buyer's guide

Roadmap to an Electron Beam or X-ray Center for Industrial Applications

Eb/X Working Group

iia

This guide is intended for executives, strategic decision makers and others with an interest in the use of electron beams and/or X-rays for their business, but with limited prior knowledge. It introduces the topics that need consideration to allow an effective feasibility analysis of the technology, without going into technical detail. Instead, it provides links to where additional information can be found. The aim is to enable a thorough analysis of the potential of these technologies and their respective effect on the business. It also describes current applications of the technologies to demonstrate their potential.

This document was authored by the Eb/X working group of the iia with input from other iia members and financial support from the U.S. Department of Energy's National Nuclear Security Administration (DOE/NNSA) Office of Radiological Security (ORS).

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Introduction

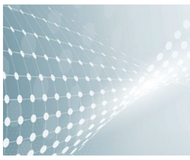
Many people new to the commercial-scale electron beam (e-beam) and X-ray technologies lack easily accessible information on what these could do for their processes or what they need to consider before embarking on the implementation of these technologies. This roadmap will provide a guide to planning, developing and constructing an e-beam or X-ray facility that is not biased towards either technology. It will enable decision makers to perform an effective feasibility analysis and establish a bankable business plan for these technologies.

The intended audience of this roadmap are executive and strategic decision makers who have established business models, perhaps with other technologies, but wish to evaluate the introduction of or transition to e-beam or X-ray. This may be for expected cost reduction or strategic advantages (e.g. transport cost, sterilization cost, just-in-time on-site, flexible operation hours, etc), the phase-out of chemical methods (e.g. Methyl-Bromide), regulatory hurdles of other methods (e.g. EtO emissions), regulatory requirements for bio-security, sterility, radioactive material transport and licenses or supply chain issues.

The focus of this roadmap will be on business topics for an effective and gap-free feasibility analysis for new projects. This roadmap also focuses on current industrial applications and not on the development of new applications.

A list of key suppliers for process-relevant systems and services is being provided and maintained by the International Irradiation Association (iia) on its website.. The iia is a not-for-profit organization that supports the global irradiation industry and scientific community in advancing the safe and beneficial use of irradiation. The iia acknowledges and thanks the U.S. Department of Energy's National Nuclear Security Administration (DOE/NNSA) Office of Radiological Security (ORS) for their support with the production of this Roadmap document.

The structure of the document is as follows:



Section 1 introduces the use of e-beam and X-ray and the parameters used to describe it.

Section 2 describes the current commercial applications.

Section 3 outlines the capabilities of e-beam and X-ray and how to determine which, if either, can be used for your application.

Sections 4 and 5 provide the items that need to be considered for capital expenditures and operational expenses estimates.

1.1 Parameters used to describe irradiation

For both e-beam and X-ray options, a beam of electrons is accelerated by a particle accelerator towards the product to be irradiated. If X-rays are desired, a metal target is placed in the electron beam path to create the X-rays. To cover a specific area, the beam is spread by magnets (scanned) across a defined width and the product is moved through the scanned beam on a conveyor (see Figure 1).

Detailed descriptions of the accelerators and their parameters can be found in the iia's Accelerators for Sterilization of Medical Devices: A Guide for Prospective Buyers document which will be referred to in this roadmap as "Accelerators Guide". The key concepts and parameters of the irradiation are explained in *Table 1.*

Table 1: List of main Parameters used for e-beam/X-ray irradiation

Name	Description	Symbol	Metric unit	Typical range	Unit explained
Dose	Energy absorbed per unit mass. This describes how much radiation energy is absorbed by the product. Most products have a defined minimum dose for the process purpose to be effective and meet regulations (for example, sterility in medical products, inactivating microorganisms or insects in food, etc). There is often a maximum dose threshold to prevent undesirable product changes (for example, discoloration of polymers).	D	Gray	0.1-100 kGy	Kilo-Gray
DUR	Dose uniformity ratio. This is the ratio of the measured maximum and minimum (max/min) doses delivered to a product during irradiation. The aim of the irradiation is to keep the DUR as close to 1.0 as possible, though typically only around 1.3-1.8 is achievable at best. DUR is a common performance indicator used in quality control of the process	DUR	none	<3	Kilo-Gray
Energy	This is the kinetic energy of the electrons incident upon the product or the X-ray converter. It determines how far into the product the irradiation will penetrate, with higher penetration at higher energy, while X-rays penetrate substantially deeper (see Figure 2). Industrial applications typically do not have energy limits and up to 20 MeV is currently used for some special applications. For X-rays, the maximum e-beam energy to impinge on the X-ray converter is regulated for pharmaceutical and food applications to either 5 or 7.5 MeV, depending on the product and the country. For medical device sterilization typically 5, 7 or 7.5 MeV are used. For medical device sterilization using e-beam and X-ray with energy levels exceeding 10 and 5 MeV respectively, the potential for induced radioactivity in the product shall be assessed.	DUR	none	<3	Kilo-Gray
Power	Rate of energy delivery. The electron beam power is indicative of the energy delivery rate, i. e. dose rate: the higher the power, the higher the dose rate achievable and the faster product can be processed.	P	Watt	Typically, 10-600 kW	Kilo-Watt
Beam Current	Flux of electrons impinging on X-ray converter or product, like an electric current Within the same facility it is proportional to production capacity.	I	Ampere	Typically, 1- 100 mA	Milli-Amp
Beam width	Older standards also refer to Scan width	Wb	Meter	80-350 cm	Centimeter

[4] ISO/ASTM 51649:2015(en) Practice for dosimetry in an electron beam facility for radiation processing at energies between 300 keV and 25 MeV

Figure 1: E-beam Scanning Parameters *(Beam Width)*

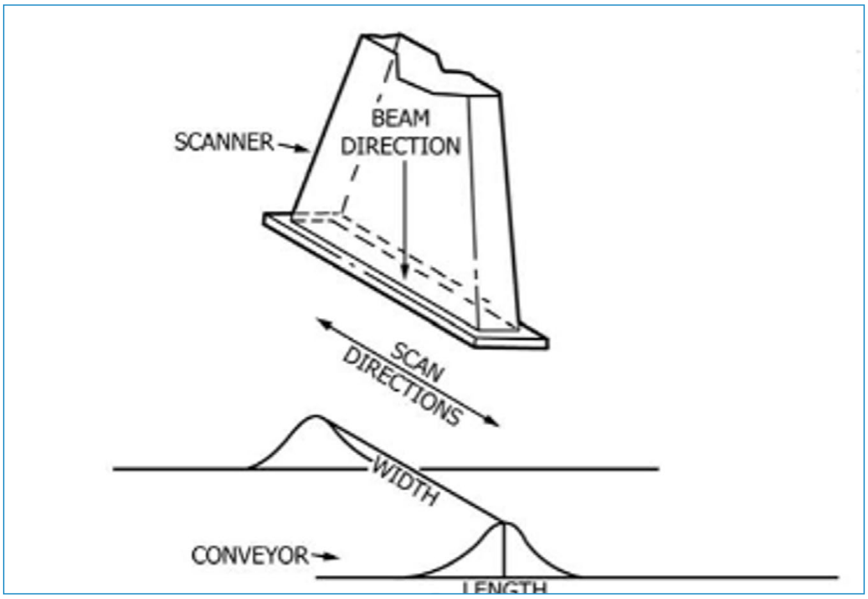
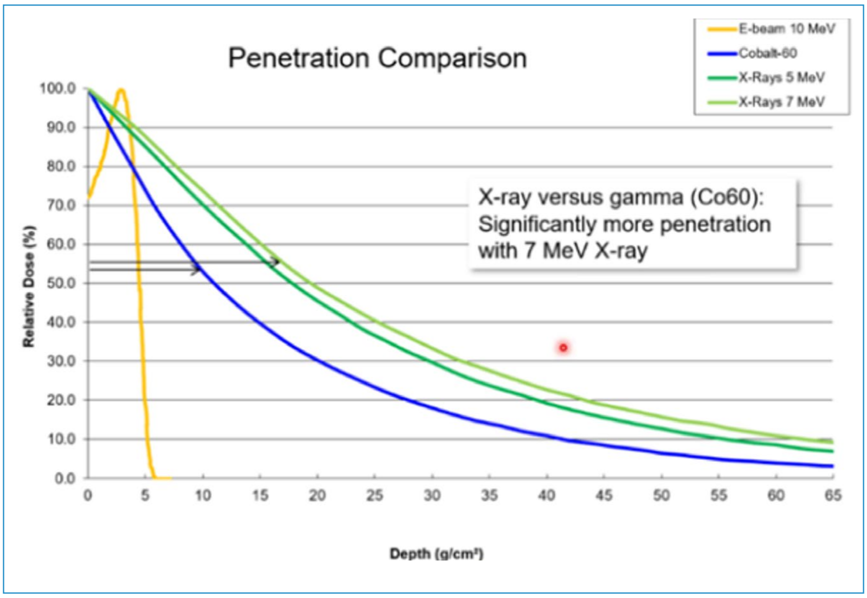


Figure 2: Penetration Comparison: e-beam, X-ray and gamma *(Accelerators Guide, Fig 7)*



Applications

Using ionizing radiation to treat products is a well-established and widely used process for many industrial applications. Key characteristics and commercially-relevant parameters will be discussed in the following sections. As with all radiation facilities, the design and build team, as well as the operators, must take local regulations into account for radiation safety and permitting.

The focus of this section is on aspects of common applications. Regulatory requirements for the manufacturing processes are not within the scope of this roadmap.

2.1 Medical Device Sterilization

Radiation sterilization works by destroying the pathogenic microorganisms on or in products, without damaging the products themselves. The terminal sterilization of medical devices, pharmaceuticals or combinations thereof are tightly regulated processes. Requirements are laid out and guidance is provided in ISO 11137[1] for sterilization by radiation. Sterilization of medicinal products is regulated in the EU in GMP Annex 1 "Manufacture of Sterile Medicinal Products"[2] . Rules and implementations in various countries differ, but the general principles are very similar.

Common for this application is a sterilization dose (or minimum dose) in the typical range of 10 to 25 kGy in order to reach the desired sterility assurance level (SAL). This is determined through microbiological analysis of the product. The maximum acceptable dose that the product can tolerate is defined by material properties in shelf-life studies. For polymers, the maximum acceptable dose is typically in the range of 40-100 kGy. For pharmaceuticals, often the container needs to be sterilized at high dose (10-25 kGy), while the medicinal part within may have to be shielded from radiation in order not to damage the drug (drug-device combination products). The short range of e-beams can be an advantage in this case.

All techniques of radiation sterilization may be considered and selected based on the product and packaging.

[1] ISO 11137-1:2006 Sterilization of health care products — Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

[2] https://health.ec.europa.eu/index_en

2.2 Phytosanitary Irradiation and Quarantine Treatment

Phytosanitary treatment for the control of pests and diseases on plants and agricultural products for quarantine control, import/export and bio-security is typically regulated by national plant protection organizations. International standards are available at the International Phytosanitary Portal (IPPC.int) at https://www.ippc.int/core-activities/standards-setting/ispms. Requirements and Guidelines "for the use of irradiation as a phytosanitary measure" are also available through the United Nations Food and Agriculture Organizations (FAO).

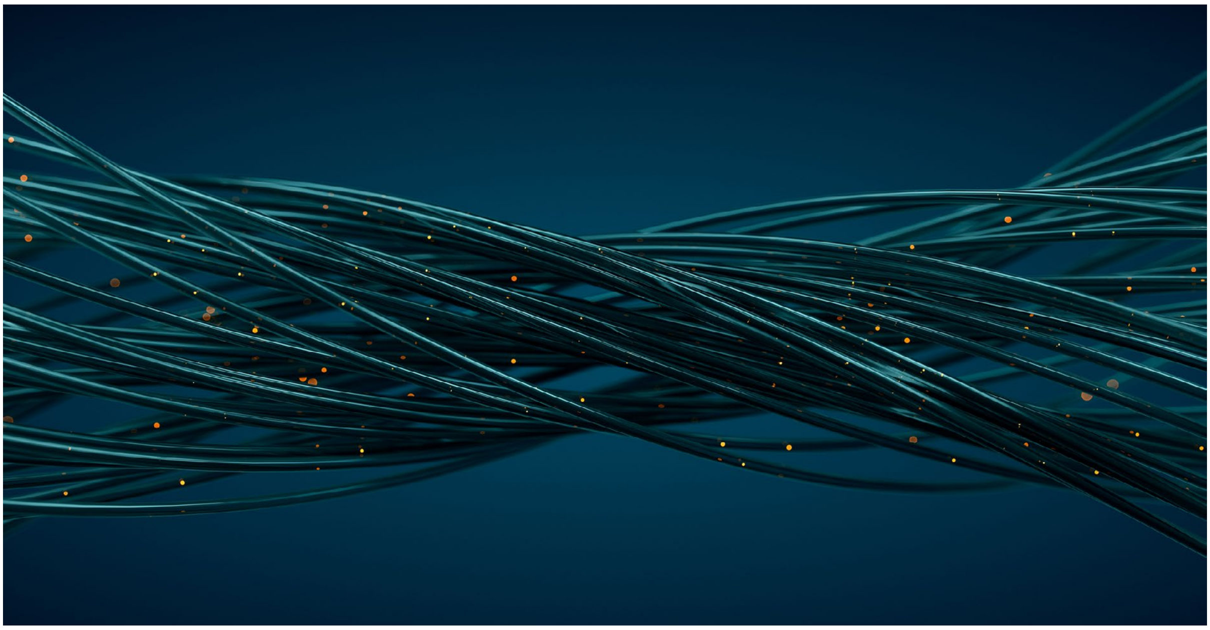
The doses are much less than for medical device sterilization, with a minimum dose as low as 50 Gy and a maximum of 1 kGy for fruits and vegetables. It is common practice to adopt principles from medical device sterilization for dose verification and validation methods.

Phytosanitary irradiation is an alternative to gas treatments and is sometimes used when regulations prohibit the use of methyl bromide, ethylene oxide or other gases to comply with import restrictions for fruits and vegetables.

Pallet integrity is typically a customer/user requirement. Due to the high density of fruits and vegetables, e-beam treatment is sometimes an option if the DUR deliverable is compatible with the minimum and maximum dose requirements. Products would be treated in cartons or crates. X-ray (and gamma-ray) treatments have a much higher penetration and are the only option for pallet irradiation.

2.3 Food and Spice Irradiation

Food Irradiation (e.g. dried fruit, spices, pet foods, meat products) has a dose range from <1 to 10 kGy. The product is typically pre-packaged in bags and less often in boxes. The packaging determines if electron beam treatment is suitable according to the achievable DUR, but more often X-ray or gamma are chosen to irradiate product pallets.



2.4 Polymer Modification

Polymer modification is widely used to improve or tailor the properties of polymer materials. Modification with irradiation by high energy beams is typically performed either by

1. using tray-based conveyors to pass the product through the beam, for example coiled tubing, granular product, sheet products or other items.
2. by strand based-product handling, such as for wire and cable, on a reel-to-reel system.

Although dose level is seldom a process requirement, the dose range for polymer modification is typically higher than 50 kGy and often over 100 kGy. Heat buildup inside the product often means that multiple irradiation passes are required to avoid overheating. Manufacturing requirements generally come from the customer and are typically based on material properties.

For cross-linking or degradation of polymers, medium to high energy e-beam is often used. For ink or surface curing applications, low energy e-beam is typically used.

Process

3.1 Selection Criteria for Electron Beam or X-ray

An overview of the typical selection criteria for e-beam or X-ray can be found in Table 4 of the Accelerator Guide. It has been updated and repeated here for convenience.

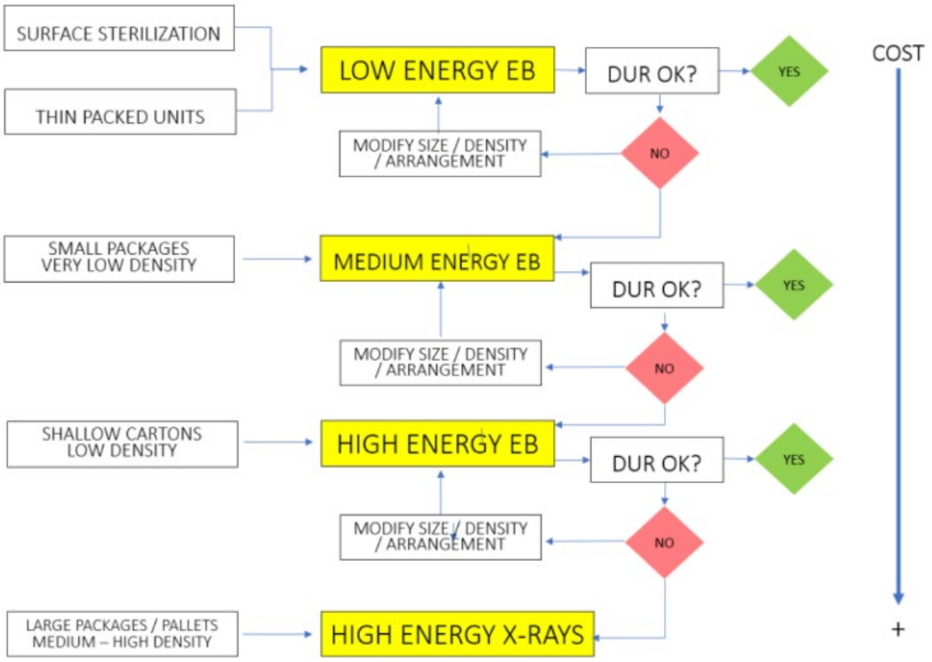
Table 2: E-beam and X-ray systems used in industry

System	Low energy EB	Low to Medium Energy EB	Medium energy EB	High energy EB	High energy X-ray
Energy range	< 300 keV	500 keV - 3 MeV	2 - 8 MeV	8-13 MeV	5– 7.5 MeV
Shielding type	Self-shielded below 3 MeV		self-shield or bunker	large bunker	
Shielding material	steel, lead		steel, lead, concrete	concrete	
Shielding footprint	up to $60m^2$		up to $200m^2$	$400\text{-}500m^2$	
Mode (typical)	Surface or thin product treatment in-line processing	wire and cable / reel-to-reel	In-line processing terminal sterilization	Terminal sterilization flexible application	
Product	unit product / designed for one product	thin strand product	low density	low to medium density	any density
Package	none / individual packs	none	Individual packs / shallow cartons	cartons	cartons, pallets
Project Cost (order of magnitude)	100k - 1,000k USD	500k - several 1,000k USD	several 1,000 kUSD	several 1,000k USD	> 20,000 kUSD

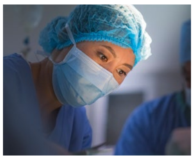
This table should be used as a general guideline and not a limiting factor. For example, in a single layer, mangos (high density) have been treated effectively with high energy e-beam. In all cases, the dose distribution and dose uniformity must be analyzed for every product in the packaging intended for irradiation.

Figure 11 of the Accelerators Guide, which shows a technology decision tree, has been reproduced here as Figure 3.

Figure 3: A simple Decision tree based on Dose Uniformity Ratio *(DUR)*



3.1.1 Product compatibility with e-beam/X-ray and the benefits



Medical: Product compatibility testing for e-beam and X-ray (e.g. for shelf-life studies for materials) may take some time. When already qualified for gamma irradiation, this testing might be shorter, even though the medical device industry is traditionally slow with changes in their processes and supply chains. This may impact the production ramp-up.

Food and Phytosanitary: Organoleptic studies seem to indicate that X-ray treatment within the prescribed maximum dose does not negatively affect taste. Nevertheless, qualification tests at X-ray facilities will provide certainty.

Polymers: The intent is to modify polymer properties. Metal-polymer interfaces as well as homogeneous dose applications may pose challenges.

Table 3 compares the benefits between various technologies for these applications. In addition, Team Nablo in the US is collecting data to verify whether e-beam and X-ray are comparable to gamma irradiation[3].

[3] Supplementing Gamma Sterilization - BioProcess International (bioprocessintl.com)

Table 3: Characteristics of Irradiation and Chemical Modalities

Criteria	E-beam	X-ray	Gamma	EtO/MB
Product presentation	Boxes, single product, stranded materials, granular	Boxes, pallets	Boxes, pallets	Pallets
Product qualification	Dose distribution must be validated for each product	Dose distribution must be validated for each product	Dose distribution must be validated for each product	Product dependent
Regulatory challenges	Radiation operating permit	Radiation operating permit	Transport for source replenishment and disposal, licensing requirements in some countries	Emissions and residual gas concentrations, upgrade to changing conditions
Service personnel qualifications	Mechanics, electrics, electronics	Mechanics, electrics, electronics	Mechanics	
Minor repairs	Supplier assisted	Supplier assisted	In-house	
Major repairs	Supplier repair	Supplier repair	Supplier assist	
Product release from process	Dosimetry and processing parameters	Dosimetry and processing parameters	Dosimetry and processing parameters	Processing parameters

3.2 Production Capability and Capacity of E-beams

Product packaging and product density and shape are crucial in evaluating whether or not e-beam can even be considered due to the limited useful range. This determination must be done by an experienced dosimetrist at an irradiation facility or with Monte Carlo simulation tools.

The Accelerators Guide explains the importance of energy in detail in Section 5.1, and also why it is crucial to understand the packaging inside boxes to be treated, density gradients inside each box and the orientation of the boxes to the radiation, as this will significantly affect the Dose Uniformity Ratio (DUR) – or even the possibility to treat the respective product at all with e-beam.

The e-beam energy determines the thickness of the product that can be treated with an acceptable dose uniformity. Electrons have a finite range in the product. In order to increase the applicability of e-beam systems, a product can be (and most often is) irradiated from two opposite sides. The Accelerators Guide Section 5.1 provides more details on range vs energy and double-sided irradiation of an homogeneous product.

For the purpose of this roadmap, we will assume that the e-beam energy has been chosen based on the DUR selection criteria in Figure 3 with support of a dosimetry expert. For more elaborate estimates on throughput, one should consult ISO/ASTM 51649[4] - The following subsections present two methods to estimate throughput.

Table 4 and Table 5 highlight how important it is to thoroughly understand the effect of product packaging on the throughput. Both methods strongly rely on an expert evaluation of the DUR for the respective beam energy and packaging.

Product qualification for e-beam is challenging. Typically, products with homogeneous density distribution of up to 0.3 g/cm^3 inside the boxes can be suitable for double-sided 10 MeV e-beam irradiation.

[4] ISO/ASTM 51649:2015(en) Practice for dosimetry in an electron beam facility for radiation processing at energies between 300 keV and 25 MeV

3.2.1 Mass processing rate

In this case, the general rule for the throughput of product in kg * kGy/h is given by

$C = 3600 \times P \times \varepsilon$

where P is the accelerator beam power in kW and ε is the fraction of the beam power delivered to the product. Allowing for small gaps between products on the conveyor and over-scanning to ensure a good DUR at the fringes, one should assume an ε=70% efficiency of this process. Hence for a 10 MeV system with P=30 kW (hence I=3mA), tight packaging of product boxes on this conveyor and a minimum dose D=25 kGy, the estimated production throughput is about 3000 kg/hour. The corresponding volume depends on the product density, but with a typical density for medical sterilization between 0.1 and 0.3 g/cm^3, this is around 15 m^3/h (see Table 4).

This formula works if all the product that is treated in this facility has the same density. It fails when the product and e-beam energy are not perfectly matched. For an e-beam center that irradiates many products, this method is not suitable.

Table 4: Example for Mass processing rate calculations

Input				Output			
Beam Power	**efficiency**	**Dose**	**Product Density**	**Mass Processing Rate**	**Throughput**	**Volume Processing Rate**	**Comment**
P	ε	D	ρ	C	M		
kW		**kGy**	**g/cm^3**	**kg * kGy /h**	**kg/h**	**m^3/h**	
30	0.7	25	0.1	75,600	3,024	30.2	I=3 mA
30	0.7	25	0.2	75,600	3,024	15.1	I=3 mA
30	0.7	25	0.3	75,600	3,024	10.1	I=3 mA

3.2.2 Area Processing rate

The "Unit-rule" is very easy to remember: 1m beam width, 1m/min conveyor speed, 1 mA of beam current, results into 1 Megarad (=10 kGy) surface dose. This simple method works for e-beam energies > 2 MeV and is independent of product density and type. Hence the area processing rate A in m^2/min is given by

$$A=v*W_b= I/D*10$$

where I is the beam current in mA, v is the conveyor speed in m/min, Wb the beam width, and D the dose in kGy. Under the pre-requisite that the product box has been validated based on the DUR selection process described above, the Volume processing rate in m^3/h for single sided irradiation can be calculated by

$$V=A*h_s*60*\varepsilon=I/D*h_s*600*\varepsilon$$

where h_s is the product box height in meter, and ε= 70% is a good assumption also for this method. In this case h_s is the box height that has been validated by the DUR selection criteria for single sided treatment. Treatment from opposite sides is typically used when the product height for single sided treatment is not sufficient to treat the respective product or product box. Technical details on this for homogeneous products can be found in section 5.1 of the Accelerators Guide.

For treatment from opposite sides, the product will pass in front of the beam twice, typically with the same surface dose D. The product height h_{ds}, again validated by the DUR selection criteria, is typically $h_{ds} > h_s$. However, since two passes are needed, the volume processing rate is given by

$$V = I/D * h_{ds} * 600 * \varepsilon * 1/2$$

This method for calculating the throughput has the advantage that it works for all products in the proposed facility. It requires a more detailed analysis for the products to be irradiated for its dose distribution and DUR.

Further guidance on this can be found in *ISO/ASTM 51649*.

Table 5: Example for Area Processing Rate calculations – single sided

Input					Output			
Beam Current	Dose	Product height	efficiency	Scan Width	Area Processing Rate	Conveyor speed	Volume processing rate	Comment
I	D	h_s	ε	W_b	A	v	V	
mA	kGy	m		m	m²/min	m/min	m³/h	
1	10			1	1	1	0.0	"Unity Rule"
3	25	0.3	0.7	0.8	1.2	1.5	15.1	30 kW
3	25	0.4	0.7	0.8	1.2	1.5	20.2	30 kW
3	25	0.5	0.7	0.8	1.2	1.5	25.2	30 kW

3.3 Production Capability and Capacity of X-rays

For X-rays, as in gamma irradiation facilities, the product will always be treated from two sides in two or four passes. For a pallet, this means that it must be rotated 180° after the first pass in front of the beam and receive the same dose from the opposite side.

Up to now, most X-ray centers apply the dose in product overlap mode, whereas in gamma irradiation both source overlap and product overlap are common. The difference is explained in Figure 4. For product overlap, each product container is presented to the beam in 4 passes as indicated in Figure 5. For details, please refer to section 10.2 in the Accelerators Guide.

Figure 4: Source and Product Overlap explained.

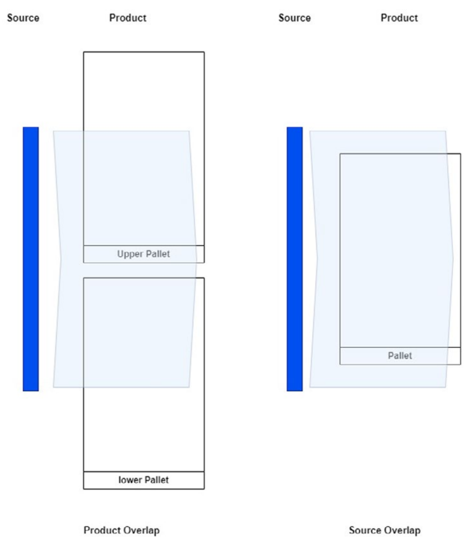
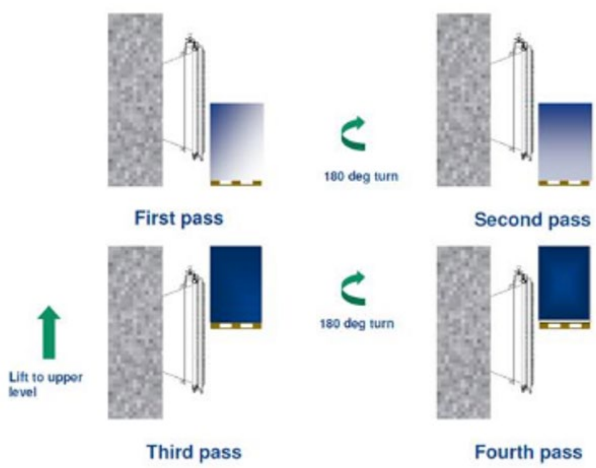


Figure 5: Two sides and two levels of X-ray exposure (one level represented only) (Credit: STERIS AST)



The production capacity (also called "throughput") depends on the average density in the product container (i.e. pallet). The packing arrangement of the product in the container is important so that the average density (total mass/total volume) is truly representative of the product. The dose uniformity is a result of several aspects but can be approximated by the product thickness in the beam direction and the average density.

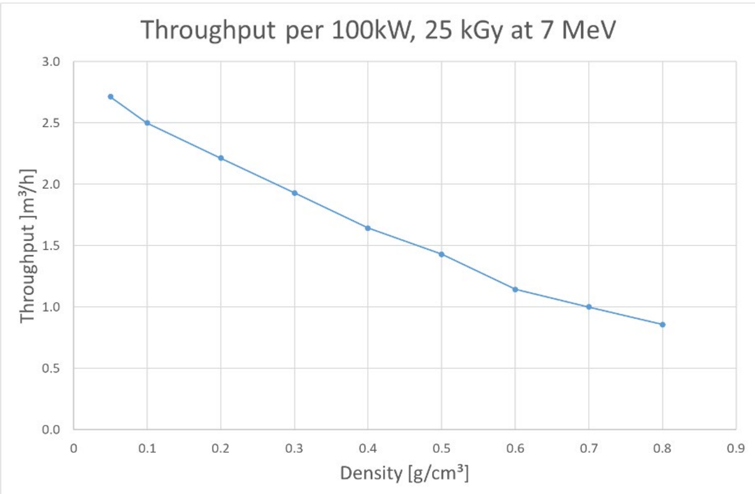
Figure 6 provides guidance on production capacity for a 7 MeV X-ray system with source overlap. The data have been taken from Figure 31 in the Accelerators Guide and are based on Monte Carlo simulations. For a 5 MeV X-ray system, approximately 25% less throughput should be expected.

Experimental case studies with pallets of high-density fruits have shown a 20-25% reduced production capacity, compared to the graph in Figure 6.

The DUR can be expected to be around 1.3 at low densities. The DUR increases for higher densities. Simulations for medical devices with densities of 0.3g/cm^3 predict a DUR=1.5, while experimental studies with mangos (ρ=0.3g/cm^3) and dates (ρ=0.5g/cm^3) show DURs of 2.2 and 2.9, respectively.

Therefore, any simulated production capacity data should be used with caution. An experimental verification should be performed during the feasibility analysis phase of the project.

Figure 6: Production Capacity X-ray at 7 MeV for 25 kGy per 100kW



3.4 Production Capacity Comparison: E-beam, X-ray and Gamma

The following comparison has been compiled base on A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products, iia whitepaper, August 2017. The throughput numbers have been taken from the referenced whitepaper without a detailed review of the specific systems.

For e-beam and X-ray, the range in throughput estimates is dependent on factors including the conversion efficiency of the accelerator, the design of the product conveyance and the specific product being irradiated and its packaging. For gamma, the range in throughput estimates is dependent on factors such as the design of the source, number of product conveyance passes by the source, the design of the product conveyance and the specific product being irradiated and its packaging.

Table 6 has been compiled for 3 very specific scenarios: 1) a 10 MeV e-beam system with a box conveyor, a 7 MeV X-ray pallet irradiator based on an IBA Rhodotron using 2 passes and source overlap, and a Nordion JS-10000 hanging tote irradiator using 4 passes in product overlap mode. A cost efficiency decision between any of these technologies must always include the specific facility design, equipment, product presentation to the radiation source or beam, and the production capacity and DUR that can be achieved in that specific scenario.

Table 6: Compilation of estimated throughput of medical devices at 25 kGy and with a DUR < 1.8

Product Density	10 MeV e-beam, box conveyor 80 kW		X-ray 7 MeV pallet conveyor 560 kW		Gamma, JS1000 tote box irradiator 4 MCi	
g/cm³	low	high	low	high	low	high
million cubit feet per year						
0.1	3.50	10.50	3.73	7.40	3.25	5.50
0.2	1.80	5.30	3.15	6.50	2.60	4.40
0.3	1.20	3.70	2.50	5.20	2.00	3.40
1000 m³ per year						
0.1	99	297	105	210	92	156
0.2	51	150	89	184	74	125
0.3	34	105	71	147	57	96

3.5 E-beam and X-ray in the same facility?

Table 7 outlines the pros and cons for e-beam and X-ray located in the same facility. In general, any combination of one accelerator providing both e-beam and X-ray is a compromise that results into lower return of investment.

Table 7: Pros and Cons for e-beam and X-ray in the same facility

Accelerator	Underbeam	Pro	Con
one accelerator for both	E-beam optimized conveyor, X-ray target added at same energy	• lowest CAPEX	• very limited efficiency • potentially X-ray above regulatory limit • built often, but rarely used in production
	E-beam optimized conveyor, X-ray target added at 5 or 7.5 MeV energy	• lower capex than two converyors • R&D possibilities	• limited use cases, but for the occasional use may be better than sending a customer away
	two conveyors, one optimized for E-beam, the other for X-ray	• industrial production in both modes • independent access to each vault	• only one mode can be used • production capacity in X-ray mode much lower than in EB • complex beam line • power limitation for X-ray due to machine availability
	X-ray optimized conveyor, target removable		• E-beam with 5 or 7.5 MeV not suitable for many products • Additional maintenance concerns • power reduction required for EB operation
separate accelerators	two conveyors, one optimized for E-beam, the other for X-ray	• highest flexibility and efficiency • design of each system independent, according to respective business plan	• highest CAPEX - two independent vaults

3.6 Sustainability

Sustainability is vital in radiation processing, encompassing environmental impact, organizational structure and partnerships. The UN's seventeen Sustainable Development Goals highlight its importance globally.

In radiation processing, sustainability extends beyond choosing technologies like e-beam or X-ray. It involves organizational interactions with people, partners and the environment. Sustainable practices are essential for meeting customer expectations, as clients prioritize sustainability in their service providers. These considerations include internal and external factors, impact the supply chain and vary by operation, technology and region.

Transport of Goods: The carbon footprint from transporting goods is significant. Organizations should minimize this by choosing partners who offer efficient, low-carbon transport options, reducing distances, and optimizing load fill.

Energy Consumption: Radiation processing with e-beam and X-ray accelerators is energy-intensive. Sustainable operations depend on electricity sources, with greener options like hydro, solar, wind power or nuclear. Energy converted into heat can be repurposed for heating and cooling, though its intermittent availability must be managed.

Supply Chain: Sustainability involves waste and recycling rates, greenhouse gas emissions, the carbon footprint of life-cycle products, water usage and ecological impact.

The iia encourages organizations to aim for high sustainability targets to minimize their environmental impact. This includes reducing waste, using biodegradable materials and limiting toxic emissions.

E-beam and X-ray can improve sustainability if it reduces or eliminates transport to external treatment facilities. The energy usage of e-beam and X-ray should also be compared to the manufacture, transport and disposal of chemical alternatives. E-beam and X-ray require no other inputs besides electrical power.

Capital Expenditure Elements Of A Facility

The key expenditure elements of e-beam and X-ray facilities are shown in the table below. These are for sterilization facilities, but also apply to other applications. The Accelerators Guide provides more detailed descriptions in its Section 12 and 13.

Estimated capital expenditure (CAPEX) for an e-beam or X-ray facility are shown in Table 8.

Category	Items	Options/Comment
Project feasibility study	Product suitability Regulatory approval	If change of sterilization modality
	Dose distribution studies	External service
	Market study and business case	Consultant
Project Management	Selection of process equipment	Internal and external resources Time and travel Meetings with consultant and vendors
Regulatory compliance	Commissioning License Fee Operational License Fee Annual Operations Fees Radiation Safety Officer training	Consultant to guide process if no expertise in the company
	Ozone abatement determination Compliance with regulatory bodies requirements for medical products	
Land	Real estate fees Taxes	For greenfield facility
Building and shielding	Permitting Shield / bunker Storage space / loading and unloading areas / docks Offices / technical rooms (control, dosimetry, …)	Creation or modification Design and construction Fitting a large bunker in an existing building can be more expensive than constructing a new building
EB or X-ray generator	Accelerator	Beam line(s) design
Ancillary systems	Water cooling	Tower or chiller
	Electrical supply	UPS
	Ozone removal fan	
	Compressed air	
	Technical gases	Dry air, dry nitrogen, helium
Product handling	Under beam control	
	Shield and warehouse conveyor	Box flipping system, palletization robot, Automated Guided Vehicles, automatic storage equipment, forklifts Cost can exceed accelerator depending on level of complexity and automation"
	Infeed and outfeed conveyors	
Safety and security systems	Accelerator, conveyor, shield/bunker safety Facility/warehouse safety Personnel dosimetry	Access control Video security and process monitoring Fire extinguishing system Radiation dose meters Individual dosimeters

IT **Process control system** **Product tracking system**	PLCs/PC - Network Software suite Bar code printer and reader Security software and devices	Integration with inhouse ERP
Spare parts	Initial stock	Consumables
		Electron source
		RF amplifier tubes
		Cathodes
		Belts
		Chains
		Bearings
		Sprockets
Equipment installation	Equipment rigging Connection of specific equipment Training	Installation cost often included in price of the equipment. Client may have to provide cranes, specific tools and staff (e.g. electrician, plumber, welder)
Process validation	IQ-OQ-PQ	Consultancy services
Dosimetry	Dosimeters Dosimetry system Calibration	Many hundreds for EB, less for X-ray More than one system for RB and X-ray External services
Other costs	Transport, shipping Import duties Insurance Tools and fixtures specific to process validation and maintenance Maintenance contract after warranty	

Table 8: Capex items with typical cost range

CAPEX Item	typical cost in 1,000 USD	
	low Energy	high Energy
Accelerator electron beam	300	5,000
Accelerator X-ray	300	9,000
Radiation Shield	500	3,000
Warehouse (without refrigeration)	500	5,000
Product Handling with low level of automation	200	3,000
Ancillary systems	200	1,000
IT Process Control	50	400
Safety System (if not included in accelerator price)	50	200
Shipping, installation (if not included in accelerator price)	50	250
initial spare parts set	100	300
Feasibility	10	50
Design Consultancy & Project Management	50	300
Radiation Permits and Registrations	10	50
Process Validation, Certifications, Accreditations	10	30
Dosimetry Equipment	5	50

It should be noted that, depending on the level of automation, the upper limits are examples. In 2023 and in Europe, a complete and fully automated X-ray sterilization facility with 560 kW of beam power was estimated to require a budget in the region of EUR 50 Million (~US$ 55 million).

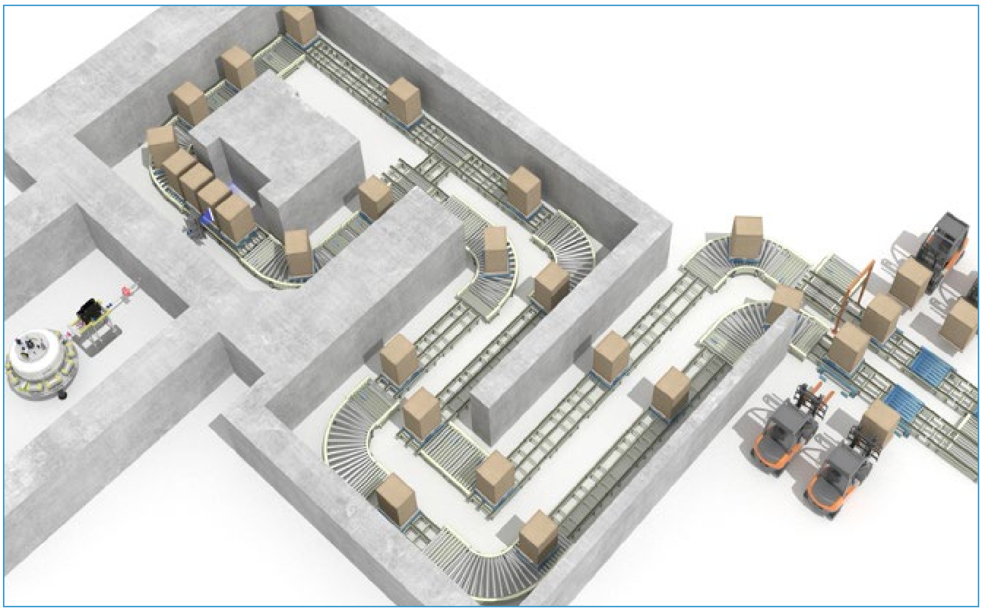
4.1 Facility Layout

The facility layout and size of the warehouse is determined by standard production processes, such as incoming product staging, outgoing product staging, product segregation into non-treated, treated and quarantine sections. Sufficient loading docks should be planned.

Figure 7 and Figure 8 show typical layouts of large e-beam and X-ray facilities, respectively. Warehouse needs should not be underestimated, as service disruptions could fill the incoming product storage quickly, and truck delays may require a buffer also in the outgoing storage areas.

Figure 7: Typical Layout on an E-beam Multi-Purpose Facility (from Accelerators Guide)

Figure 8: Typical Layout of an X-ray Facility (Credit LTXD)



Operations

5.1 Operational Cost

The operational cost categories are summarized in Table 9.

Staffing: An e-beam or X-ray plant requires many of the same staff as any production facility. Special expertise is required for maintenance, health and safety and quality assurance.

Depending on the level of support by the accelerator vendor, local technicians should be well versed in electronics, electrical and mechanical systems. Personnel with a technical diploma or vocational electrical engineering degree will be needed to carry out routine tasks and first level diagnosis.

A radiation safety program must be implemented and one or more radiation safety officers (RSOs) must be appointed. While the workload for the RSO is likely to be less than 10% FTE, many regulatory agencies require their presence on site or within easy reach of the site during operation.

Quality assurance responsibilities, either by regulatory or end-customer requirements, require appropriate equipment and well-trained personnel. Depending on the application, this may include a dosimetry or rheology laboratory with trained personal.

Utilities: As a general rule, the electrical hookup power is more than three times higher than the rated beam power. Further, a chilled-water cooling system for the accelerator needs to be rated for the wall-plug power of the accelerator and consumes about 20-30% of its cooling power rating in electrical energy. Product handling, depending on the level of automation, can require 100kW or more.

In summary, a 100 kW e-beam or X-ray facility may easily require 500kW continuous electrical supply during operation, in addition to warehouse or office cooling requirements. A 560 kW X-ray facility may require a 2000 kVA electrical hookup.

Operators of e-beam or X-ray facilities of this size should consider purchasing power at medium tension (10-15kV) and use their own power transformers to reduce utility cost.

Maintenance contracts provide the facility owner with an uptime guarantee, access to highly trained vendor support and potentially fast-track delivery of critical spare parts. A maintenance contract can be an expensive line item in the operations budget. Terms and Conditions should be negotiated together with the purchase agreement to eliminate unplanned costs at a later stage.

Table 9: Operating Cost Categories

Operational Cost Category	
Staff	
Facility Management, Admin, Sales	
Service Technicians & Radiation Safety Officer	
Product handlers	
Quality Assurance, Dosimetry	
Maintenance Contract, Sparts	
accelerator	3-7% of the Cost
product handling	3-5% of the Cost
ancillar equipment	~3% of the Cost
Utilities (especially Electrical Power)	100k USD to 1500k USD
Process specific Consumables	
Dosimeters	
Phantom Material	
Product Qualifications	

5.2 Constraints, Risks & Mitigations

5.2.1 Community Acceptance, Health & Safety

Securing public acceptance of radiation-producing machines should be addressed in a pro-active way. These key stake-holders can delay construction significantly, and even impact operations. Town hall meetings and a form of direct contact for concerned citizens are an important part of a transparency strategy.

5.2.2 Partial carrier and ineffective loading patterns

Most production capacity calculations are based on optimum use of the beam and product handling system. Variations in the product mix, partially filled pallets and small batches of customer product can significantly impact the production capacity and therefore the treatment cost. Moreover, these changes or variabilities may jeopardize the irradiation process efficiency if not qualified.

5.2.3 Utility Outages

Frequent or longer lasting utility outages significantly impact production. A flywheel uninterruptible power supply (UPS) could mitigate short term electrical outages. For longer outages, a cost-efficient solution must be evaluated against the cost of the outage. Not all components of the accelerator system have the same requirements with regard to interruptions. Therefore, the total power of the system is not necessarily the capacity required for the UPS.

5.2.4 Customer Requirements and Inter-Product Compatibility

Product mix in the facility is important to ensure commercial risk diversification. Attention needs to be paid to customer or regulatory requirements on product segregation and co-use of spaces for very different products (e.g. pharma/medical products and food).

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