INTERNATIONAL IRRADIATION ASSOCIATION

2023 LEADERSHIP PROGRAM - RT1

Selection of technology from a customer & patient perspective

Sterility Assurance Career Opportunities in Healthcare

25 April ‘23

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Building Needed Leaders that will Last

O1 History and development of radiation processing - Yves Henon

O2 Introduction to radiation chemistry – Xavier Coqueret

RS1 Radiation chemistry: basic reactions, dosimetry

RS2 Radiation chemistry applied to polymers

03 Introduction to Radiation Biology - Yves Henon

RS3 Further radiation biology

O4 Applications of radiation processing – Dagmara Chmielewska-Śmietanko

RA1 Industrial polymer processing - XV

RA2 Medical devices and bio-pharma – DC-S

RA3 Phyto-sanitation and food treatment - YH

RA4 Environmental applications - DC-S

O5 Introduction to radiation technology - Samuel Dorey

RT1 – RT3

Abbott

ASTF

International Irradiation Association / Leadership Program

Selection of technology from a customer & patient perspective

Sterility Assurance Career Opportunities in Healthcare

- Introduction to Abbott Medical Devices (high value, “low” volume sterilization)
- End-to-End Microbiological Quality & Sterility Assurance (AAMI TIR 100)
  - R&D – Material Compatibility (AAMI TIR 17)
  - Plan / Source – Drivers for change: Supply Chain & Sustainability
  - Make / Sterilize** – Sterilization / Packaging Validations & Processes
  - Deliver / Customer – Patient Risk
- Conclusion

MEDICAL DEVICES

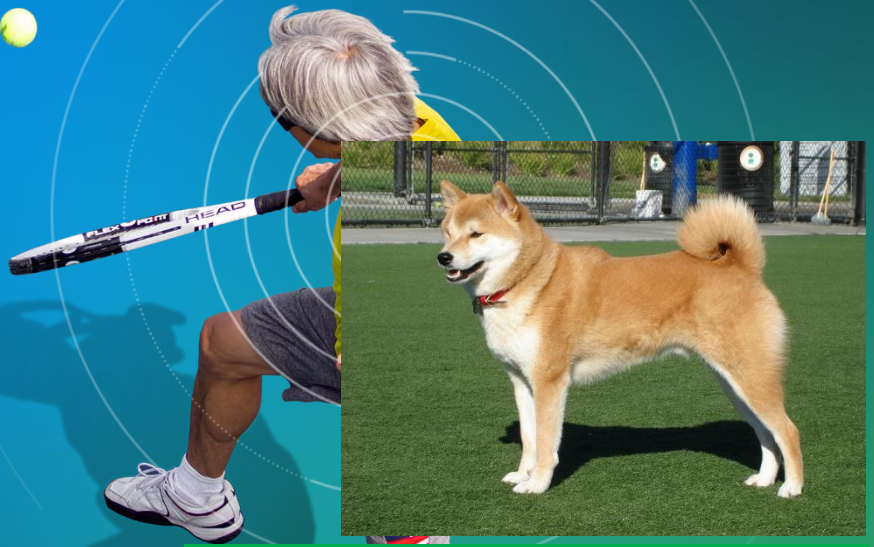
Leading in connected care with less-invasive, more-accurate technologies

DIABETES CARE

CARDIOVASCULAR

- Vascular care**
- Structural heart
- Heart failure
- Electrophysiology
- Cardiac rhythm management

NEUROMODULATION



- Abbott is a world leader with a broad portfolio of **advanced healthcare technologies**
- Technologies that are faster, more effective, & less invasive

Sustainable Sterilization: EO

- E-beam & Advanced E-beam
- Alternative gas sterilization, AGS

DIABETES CARE DEVICES

Continuous glucose monitoring

Providing accurate results faster and with greater convenience, so people can continuously monitor their glucose levels with minimal pain or disruption

#1 worldwide, with nearly 3 million users

FREESTYLE LIBRE

- Eliminates routine painful fingersticks
- Delivers unsurpassed 14-day accuracy and real-time glucose readings every minute
- Provides actionable insights for improved outcomes
- Affordable and accessible to millions of people worldwide
- Compatible with FreeStyle LibreLink and LibreLinkUp, smartphone apps that let people monitor their glucose without the use of a separate device, then share their data with caregivers remotely

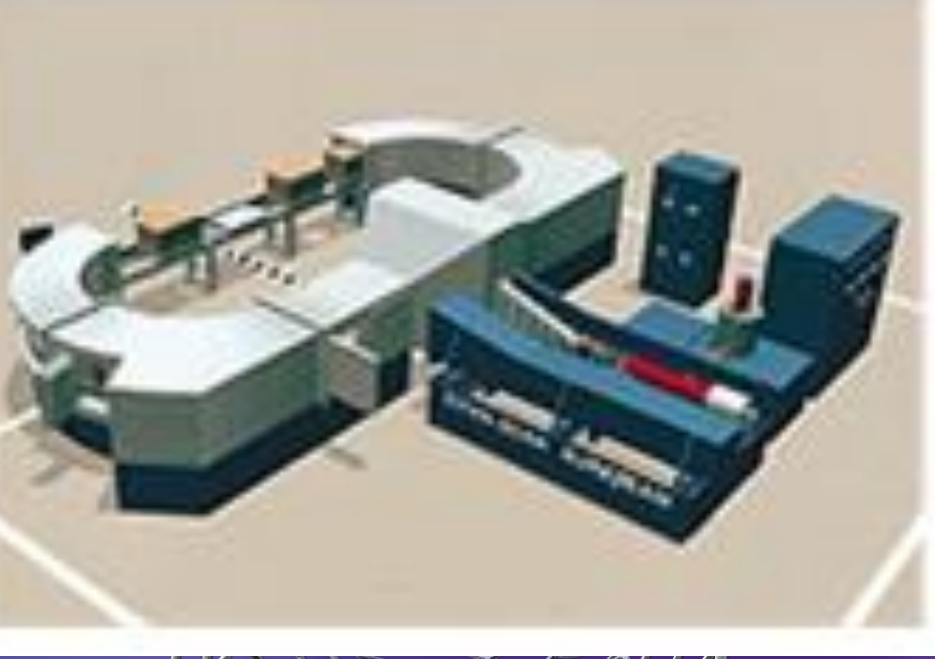
LIBRE SENSE

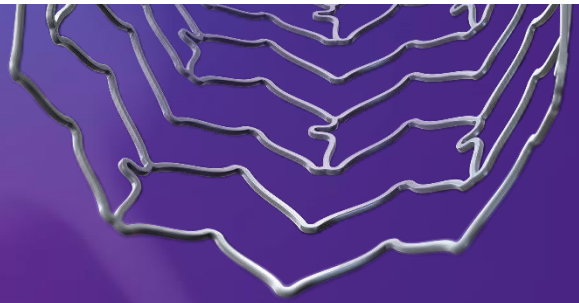
- Collaboration with sports technology company Supersapiens allows athletes without diabetes to learn more about their glucose levels and the correlation between fueling and athletic performance

100% E-beam & Advanced E-beam

AGS investments for Lingo Next Generation Products

Products may not be available in all markets





Huge 'Soft' EO initiative

CARDIOVASCULAR DEVICES

Vascular care

30% E-beam
10-yr journey in 1990s

Temecula, CA
Stds Development
Collaboration

Broad portfolio of devices designed to optimize percutaneous coronary intervention (angioplasty) procedures

MARKET-LEADING STENTS

Xience Sierra system designed for complex cases

DIAGNOSTIC AND IMAGING DEVICES

Help doctors assess arterial blockages prior to placing our market-leading stents

FULL PORTFOLIO OF VESSEL-CLOSURE DEVICES AND CATHETERS

Allows physicians to make optimal treatment decisions for each individual patient

Products may not be available in all markets

CARDIOVASCULAR DEVICES

Structural heart

Broadest portfolio of heart-valve repair and replacement technologies

CUTTING-EDGE TRANSCATHETER VALVE-REPAIR DEVICES

- ***MITRACLIP* and *TRICLIP***
  Repair for leaking mitral and tricuspid valves
- ***TENDYNE***
  Novel mitral-valve-implantation system

TRADITIONAL MECHANICAL AND TISSUE HEART VALVES

- ***EPIC***
  Aortic and mitral stented tissue valves
- ***MASTERS HP* 15 mm**
  The world's smallest rotatable mechanical heart valve

DEVICES TO TREAT HOLES WITHIN THE HEART

- ***AMPLATZER* PFO and *AMPLATZER AMULET***
  Reduce the risk of stroke
- ***AMPLATZER PICCOLO***
  A tiny, first-of-its-kind device designed to fix a congenital heart defect in premature babies

35% Steam, Liq Chem & AP

FDA Innovation Challenge – Soft EO

AGS Opportunity

E-beam Opportunity

Products may not be available in all markets

CARDIOVASCULAR DEVICES

Heart failure

Early Product in Temecula VHP chamber!

AGS Opportunities

Therapies across the heart-failure disease spectrum:

CARDIOMEMS HF SYSTEM

Pulmonary-artery-pressure monitoring provides early detection of worsening heart failure

HEARTMATE 3 LEFT-VENTRICULAR ASSIST DEVICE

Mini heart pump for patients in advanced-stage heart failure is the first to use *Full MagLev* flow technology

CENTRIMAG CIRCULATORY SUPPORT SYSTEM

Machine that temporarily takes over the function of the heart and lungs so they can rest and heal

Products may not be available in all markets

E-beam Opportunities AGS Opportunities

CARDIOVASCULAR DEVICES

Electrophysiology

Portfolio includes:

ADVISOR HD GRID MAPPING CATHETER, *SENSOR ENABLED*

First-of-its-kind electrode configuration to create more highly detailed maps of the heart

ENSITE X

Best-in-class cardiac-mapping system provides 3-D images of the heart and its activity

TACTICATH ABLATION CATHETER, *SENSOR ENABLED*

Next-generation device that is designed for ease of use

Products may not be available in all markets

CARDIOVASCULAR DEVICES

Cardiac rhythm management

Portfolio includes:

IMPLANTABLE CARDIAC MONITORS

World's first and only insertable cardiac monitor that is smartphone-compatible

CARDIAC RESYNCHRONIZATION DEVICES

Help the heart pump in a more coordinated way

IMPLANTABLE CARDIAC DEFIBRILLATORS

MRI-safe devices that help slow abnormally fast-beating hearts

PACEMAKERS (TRANSVENOUS & LEADLESS)

MRI-safe devices that restore normal heart rhythm

Products may not be available in all markets

AGS Opportunity

NEUROMODULATION DEVICES

Chronic-pain and movement-disorder therapies

Global leader in chronic-pain solutions

UNIQUE PAIN-MANAGEMENT PORTFOLIO INCLUDES:

- Radiofrequency ablation
- *BurstDR* spinal-cord stimulation
- Dorsal-root-ganglion stimulation

INFINITY DEEP-BRAIN-STIMULATION (DBS) SYSTEM

Targeted patient-specific treatment to help address the symptoms of Parkinson's disease and essential tremor

Products may not be available in all markets

AAMI TIR 100

End-to-End Microbiological Quality & Sterility Assurance

Figure 1—End-to-end Process

STERILIZATION PILLARS

Sustainable sterilization foundation

TRAINING & DEVELOPMENT

Competency based training for in areas of Radiation, Alternative gas sterilization, ethylene oxide, packaging/sterile barrier, and microbiology

ACCESS TO TECHNOLOGY

Access to R&D E-beam and Advanced E-beam, AGS development chambers and ramp up dynamics of novel technologies. Advancing micro dosimetry and LEEB.

R&D: MATERIAL COMPATIBILITY

Building comprehensive material database for sterilization modalities and upstream integration with R&D

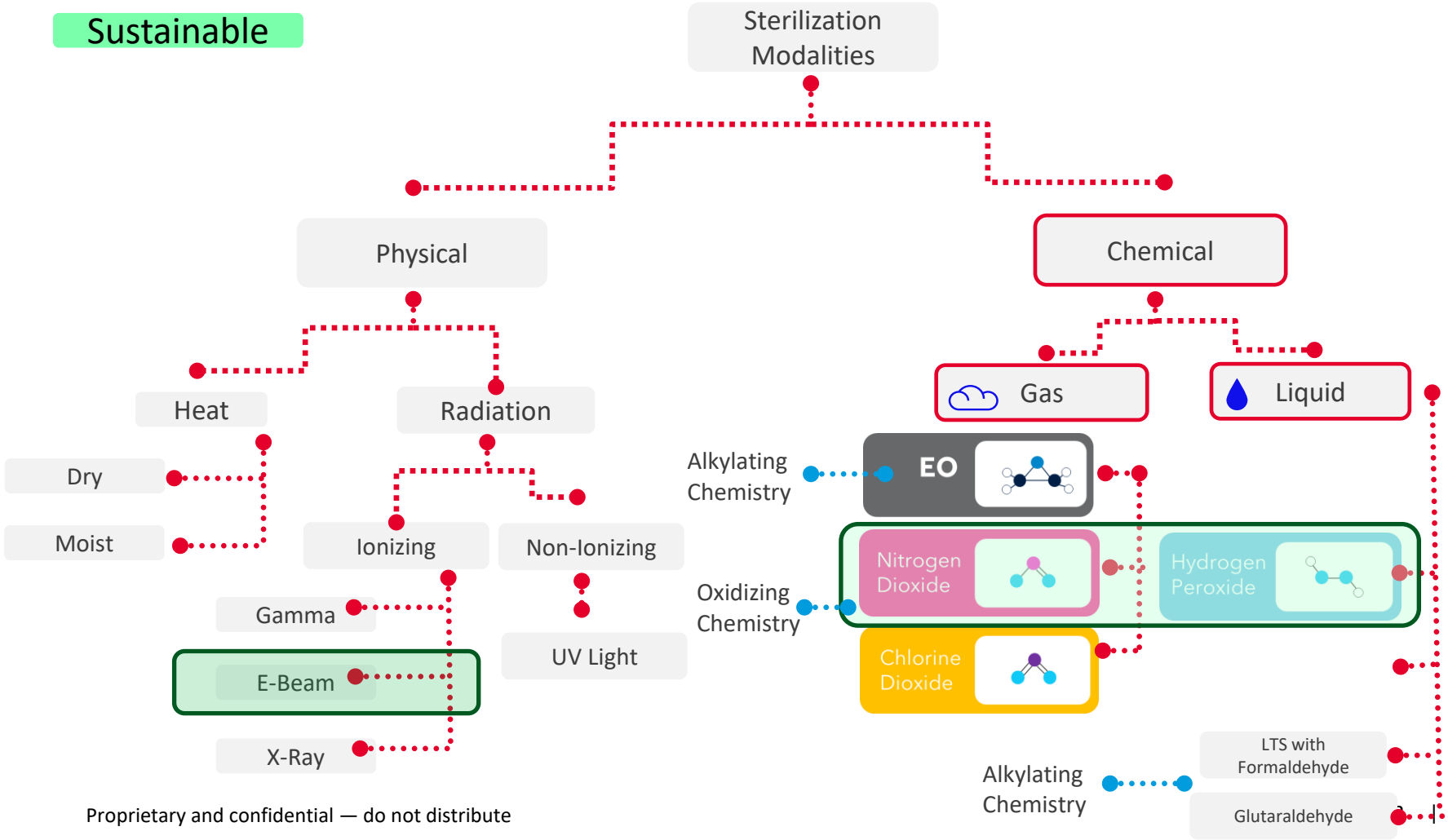
LETHALITY

Alternative SALs
Development of special AGS use case cycles for complex lumen and gentle corners with novel technologies

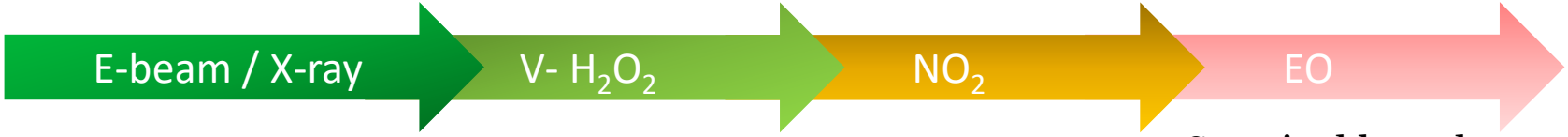
REGULATORY

Industry collaboration and developing global (FDA, EMA and regional) submission strategies for novel technologies

Sustainable



Sustainable sterilization path from traditional EO Ster'n



Radiation
- Material compatibility
- Micro-dosimetry
- Electronics shielding
- Monte Carlo modeling

Lethality
- Surface
- Complex

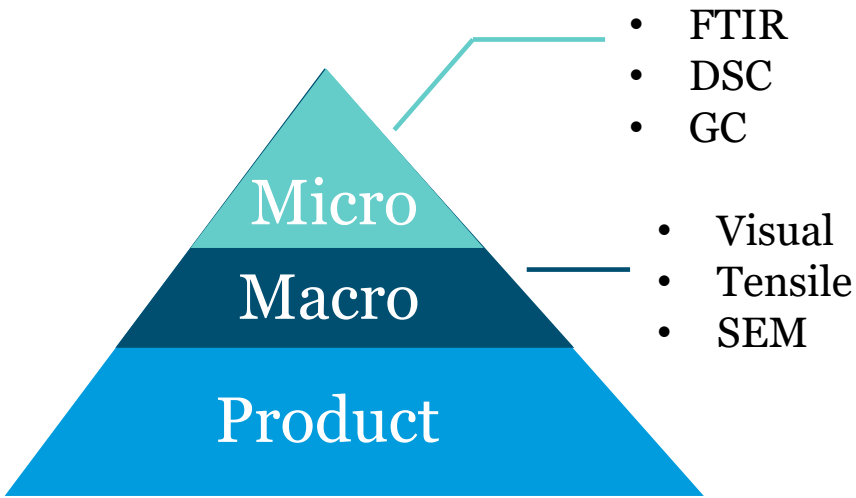
Compatibility
- Chemistry
- Material / coupons
- Product performance

Sustainable cycle
- > 30% reduction

Product Evaluation

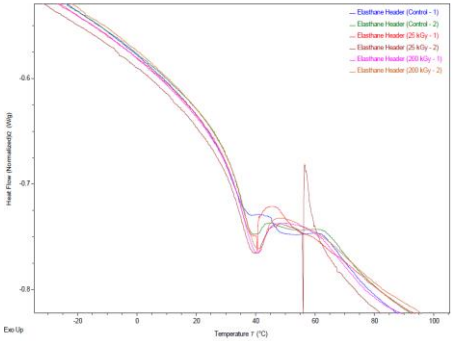
Assurance of Sterility Task Force (ASTF)

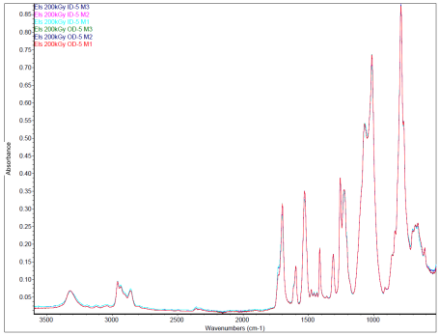
Identify Products	Evaluation	Feasibility	Pre-Val	Validation
• E-beam or Advanced E-beam • VHP or NO2 -	• Material assessment • Standard Cycle • Visual sample processing	• Lethality • Functional testing • Mitigate “High Risks”	• Cycle Development • Increased sample size • Include aging/conditioning	• Install/Qualify Equipment • Micro testing • Biocomp testing • Packaging testing • DV, PPQ



- FTIR
- DSC
- GC

- Visual
- Tensile
- SEM





Designed for sustainable sterilization

Input

- Material compatibility / characterization
- Packaging compatibility (sustainability)
- Infrastructure (network & capacity)

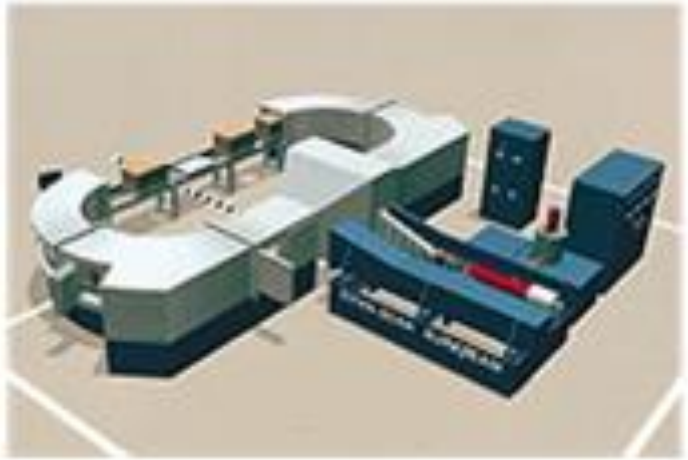
Output

- Sterilization effects - Product risk assessment
- Reduced packaging
- Reduced emissions (transportation)
- Reduced residuals
- Reduced capacity constraints
- Reduced risk to Abbott's reputation

End-to-End Microbiological Quality & Sterility Assurance

Figure 1—End-to-end Process

Drivers for change – Innovation over Decades



- **Three drivers over the decades**
  - Supply Chain … 1990s
  - Sensitive Combination Products … 2000s to present
  - Sustainability … 2015 to present
- **Business cases required for all changes … and business savvy**
  - What are current business priorities … cash … customer responsiveness … cost?
  - What is management focus … compliance … get product to market … key projects?
  - How are costs quantified?
  - How are savings quantified?
  - …
- **Partners for Change**

End-to-End Microbiological Quality & Sterility Assurance

Figure 1—End-to-end Process

Sterilization / Packaging Validations & Processes

- **Traditional & Classic Role of Sterility Assurance SMEs, e.g.,**
  - Define product, packaging and material compatibility
  - Define lethality of product
  - Define sterilization process
- **Examples of standards**
  - 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
  - ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **Huge value to all medical device companies and beyond**

End-to-End Microbiological Quality & Sterility Assurance

Figure 1—End-to-end Process

Patient Risk – New Paradigms!

- **Aseptic Processing vs Terminal Sterilization**
- **Terminal Sterilization at ‘Alternative SALs’**
- **Packaging**
- **Risk of Infection in a healthcare facility**
- **Microbiological Quality - appropriate**
- **Infection risk vs regulatory risk**

Bryans, Hansen, Lam, Lambert Elsevier Press, H2’19

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ASTF

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life. to the fullest.®

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Curriculum

110 Learning Outcomes

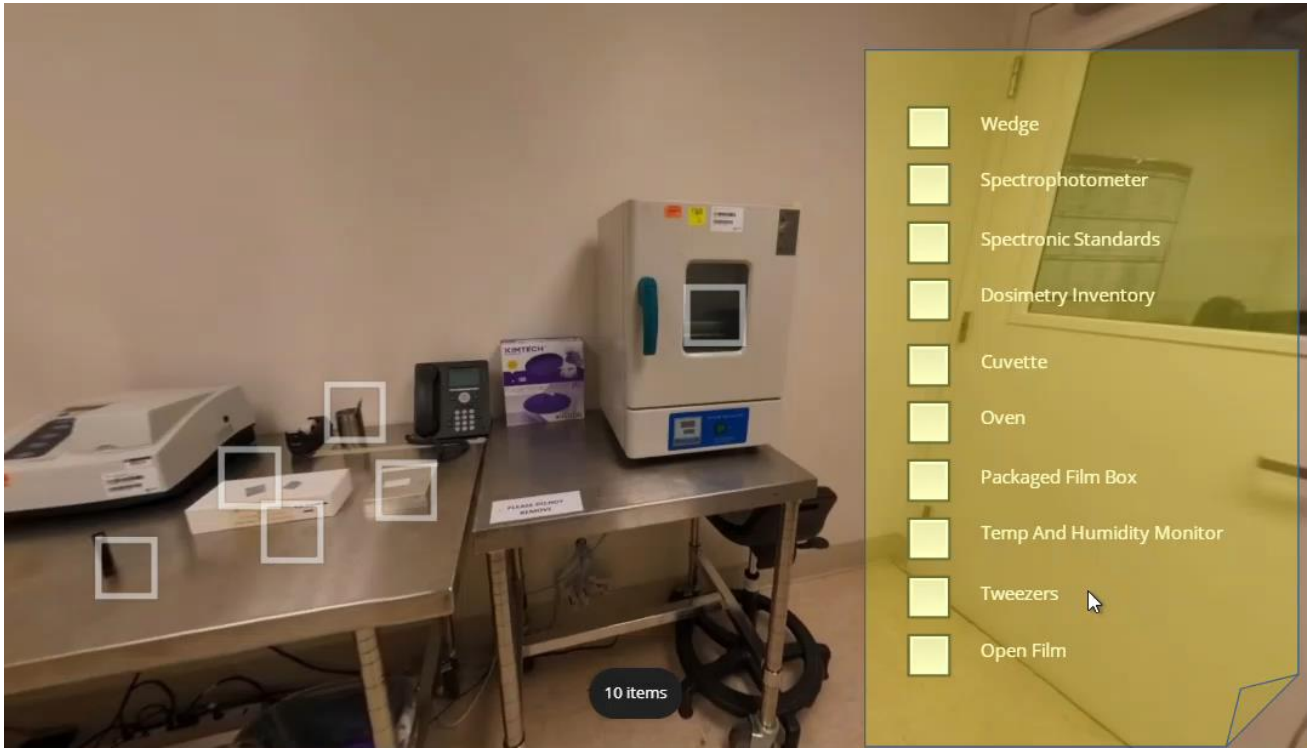
- 8 CBT modules linked to ISO & ASTM standards

Industry collaborators

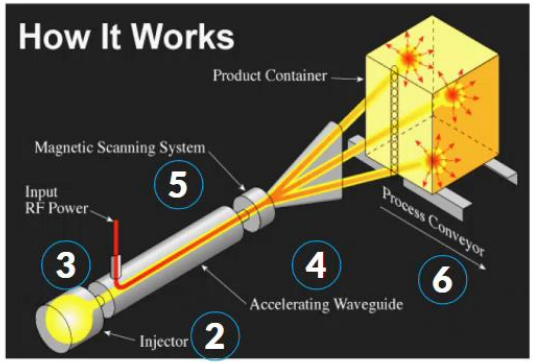
- Med Dev Manufacturer (Abbott, BD, Boston Scientific, KCI, J&J)
- Standards Development (AAMI / ISO)
- iiA (international irradiation association)
- Contract sterilizers (Sterigenics / Steris)
- Interest groups (The Panel)

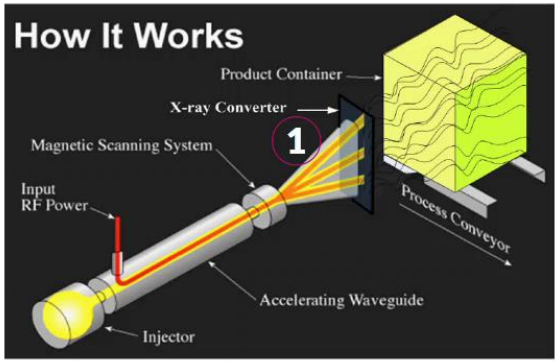
Healthcare Products Radiation Sterilization Curriculum Module	Know	Understand	Execute	Demonstrate	Competence	
Maximum acceptable dose: ISO 11137 Parts 1, 2 and 3, TS13004, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax, acc) for a product	K	U	A	A	KUAA	Acknowledge Competence
Dose Establishment: VDMAX 15 & 25 / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST67	K	U	A		KUA	
Performance Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.	K	U	A	A	KUAA	
Operational Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.	K	U			KU	
Dose Audit & Dose Augmentation, and routine maintenance/Requalification: ISO 11137 Parts 1 and 2, part 4	K	U	A	A	KUAA	
Dosimetry and terminology: ISO/ASTM 52628, E3083	K	U	A	A	KUAA	
Dosimetry System Calibration: ISO/ASTM 51261, ISO/ASTM 51707	K	U			KU	
Irradiation (technology specific) and terminology: ANSI Category II, III and IV standards. ASTM Gamma, ebeam, Xray documents. IAEA Safety Series 8.	K	U	A	A	KUAA	
Reading and Handling dosimeters: ISO/ASTM 52628 Used in conjunction with the relevant ISO/ASTM standard that pertains to the dosimetry system being used: ISO/ASTM 51275 (for radiochromic film) ISO/ASTM 51607 (Alanine-EPR Dosimetry System) ISO/ASTM 51650 (Cellulose Triacetate Dosimetry System) ISO/ASTM 51276 (for PMMA) ISO/ASTM 52701 on Influence Quantities ISO/ASTM 51707 on Uncertainties may be adequate in addition to 52628.	K	U	A	A	KUAA	
Product Family Adoption: AAMI TIR 35	K	U	A	A	KUAA	

Interactive



Problem oriented training





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