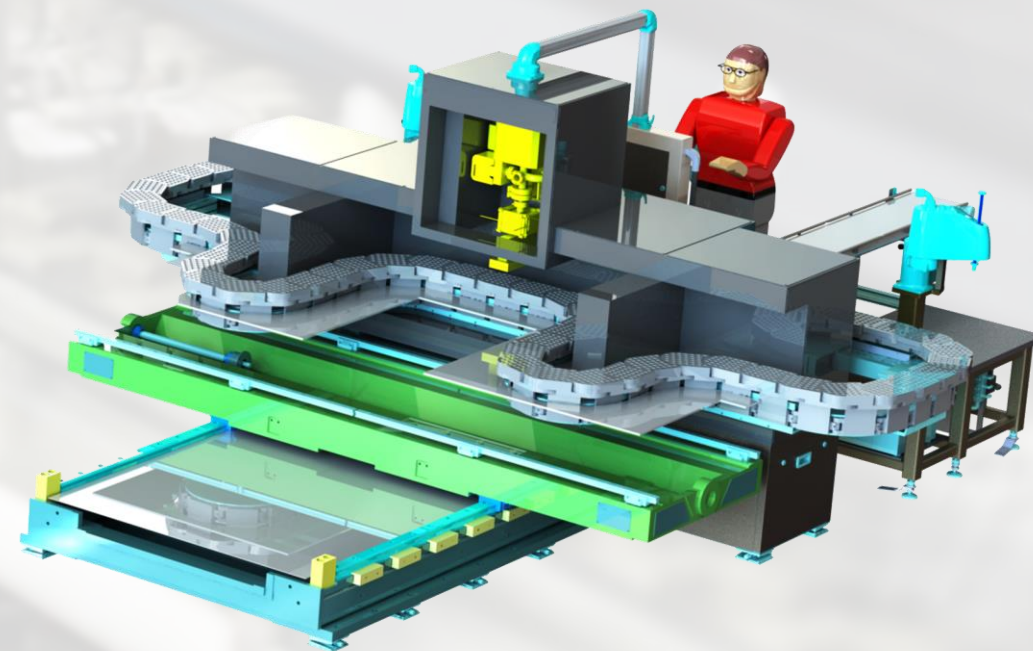


PRACTICAL IMPLEMENTATION OF IN-HOUSE ELECTRON BEAM STERILIZATION



ALEX FOLZ | *Applications Engineer II*
ATS Life Science Systems



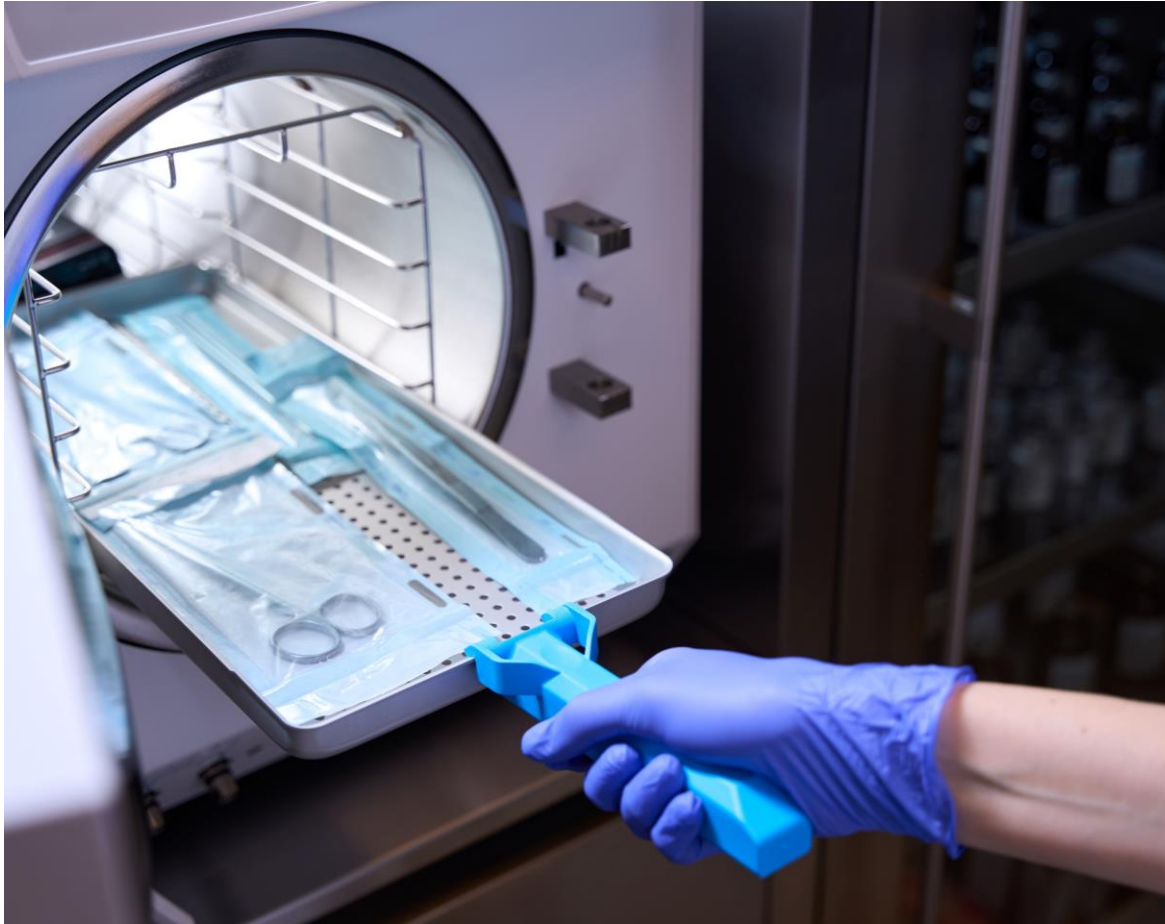
- 01** ■ Classical Sterilization Methods
- 02** ■ Limitations Of Classical Methods
- 03** ■ Why E-beam: Overcoming Limitations
- 04** ■ In-house E-beam: Anatomy Of The Equipment
- 05** ■ In-house E-beam: Retractable Shielding Theory
- 06** ■ Summary & Questions



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Steam, EtO, Gamma, & X-Ray

01 | CLASSICAL STERILIZATION METHODS



Process

- Traditionally utilizes an autoclave system
- Devices to be sterilized exposed to steam at elevated temperature and pressure
- Moisture (hence the steam) lowers the temp/pressure threshold at which organisms are eliminated

Benefits & Use Cases

- Effective for products that can withstand inherent heat and moisture of the processes (for example, medical surgical tools)
- Low cost, relatively low safety burden due to minimal hazardous byproduct



Process

- Bulk product placed in chamber, air evacuated, replaced with EtO
- As EtO can penetrate plastics, process can be completed after primary packaging of device
- Alkylation of organisms is mode of sterilization

Benefits & Use Cases

- High material compatibility (thus, ~50% of single use med. devices sterilized this way)
- Capable of sterilizing products that are heat or moisture sensitive
- Bulk sterilization (e.g., entire pallets of product at a time)



Process

- Devices to be sterilized exposed to radioactive Cobalt-60, which generate gamma rays while decaying
- Gamma ray photons from Cobalt-60 permeate through devices (including plastic packaging)
- Deliver ~5-10 kGy/hr of radiation to devices
- Breaking down covalent bonds of DNA is the mode of sterilization
- Source is lowered into shielding system (e.g., water bath) once process complete

Benefits & Use Cases

- ~30% of disposable med. devices sterilized via Gamma Radiation
- Deep/uniform material penetration
- Bulk sterilization
- Minimal power utilization for processing



Process

- Bremsstrahlung effect used to convert high energy electrons to wide spectrum of X-rays
- X-rays directed at devices to be sterilized
- Dependent upon power, dose rate in range of ~10x Gamma Sterilization
- As X-ray is also a radiation modality, damage to DNA structure of organisms is method of sterilization

Benefits & Use Cases

- Highly uniform dose/deep penetration
- Faster dosing process than Gamma radiation
- No hazardous materials (toxins, radioactive byproducts, etc.), safety hazard removed when X-Ray turned off



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Steam vs EtO vs Gamma vs X-Ray

02 | LIMITATIONS OF CLASSICAL METHODS

STEAM/AUTOCLAVE LIMITATIONS



Limited materials of construction for device to be sterilized

Robustness/design of sterile barrier to be able to withstand pressure

While limited safety impacts make hospital settings a perfect use case, aggressive nature of process **limits use case for plastic/single use medical devices**

ETO LIMITATIONS



EtO is a known carcinogen, among other negative health effects

- Risks in both minimum viable emissions & accidental release to employees and general population
- Environmental Impacts beyond human health
- Many examples of pending/settled litigation related to the release of EtO

Ever shifting policy/regulatory mandates regarding EtO

Lengthy exposure time (~1-6 hours), not including aeration time/other phases of process (which can consume several days -> week)

Cosmetic (discoloration of product, odor can remain w/ product after sterilization)



Cobalt-60 Radiation Source Can't Be Turned On/Off

- Can only be deposited behind added shielding (e.g., water bath)
- Both safety and disposal become challenges

Cost

- Typical costs ~\$15/curie
- Small Gamma facility ~\$4.5M of Cobalt-60/year
- Due to half life of Cobalt-60, ~12% of supply lost/year to decay (~5 year half life)

Exposure time (~2.5-3 hours)

Cobalt-60 is a byproduct of nuclear reactors; availability of material a concern if volume of reactors coming online doesn't keep up with material demand



Inefficient conversion of high energy electrons to X-rays via Bremsstrahlung effect

- Only 5-10% of initial E-beam power converted to X-ray
- Leads to high power requirements & energy costs

Additionally, higher beam energy requirements lead to heavier shielding requirements (e.g., bunker)

While exposure time (~30 minutes) is shorter than Gamma, this still limits process to bulk pack sterilization

Limited facilities dedicated to X-ray sterilization

COMMON LIMITATIONS



Lengthy Process Times & Challenging Safety Requirements

Combining together, majority of medical device sterilization is not done inline w/ manufacturing (often not even in same facility)

Requires:

- Additional transports steps
- Significant WIP stocks
- Added packaging considerations/studies

Depending on efficiency of process, can take up to 8-9 days from device manufacturing to sterilization complete.





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Overcoming Limitations

03 | WHY E-BEAM

IS E-BEAM THE SOLUTION?

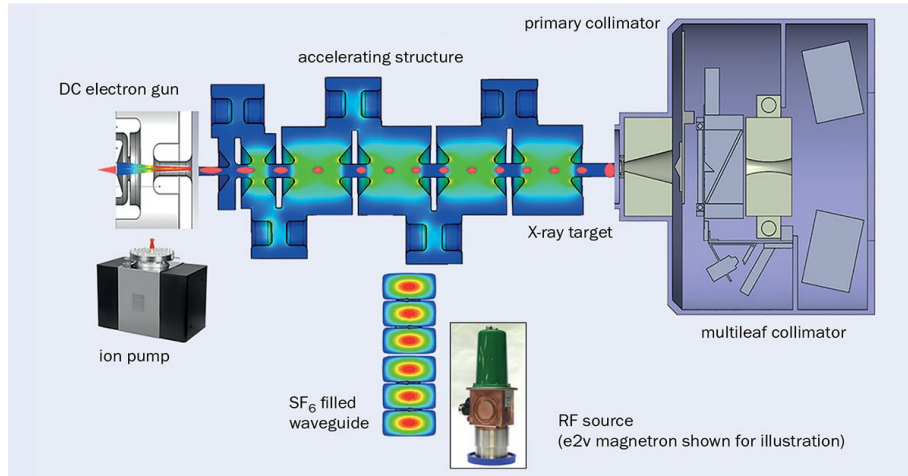


Image Credit: D Angal-Kalinin/G Burt/M Dosanjh



Process

- LINAC (linear accelerator) accelerates electrons along a linear beam path
- Unlike X-ray, electrons directly penetrate product vs. first being converted to X-ray via Bremsstrahlung
- Yields higher dosing rate, but lower penetration than X-ray
- Also a radiation modality: Destruction of organism DNA is the mode of sterilization
- No electrons emitted after power down (e.g., operator safe when off)

Benefits & Use Cases

- Fast sterilization time (dependent on product size, but think seconds) due to high energy nature of beam
- More energy delivered to part – no X-ray conversion losses
- Safe, no radioisotopes required
- Mature technology based on medical LINACs
- Process directly after primary packaging complete or closure of sterile barrier
- Best option when in process sterilization is a requirement

Dose **Uniformity** Is Material Sensitive

For **Lower** Energy/Power **Units**:

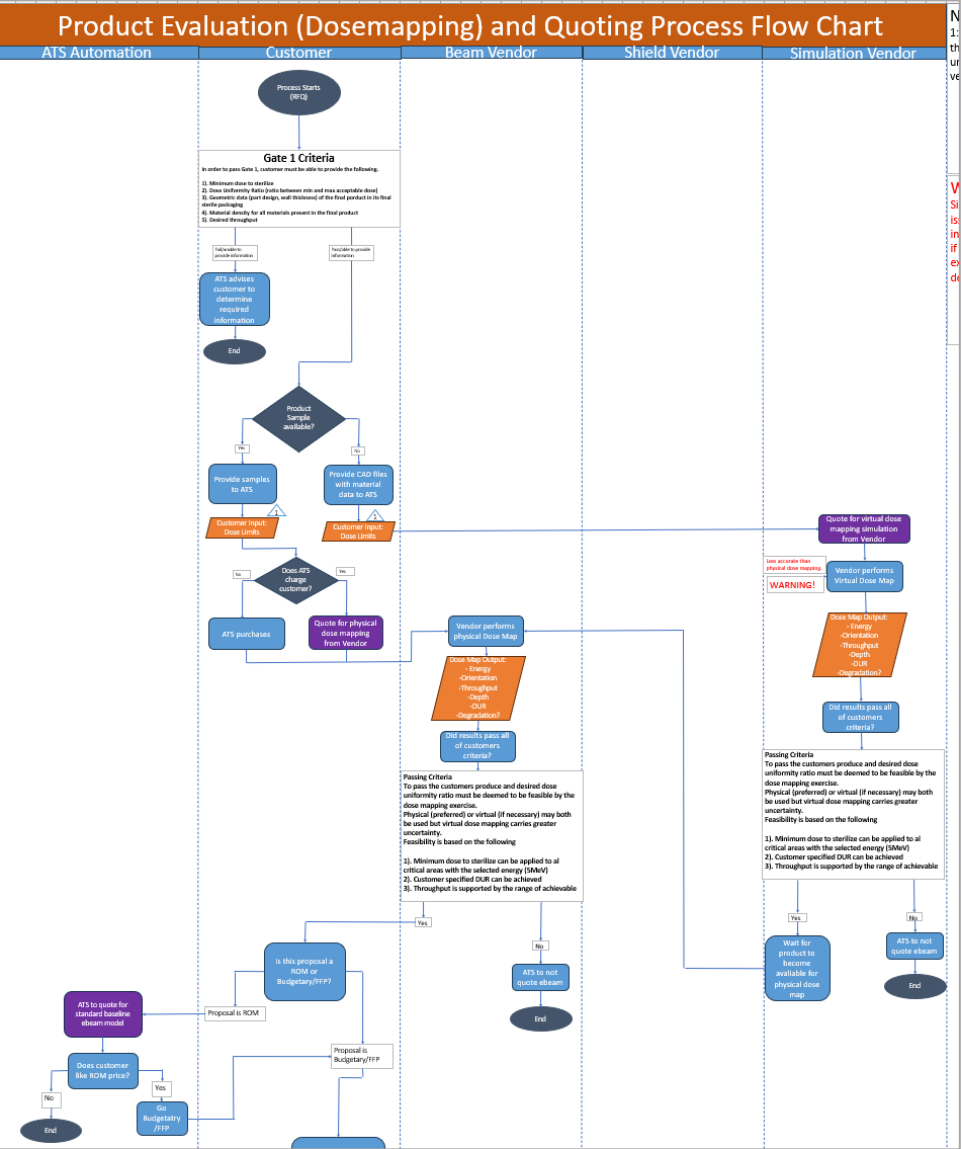
- Limited penetration depth
- Limited to processing a single layer of assemblies
- System Rate dependent upon product footprint, among other factors

Material Limitations:

- Can cause material degradation in some cases
- For example, Teflon known to degrade w/ exposure to E-beam
- Consult Team Nablo findings on material compatibility testing

Wise To **Verify Process** Specifications Of Product After Converting From Other Sterilization Modalities

UNDERSTANDING LIMITS | ANALYSIS & DOSE MAPPING



ATS has an in-depth process to verify technical feasibility of E-beam sterilization prior to entering a quoting phase

NEEDS FROM A CUSTOMER

Product Information:

- Product drawings, specifications (weight, density, etc.)
- Material specifications
- Device requirements/specs (e.g., pull force, leak rate, etc.)
- Rate of manufacture (in parts per minute)

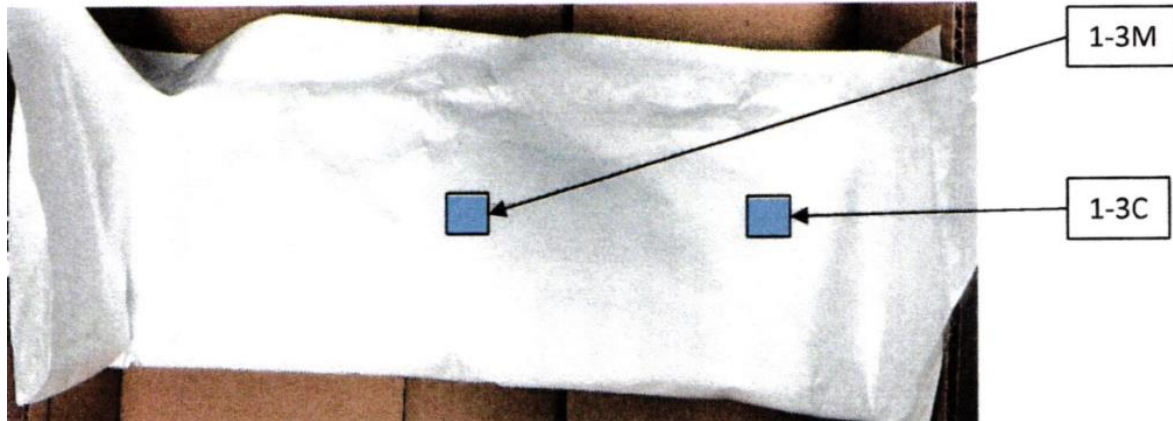
Sample product

Minimum and maximum allowable radiation dose (in kGy)

In absence of dosing requirements: ATS targets delivering minimum of 25kGy to product w/ Dose Uniformity Ratio (DUR) of ~2.0

DOSIMETER PLACEMENTS

Direction of Beam: Into Page



Direction of Beam: Into Page

ATS STEPS/COMMITMENTS TO CUSTOMER

Obtain **expected DUR** for the product based on dose map testing:

- Determines technical feasibility

Process includes intelligently locating dosimeters under part and passing under a representative E-beam system

Repeat 3x times to gauge stability/repeatability

Calculate product speed under the LINAC to achieve acceptable dose based on dose mapping + theoretical calculations:

- Determines commercial feasibility

	Initial Dose Map	1st Replicate Dose Map	2nd Replicate Dose Map	Supplemental Replicate Dose Map (if needed)
Job	36538	36538	36538	36538
Work Order	60866	60866	60866	60866
Date of Irradiation	3/4/2026	3/4/2026	3/4/2026	3/4/2026
All doses in kilogray (kGy)				
Average Reference Dose	21.8	21.3	21.3	21.3
Minimum Internal Dose	18.2	18.3	18.5	19.0
Maximum Internal Dose	26.3	28.2	28.1	26.7
Ratios				
Min Internal / Avg Ref Dose	0.83	0.86	0.87	0.89
Max Internal / Avg Ref Dose	1.21	1.33	1.32	1.26
DUR (Dose Uniformity Ratio)	1.45	1.54	1.52	1.41

DESIRABLE PRODUCT TRAITS



Small Batches or Individual Products

Products Enclosed by Sterile Packaging/Barrier

- Packaging needs to be capable of maintaining a sterile environment inside
- Primary packaged - Flow wrapped, blister packed, etc.
- Sterile barrier could also be integral to product – foil sealed

Product Compatibility

- Relatively uniform density top to bottom
- Smaller parts
- Minimal dead volume





SCAN NOW.

Request
your **Analysis** and get your
Product Dose Mapped
by an ATS SME

WHERE ARE YOU ON YOUR **E-BEAM JOURNEY?**

- Early Exploration
- Evaluating A Specific Product Now
- Ready To Spec Equipment
- Other

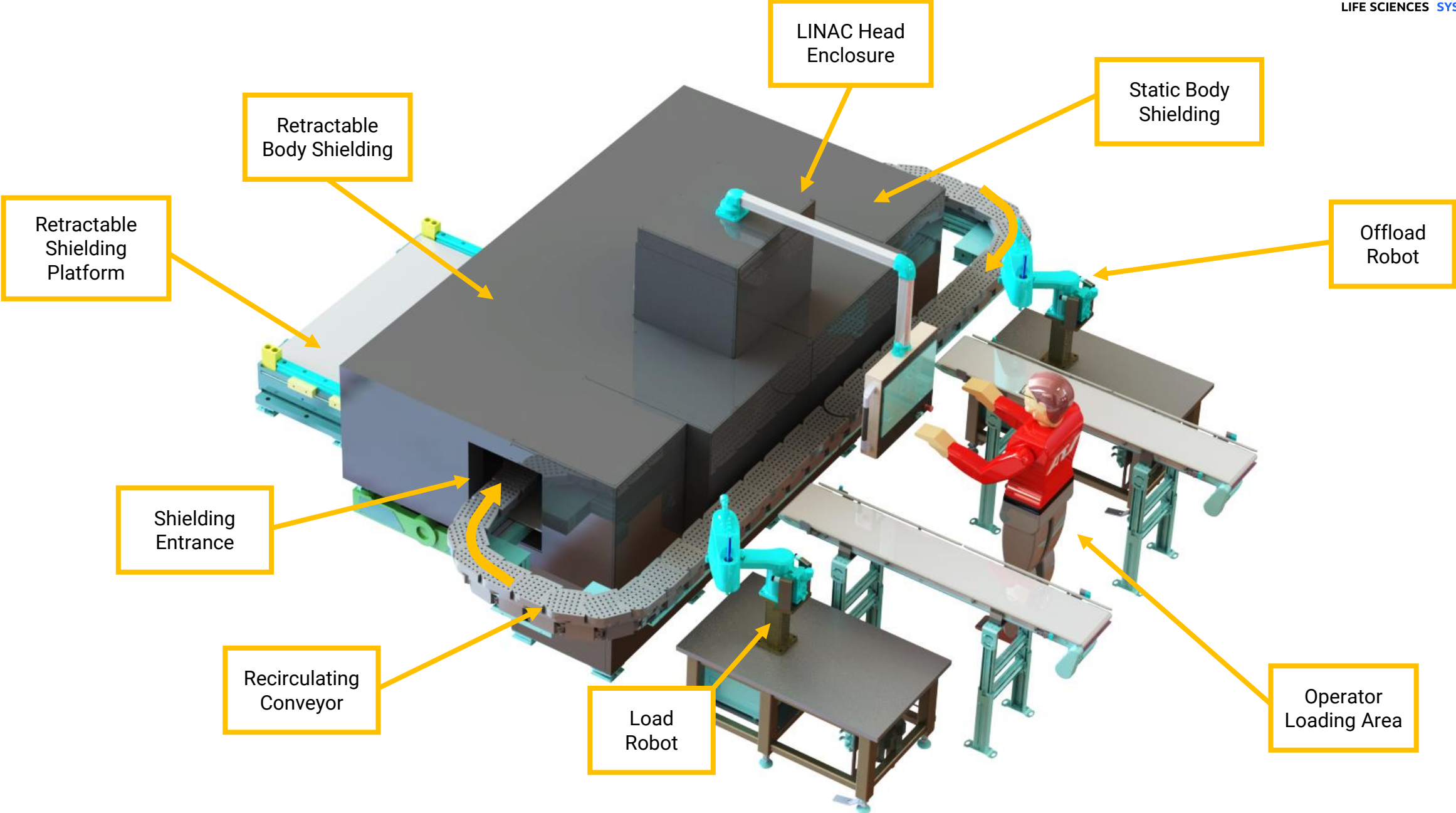


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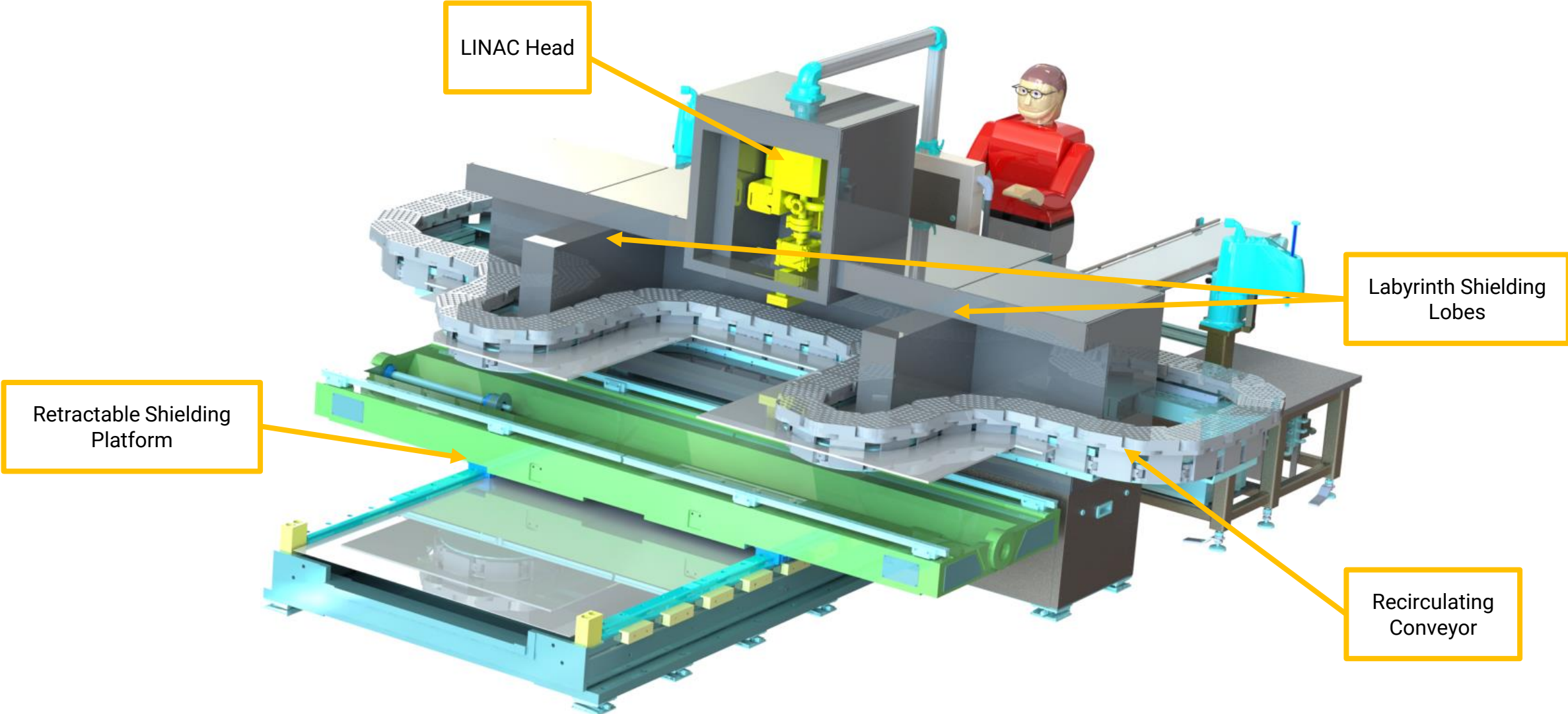
Anatomy Of The Equipment

04 | IN-HOUSE E-BEAM | OVERVIEW

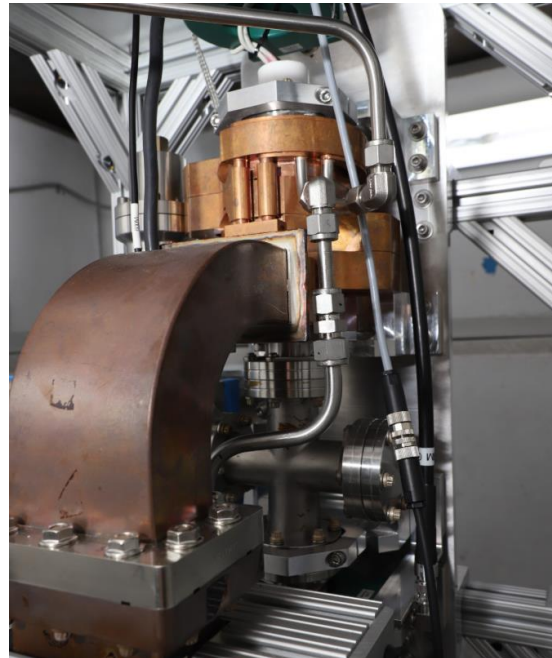
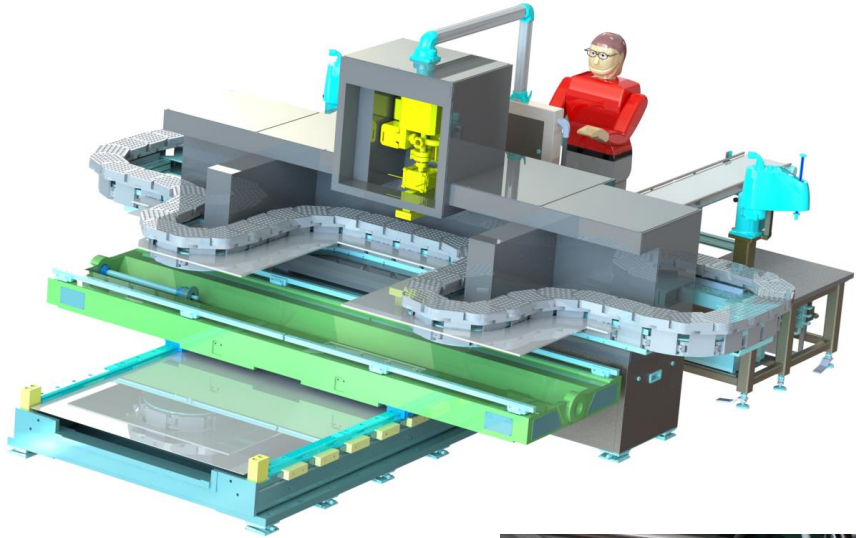
OVERVIEW | REPRESENTATIVE ATS SYSTEM



OVERVIEW | OPENED-UP REPRESENTATIVE ATS SYSTEM



Patent pending
No. 64/069,478



Integrated LINAC Specifications

- Energy Level: 3-5 MeV
- Power: Up to 2 kW, dependent on energy level
- Energy and Power levels balanced to achieve uniform dose for single part layer while enabling integrated/self shielding
- Beam profile: variable, but 8-12" in width
- Dosing rate: Product, energy, and power dependent but typically 1-2 orders of magnitude greater than X-ray

Supporting Hardware

- **LINAC Head:** Produces the electron beam for sterilization
- **RF Generator:** Generates RF that travels through the waveguide to the LINAC Head
- **Modulator Rack:** Supplies pulses of energy to the RF Generator
- **Chiller:** Cools both the RF Generator and the LINAC Head

How Will Parts Travel Through Sterilization Zone?

- LINAC head resides above the conveyor
- Customizable width of line (pending part geometry)
- Continuous movement of parts on the conveyor

CONVEYOR DETAILS

Recirculating, Metallic Precision Link Conveyor

- Servo driven for speed/position control
- Metallic to mitigate degradation of components which pass beneath LINAC

Conveyor position feedback allows traceability of products as they pass underneath the LINAC

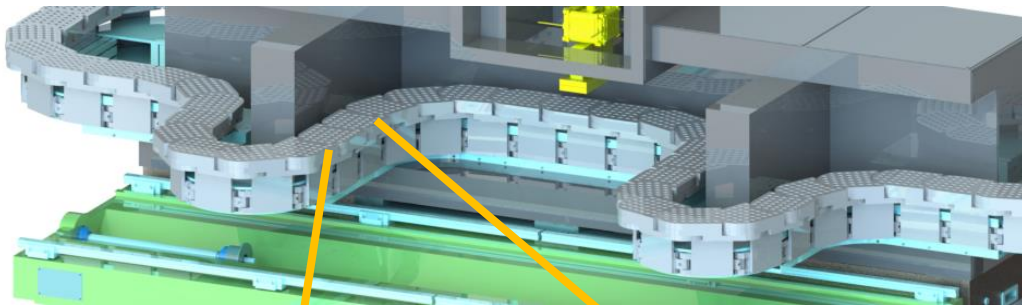
Speed of conveyor synced with LINAC instantaneous current to ensure every mm of product is dosed repeatably

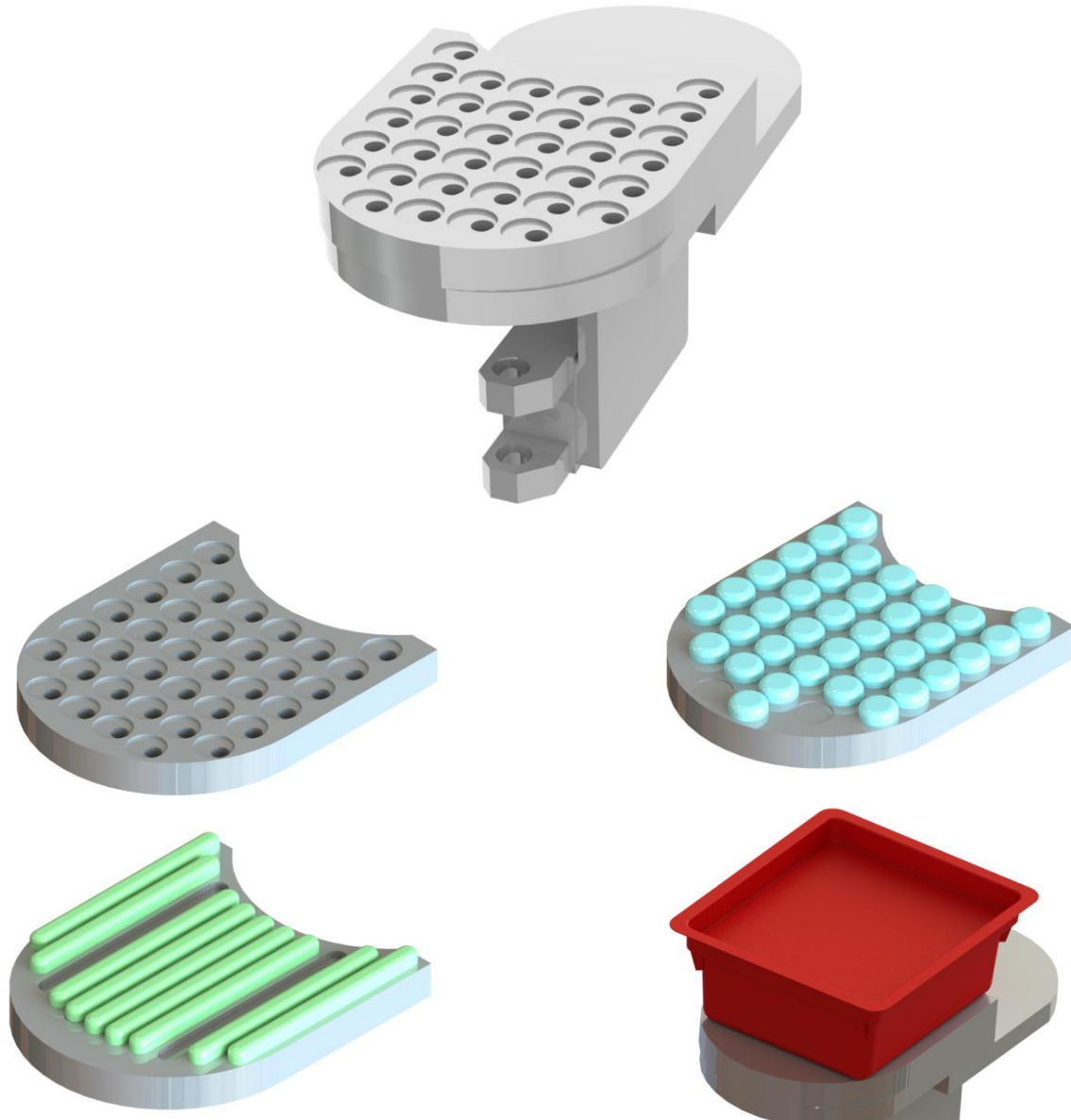
Nests Consist Of Aluminum Plates. Products Can Be:

- Embedded directly into pockets in the nest
- Deposited to a bin or fixture placed upon the nest

Components which could be degraded by LINAC (greased bearings, for example) are shielded beneath Aluminum plate nests

Tight radiused curves drive minimum footprint of labyrinth





NEST PLATE DESIGN

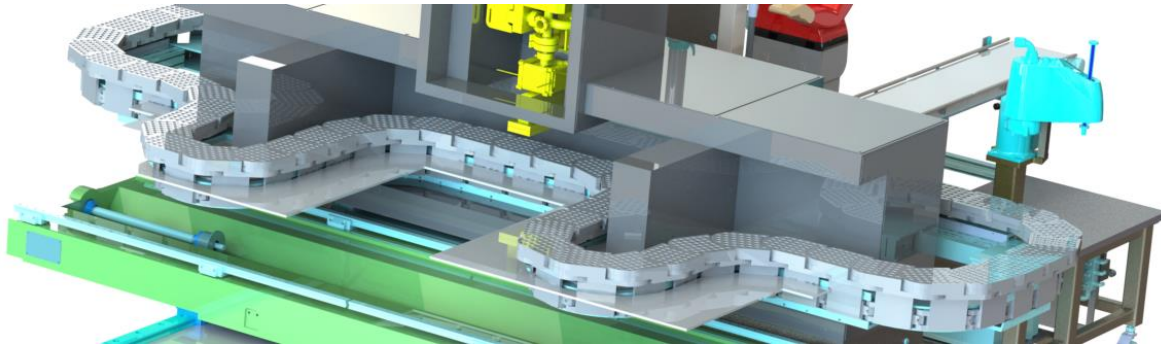
Recirculating conveyor nests/link plates made up of scalloped Aluminum plates

- Plates pass directly beneath the beam path each cycle of the conveyor
- Dual level, overlapping plate design ensures consistent cross section of Aluminum plate passing beneath the LINAC
- Dense packing of product under the LINAC
- Tight bend radii for shielding

A PART OF THE SHIELDING!

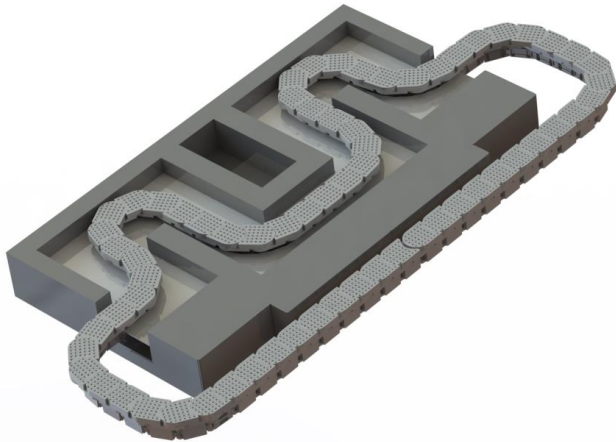
Once electrons reach plate, their sterilizing job is done!

- Aluminum plates stop residual electrons and produce limited X-rays that are more readily shielded
- Reduces shielding requirements for the remainder of the machine, making self shielding viable



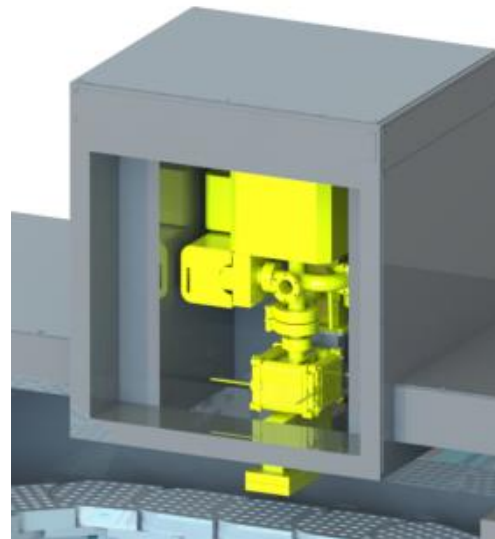
Labyrinth Path

- Design prevents scattered radiation from escaping the system
- Labyrinth eliminates direct line of site from LINAC to manufacturing personnel, ensuring radiation is at safe level outside of shielding
- Doesn't require actuated doors at entry/exit; facilitates high throughput



Reflection back to the LINAC head

- Shielding directly around the head to capture reflected scatter off the LINAC Head

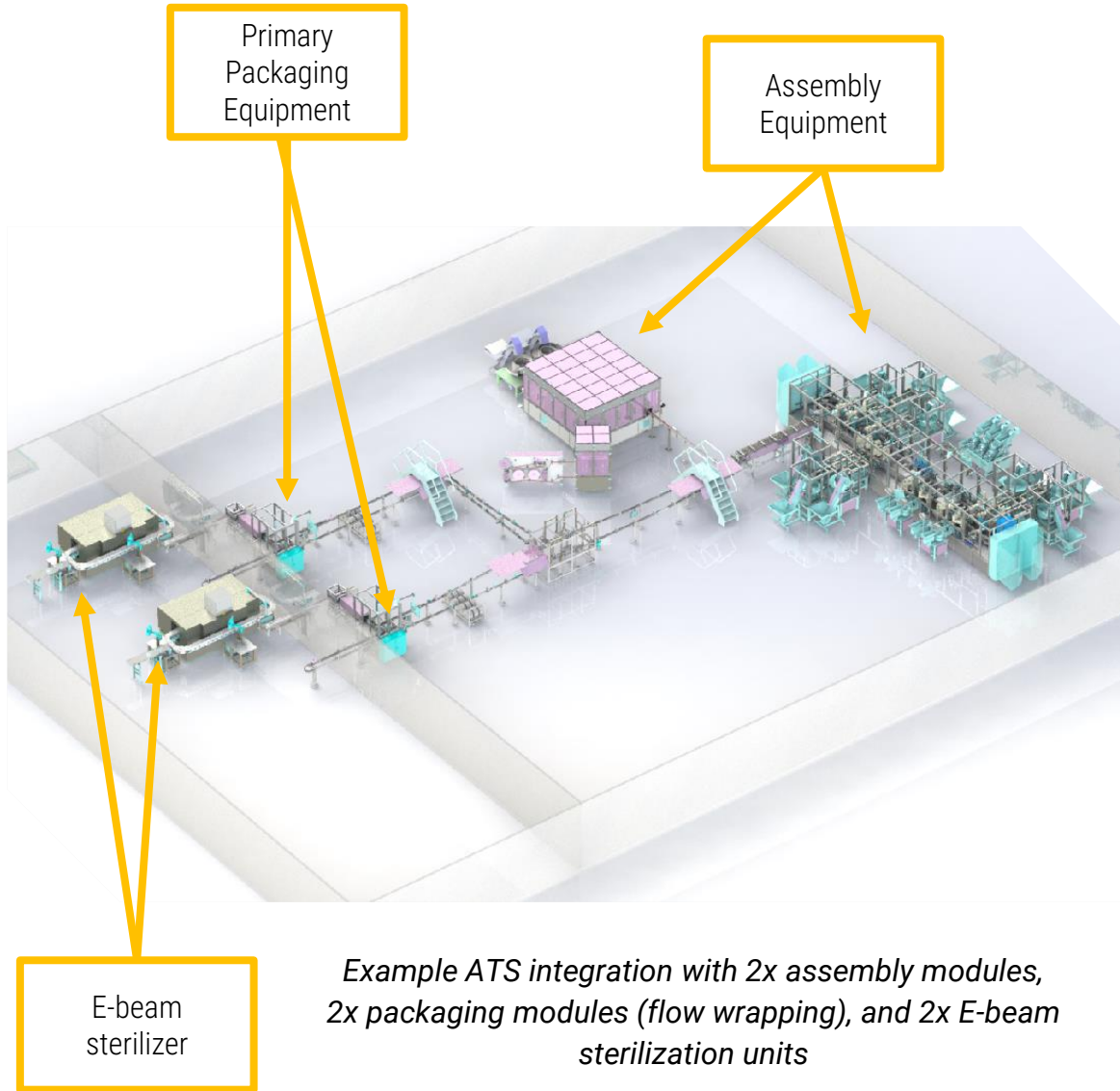


Retractable Shielding

- Shield clamshell opened via lead screw mechanism to achieve mechanical advantage (~50,000+ lbs. of retractable shield)
- Required to perform maintenance inside of unit

More details in Retractable Shielding Theory

IN-HOUSE INTEGRATION CAPABILITY



Examples of Upstream Equipment:

- Assembly equipment
- Test equipment
- Process equipment

Examples of Inline w/ Primary Packaging:

- Sealing/blister packing
- Bagging
- Flow Wrapping
- Foil sealing
- Dependent on design of sterile barrier, E-beam unit can be inside OR outside of the cleanroom (outside preferable given mass of system)

Examples of Stand-Alone Integration:

- Not required for system to reside inline
- Tray Handling of product @ infeed/outfeed
- Manual Loading and Unloading

MACHINE CONFIGURATION & QUOTING NEEDS

Product

- Packaging state as it arrives at the sterilization equipment

Connected Equipment

- Config of product entering E-beam sterilizer (Fixtured in trays? Loose on conveyors? Etc.)
- Required config of product leaving E-beam sterilizer- typically driven by secondary packaging needs

Footprint Restrictions

- Size of install location
- Weight bearing capability of floor at install location
- Facility ingress route to the install location

Sterilization / E-beam Specifications

- Min/Max allowable dosage
- Product Density
- Other product process specifications
- Beam Energy/Current (output of above)

Safety & Shielding

- Install location
- Customer HSE requirements beyond local regs.



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Retractable Shielding Theory

–

How is radiation shielding designed and validated?

05 | IN-HOUSE E-BEAM

Why Is It Necessary?

- To protect personnel from radiation
- Primarily x-rays but also electrons

What Is It?

- Shielding comes in the form of thick, dense materials
- Often lead skinned in stainless steel

Systems which need to convey material in and out utilize a conveyor labyrinth to provide additional scattering and protect operators




Electrons Are Delivered To The Product

- Some are absorbed when delivering dose
- Some electrons 'scatter' off the product and surroundings – particularly the Aluminum plate conveyor nest positioned directly beneath the product

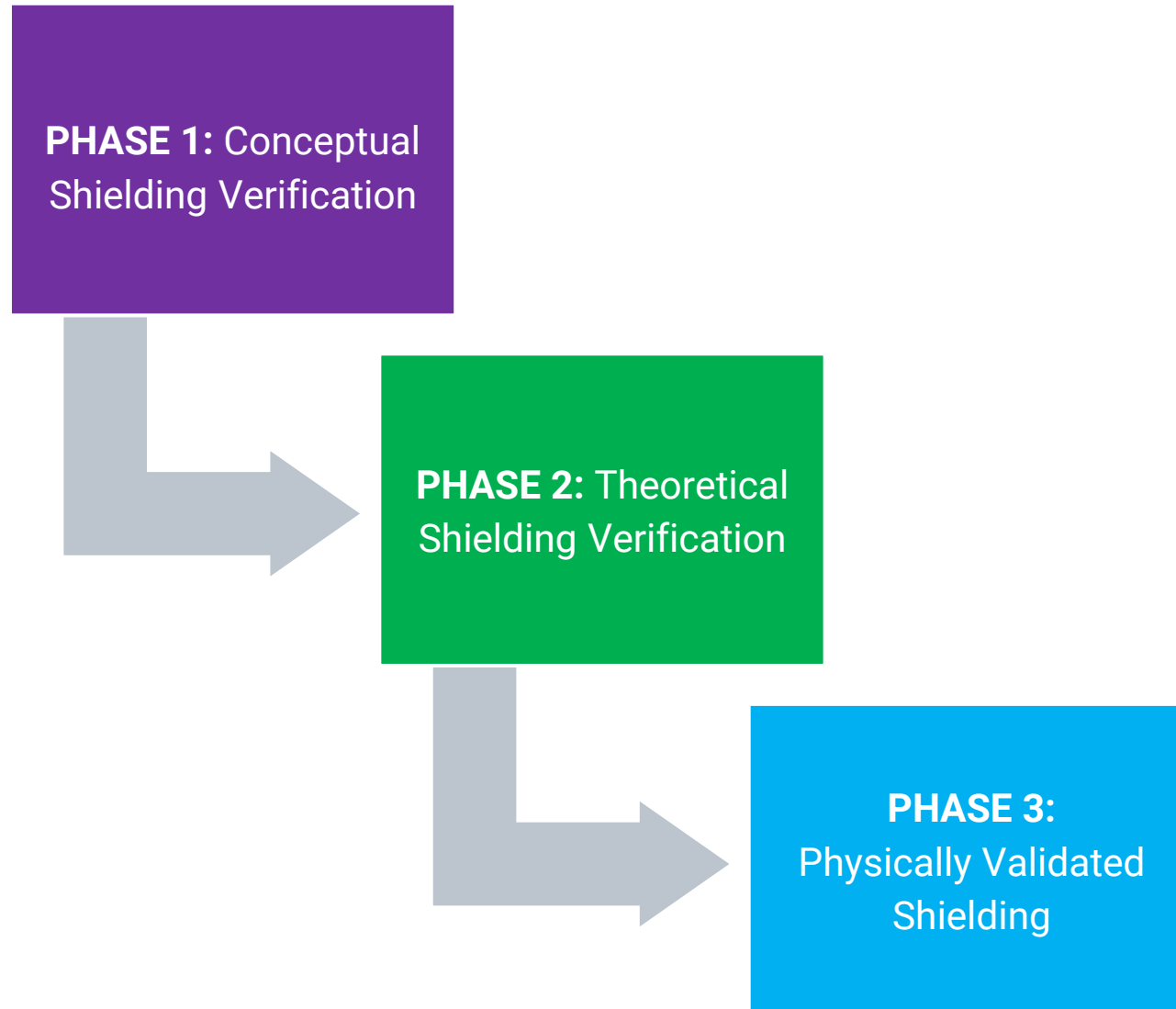
When Electrons Scatter, They Produce X-rays

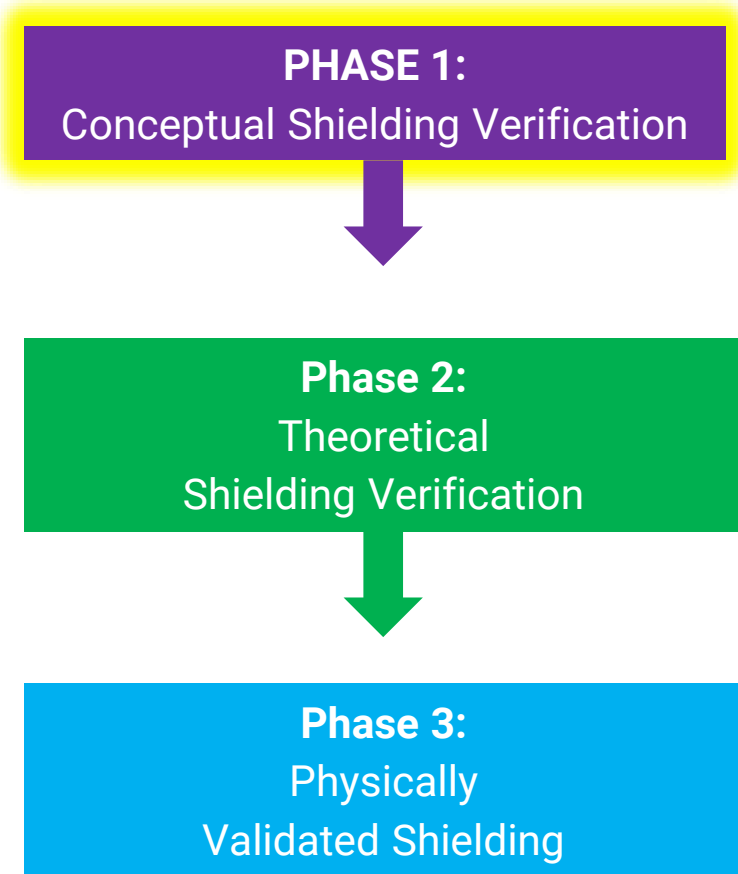
- The main goal of shielding is to protect against these x-rays

Radiation Protection Hierarchy

- Time 
 - Distance 
 - Shielding 
- Not Always Possible In An Industrial Environment!

SHIELDING VERIFICATION PROCESS





Define the Radiation Environment Inside the Machine

- Driven by process requirements
- Beam Energy
- Beam Current
- Dose to Sterilize
- Part Design

Define the Radiation Environment Outside the Machine

- Allowable dose rate at customer site
- Absent customer requirement, shield design will target external radiation leakage less than or equal to 0.5 microSv/hr when measured at expected operator locations

Outcome: Are modifications to ATS standard shielding package expected?

Relevant Legislation

- R.R.O. 1990, Reg. 861: X-RAY SAFETY
- 21 CFR 1020.40

PHASE 2 | THEORETICAL SHIELDING VERIFICATION

PHASE 1:
Conceptual Shielding Verification



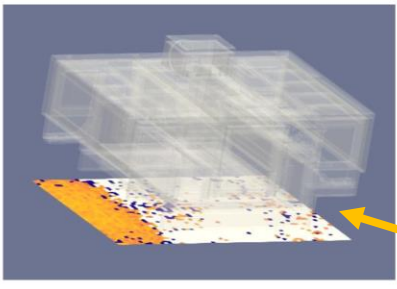
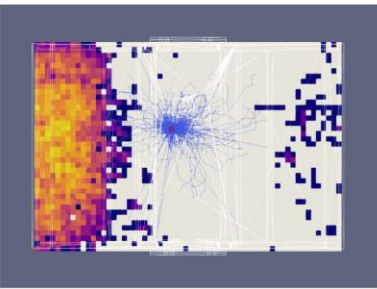
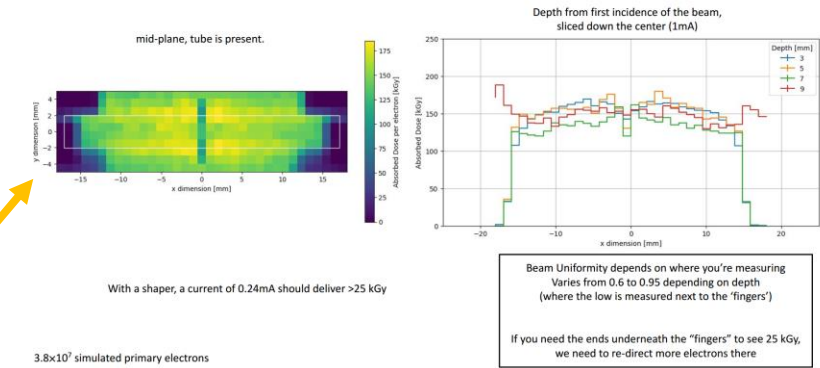
Phase 2:
Theoretical
Shielding Verification



Phase 3:
Physically
Validated Shielding

- SIMULATION**
- Dependent on results of phase 1, Phase 2 begins with standard or modified shielding package
 - Iterations are done to verify shielding design and beam operation prior to build
 - Simulations done using Monte Carlo technique

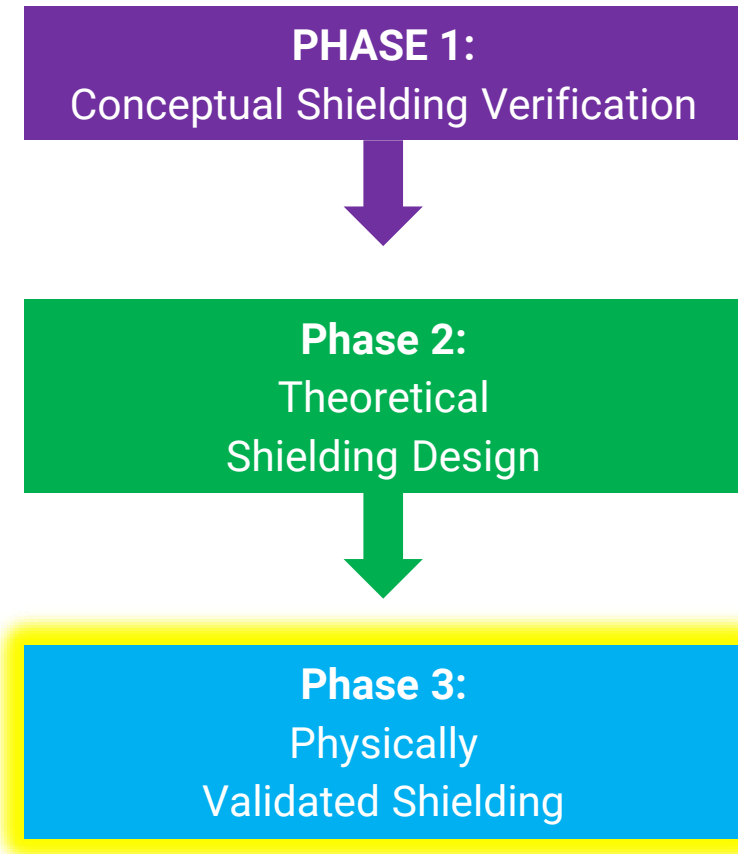
Simulation showing dose delivered to product. Determines necessary beam current.



- Simulation showing dose rate outside of the shielding.
- Iteration on shielding design based on results (if required).

	Highest Pixel [mGy/hr]	Avg [mGy/hr]
Tray Side	9.7	0.2
Empty Side	35	5.3

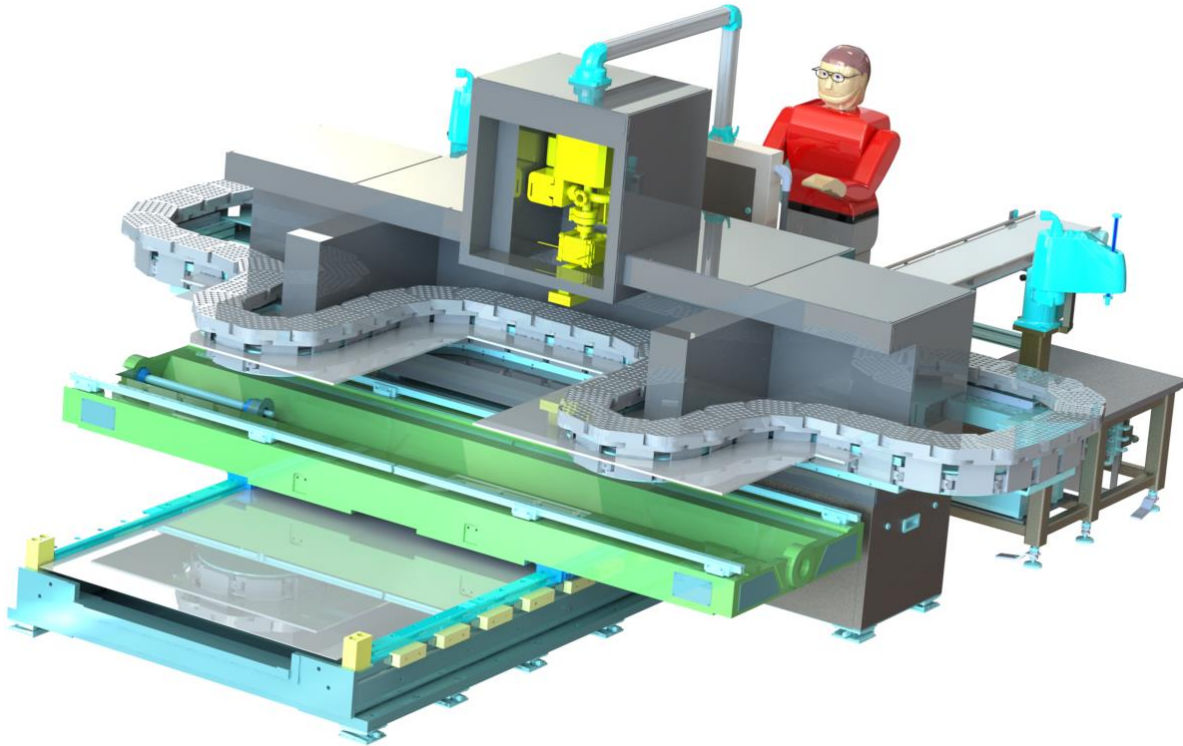
PHASE 3 | PHYSICALLY VALIDATED SHIELDING



Physical Validation

- Test shielding – adequacy test to validate integrity of construction
- Controlled ramp up procedure to identify hot spots (if any)
- Patching hot spots as required
- Operational tests to ensure emissions meet customer health and safety requirements

**All part of the ATS integration plan
prior to delivery to customer site**



*Patent pending
No. 64/069,478*

E-Beam Benefits:

- More energy delivered to part – no X-ray conversion losses
- Safe, no radioisotopes required
- Mature technology based on medical LINACs
- Process directly after primary packaging complete or closure of sterile barrier
- Best option when in process sterilization is a requirement



QUESTIONS?



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Phone: (224)-575-3766

WHERE ARE YOU ON YOUR **E-BEAM JOURNEY?**

- ➔ *Early Exploration*
- ➔ *Evaluating A Specific Product Now*
- ➔ *Ready To Spec Equipment*
- ➔ *Other*



SCAN NOW.

Request Your **Analysis** and Get
Your **Product Dose Mapped** by an ATS SME