The National Academies of Sciences, Engineering, and Medicine
Committee on radioactive sources and alternative technologies
Washington DC, USA June 26, 2020

The International Irradiation Association Applications & Alternative Technologies

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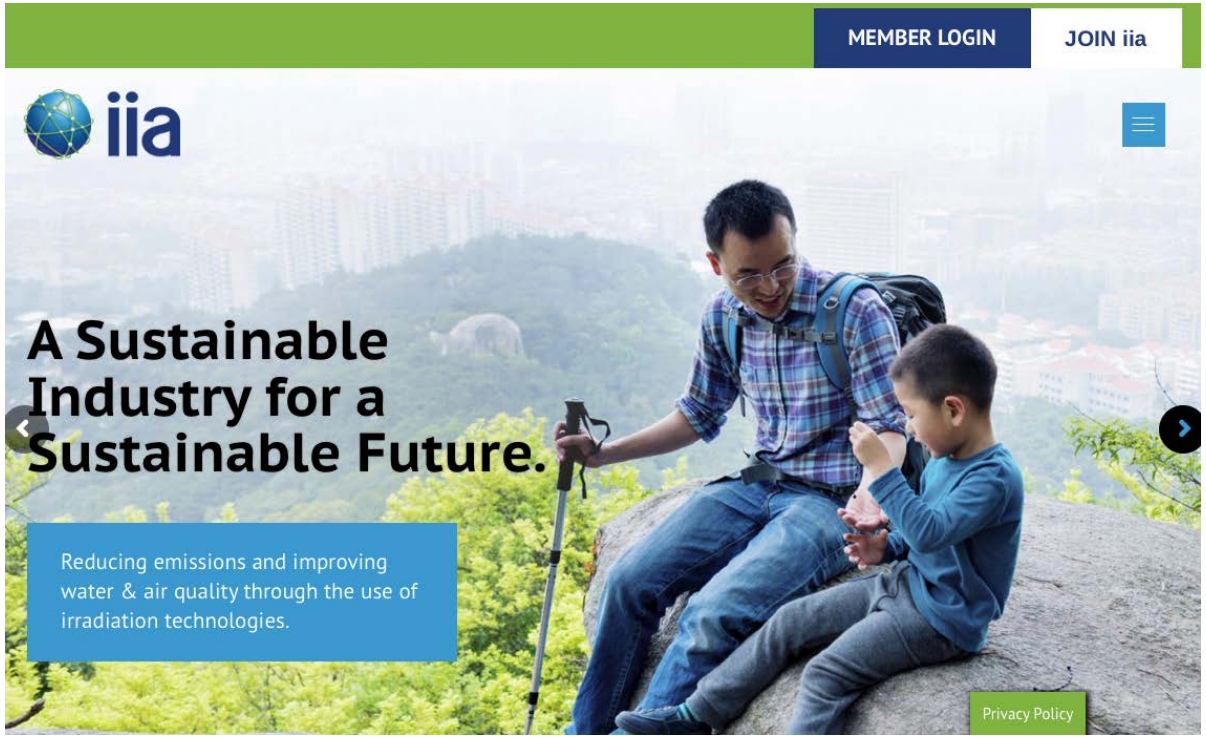
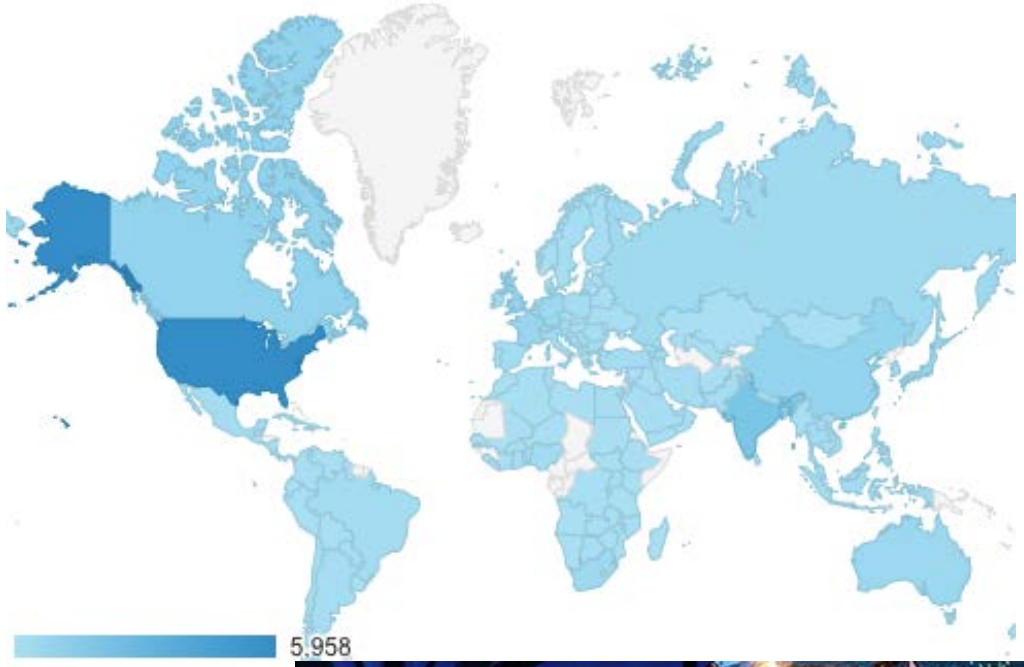
Agenda

- **Association**
- **Applications**
- **Radiation Processing Business**
- **Technologies**
- **Conclusion**



The association

- **Not-for-Profit. NGO status with IAEA**
- **Technology Neutral**
- **~ 80 Members, 6 continents**
- **Website 30,000 visitors 165 countries**
- **Communications – Direct, Conferences, Newsletter, Social Media**
- **Affiliates & Working Relationships**



The association

- New entity & branch

SfSAP
society for sterility assurance professionals

https://sfsap.org/

To define how the competence of sterility assurance professionals can be demonstrated

Initial funding from iia, AAMI and ASTM and in collaboration with leading medical co's

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PSiP
phytosanitary irradiation platform

https://psipglobal.org/

To advance the commercial application of irradiation as a phytosanitary measure globally

Branch of iia

Applications

Some applications use only or mostly

Gamma or E-beam

Main commercial applications

- **Enhancement of polymers: number 1 use of irradiation**
  - Through cross-linking, polymerization or grafting
  - Application to wires and cables, piping, heat shrinkables, foams, etc.
  - Continuously innovating

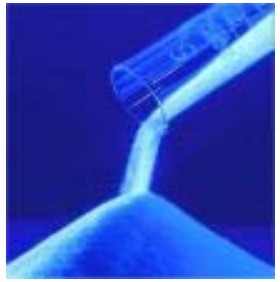
- **Sterilization of disposable medical devices**
  - Irradiation preferred when materials are suitable
  - Main activity of irradiation service providers except in China
  - Annual growth rate ~8%

Other commercial applications

Pharma & food packaging

Microbiological safety

Pharmaceutical and cosmetic ingredients



Microbiological safety

Rawhide pet toys

Prevent microbial cross-contamination

Food irradiation

Food safety and security

Phytosanitary irradiation

Crop protection

Beehives sanitation

Bees health

Other commercial applications

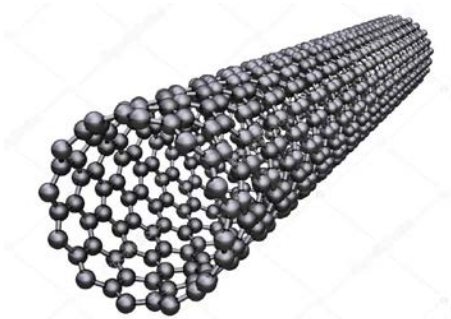
Semi-precious gemstones

Higher commercial value

PTFE scraps

Reuse after micronization

Nanomaterials



New products / materials

Wastewater treatment

Cleaner waters

Wood-plastic composites

Resistance to wear

Non-commercial applications

Cultural heritage

Preservation

Mutation breeding

Agricultural productivity

Sterile Insect Technique

Crop protection

Tissue banks

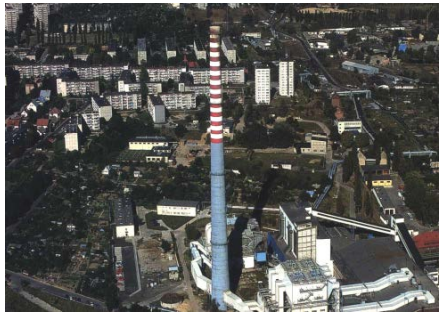
Allograft sterilization

Elimination of anthrax in mail

Biosecurity

Developing applications

Flue gas treatment



Cleaner air

Sludge treatment

Hygiene

Inactivation of bio-hazards

Safer environment

Ships ballast water

Prevent bio-invasion

The radiation processing business

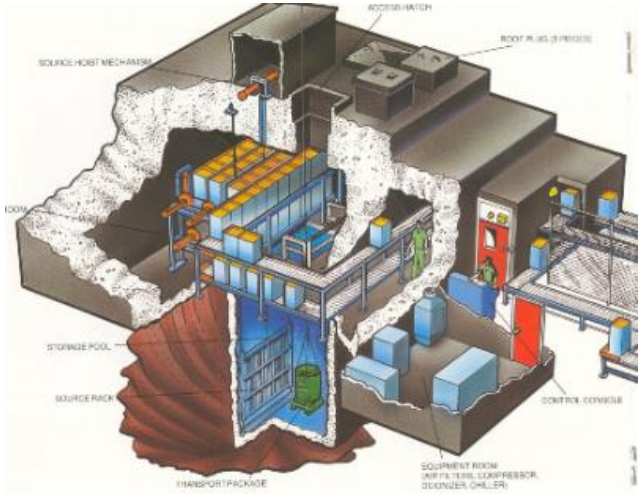
- **Multibillion USD business growing by 5-10 % a year**
- **Capital intensive, consolidation and evolution**
- **Contractors, suppliers, manufacturers, science**
- **Research universities and institutes**

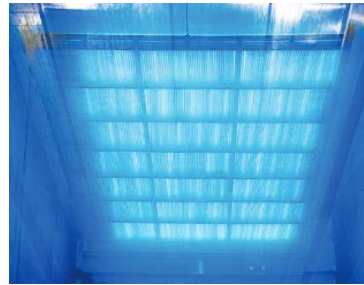
The radiation processing business

- **Out-sourced radiation processing**
  - Very large volumes processed for manufacturers in many industries: medical disposables, biotech products, packaging, etc.
  - Gamma dominant
  - Ranges from multinational players to SMEs (one country, one site, one technology)
- **In-house radiation processing**
  - Wire & Cable (Raychem), tires, cables (large and medium size companies)
  - Medical devices manufacturers (*e.g.* BD, Boston Scientific, JnJ),
  - Accelerators dominant
- **Relative importance of technologies and applications vary according to regions**
- **Excellent safety & security record**

Technology - Cobalt 60 - Gamma

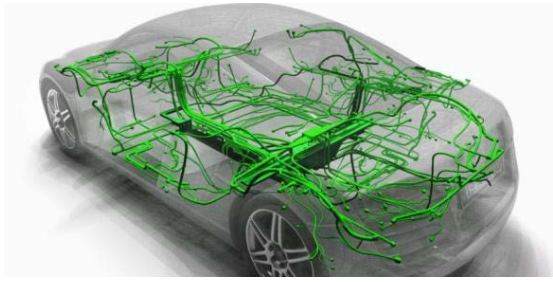
- ~ 260 commercial gamma irradiators (> 0.3 MCi)
- > 400 million curies of cobalt-60 installed
- Procurement of cobalt-60
- Simple, robust and mature technology
- Challenges: cost, regulatory, disposal
- Dynamics: Few new applications or gamma irradiators being built





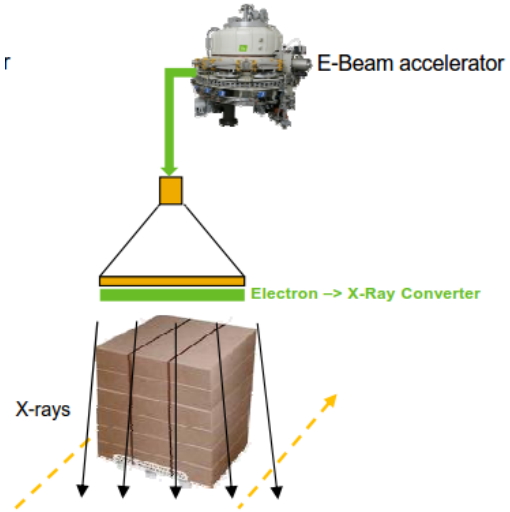
Technology - Accelerators - Eb

- Typically between 100 keV and 10MeV for radiation processing
- Globally more than 3,000 accelerators in use.
- Robust growth with > 150 units installed each year
- Multiple suppliers: North America, Russia, Europe and China
- Reliability has improved considerably
- Not well suited where quality of electricity supply is poor



Technology - Accelerators - X-ray

- Industrial use of X-ray still in its infancy
- Limited number of manufacturers can supply suitable accelerators
- Adoption (medical device) slow: cost/re-registration, limited availability/lack of back-up, familiarity, risk aversion, first mover reluctance.
- Will increasingly compete with gamma as economics improve.
- In 2020 number of new X-ray units and gamma units comparable.



Technology investment – decision criteria

Technology selection based on multiple factors:

- **Market Demand and Product Requirements:** forecasting demand/volume.
- **Material compatibility**: product and packaging
- **Density / DUR / Operational:** Bag, box, pallet, reel or tray.
- **Knowledge & Reliability:** investment and operational**.**
- **Investment Returns**: break-even point, cashflow & ROI.
- **Conversion Cost**: (re)registration & (re)validation for healthcare products.
- **Speed & Time**: Processing time / throughput / logistics.
- **Regulatory**: compliance and/or licensing costs / complexity.
- **Investment horizons and expansions options:** years.

Alternative Technology needs

ACCELERATORS

- **Improve efficiency**: power consumption/pulsed beams
- **Improve flexibility**: design and customization/ multiple beams/variable energies
- **Improved controls**: computing and software, mathematical modelling, remote diagnostics

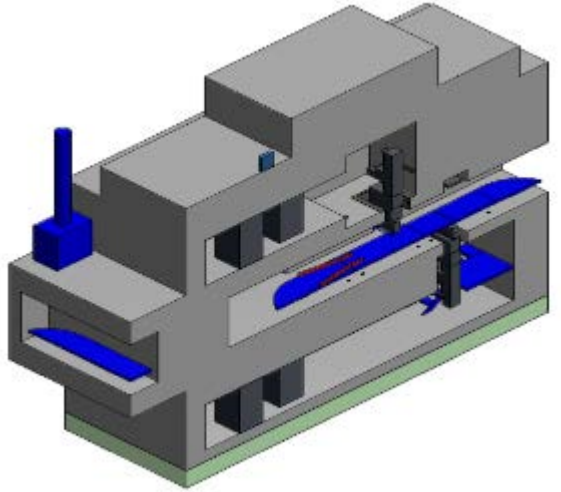
Technology - Accelerators

Examples of development:

IBA Industrial

E-beam and X-ray from a single accelerator:

Maximum flexibility to treat wide product range by moving x-ray target in or out



MEVEX Corporation

2 accelerators above and below conveyor:

High throughput, low DUR, no product flipping. Maximum flexibility and back-up

Technology - Low energy electrons and X-ray

- Potential surface treatments for decontamination probably underestimated in the past
- Equivalent effects to high energy electrons and X photons on microorganisms
- Avoids need for bulky shielding
- Easy to integrate into existing processing lines
- New lamps have now come in addition to machines

Leibniz-Institut für Polymerforschung Dresden

Technology - In-line EB treatment spreading in industry

Liquid Packaging

Tetra Pak® E-beam
aseptic filling system

Shibuya Kyogo
On-line EB sterilization of PET bottles

Biopharma

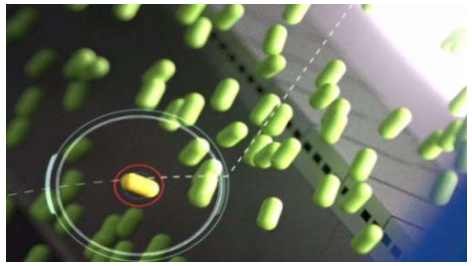
Getinge E-beam Tub
Sterstar Sterilizers
(empty syringes)

ITHPP
(pulsed
électrons)

Technology - Low energy electrons and X-Ray

Recent developments :

New metal-ceramic lamps (300 kV electrons) + product presentation



Microbial decontamination
of dried food ingredients

BÜHLER

First machines in the US, Spain and Germany

Surface decontamination of seeds
(alternative to pesticides)

EVONTA
EVONTA-Service GmbH

First machines in Germany and the Netherlands

Technology - Low energy electrons and X ray cabinets for research and SIT

EB cabinets

Radsource

X ray cabinets

(Reliability needs to be improved to deploy SIT programs)

Summary

- **Gamma.** Well established and robust technology. Still favoured by many.
- **E-beam.** Growing number of facilities / applications. Dynamic & innovative
- **X-ray.** No significant market share yet but increasingly attractive
- **Low energy electrons and X-ray.** Developing & promising for online processing.

All technologies have their pros and cons

Outlook

- At this moment, all technologies have their relevance and are needed
- All technologies will continue to co-exist over the short and mid-term
- No switch between technologies but more likely a progressive transition
- Gamma growth mostly through maximizing use of existing irradiators
- Gamma operators consider alternative technologies when capacity reached
- Market should remain the main driver of evolution

The iia is technology neutral

Thank You

https://iiaglobal.com