Draft Nordion Letter re Appropriations Bill

Dear XXXXXXXXXXX

Nordion is the global expert in the design, construction, and maintenance of commercial gamma irradiation sterilization systems, and the world's leading supplier of Cobalt-60, the isotope that produces the gamma radiation required to destroy harmful micro-organisms. Nordion's 50+ year history provides it with the experience, expertise and leadership necessary to meet global gamma processing requirements, and to assist in development, implementation and maintenance of standards, processes and practices which have and will continue to contribute to its exemplary safety and security record.

Gamma radiation is a form of pure energy characterized by its deep penetration and low dose rates. Gamma irradiators are powered by Cobalt-60, effectively killing microorganisms throughout the product and its packaging with very little temperature effect and no residues. The amount of radiation required to sterilize products depends on the type of product and its physical characteristics (i.e. dimensions, density, finished or packaged form). Dosimetric release allows products to be processed, verified and immediately released for shipment.

Cobalt-60, in Special Form sealed sources, is used to sterilize a broad array of products, from single use medical disposable products (gloves, gowns, sutures, catheters, syringes, endoscopic products, tissue for transplant, etc., food, and consumer products (contacts lenses/solutions, cosmetics, hygiene products, etc,) (Appendix 1). It is estimated that some 300 million cubic feet of medical disposable products (approximately 40 percent of US produced medical disposable products) are sterilized by approximately 50 US gamma irradiation facilities each year. Further, the US produces approximately 50 percent of all medical disposable products used globally, with a growth rate in this market segment of roughly 5 – 7 percent per year. The penetration qualities of Cobalt-60 allow the use of a broad variety of impermeable packaging materials as well as the sterilization of products in their final shipping configuration. Furthermore, the gamma irradiation sterilization process itself has proven to be extremely reliable in that there is only one variable (product exposure time) to be controlled during the sterilization process. This is extremely important given that the sterilization process is required, on an ongoing basis, to continue 24 / 7, 365 days per year to meet the time sensitive and volume requirements of the healthcare industry. For these and other reasons, Cobalt-60 gamma irradiation has helped foster the growth of the medical device industry and has become the sterilization method of choice by industry.

From a security and regulatory perspective, it is important to note that the gamma radiation industry and irradiator owners are strictly regulated and follow security measures that meet International Atomic Energy Agency (IAEA) guidelines as well as stringent U.S. Nuclear Regulatory Commission (NRC) requirements including the latest requirements contained in Title 10 of the Code of Federal Regulations Part 37, which became mandatory for NRC licensees in March 2014. Key elements of the regulations include: background checks and fingerprinting to help ensure that people with access to risk-significant radioactive sources are trustworthy and reliable; personnel access controls to restrict access to areas where risk-significant sources are used or stored to authorized personnel; security barriers; security plans and procedures to deter, detect, assess and respond to unauthorized attempts to access risk-significant radioactive sources; coordination and tracking of shipments of risk-significant radioactive sources, including multiple controls involved in the shipping process; and coordination and response planning between licensees and local law enforcement agencies.

The 2008 National Academy of Sciences' Nuclear and Radiation Studies Board (NRSB) undertook a study on Radiation Source Use and Replacement. The focus of the study was to review current uses of radiation sources to assess whether such sources can be replaced with equivalent or improved processes that do not use radioisotopes, or whether current radiation sources can be replaced with other radiation sources that pose lower health and safety risks in the event of a terrorist attack or accident. During the past 7 years, the importance of gamma radiation using Cobalt-60 remains undiminished. In further recognition of gamma sterilization technology and irradiator facilities, the report noted, in part :

- Because the array of applications of these radiation sources is so broad and the applications are essential to securing health, safety, and prosperity, the devices are licensed for use and found in every state in the nation. Some types of radiation sources should be replaced with caution, ensuring the essential functions that they perform are preserved
- Gamma irradiation has proven performance in killing pathogen and is one of the preferred methods as evidenced by the quantity of product irradiated each year
- Panoramic irradiators are somewhat self protecting against attacks that require human proximity because exposure to a 37,000 TBq (1 million Ci) Cobalt-60 source (at I meter separation) would result in an incapacitating dose in about 10 seconds. Furthermore the thick concrete structure provides additional security from sabotage attacks, and there are Compensatory Measures (special security requirements) mandated by the U.S. NRC at all of the large U.S. panoramic irradiator sites. Panoramic irradiators include fairly robust access controls and alarms with response by armed security personnel, along with other measures. After review of the risks associated with some source and devices, considering more fully the potential for contamination from and attack, the U.S NRC might conclude that more stringent measures are needed at facilities licensed for some category 1 and 2 sources and devices

Alternative sterilization methods exist for many medical devices but there are a variety of challenges associated with those alternatives. Ethylene Oxide (EO) has obstacles associated with potential absorption issues, associated off gassing and Environmental Protection Agency (EPA) emission control constraints. In addition, it is a lengthier sterilization process, requiring the investment and addition of several extra days of inventory to fill the production stream. Electron beam radiation technology is applicable for low or homogeneous density products or those without complex designs. This is because the accelerated electrons have a mass and a charge, which means they cannot effectively penetrate denser products, and there is a backscatter phenomenon, making it ineffective for many products. X-ray is a potential technology but less than 7% of the electron beam energy is converted into photons that can be used to sterilize the product. X-ray technology still needs to prove the claim that its electrical cost and efficiency is equivalent to that of Cobalt-60 gamma irradiation. Appendix 2 is a Draft White Paper produced by the Gamma Industry Processing Alliance (GIPA), an industry association representing the major North American gamma irradiation facilities, which compares Cobalt-60 gamma with x-ray technology.

Because it is a cold sterilization process, gamma radiation is ideal to treat a wide variety of plastic based products and complex designed products which cannot be sterilized with steam or heat. Further, because of its high energy, gamma sterilization is effective with dense and thick products, being used to sterilize many products in final packaging in the actual shipping boxes. Gamma radiation leaves no sterilant residues, does not make the product radioactive, and humidity or pressure are not involved in the sterilization process.

Significant discussion continues about the end-of-life management of sealed sources. Nordion commits to customers to the return of its sources when they are "spent", typically 20 – 25 years after initial supply when the warranty has expired. The spent sources are either recycled, where the Cobalt-60 is removed, inspected and re-encapsulated with new Cobalt-60 to produce new sources which will be sold for another 20 – 25 year lifespan, or they are sent offsite for disposal. When sent for disposal, they are

held at reactor sites where the Cobalt-60 was initially produced. Canada is planning to build a DGR (Deep Geologic Repository) and the site selection process is now underway.

Section 402 mandates the elimination of sealed sources within 15 years. If Cobalt-60 gamma irradiation were withdrawn as a sterilizing method, 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. In the U.S., alternative sterilization methods may require submissions of new 510(k)s, or premarket approvals (PMA) or PMA supplements to the FDA, depending on the regulatory classification of the product and the product design or other changes required. Further, movement to alternative sterilization methods will divert financial and human resources currently directed at new product development, causing the delay or loss of new products intended to provide better patient outcomes for several years as scarce resources (product scientists, designers, engineers, clinicians and regulatory personnel) are focused on this effort. The device industry will in effect move sideways instead of forward at great expense for an extended period of time during which the leading global position of US medical device manufacturers would be seriously damaged. It will lead to a great number of products needing to be redesigned, redeveloped, validated and obtain regulatory approvals. It is safe to say it will require a multi-billion dollar investment. These costs will ultimately be passed on to the healthcare system and patients without yielding concomitant advances or positive outcomes for patients.

Further, given the amount of electricity used by X-ray technology and the current contribution of energy production to greenhouse gas emissions, it is important to consider the impact of conversion on the environment. Replacing the US installed capacity of gamma with x-ray using the conversion of 120KW per MCi with a conservative 7200 hours/year of operation and average US CO_2 emissions of 1.367 lbs./KWh, it would result in an annual increase in greenhouse gas emissions of 237 million pounds.

Finally, for those companies that own and operate Cobalt-60 gamma irradiators, there will also be hundreds of millions of dollars in costs associated with the decommissioning of the facilities. There will also be a loss of U.S. employment associated with the decommissioning of Cobalt-60 gamma irradiation facilities. Such a move would simply move gamma processing off shore, with subsequent reliance on potentially less controlled quality and integrity of sterile products, and possibly, less security in the process cycle.

Nordion requests that you consider the adverse implications of Section 402. We urge that this section is removed from the Energy and Water Development Appropriations Bill.

Thank-you for considering this request and we would welcome an opportunity to further discuss this with you or your staff to help you better understand the needs and the importance of the gamma irradiation industry.

Sincerely,