

The Honorable Dianne Feinstein – Chair  
Subcommittee on Energy and Water Development  
Committee on Appropriations  
United States Senate  
Washington DC  
20510

3 November 2014

Dear Chair Feinstein

I am writing to you on behalf of the International Irradiation Association to express our views on Section 402 of the FY 2015 Senate Energy and Water Development Appropriations Bill.

The International Irradiation Association (iia) is a global organization and a recognized NGO of the International Atomic Energy Agency.

Our Association is concerned that the draft legislation could have unintended consequences which would be extremely damaging and costly to the economy of the United States as it could result in irradiation using cobalt 60 becoming unavailable to businesses and research establishments operating in the United States.

The Irradiation sterilization of medical products using cobalt 60 was first introduced in the United States 50 years ago facilitating the development and growth of the single use medical disposable market that is estimated to be worth in excess of \$78 Billion to the US economy. Today the sterilization of medical disposables using cobalt 60 gamma irradiation accounts for 40% of all sterilization requirements. This technology has, throughout the past 50 years, had an exemplary safety record and operates in accordance with the standards established by the US NRC including latest requirements contained in Title 10 of the Code of Federal Regulations Part 37 which became mandatory for NRC licensees in March 2014 and which appear to address many of the issues that are referenced in section 402 of the draft Bill.

The unique penetrating qualities of the 1.25 Mev (average) photons emitted from cobalt 60 and the absence of residuals in those irradiated products provide tremendous flexibility in product design. The penetrating qualities of cobalt 60 have allowed the development of, and helped promote the use of, intricate complex medical device designs. Since the 1970's gamma radiation compatible plastics have been developed to satisfy the growing demand for gamma sterilization of single-use medical devices. As a result there is now a worldwide installed base of cobalt 60 of approximately 400 million curies, contained in more than 180 large-scale gamma facilities. The United States has just over 50% of the total cobalt 60 installed base contained in 50 commercial irradiation facilities which are estimated to sterilize approximately 300 million cubic feet of medical products annually. Of these facilities thirteen are owned and operated by seven multi-national medical device companies.

If cobalt 60 gamma radiation were withdrawn as a sterilizing method in the United States many existing products would not be able to be sterilized in their current configuration or composition, and thus, may not be available until substitute material or redesign is identified and implemented. Furthermore in the United States alternative sterilization methods may require submissions of new 510(k)s, premarket applications (PMA) or PMA supplements, depending on the regulatory classification of the product and the product design or other changes required. Re-certification and/or redesign would divert resource from the development of new products or result in certain products being withdrawn from market without alternatives becoming available and could weaken the leading global position of the U.S. manufacturers with a consequential adverse impact on the economy and jobs.

Should legislation be introduced that would limit or prohibit the continued use of gamma irradiation technology it could lead to less effective security for irradiation sources stemming from the need to safely dispose of hundreds of millions of curies of cobalt 60. It should also be recognized that for those companies that own and operate cobalt 60 gamma irradiators, there will also be millions of dollars in costs associated with the decommissioning of each facility before the natural economic "end of life" of the co-60 when the costs of disposal are manageable and at their lowest point. Forced decommissioning could result in companies going into bankruptcy and, as a consequence, security over the cobalt source could be weakened whilst the cost of disposal could fall to the regulator/government. The costs of the transfer from cobalt 60 gamma irradiation to alternate sterilization methods could be a further burden the U.S. healthcare system. In the event that cobalt 60 irradiators were banned in the United States many U.S. Medical product companies would probably move their manufacturing operations out of the country.

In addition to the large and well established US healthcare sterilization market gamma irradiation using cobalt 60 is used extensively to ensure that a vast range of products are made safe, to provide US boarder security against the risk of pest infestation and to create or improve the characteristics of a wide range of materials used in the US defense, aviation and automotive industries. Appendix 1 to this letter lists products that are currently processed using cobalt 60 gamma irradiation.

The International Irradiation Association (iia) supports the safe and beneficial use of all forms of irradiation including cobalt 60 gamma, electron beam and X-ray. The use of electron beam is a well established and accelerators are used to improve the characteristics of a wide range of materials and products. The technology complements gamma irradiation using cobalt 60. X-ray is a developing technology that requires access to stable and reliable power source. The power conversion of X-ray raises issues of cost and environmental impact. From a safety, security or environmental perspective we see no reason to legislate for change. If appropriate this will happen naturally. Cobalt 60 has demonstrated, over the past 50 years, that it has made a tremendous net positive contribution to the health, welfare and safety of a significant proportion of the U.S and indeed world's population.

We recognize that U.S. radiological security is an important part of national security and that such policy should be subject to continuous review and improvement. The latest US NRC requirements contained in Title 10 CFR Part 37 are the result of such ongoing reviews and initiatives. We believe that the NRC, as an independent Commission, is best placed to develop the US regulatory framework.

Thank you for allowing us to express our views on this very important topic. We would be happy to provide any further clarification that you may require.

Yours Sincerely

John Masefield

Chairman

## **Appendix 1**

The following list highlights products that are currently processed using gamma irradiation using cobalt 60. It is not an exhaustive list but is intended to highlight the diversity of the products that are processed using the technology.

### **(1) Medical Products**

#### **Single Use Devices**

Surgical drapes, Gowns, Gloves, Gauze, Surgical dressings, Specimen containers, Sterile clean-room garments Other disposable, single patient use products include: syringes (pre-filled and un-filled, and insulin, epidural, spinal, dental and veterinary) needles, blood collection tubes, intravenous sets, parenteral sets, HIV and other blood assay testing plates, collection swabs, ophthalmic solutions, oxygenators, cannulas, catheters, dialyzers, custom kits, endotherapy devices for gynecologic, ophthalmic, general, or plastic surgery. Labware (plates, bottles, tubes, flasks, filtration units etc) including materials used in stem cell research.

#### **Implantable Medical Devices**

Implantable medical devices using gamma processing include among others: Orthopedic joint replacements including knees, hips, shoulders, vertebrae and other joints along with dental implants. Human tissue used in "transplant "operations.

### **(2) Food Safety, Consumer Goods and Industrial Applications**

A growing range of food products such as meat, poultry, seafood and spices are processed in order to prevent illnesses resulting from contamination with microorganisms such as *E.Coli* and *Salmonella*. Food packaging and feed for veterinary and laboratory animals. Nuclear Reactor testing components.

### **(3) Phytosanitary**

Food such as exotic fruit is treated to eliminate pests prior to export to other countries, in order to protect domestic crops in the importing country from infestation. Sterile Insect Technique (SIT) uses irradiation to reduce or eliminate the population of specific pests in growing regions.

### **(4) Materials Modification**

Polymers are irradiated in order to strengthen chemical bonds through a process called crosslinking. This has the effect of making the polymer stronger, tougher and more resistant to heat. Under different conditions, polymers can also be irradiated to weaken chemical bonds, usually in preparation for further processing.