

The Path Ahead

Scientific Forum IAEA General Conference Vienna; 2015 Sept. 15 – 16

Paul Gray; V.P. External Relationships and Global Logistics, Nordion Chairman; International Source Suppliers and Producers Association

About Nordion

nordion SCIENCE ADVANCING HEALTH

Nordion is a health science company that provides market-leading products used for the prevention, diagnosis and treatment of disease.

We've been **delivering safe**, **high-quality products** to global customers for more than 60 years.

To best serve the diversity of our customers' requirements, we are organized into two business units – **Gamma Technologies** and **Medical Isotopes**.





Nordion's Global Footprint



APPROXIMATELY **375 EMPLOYEES**

AROUND
30 PRODUCTS

SUPPLY OVER
500 CUSTOMERS

ACROSS MORE THAN
40 COUNTRIES



Leading Providers in...



GAMMA TECHNOLOGIES

LEADING PRODUCTS > & SERVICES

- Irradiator designs
- Cobalt-60
- Applied research services
- Irradiator maintenance, upgrades and training services

VALUE >

- Extensive cobalt processing expertise, regulatory expertise, worldwide logistics capabilities and distribution network
- Full lifecycle management of Cobalt-60 (cradle-to-grave)
- One stop solution for all gamma processing needs



MEDICAL ISOTOPES

- Isotopes for cardiology, neurology, oncology and research applications
- Applied R&D services
- Contract manufacturing services
- Medical imaging services
- Extensive processing expertise, regulatory expertise, worldwide logistics capabilities and distribution network
- 80,000-ft² state-of-the-art cGMP manufacturing facility
- Proven as a trusted source for a breadth of critical isotopes





Medical Device Sterilization





Other Applications



In addition to Medical Devices:

- Consumer products (cosmetics; bandages, contact lenses and solutions)
- Phytosanitary treatment of wide variety of foods
 - 55: The # of countries that have approved the use of irradiation
 - 500,000: The # of metric tons of food products commercially irradiated each year
- Drug Discovery



Medical Device Industry



- Global Medical Device market is estimated to have a value in excess of \$200 Billion annually
 - ✓ Medical device demand continues to grow at a 5 to 7% / yr. rate due
 to aging population and greater access to healthcare globally
- Thousands of Medical Device companies globally
 - √ 80% of medical device companies are smaller companies, in which sterilization switching may be difficult.
 - ✓ Many of these companies are also global companies that have manufacturing and distribution sites located throughout the world
 - ✓ Many companies are establishing themselves in growing economies and need reliable, simple and safe technology that they can rely upon



Medical Device Industry

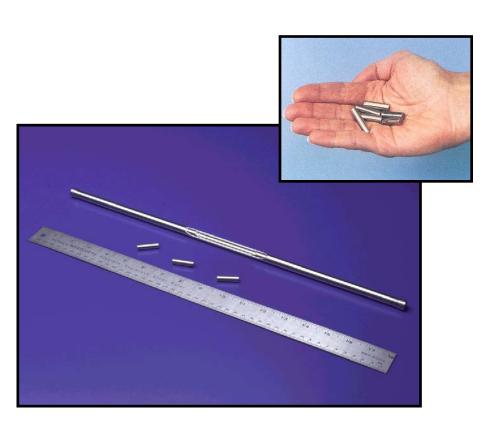


- Single use, medical device sterilization is a critical function of this market, using the following technologies:
 - Cobalt-60 Gamma: ~ 40% volume processed
 - Ethylene Oxide (EO): ~ 50% volume processed
 - E-Beam (accelerator based): ~ 10% volume processed
 - X-Ray (accelerator based): ~ 0% volume processed
- Sterilization facilities are comprised of manufacturer's in-house and outside contract :
 - Most sterilization sites operate 24/365 days per year (1 year = 8760 hours)
 - Gamma PI sites typically operate with 95 98% efficiency (8300 8600 hrs/yr)
 - Device composition, density, complexity, packaging, kitting, turnaround time,
 equipment reliability & quality control of process are critical to the device manufacturer
 - Technology validation costs vary widely by technology and product. These costs include such tests as bioburden, product sterility, method suitability testing, accelerated aging, biocompatibility and verification dose
 - As the last step in manufacturing, devices can go immediately to the end-use healthcare facilities and labs after gamma sterilization



Cobalt-60





•Cobalt-60 sources emit gamma radiation this energy is harnessed to eliminate pathogens and microbes

Cobalt-60:

- A solid metal
- Non-fissionable
- Non-soluble
- Non-dispersible
- Non-flammable
- Sources and containers licensed
- 5.25 year half-life

•Produced in power reactors (Co-59 to Co-60)



Cobalt-60 in Irradiators



Cobalt-60 slugs in a source

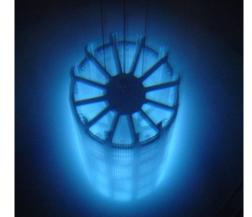


Source module



Source rack

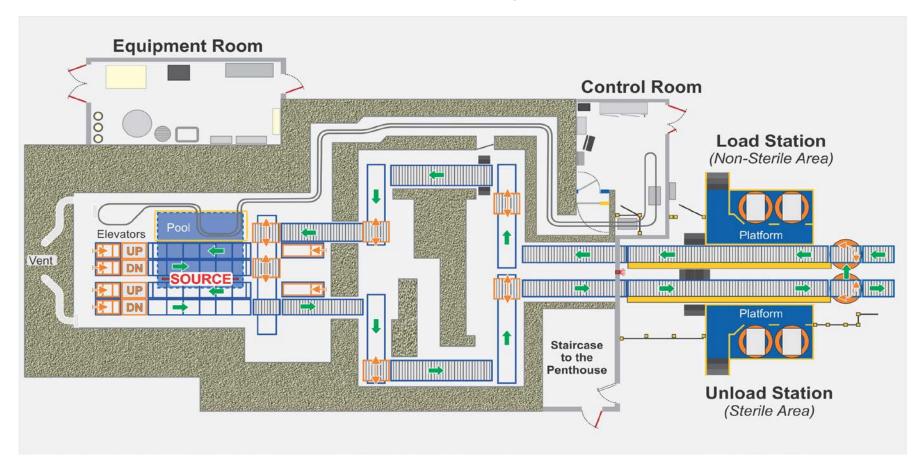




Gamma: Simple and Reliable Design

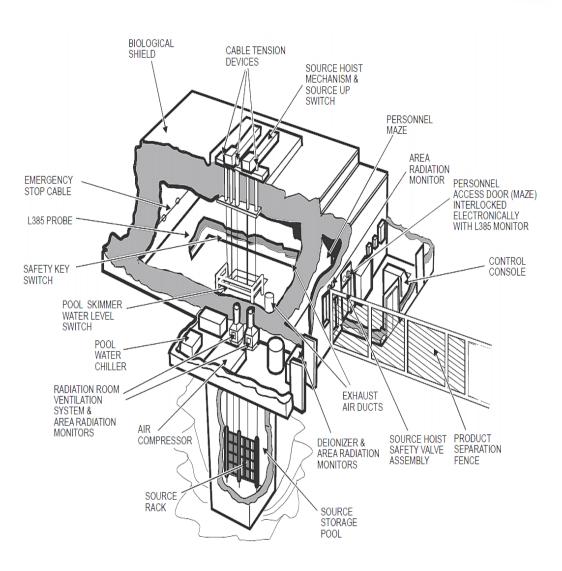


- Components are all simple machinery requiring low level maintenance and upkeep (i.e. product handling system conveyors, pneumatic racks)
- Gamma does not require any high power or complex machinery to deliver the radiation to the product in a highly reliable manner



Gamma Irradiator Safety





- Gamma Systems have a long and highly reliable safety and security record.
- All safety components are simple in design and easy to maintain.
- Main safety issue is the source which utilizes gravity for reliable return to safe position.

Gamma System Design



Cobalt Use

 Cobalt-60 is a simple and highly reliable radiation source that does not require high power or complex machinery to operate (continuous, consistent, uniform)

Dose Delivery

 Gamma rays are highly penetrating, permitting easy and reliable use on multiple types of product and with simple and accurate dose prediction

Product Size Flexibility

 Gamma has many different well proven system designs to handle product in smaller totes all the way up to full pallets giving wide product type flexibility

Labour

 Due to simple design, gamma does not require high level technical operators or maintenance personnel unlike machine source systems

Cost

 Most capital costs are in the building and conveyor. Many gamma systems have a long life of over 30 years with only few upgrades required during the life for reliability

Economic and Experience Summary



Attribute	Gamma	E-Beam	X-Ray
Reliability	Excellent	< Gamma	< E-Beam
Maintenance / Spare Parts	Low costs	High Costs	Very High Costs
Equipment Complexity	Low	Moderate	High
Source Complexity	None	High	Very High
Penetration-High Density	Effective	Poor	Effective
Environmental Impact	Source Disposal (no impact) & minimal CO ₂ emissions	High Energy Usage & High CO ₂ emissions	High Energy Usage & High CO ₂ emissions
Market Share	High	Low	Minimal

Gamma Summary



- Gamma systems have been operating for over 60 years on all continents.
- Over 200 gamma facilities operating globally with more than over 400 MCi in operation.
- Gamma rays are highly penetrating and can process many types of products with very predicable results
- Most products requiring radiation treatment today have been fully qualified already for gamma
- Approximately 45% of all single use medical disposal devices are sterilized with gamma

Gamma Summary



- Gamma technology does not require complex machinery or highly sophisticated power sources to operate
- Gamma is normally operated by staff with minimal technical training.
- Gamma does not require complex maintenance practices to operate reliably
- Most gamma systems operate at over 95% reliability
- Many gamma systems operate for over 30 years with minimal up keep for safety and support