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Atoms for Peace and Development

Exploring the Role of Alternative Technologies to Reduce the Risks and Liabilities Posed by High Activity Sources

Valeriia Starovoitova

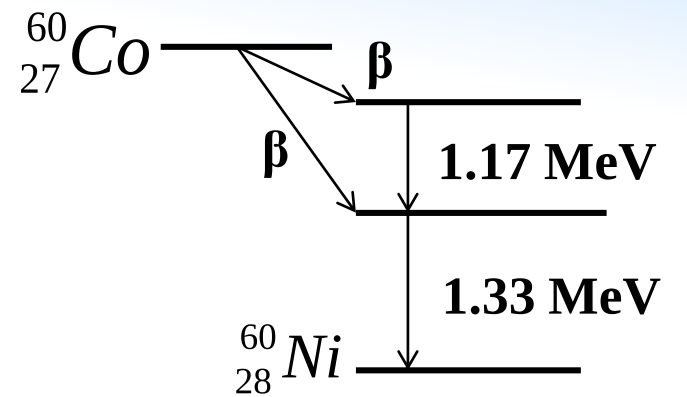
Radioisotope Products and Radiation Technology Section
Department of Nuclear Sciences and Applications
International Atomic Energy Agency

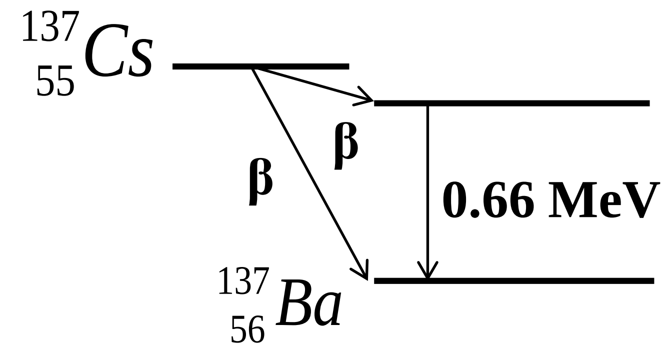
High activity sources

Co-60	Cs-137
5.3 years	30 years
1.17 MeV and 1.33 MeV	0.66 MeV

Uses:

- Industry (sterilization, NDT, gauges, well logging)
- Medicine (teletherapy, blood irradiation, tissue graft sterilization)
- Agriculture (phytosanitary uses, SIT)
- R&D (biology, chemistry, material science)





Why Alternative Technologies?

Sources can be dangerous both accidentally and on purpose….

2010

- New Delhi – A man died after handling radioactive scrap metal containing ^{60}Co.

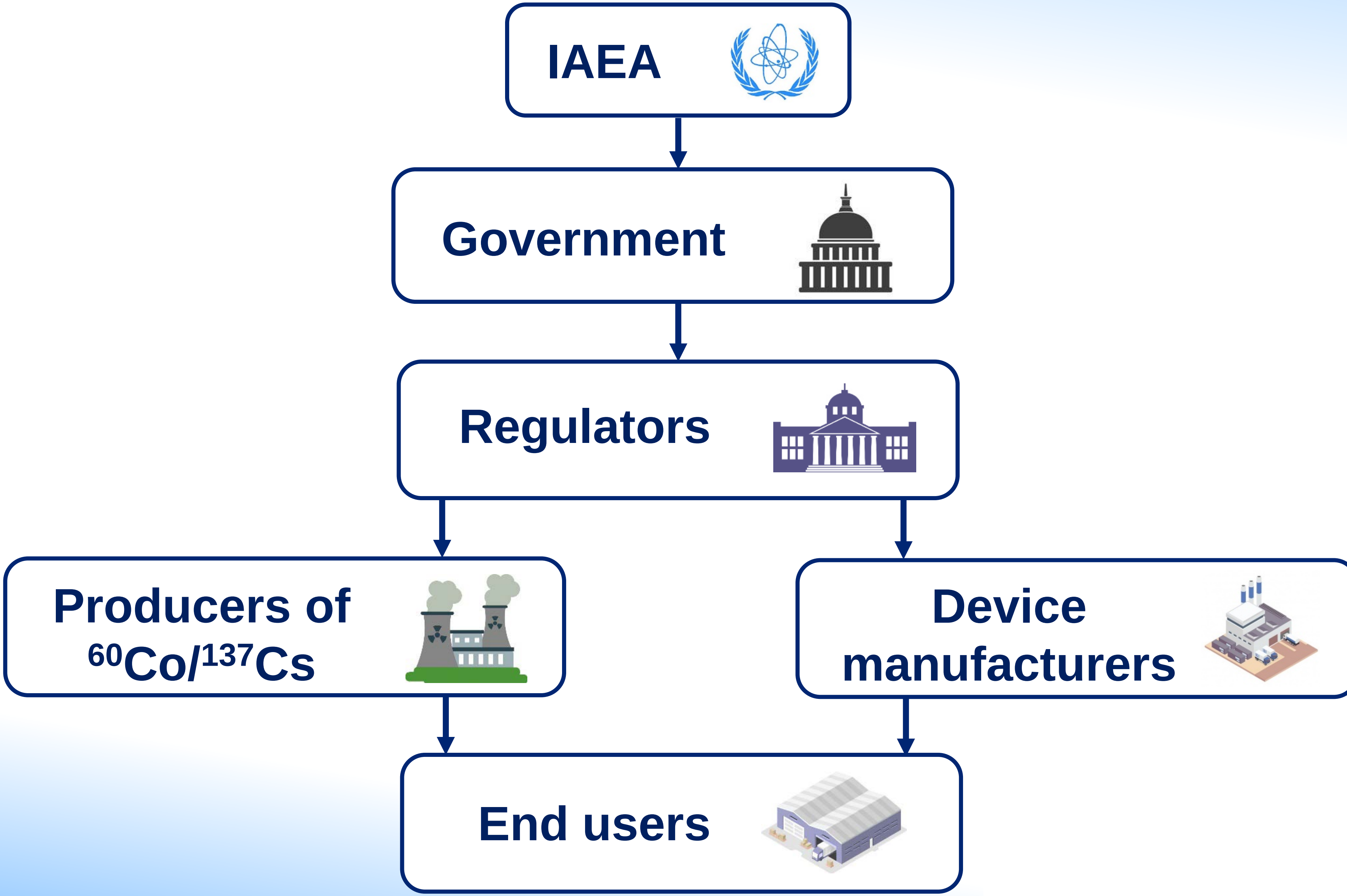
2013

- Tijuana - A truck transporting ^{60}Co source from a hospital to a waste storage facility was hijacked. The thieves could have received a fatal dose of radiation.

1993

- Russia - ^{137}Cs source was hidden in an office chair to kill the CEO of a company.

Key Stakeholders

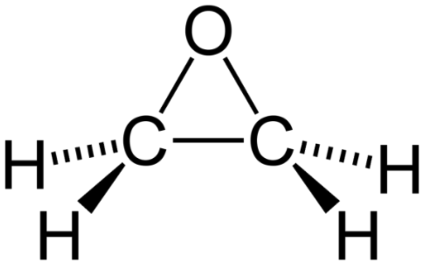


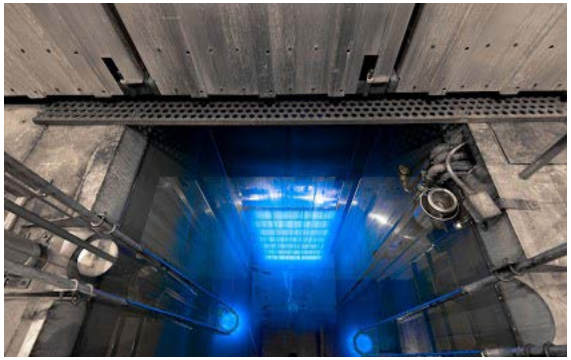
Whether to Adopt Alternative Technologies?

- What are the advantages and disadvantages of high activity sources?
- What are alternative options and which one would work the best?
- Will it provide comparable result?
- How reliable is the alternative technology?
- What are the costs?
    - Capital costs (purchase the device and retrofitting the facility)
    - Operational costs
    - Licensing and Regulations
    - Security
    - New personnel and training
    - Disposal costs

Sterilization of Medical Products

- Moist heat sterilization (autoclaves)
- Chemical treatment (Ethylene oxide, EO)
- Radiation





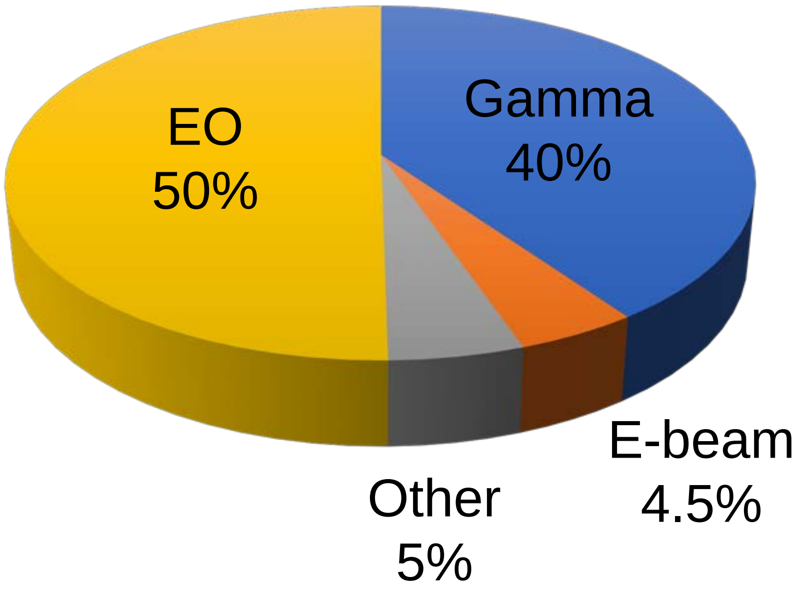
Many medical products are designed with a pre-selected sterilization method and changing this method could require costly redesign and revalidation for the product as well as a revalidation of the sterilization process.

Sterilization of Medical Products

Majority of medical product manufacturers are small and medium size companies, which rely on irradiation service providers.

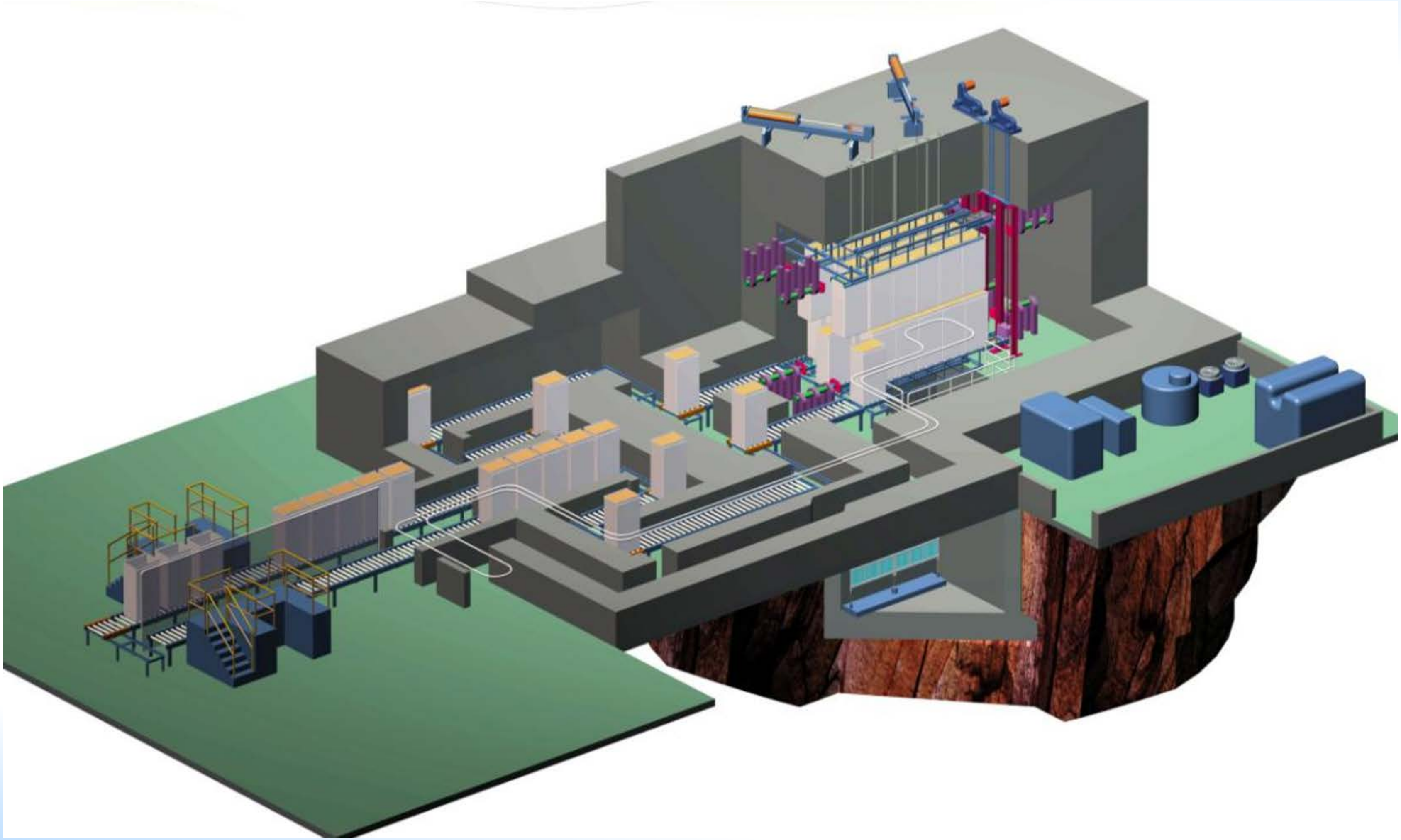
Co-60 (400-500 MCi worldwide) is used for about 40% of sterilization market (~85% of the radiation sterilization market). Typical industrial irradiator contains 1-5 MCi of Co-60 and can irradiate millions of ft^3 per year.

Breakdown of the Sterilization Market



Adopted from www.iia.com

Typical Co-60 Irradiator

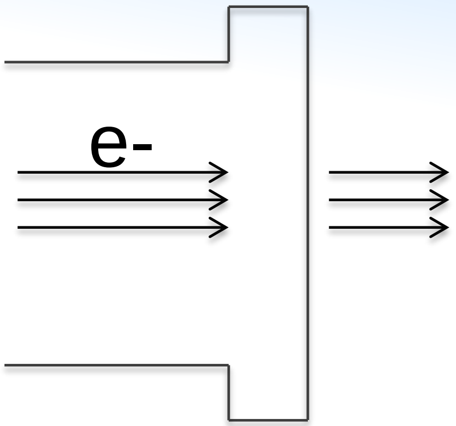


Adopted from www.nordion.com

Existing Alternative Technologies

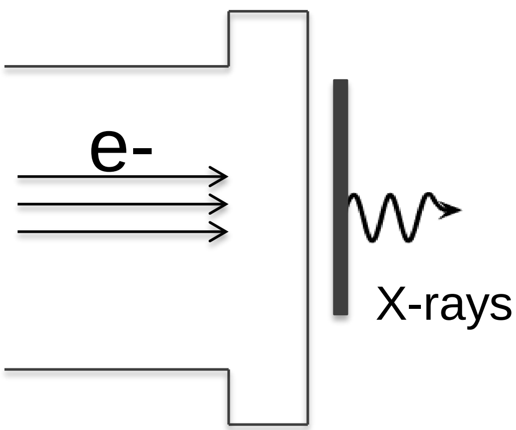
- **Direct e-beam**

  Low penetration depth (used for thin and low density materials)



- **X-rays**

  Good penetration, but power lost when converting electrons in photons



Typical E-beam/X-ray Facility

Adopted from www.iba-industrial.com

Pros and Cons

Co-60 irradiators:

- Common, simple, proven technology
- Decay and need replacement
- Source cost increases, transport and logistics get more and more complicated
- Waste disposal is an issue

Electron accelerators:

- No security concerns
- Can be used in two modes: direct e-beam (up to 0.25 g/cm^3) and x-rays (up to 0.5 g/cm^3)
- Require reliable power supply and highly skilled operators

It is estimated that ~100 kW of e-beam is equivalent to 1 MCi of Co-60

Transition: Technical Challenges

- Reliability of accelerators and back-up options: spare machines or service center
- Beam stability in accelerators: energy, current, beam spot
- Dose distribution in products: e-beam vs. x-ray vs. gamma
- Radiation effects on materials: discoloration, etc.
- Facility conversion is difficult: retrofitting existing gamma vault and drop-in replacement is often not possible

Transition: Regulatory Challenges

- As products are often shipped to different countries, multiple approvals are needed and the process can take years.
- Gamma sterilization is common, but e-beam, and especially x-ray are often not well described in regulator manuals, which brings a lot of uncertainty in the licensing process.
- “Grandfather clause”: if a manufacturer had a medical device on the market for decades, it is likely that the regulatory standards for testing and approving these products would have gotten tighter, and the product may no longer be in compliance.

Transition: Economical Challenges

- Cost of Co-60 is almost tripled in the last 30 years, from ~1 US$/Ci in 1990, to ~2 US$/Ci in 2005, and ~3 US$ /Ci now. Regulations and logistics become more and more challenging. Accelerators, on the other hand, become more reliable and less expensive.

- However, often sterilization represents only few percent of the cost of the medical device. On the other side, cost of conversion could be extremely expensive and take several years.

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Conclusions

- Current Co-60 sterilization providers are heavily invested in the existing facilities and switching to the alternative technologies will not be a quick and easy process. Introducing restrictive regulations on Co-60 will be disruptive and very expensive.

- To accelerate the process a number of hurdles needs to be overcome:
  - Develop reliable accelerator technologies
  - Develop well-documented comparisons of the three modalities' impact on medical device materials
  - Work with regulatory agencies as they are the bottleneck to change, especially with legacy products.

THANK YOU FOR YOUR ATTENTION!