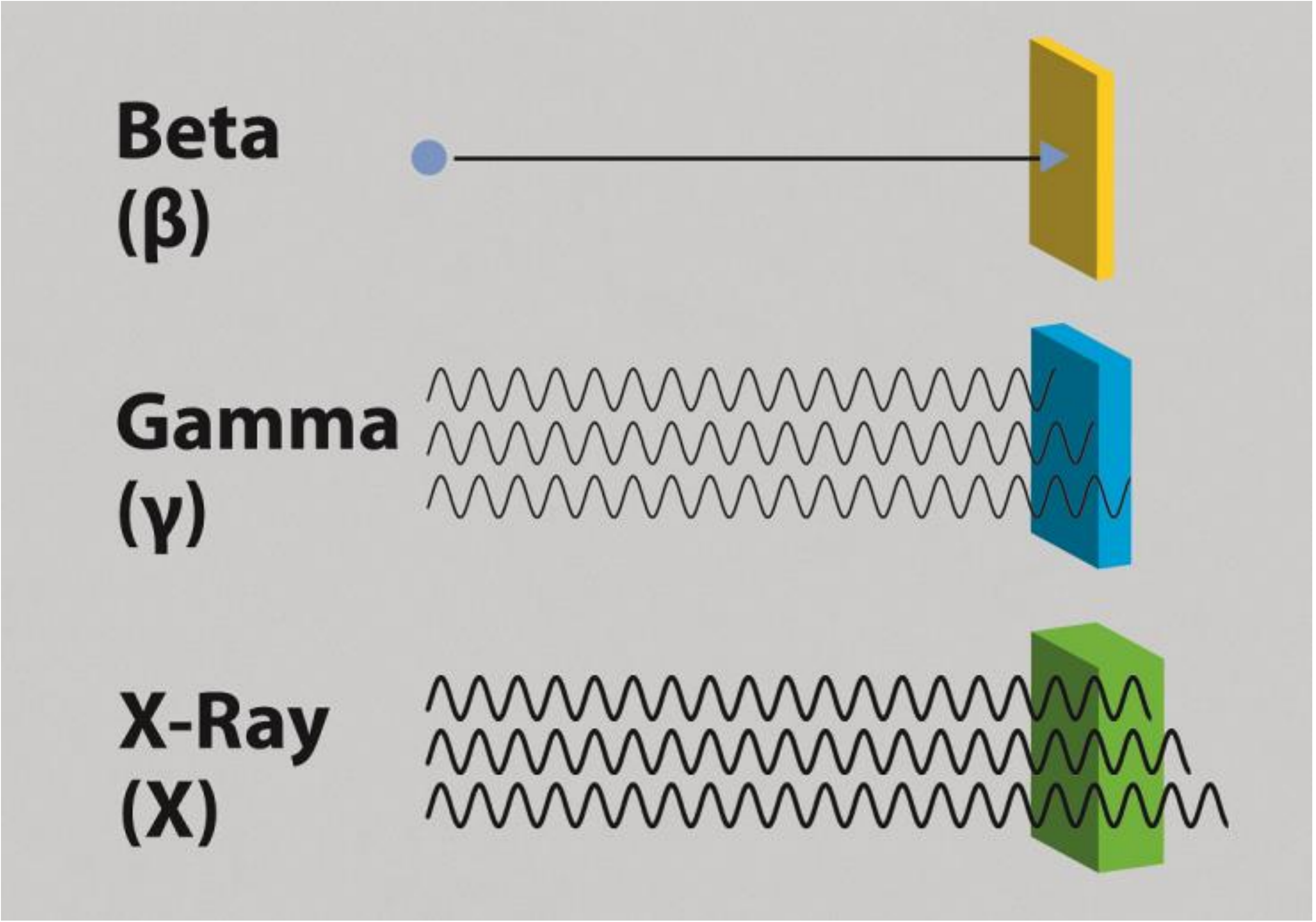
Electron and Photon

- **What is an Electron?**
  - It’s a particle with a negative charge.
  - Strong interaction when colliding with other atoms (poor penetration) because of electric field interactions.
  - Loses most of its energy by ionizing atoms.

- **What is a Photon?**
  - A Photon has no charge and no mass.
  - Produced due the Bremsstrahlung resulting a high-energy electron deflected in the electric field of an atomic nucleus.
  - Carries away only a part of the electron energy.
  - Not easily stopped (good penetration) because it has no surrounding electric field.
  - Loses most of its energy by ionizing atoms.

Physical Properties Effect Penetration



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Why do we use Cobalt 60?

- Commonly referenced Gamma sources are
  - Cobalt 60
  - Cesium 137

- We use Cobalt 60 as do almost all commercial irradiators world wide because:
  - Emitted photons penetrate deeper into product than Cesium 137 photons
  - Cobalt 60 can be produced to high specific activities
  - Can be made into compact sources (easier, safer to work with)
  - Not water soluble (safe storage)

Radioactive Material: Cobalt 60 Encapsulated

- Cobalt 59 is an inactive natural metal, which is converted in a nuclear facility by bombardment with neutrons to become partially active Cobalt 60
- Cobalt 60 has a half life of 5.3 years
- A cobalt-60 source emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions.
- Cobalt 60 metal pellets are double encapsulated in 'pencils' - "Sealed Source"

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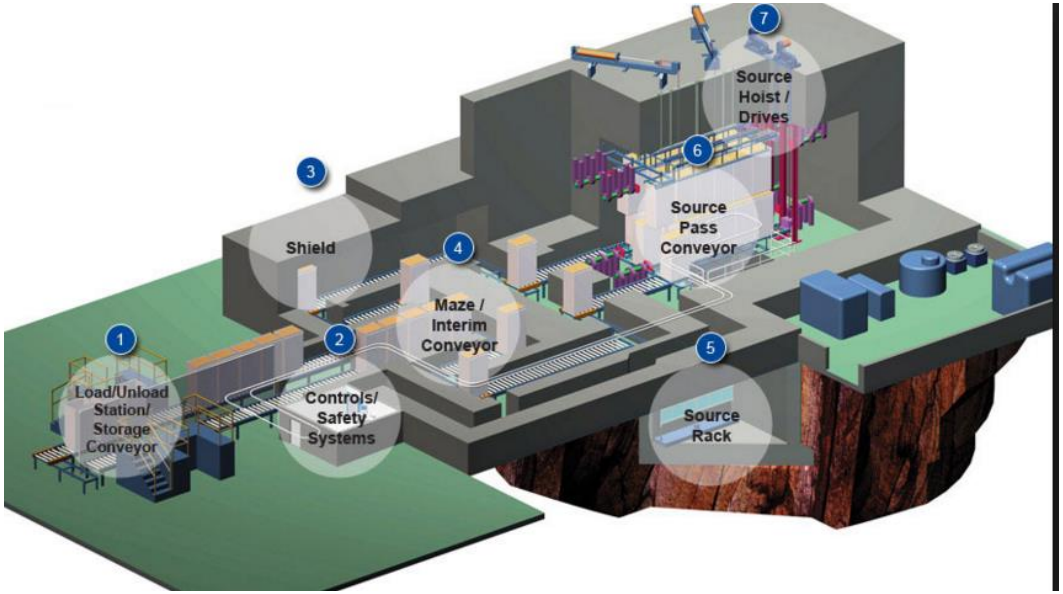
Gamma Irradiator

- **Cobalt 60** (to provide photons)
- **Pencils** (constructed from stainless steel to hold Cobalt 60, with double encapsulation)
- **Source Rack** (to hold pencils an allow movement and storage of Cobalt 60)
- **Carriers or Totes** (hold cartons so they can be transported into irradiator, through the energy field and back out of the irradiator)
- **Conveyance System** (allows for controlled movement of carriers)
- **Containment** (safe storage of source when not in use)



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Irradiator Types

Process

- Continuous
- Batch
- Incremental

Process Load

- Tote
- Pallet

Radiation Field

- Product overlapping
- Source overlapping

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Typical example: Gamma unit in Switzerland

Outside storage and loading station

Middle: loading/unloading station
Left side: treated storage
Right side: untreated storage

One Carrier (2 shelfs) at the loading station waiting for Pallets to be inserted

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Gamma: Applications

Gamma processing is most successful with medium and high density products. Actual application will depend on specific processing equipment capabilities. Due to the lower dose rates Gamma is less economic on high dose application like crosslinking of cables, but mostly on sterilization applications

- Sterilization Products such as:
  - Sterilization of medical devic es in class II and III (implants)
  - Terminal sterilization of pharmaceuticals
  - Sterilization of all kind of primary packaging material like syringes, vials, bottles aso.
  - Gauze, drapes, towels
  - Bandages, wound care dressings
  - Lab ware, bottles, caps, containers
  - Tubing sets, procedure trays, catheters
  - Animal bedding, spices, agricultural and consumer goods appropriately packaged.

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E-Beam - Theory

- Electrons (E-Beam, beta particles) from a heated filament extracted are accelerated through an evacuated tube (similar to a TV cathode ray tube). Electrons are focused into a beam which scans across product on a conveyor
- In its simplest terms, the bombardment of a material with high-energy electrons results in a cascade of high-energy electrons moving through the target material
- Products then pass through this curtain of electrons to receive the required dose of radiation
- The dose given to product, is controlled by a combination of the beam current, under-beam conveyor (UBC) speed and the beam scanning length.

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E-beam Accelerator Terminology

- **MeV** (million electron volts)
  - ✓ Energy (speed) of the electrons; directly controls the penetration capacity within the product.
- **mA** (milliamperes); beam current
  - ✓ Quantity of electrons produced; determines product speed under the beam
- **m/min** (meters/Minute); conveyor speed
  - ✓ The relation speed to beam creates the dose rate and as a consequence the time being exposed to ionising radiation
- **kW** (kilo Watt); Irradiator power
  - ✓ = MeV * mA (ex. 10 MeV * 15 mA = 150 kW), gives the throughput
- **Scan length** (Beam profile)
  - ✓ dimension of the irradiation zone perpendicular to the direction of product movement at a specified distance from the accelerator window

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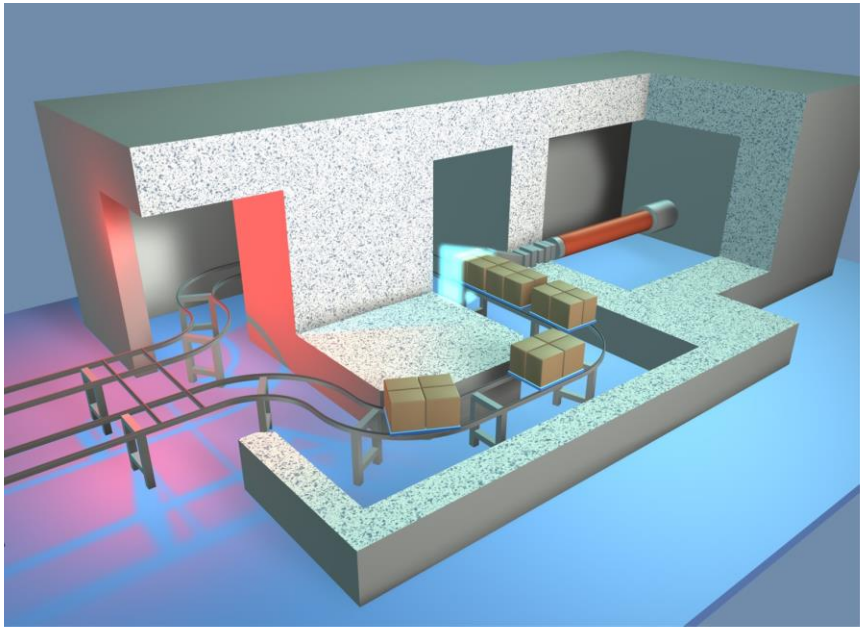
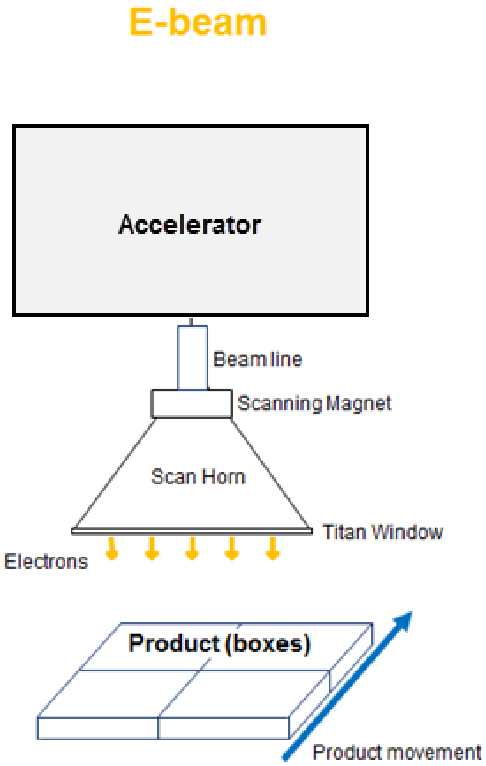
E-beam System – Cut away schematic





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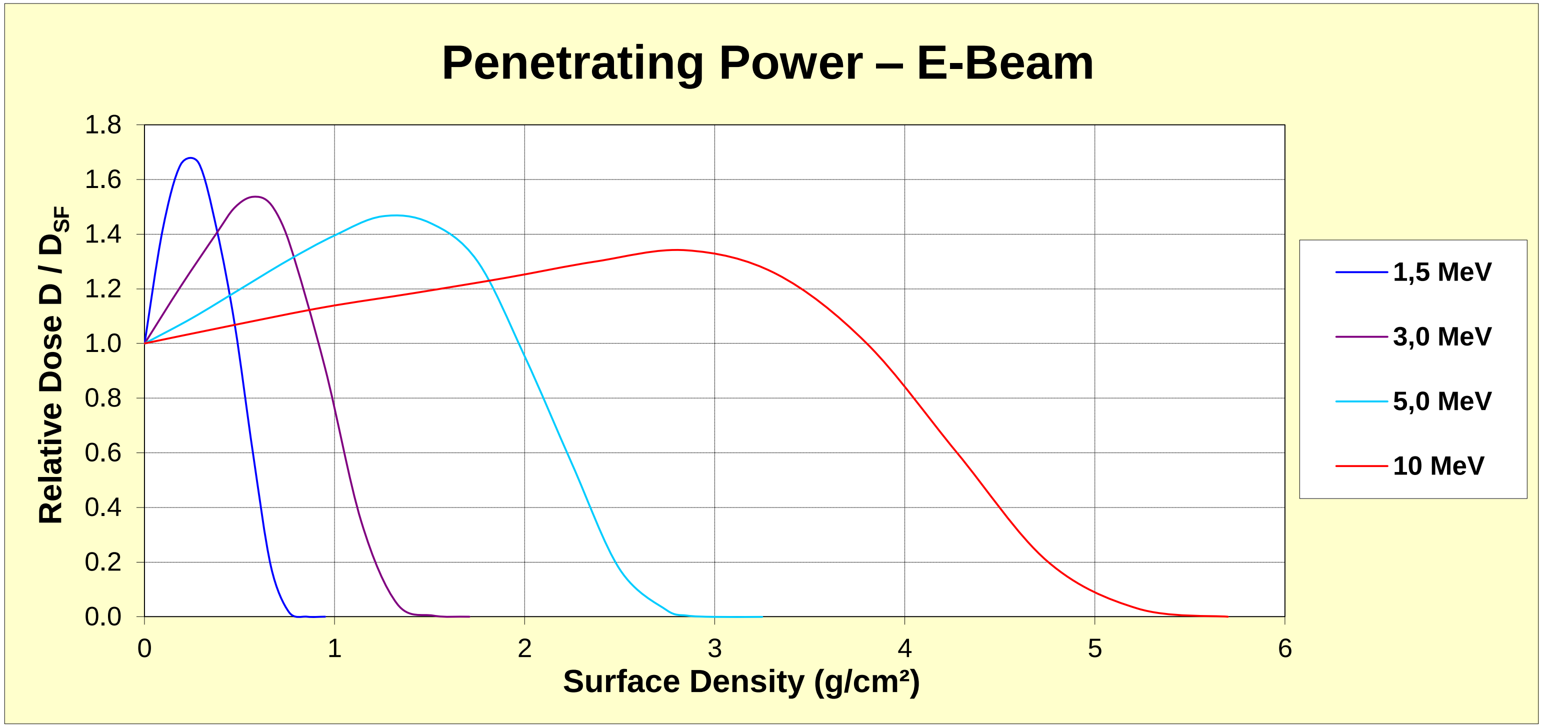
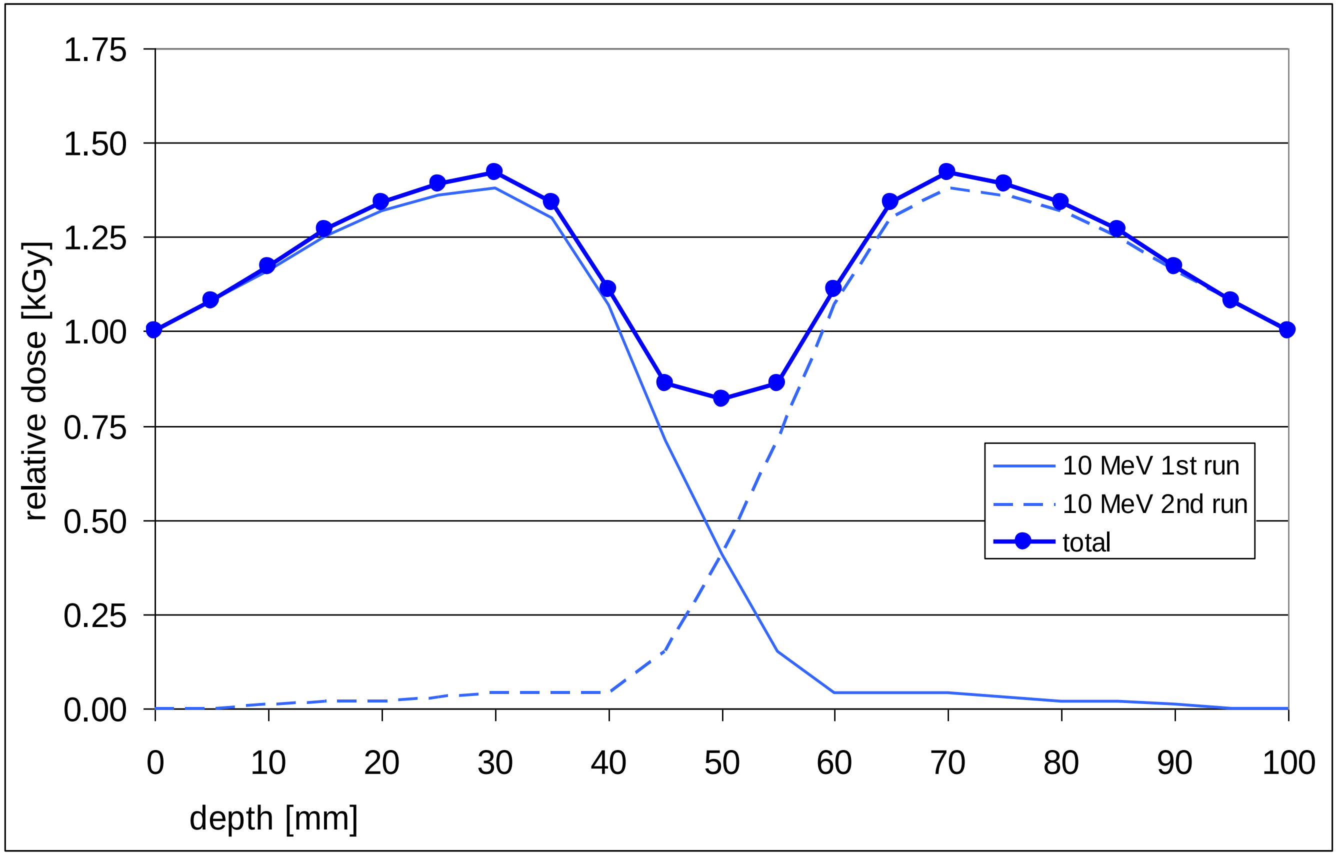
E-Beam Comparative Penetration



E-Beam Comparative Penetration



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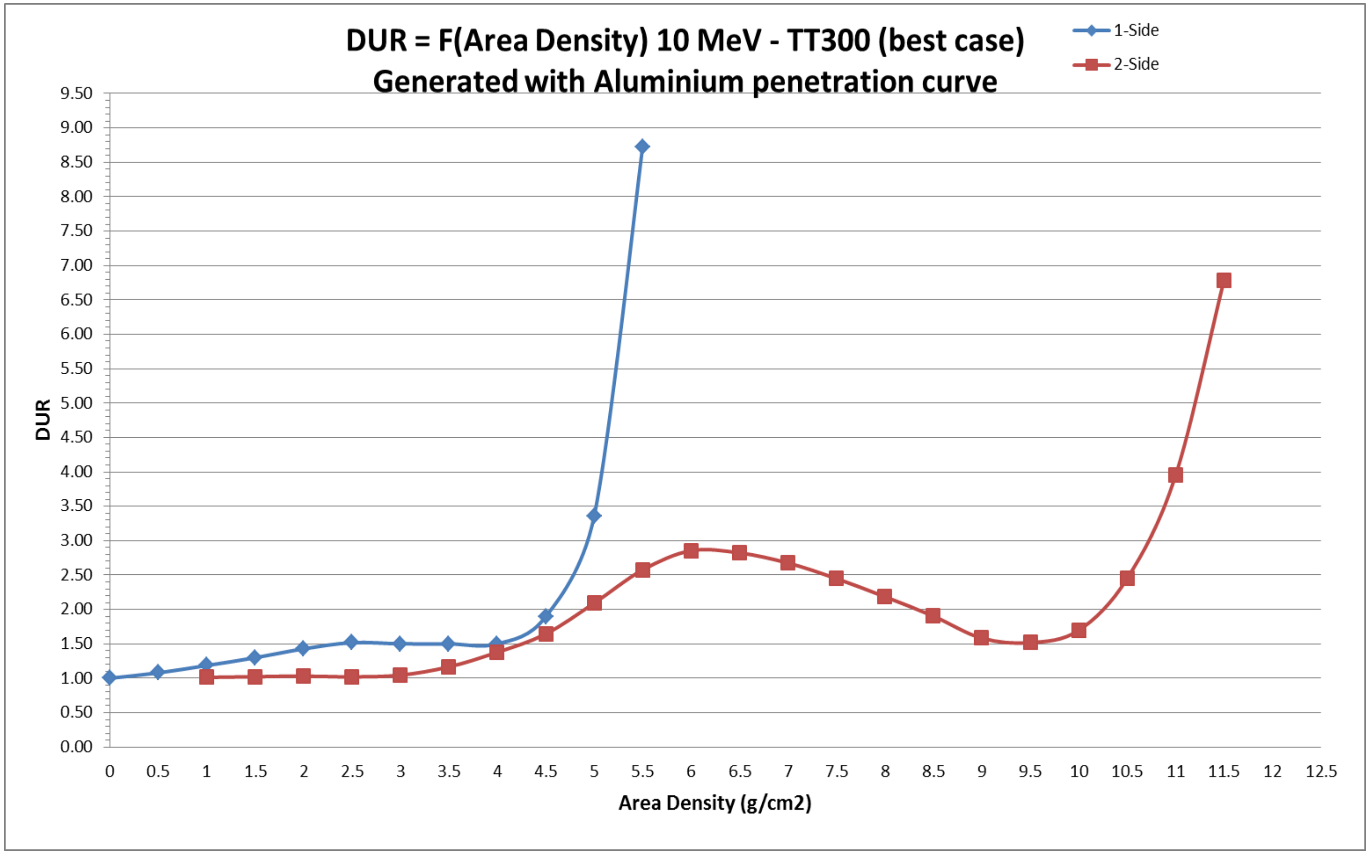
E-Beam - Penetration



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E-beam: Applications

Electron beam processing is most successful with low to medium density, homogenous products. Actual application will depend on specific processing equipment capabilities.

- Sterilization Products such as:
  - Gauze, drapes, towels
  - Bandages, wound care dressings
  - Lab ware, bottles, caps, containers
  - Tubing sets, procedure trays, catheters
  - Animal bedding, spices, agricultural and consumer goods appropriately packaged.
- Technical Application such as:
  - Crosslinking of Wires, Cables, heatshrinkables, hot water tubing, films, foams and injection moulded parts
  - Gemstones like Topaz, Diamonds a.o.
  - Semiconductors

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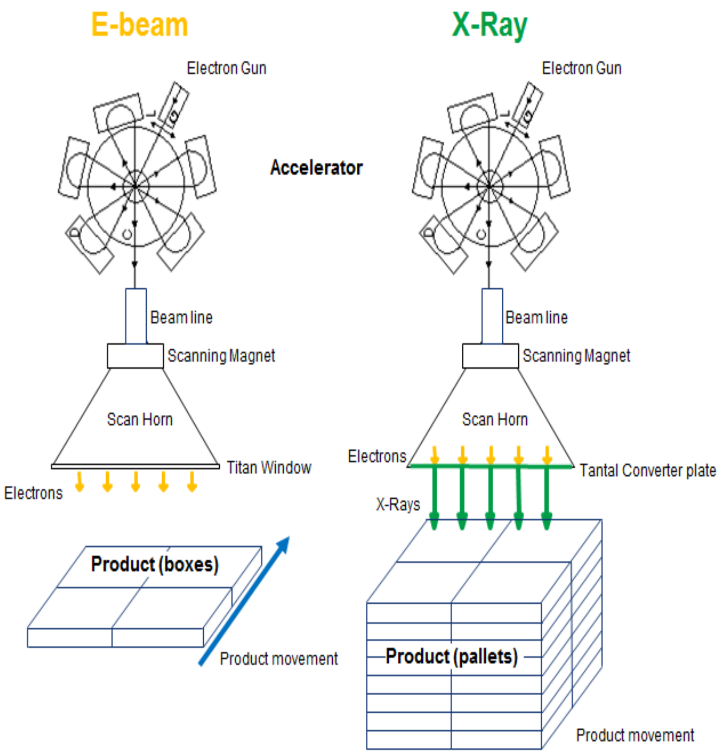
X-Ray – Principles… it starts as an Ebeam

- X-ray starts as an Ebeam, where electrons are generated and accelerated to gain energy.
- Electrons are generated in a vacuum environment by the source (electron gun), located at the outer wall of the cavity. The electrons are then drawn away and accelerated by the radial electric field, which transmits energy to them. Through a series or re-circulations through the cavity, the electrons are further accelerated which increases the energy.
- At the exit of the accelerator, the cylindrical shaped beam of high-energy electrons is transported through the beam line from the accelerator to the radiation vault.
- Electrons hit at the end a converter plate made of Tantalum where conversion into X-Ray (photon) takes place and then hits the product.



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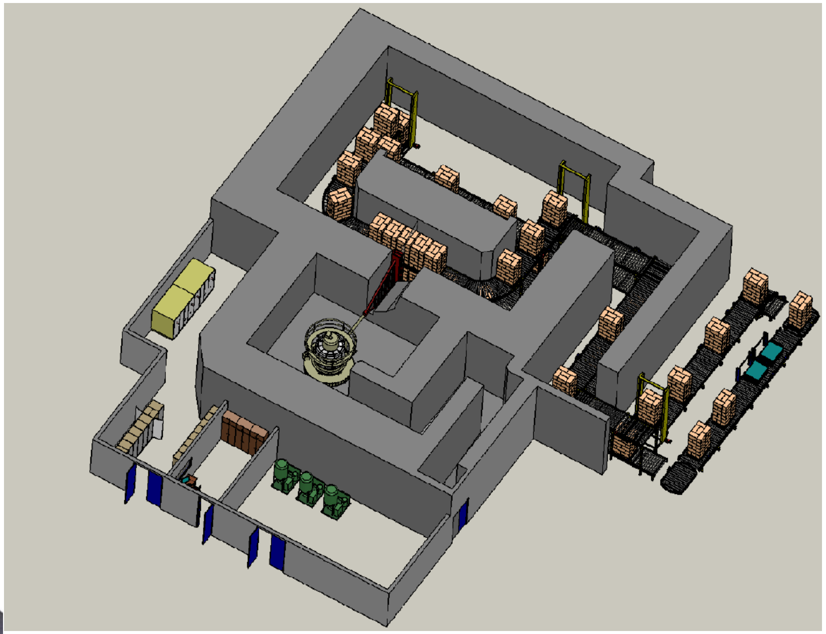
X-Ray - Principles

- High-energy X-rays are similar to Gamma rays,
- Photons used to irradiate large packages and pallet loads of medical devices.



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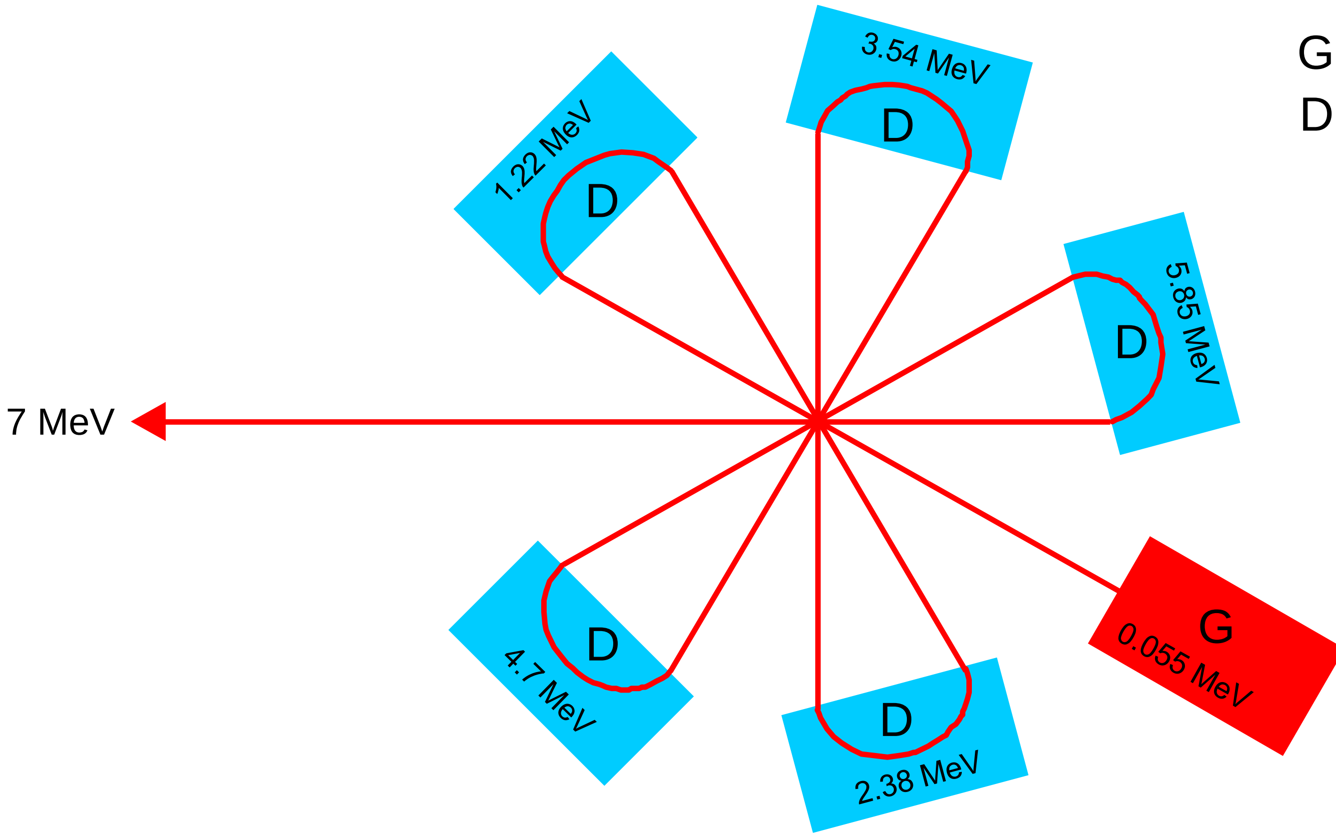
X-Ray - Principles

Operating Principle of the Rhodotron TT1000

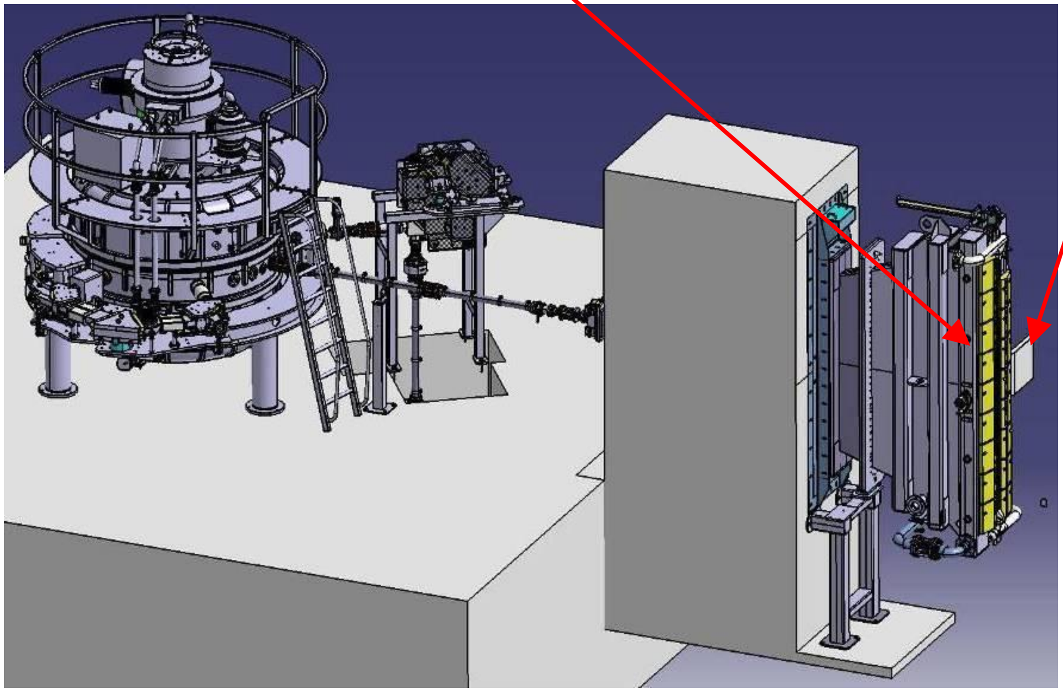
G = Electron Gun
D = Magnets



Electrons are injected 107 Million times/s

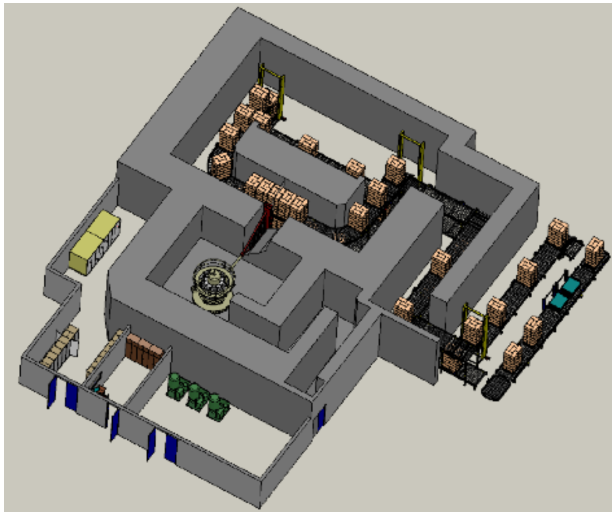
X-ray: the E-beam becomes X-ray

Electrons that were produced in the Rhodotron Ebeam, bombard a tantalum plate (converter) to **become X-ray**



X-Ray – Presentation of Products for irradiation

- Facility is designed to operate the process similar to a Gamma Pallet Irradiator where
- Pallets are supplied to a conveyor which transports the pallet to be presented to the X-ray source
- All key parameters are continuously monitored for being within the predefined limits.
- Irradiator and conveyor design allow:
  - Great flexibility as the dose is a function of the increments.
  - Treatment of pallets with different increments specification (or dose requirements) and different densities in the same time.
  - Continuous movement of pallets leading to less time at the irradiation source (benefits of which will be explained further).
  - Continuous process allows for scheduling and lead-time optimization



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X-ray: Applications

X-Ray processing is the combination of E-Beam with Gamma and even specialized for very high density products. Actual applications will depend on specific processing equipment capabilities.
Due to the much higher dose rates when compared to Gamma, X-ray can combine the usage of Ebeam application and Gamma application

- Sterilization Products same as Gamma such as:
  - Sterilization of medical devices in class II and III (implants)
  - Terminal sterilization of pharmaceuticals
  - Sterilization of all kind of primary packaging material like syringes, vials, bottles aso.
  - Gauze, drapes, towels, Lab ware, bottles, caps, containers
  - Bandages, wound care dressings, tubing sets, procedure trays ans so on
  - Animal bedding, spices, agricultural and consumer goods appropriately packaged.
- Technical Application such as:
  - Crosslinking of plastics
  - Gemstones like Topaz

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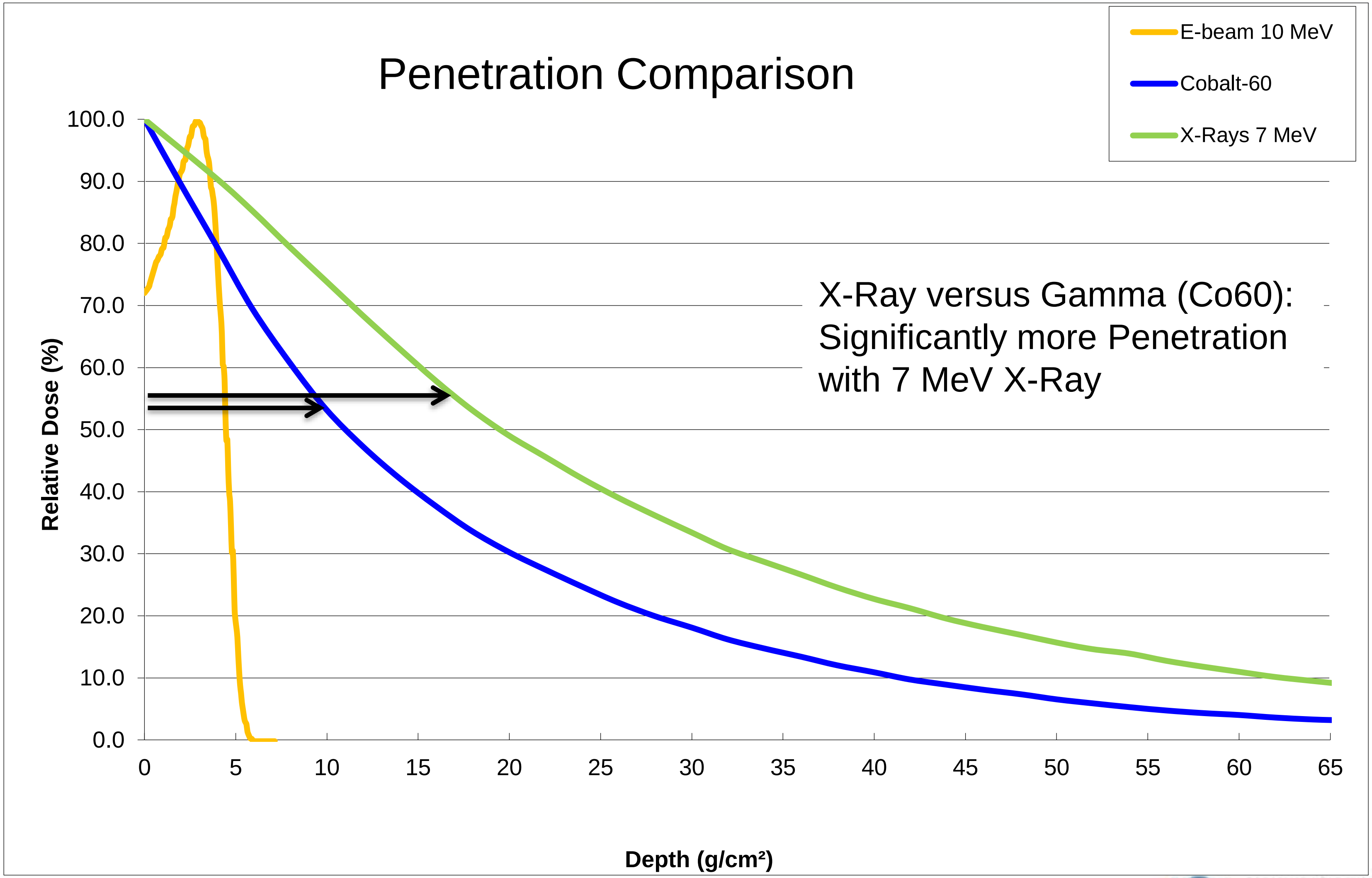
Sterilization methods with Ionising radiation



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Technology Comparison

Source	Electron Beam @ 10 MeV	Gamma Rays with Co60		X-Rays @ 7 MeV
penetration	limited: one side about 350 mm at density 0.1	big (entire pallet)	big (entire tote)	very big (up to **entire pallet**)
Homogeneity (DUR)	good to average: ≈ 1.5 (one side) to 2.8 (double side treatment)	good: (≈ 1.5 for pallets of 400 kg)	**very good:** (≈ 1.3-1.5 for boxes)	**very good**: (≈ 1.3 for pallets of 400 kg)
Economic	varied (very good to poor)	good		good
ISO 11137 accepted	yes	yes		yes
Tolerance for inhomogeneity	small, poor	good		**very good**
Ozone impact	small	big		small (close to E-beam)
Heat development	treatment room is cold Add. ≈ 5°C/10 kGy dose	treatment room is ≈ 35°C Add. ≈ 5°C/10 kGy dose		treatment room is cold Add. ≈ 5°C/10 kGy dose Max temp much lower than in Gamma
Typ. Dose rate	**≈ 500 – 30'000 kGy/h** (part of a box under treatment)	**≈ 0,5 - 20 kGy/h** (≈ 20 pallets under treatment)		**≈ 100 - 500 kGy/h** (part of pallets under treatment)
Polymer acceptability	good	limited		**good**

Many thanks for your interest