Gamma
Safe. Secure. Vital.

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GIPA
Gamma Industry Processing Alliance

November 7, 2014

The Honorable Diane Feinstein
Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
U.S. Senate
Washington, DC 20510
Fax: (202) 228-2322

The Honorable Lamar Alexander
Ranking Member
Subcommittee on Energy and Water Development
Committee on Appropriations
U.S. Senate
Washington, DC 20510
Fax: (202) 228-2322

Dear Chairman Feinstein and Ranking Member Alexander:

We are writing to you on behalf of the Gamma Industry Processing Alliance (GIPA) to provide our position regarding Section 402 of the Fiscal 2015 Senate Energy and Water Development Appropriations Bill.

GIPA represents gamma processing industry leaders with a Mission to ensure that the industrial use of gamma irradiation remains a safe, secure and vital processing technology for the sterilization of healthcare products, for the enhancement of food safety, as well as for other agricultural and industrial applications.

Commercial irradiation sterilization systems use Cobalt-60 as the isotope that produces the gamma radiation required to destroy harmful micro-organisms. This industry has been in existence for many decades and GIPA represents all major North American companies that use gamma sterilization. We have a singular focus of maintaining and continually developing 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.

Cobalt-60, in Special Form sealed sources, is used to sterilize a broad array of products including single use medical disposable products (gloves, gowns, sutures, catheters, syringes, endoscopic products, tissue for transplant; food; and consumer products (contacts lenses/solutions, cosmetics, hygiene products)) (Appendix 1). 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 impacting factors. Estimates indicate that some 300 million cubic feet of medical disposable products (approximately 40 percent of all US produced medical disposable products) are sterilized by approximately 50 US gamma irradiation facilities each year. 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. One of the key attributes of Cobalt-60 is the ability for gamma to sterilize product in a broad variety of impermeable packaging materials as well as products in their final shipping configuration. This technology is extremely reliable, necessary given that sterilization facilities operate, on an ongoing basis, 24/7, 365 days per year to meet the time sensitive and volume requirements of the healthcare industry.

GIPA members pride themselves on their long established and maintained exemplary safety and security record. Our facilities are highly regulated, both through security measures that meet International Atomic Energy Agency (IAEA) guidelines as well as stringent U.S. Nuclear Regulatory

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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 Part 37 include: background checks and fingerprinting to help ensure that people with access to risk-significant radioactive sources are trustworthy and reliable; personnel controls, for authorized personnel, to restrict access to areas where risk-significant sources are used or stored; 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 and federal agencies.

Section 402 of the draft Bill references the need to look for replacement technologies to meet the critical and life-saving needs of product sterilization. A similar reference was made in the 2008 National Academy of Sciences' Nuclear and Radiation Studies Board (NRSB) report which undertook a study on Radiation Source Use and Replacement. The focus of the study was to review current uses of radiation sources and to assess whether such sources could be replaced with equivalent or improved processes that do not use radioisotopes, or whether current radiation sources could 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 concluded, 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 pathogens 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 1 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.

(NOTE : the points noted above were prepared in 2008, well in advance of the comprehensive and additional requirements set out by Part 37)

Alternative sterilization methods do exist for many medical devices but significant challenges exist with those alternatives. Ethylene Oxide (EO) is a much lengthier sterilization process and has potential absorption issues, associated off gassing and Environmental Protection Agency (EPA) emission control constraints. Electron beam radiation technology is applicable for low or homogeneous density products or those without complex designs. This technology cannot effectively penetrate denser products, and there is a backscatter phenomenon, making it ineffective for many products. X-ray is another potential alternative technology but less than 7% of the electron beam energy is converted into photons that can be used to sterilize the product, and it still needs to prove the claim that its electrical cost and efficiency is equivalent to that of Cobalt-60 gamma irradiation. 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 CO2 emissions of 1.367 lbs./KWh, it would result in an annual increase in greenhouse gas emissions of 237 million pounds.

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End-of-life management of sealed sources is a topic under significant discussion of late. Suppliers of Cobalt-60 sources commit to the return of their sources from customers once they have reached the end of their useful life, typically 20 – 25 years after initial supply. The spent sources are either recycled, where the old Cobalt-60 is incorporated into new sources which are then sold for use in irradiation facilities for a further 20 or more years; re-used where the sources are re-encapsulated or over-encapsulated for alternative uses; or sent for disposal, typically at reactor sites where the Cobalt-60 was initially produced.

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 years to come 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.

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 drive 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.

GIPA strongly urges you to consider the adverse implications of Section 402, and to vote in favor of removing this Section 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,

Paul Gray
Chairman, GIPA

Robert E. Moss
President,
Steris Isomedix Services, Inc.

Philip Macnabb
President and COO
Sterigenics International LLC

Appendix 1 Applications Using Co-60 Gamma Irradiation

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

Disposable Devices
Surgical drapes, Gowns, Gloves, Gauze, Surgical dressings, Specimen containers, Sterile clean-room garments.

Single Use Devices
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.

Implantable Medical Devices
Implantable medical devices using gamma processing include among others: Orthopedic joint replacements including knees, hips, shoulders, vertebrate and other joints. Dental implants.

(2) Food Safety

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 is also treated with irradiation.

(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.

(5) Consumer Products

Cosmetics and other consumer products, typically those made with natural ingredients (e.g. dog chews made from pigs' ears), are irradiated in order to reduce bacteria. Equipment necessary for drug discovery and related applications that needs to be sterile such as labware (i.e. plates, bottles, tubes, flasks, filtration units, etc.). Also for equipment used in high risk processes such as stem cell research, and in laboratories for the provision of sterile feed for lab animals.

(6) Nuclear reactor component testing

nordion
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Ranking Member
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Dear Chairman Feinstein and Ranking Member Alexander:

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,) (see Appendix 1). It is estimated that close to 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
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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 alternative 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. 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 CO2 emissions of 1.367 lbs./KWh, it would result in an annual increase in greenhouse gas emissions of 237 million pounds

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

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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.

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,

Scott McIntosh
President, Gamma Technologies and Corporate Services

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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.

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(6) Nuclear reactor component testing

Sterigenics.

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The Honorable Lamar Alexander
Ranking Member
Subcommittee on Energy and Water Development
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Dear Chairman Feinstein and Ranking Member Alexander:

Sterigenics International, LLC ("Sterigenics") is writing to express our view regarding Section 402 of the Fiscal 2015 Senate Energy and Water Development Appropriations Bill. As a user of Cobalt-60, this Bill would have significant impacts on our business as well as the overall US Healthcare system.

Sterigenics is the global market leader in contract sterilization services, with 38 sterilization facilities in 12 countries. Sterigenics has almost 90 years of experience in Sterilization Services and we are experts in all the major modalities of sterilization. In the United States, we operate 24 sterilization facilities, of which 14 utilize Cobalt-60 for gamma irradiation of medical devices, food packaging, and other products. Sterigenics also owns Nordion, the world largest producer of Cobalt-60 (Co-60) which is used in commercial and government irradiation facilities. Nordion has over 50+ years of experience in the processing of Cobalt-60, logistics of sources, disposal of depleted sources, irradiator design and installation, and service.

In addition to the cobalt gamma radiation technology, Sterigenics utilizes other types of sterilization technologies including ethylene oxide processing, electron-beam radiation, and x-ray radiation. All technologies are used to sterilize medical device and pharmaceutical products. It is important to note that not all medical device and pharmaceutical products can be treated effectively by all technologies. Sterigenics works carefully with each customer to assist in the selection of the proper sterilization technology for their products. For some products (i.e. endoscopic equipment, tubing, alcohol swabs, tissues for transplant to name a few), only cobalt gamma radiation can be used for proper and effective sterilization. Therefore, cobalt gamma

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radiation plays a critical role in protecting public health with the safe and efficient delivery of sterile medical devices and pharmaceutical products to the medical community.

Cobalt gamma radiation is a form of pure energy characterized by its deep penetration and low dose rates. Gamma irradiators are powered by Cobalt-60, and these irradiators effectively kill microorganisms throughout the product and its final packaging with very little temperature effect and no residues. The amount of radiation required to sterilize products depends on the type of product, its physical characteristics, and final packaging form. 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.

Cobalt-60 is used to sterilize a broad array of healthcare-related products. These products include many single use medical disposable products (gloves, gowns, sutures, catheters, syringes, endoscopic products, bone-replacement implants, tissue for transplant, etc.), and consumer products (contact lenses/solutions, cosmetics, hygiene products, etc,). In addition, Cobalt-60 is also used to reduce the bio-burden on various food products such as spices, red meat, and pet treats. So, the list of cobalt-treated products is very lengthy. It is estimated that about 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. Furthermore, our gamma sterilization services are needed continuously on an ongoing basis. Sterigenics sterilization facilities operate 24 hours a day, 7 days a week and 365 days a year to meet the time sensitive and volume requirements of the healthcare industry. Cobalt-60 gamma irradiation is absolutely necessary to meet the healthcare industry's sterility demands.

From a security and regulatory perspective, 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.

In 2008, The National Academy of Sciences published 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. In this study,

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they encouraged further support to government and industry to try to replace radiation sources where available. Since this report has been published, industry and government have continued to review alternative technologies but they have not found a viable replacement technology. Therefore, cobalt gamma radiation remains a necessary technology for sterilizing the wide array of healthcare products.

Alternative sterilization methods exist but there are a variety of challenges associated with those alternatives. Ethylene Oxide (EO) has obstacles associated with potential EO absorption issues, associated EO 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 technology cannot effectively penetrate denser products, 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. Such inefficiencies result in much higher electricity usage and increased greenhouse emissions. In addition, the x-ray technology is not widely accepted by many healthcare customers. Therefore, many healthcare companies still require Cobalt-60 gamma radiation to effectively sterilize their products.

Section 402 mandates the elimination of sealed sources within 15 years. If Cobalt-60 gamma irradiation were withdrawn as a viable sterilization technology, many existing products would not be able to be sterilized in their current configuration or composition. This would have a significant impact on the healthcare community and public at large. As a result, those products sterilized with cobalt radiation would need to be redesigned completely. The costs and timing associated with such medical product redesigns are significant. 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. 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. This work to redesign products will also result in significant costs in the multi-million dollar range.

Finally, for Sterigenics and other 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 gamma radiation facilities. There will also be a loss of U.S. employment associated with the decommissioning of Cobalt-60 gamma irradiation facilities. Such a government-required technology switch would simply move gamma processing off shore. The safety, quality, integrity and security of such off-shore sterilization operations cannot be guaranteed.

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Therefore, Sterigenics would like to emphasize the current need and importance of Cobalt-60 radiation for the sterilization of current medical devices and pharmaceutical products. Although there has been some testing around x-ray, this technology has not been proven as an effective alternative to Cobalt-60. So we do not recommend eliminating a process critical to global health without having a viable alternative developed. In addition, the costs for switching technologies for both the sterilization and health care industries are exorbitant, and the Cobalt-60 industry has addressed the identified security concerns and continues to improve such security. For these reasons, Sterigenics requests that you consider the adverse implications of Section 402 outlined in this letter. We urge that this section is removed from the Energy and Water Development Appropriations Bill.

We appreciate you considering this request and we welcome an opportunity to further discuss this with you or your staff to further explain the needs and the importance of the gamma irradiation industry.

Sincerely,

Philip Macnabb
President

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INTERNATIONAL SOURCE SUPPLIERS AND PRODUCERS ASSOCIATION
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SAFE AND SECURE AT THE SOURCE

November 10, 2014

The Honorable Carl Levin
Chairman
Committee on Armed Services
U.S. Senate
Washington, DC 20510
Fax: (202) 228-0036

The Honorable James Inhofe
Ranking Member
Committee on Armed Services
U.S. Senate
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Fax: (202) 228-0036

Dear Chairman Levin and Ranking Member Inhofe:

The International Source Suppliers and Producers Association (ISSPA) is a non-governmental organization that is comprised of companies who are international industry leaders in the manufacture, production and supply of sealed radioactive sources and/or devices that contain sealed radioactive sources. ISSPA members work closely with national regulatory authorities, as well as the International Atomic Energy Agency to encourage continuous improvements in the safe and secure use and end of life management of sealed radioactive sources.

Our industry is very concerned with, and requests your opposition, to Section 402 of the FY 2015 Senate Energy and Water Development Appropriations Bill. We believe the proposed language in Section 402 will significantly restrict the beneficial use of radioactive sources and materials without any discernable improvement in the safety and security of these materials.

Radioactive sources have been used safely and securely across the United States for decades. The vital role these sources play in our everyday lives is often overlooked and underappreciated. In medicine, radioactive sources save lives; treating cancer, sterilizing medical equipment, and irradiating blood components. Industrial radiography is utilized to inspect metal components and welds for defects ensuring our bridges, pipelines, aircraft, ships, and vehicles are safe. Gauging devices measure, monitor, and control the thickness of sheet metal, textiles, paper, and other products as they are manufactured. They are also used to measure or control material density, flow, level, thickness, or weight, and so forth, ensuring our manufacturing processes are accurate and efficient. Radioactive sources are an essential component in oil and gas exploration and are used at our borders detecting the illegal entry of aliens into the United States and to screen cargo for illicit materials, including nuclear materials and explosives.

Following the events of September 11, 2001 the U.S. Nuclear Regulatory Commission (NRC) began issuing orders to radioactive material licensees requiring additional security measures and increased controls in regards to the possession, use and transfer of radioactive materials in quantities of concern. Since then, the NRC, Agreement States and the industry have taken significant actions to further enhance the security of radioactive materials. Most recently, the NRC issued extensive new regulations (10 CFR Part 37) which expanded on and codified the security orders that had been put into place after September 11. These regulations are in the process of being implemented across the

country and will be subject to a full inspection and enforcement program. These orders and subsequent regulations were developed based upon the results of vulnerability assessments, gap analysis and cost effectiveness of the enhancements. These considerations formed the safety and security basis for the existing requirements which were developed using a performance-based and graded approach taking into account the relative risk and quantity of material possessed by licensees.

Section 402 would expand the scope of materials subject to enhanced security without any regard to the relative risk which is inconsistent with the risk-based approach adopted by the Federal Government, through the Energy Policy Act of 2005 task force.

We are also extremely troubled by the Section 402(f) which essentially phases out the beneficial use of radioactive sources within 15 years. This would have a multi-billion dollar impact on the industry, would stifle research and development and could drive businesses overseas, which would ultimately result in a reduction in safety and security as the applications that utilize these materials will move to countries with less comprehensive regulatory authorities. Further, the impact on the American economy and workforce would be extremely significant.

ISSPA recognizes the importance of radioactive source security and ISSPA members have supported efforts of the National Nuclear Security Administration for implementing voluntary security enhancements, which extend beyond regulatory requirements. ISSPA representatives have supported joint Industry/Government security meetings through the Nuclear Sector Coordinating Council and Government Coordinating Council and we work closely with the International Atomic Energy Agency developing safety and security standards for radioactive sources. We believe it would be inappropriate to expand the current radioactive source security requirements without first monitoring the implementation of the existing security requirements promulgated in the NRC Orders and in the Part 37 regulation and assessing their utility and effectiveness.

We thank you for your attention to this important matter. If you have any additional questions, please feel free to contact Mr. John Miller at 208 524-5300 or Mr. Paul Gray at 613 593-3400 Ext. 2483.

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