Radiation Processing in a Changing World

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Introduction

The world is constantly changing

- Negative changes or influences include:

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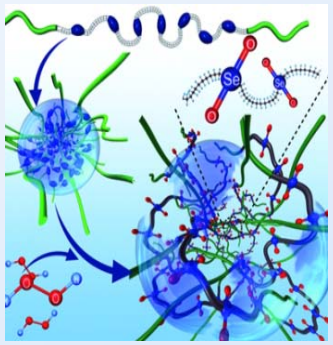
- Positive changes or influences include:


Introduction

What impact will these positive and negative influences have on the application of ionizing radiation?

- **Regulatory initiatives** – safety and security of radioactive materials
- **Commercial and other events** – impact on availability and sources of Cobalt 60 supply
- **Technology changes** – research & development and growing acceptance of Eb and Xray technologies
- **Innovation & Science** - new opportunities for the application of irradiation technology

Safety and Security

In the U.S.A. the fundamental laws governing the civilian uses of nuclear materials and facilities was enacted by the **1954 Atomic Energy Act.**

The U.S. **Nuclear Regulatory Commission (NRC)** was established by the Energy Reorganisation Act 1974 - formulates policies, develops regulations governing nuclear reactor and nuclear material safety, issues orders to licensees, and adjudicates legal matters.

The **National Nuclear Security Administration (NNSA)** was established by Congress in 2000 as an agency within the U.S. Department of Energy, responsible for the management and security of the nation's nuclear weapons, nuclear nonproliferation, and naval reactor.

Safety and Security

New standards and regulations are constantly being formulated safety and security is an increasingly important issue. NNSA has been operating a program called **GTRI**.

Irradiation technology is extremely widely used. The greatest risk is often associated with relatively small amounts of radioactive material used in mobile or portable devices. Security however is only as strong as the weakest link.

US NRC Regulations 10 CFR Part 37 & Draft US Appropriations Bill

Safety and Security

US NRC Regulations 10 CFR Part 37 was a natural evolution

Section 402 (Draft U.S. Appropriations Bill) came out of the blue:

S402 generated a strong and highly coordinated response from regulators (US Nuclear Regulatory Commission NRC) as well as industry associations, hospitals and corporate enterprises.

Section 402

Required the NRC to discard its established regulatory framework in favor of mandatory security standards established by the National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI) for "High Risk Radiological Material."

Section 402(a)(2) directed NRC to, "actively enforce NNSA GTRI security standards"

Section 402(f), which as written would have mandate the eventual prohibition of NRC licenses for workhorse radioisotopes such as cobalt 60 without due consideration of the cost, reliability, risks and overall effectiveness of potential substitute technologies.

Regulatory

Response

Regulatory

The Bill was modified before being passed.

- The U.S. NRC along with the 37 Agreement States in the US retain over all responsibility for licensing.
- The requirements of a recent regulatory security enhancement by the NRC - 10 CFR Part 37 were highlighted and acknowledged
- The important role of NNSA referenced. Separately a US GAO Report on Nuclear Non Proliferation (June 2014) highlighted a number of NNSA recommendations.

NRC Regulations 10 CFR part 37

Over the 11 years leading to 2013, the U.S. NRC, Agreement States, and users of radioactive materials had been working to prevent the malicious use of these materials. The Rules have now been codified in extensive new regulations (10 CFR Part 37).

These orders and subsequent regulations were developed based upon the results of vulnerability assessments, gap analysis, and a cost effectiveness review of the enhancements.

The cost of implementation is estimated to be USD 400-500m over the next 20 years

10 CFR part 37

- The new regulation establishes security requirements for the use and transport of (IAEA) Category 1 and Category 2 quantities of radioactive materials.
- The new 10 CFR Part 37 was effective on May 20, 2013 and NRC licensees must comply with the requirements by March 19, 2014. Agreement States will have until March 19, 2016, to issue compatible requirements for their licensees.
- Access by personnel – Background checks, fingerprinting and criminal record checks, identity checks, employment and education checks, Reputation and character determination.
- Monitored detection systems onsite/offsite, electronic intrusion alarms, monitored video surveillance

Commercial & Other

Cobalt 60

Production. Canada 50%, Russia 35% and India/China 15%

Supply. Nordion, JSC Isotope, BRIT, Tongxing

Commercial. transactions and relationships – Reviss, JSC Isotope

M & A. Sterigenics & Nordion, Steris & Synergy

Cobalt 60 Availability

In March 2011 global reactor capacity and attitudes were dealt a blow by Fukushima.

Germany quickly closed 2 plants and cancelled plans to extend the life of 15 others

Over the next 5-15 years a number of reactors will close, some will be refurbished so new capacity will need to be found.

Cobalt 60 Transport

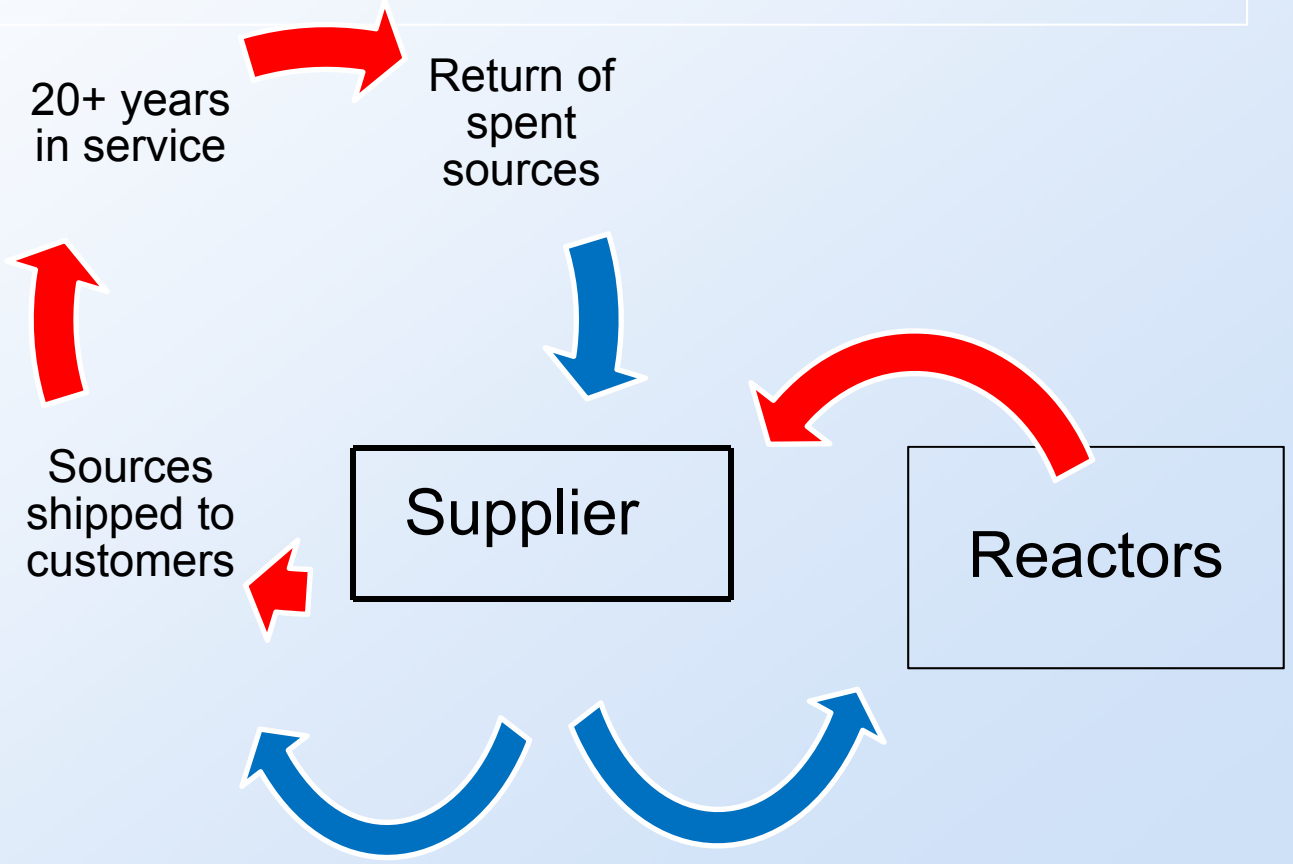
3rd Technical Meting met in Vienna Austria April 2014 – harmonization, communication and denial of shipments.

Safety Guide Schedules and Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition) (IAEA Safety Standards Series No. TS-G-1.6 (Rev. 1) published in 2014.

A Transport Facilitation Working Group (TFWG) was formed 2013 to maintain efforts on reducing denials of radioactive material shipments. The TFWG met in January and March 2014 to discuss organizational matters and develop its plans for action.

State Transportation Fees. Illinois and Indiana

Cobalt 60 Disposal



Cobalt 60 Storage

Disused Sealed Radioactive Sources (DSRS)

Dry Storage Casks at Reactor

Eventual disposal in near-surface repositories, deep geologic repositories, or boreholes

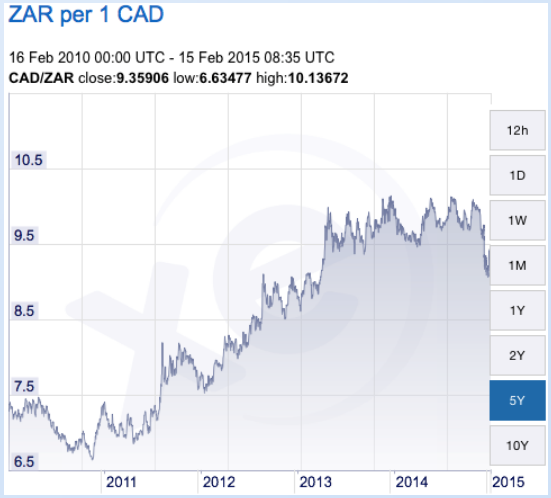
Cobalt 60 Cost

The Supply & Demand equation

Transportation costs

Long-Term Disposal / Storage

The impact of exchange rates



Electron Beam

Electron Beam has a long and proven history especially in the processing or wire and cable and heat shrink tubing.

Predominately used in-house whereas is gamma predominately provided by specialist contract operators

Growing number of well respected suppliers who have proven capability.

Electron Beam continues to have limited application in the processing of medical devices but benefits from “electronic” tag for other applications.

Technology Changes

X-ray

The penetration power of x-rays mean that the technology offers an alternative to gamma

Starting to see x-ray investment. Biggest challenges relates to energy conversion and cost.

IBA have recently introduced the Rhodotron Duo system offering EB and X-ray capability

Dasheng, Wuxi El Pont, CGN Hi Wits and Mevex are offering new innovative solutions in their Eb X-ray portfolio

Energy Source Electricity

Seen from space Africa is as dark as Siberia.

1 Billion people -16% of world population – 4% of global electricity.

75% RSA, Egypt and countries of the northern coast.

Today RSA has load shedding.

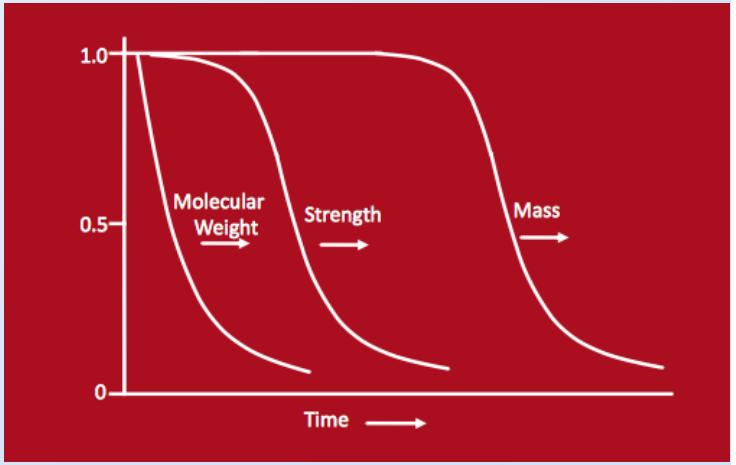
Medical Devices

Increasing use of polymeric materials as a drug delivery mechanism and as a tissue building scaffold

Tissue Scaffold

Cardiovascular Stent

An understanding of radiation dynamics is a fundamental part of product development.



Medical Devices

Bioresorbable polymer screw degrades over time leaving newly formed bone in its place. (Smith & Nephew)

Medical Devices

Increasingly products are either (a) commodity or (b) high value / complex

High Value products have very different cost structure – controlling temp, environments during both transport and processing and turnaround speed can be vital.

High tech facilities are being developed to meet these needs.

Medical Devices

Dosimetry becomes a critical component. Differences in scientific opinions exist.

ISO is currently undertaking a revision to 11137 Part 3. Challenging process.

AAMI has established a Task Group to consider aseptic processing and considerations of an alternative SAL – aim to provide input to a review of ST67

ISO is undertaking a more limited review excluding aseptic

Medical Device Sterilisation & SAL

Proposition is that SAL of 10^{-6} does not render products any safer for their intended use than those sterilized at higher SAL's (10^{-3} 10^{-4})

SAL levels of 10^{-3} 10^{-4} are commonplace for vaccines and other pharmaceutical products produced by aseptic processing. (Terminal sterilization always preferred)

Relevance to the irradiation community

Medical Device Sterilisation & SAL

Lower doses (by up to 40%), improved economics, alleviates potential co-60 supply issues, would reduce spent source disposal costs.

The International Irradiation Association (iia) has and will continue to hold Workshops to discuss the SAL issue

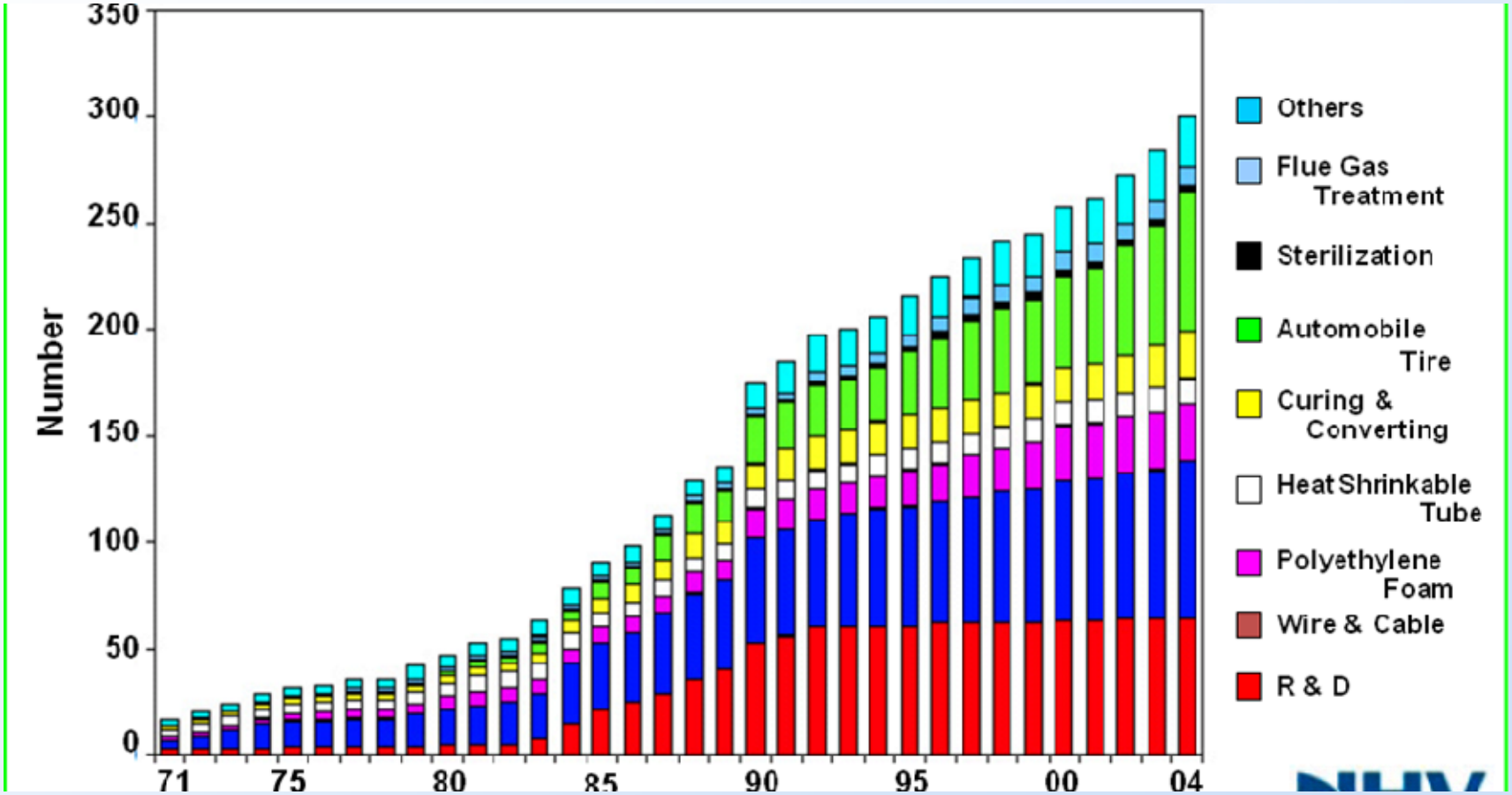
Food Irradiation

Used to improve food safety, increase food security and as a phytosanitary treatment.

Key report was the 1981 Joint Expert Committee on Food Irradiation (JECFI) established by WHO/IAEA/FAO

“Food Irradiation is decreasing in Europe, increasing substantially in parts of Asia and increasing steadily in the USA, Australasia and other regions”

Novel & Advanced Polymers



Environmental Applications

Conclusions

- Challenges yes but there is every reason to remain optimistic.
- We must embrace change and consider alternatives
- Recognise that enhanced security benefits everyone.
- As an industry we are only as strong as the weakest link
- Play to our strengths and promote the benefits that Radiation Technology offers and delivers