POLAND: A COMPREHENSIVE APPROACH TO CESIUM SECURITY

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**Abstract**

The U.S. Department of Energy’s Office of Radiological Security (ORS) cooperates with partner countries throughout the world to enhance the security of radioactive sources used for legitimate purposes. A large number of these sources are within hospitals, universities and other public establishments. High activity cesium-137 is one of the primary isotopes used to irradiate blood for the prevention of Transfusion Associated Graft versus Host disease (TA-GvHD). As member states continue to intensify their support for the implementation of the IAEA security recommendations in Nuclear Security Series No. 11, Security of Radioactive Sources, operators face a growing strain on their security resources in both financial and human capital terms. To address this challenge, ORS is pursuing a Global Cesium Security Initiative (GCSI) that focuses on enhancing physical protection of cesium irradiators and permanent risk reduction through the replacement of the device with an alternative technology or removal of the disused source.

In the course of discussions with partners, there is an emerging interest in strategies that enable the permanent reduction of the risks associated with cesium-137. Although several countries, including France, Norway, the U.S. and Japan have pursued these strategies and moved towards X-ray as a technology to achieve critical service provision, there still has been limited adoption of X-ray internationally for these uses until recently. In Poland, for example, a number of regional blood centers and hospitals have declared their intention to switch from Cs-137 to X-ray. The adoption of X-ray by the first Polish site is fairly new, but through the GCSI, ORS is working to transition at least six volunteer sites by 2020 from cesium-based irradiation to X-ray based blood irradiation. This momentum can be attributed in part to the age of the cesium devices and the procurement decision timeframe, but also the ability of the regulator to discuss the full cost of ownership for radioisotopic devices, such as security systems and disposition costs. The paper will highlight how technical exchanges among the Polish regulatory authority, waste management organization (ZUOP), radiological facilities and various subject matter experts (SMEs) created synergy to drive the risk reduction conversation. The costs associated with the security of radioactive sources can be significant. As regulators begin to enact legislation requiring sites to ensure the safe and secure disposal of old cesium-based irradiators, and as sites consider the costs of potential liability that may arise from a malicious act involving radioactive sources, they have begun to realize the true cost of securing cesium for use, particularly compared to other methods, such as X-ray based irradiation.

In the case of Poland, radioactive source licensees must provide financial resources in the form of an “escrow” to ensure the safe and secure disposition of disused sources at end of life. The focus on enhancing security requirements through more robust regulations and lifecycle management of radioactive sources, coupled with technical exchanges, is leading licensees to evaluate the complete cost of ownership and operation of radioisotopic devices. The paper will identify the challenges, best practices, and lessons to be learned from Poland’s experience grappling with the challenges of securing cesium-137 when the issue is considered holistically.

## INTRODUCTION

The U.S. Department of Energy’s Office of Radiological Security (ORS) cooperates with more than 80 partner countries worldwide to enhance the security and reduce the overall risk of radioactive sources used for legitimate purposes. A large number of these sources include high activity cesium -137 for research and blood irradiation. According to the U.S. National Academy of Sciences Committee on Radiation Source Replacement, “Cesium-137 (Cs-137) in the form of cesium chloride is a greater concern than other radiation sources based on its dispersibility and its presence in population centers across the country” [1]. These sources are typically located in very public facilities such as hospitals and universities. In order to combat the threat from cesium -based devices, ORS and its partners are engaging in a new project called Global Cesium Security Initiative (GCSI) that focuses on enhancing physical protection of cesium irradiators and reducing risk wherever possible through a range of risk reduction strategies. The GCSI project prioritizes a comprehensive approach for securing high-activity Cs-137 source based irradiators using additional protection strategies, removal efforts, or reducing the threat through alternative technologies where possible.

GCSI focuses resources where risk reduction can be maximized through either protection of the device in place in a manner that maximizes the chances of containing any attempted theft, or replacement of the radioisotopic device with a non-isotopic alternative technology that allows for the removal of the target and elimination of the threat altogether [2]. As member states continue to intensify their support for the implementation of the IAEA security recommendations in Nuclear Security Series No. 11, Security of Radioactive Sources, operators face a growing strain on their security resources in both financial and human capital terms [1]. Examples of countries already taking a reduction of source approach to these security issues include France, Norway, Japan and the Unites States. France initiated a ten-year plan to phase out their 30 cesium irradiators in 2006. Norway finished replacing all 13 irradiators in 2015, and Japan started replacing their cesium irradiators 20 years ago with 80% complete [3]. NNSA ORS started a cesium replacement effort (CIRP) in the United States in 2015, with more than 100 devices moved to secure storage by October 2019. This initiative was given even higher priority in May 2018 when Congress passed the John McCain FY19 National Defense Authorization Act (NDAA) that established a goal of transitioning all U.S. cesium-based blood irradiators to X-ray based devices by 2027.

Internationally, ORS started working with its partners to discuss GCSI in 2017, leading to several countries adopting regulations that support alternative technology and sites directly transitioning to X-ray based irradiation. As regulators start imposing regulations that ensure sites include the safe and secure disposal of old cesium-based irradiators into their cost of ownership, sites are now realizing the true cost of cesium versus alternatives such as X-ray based irradiators. An example of this new prioritization of cesium irradiator replacement can be found in Poland. The synergy between the Polish regulatory authority, the waste management organization (ZUOP), and ORS has led to several technical exchanges on the topic of GCSI.

## THE GLOBAL CESIUM SECURITY INITIATIVE

Historically, ORS promoted the protection of radioactive material in use and storage. Over time, the maturation of non-isotopic technologies available to perform the same functions has created the possibility to replace these sources with an alternative technology. This strategy, adopted by the ORS GCSI, reduces the inventory of radioisotopic devices in use around the world and results in permanent reduction of the associated risk. This strategy moves away from typical engagement with the regulator and the radiation safety officers (RSO) and cuts across the areas of responsibility of many ministries and stakeholders, including: security, health, and radiological/environmental safety. Attempting to engage stakeholders in any one of these areas without the other stakeholders quickly runs into barriers. It is because of this multiple stakeholder relationship, that ORS has conducted GCSI outreach through workshops that include participants from: regulatory authority, ministries of health, hospital administrators, radiation safety officers, and secure storage/waste management entities. By gaining concurrence and buy-in of all stakeholders, ORS has been able not only to discuss site transitions to alt tech, but to help facilitate a country-wide GCSI strategy for transitioning to alternatives where sites are willing. Under GCSI, the use of alternative technologies, enhanced physical security measures and/or additional response engagement strategies are being utilized to effectively achieve these critical GCSI objectives.

During GCSI engagements, ORS and its partners discuss the availability of ORS resources for procurement of a new X-ray based irradiator as well as resources for removal of the current cesium blood irradiator to permanent storage facilities. Often sites either have a relatively new device or may hesitate due to lack of training or knowledge about X-ray based devices. For these sites, ORS offers technical exchanges with partner sites who are already users and have already been through the transition to provide user-based feedback in order to ameliorate reluctance, as well as flexible timelines during which operators use both the cesium device and the X-ray device in order to validate that the X-ray device will, in fact, meet operational needs for the user. In cases where the site does not want to transition to alternative technologies, ORS seeks to enhance the security of the current cesium device with additional hardware known as an In-Device Delay (IDD) Kit, which can be installed in the device to significantly extend an adversary’s task time and increase the time available for law enforcement responders to arrive and interrupt a malicious act

Starting in August 2018, ZUOP from Poland and ORS have partnered to start transitioning willing blood banks and hospitals to alternatives such as X-ray based irradiation. ORS constructed its engagement strategy to lead with the consideration of alternative technologies and the prospects of permanent risk reduction and elimination of security-related costs. If sites proved willing to consider replacement of their devices after examining a range of factors including technical suitability, then investments in physical security systems to protect the devices could be avoided. However, if sites concluded that the cesium-based device was necessary and could not be replaced with a non-radioisotopic alternative, the GCSI discussion transitioned to physical security and site-responder training considerations to keep material contained at the site in the event of an attempted theft.

During physical security discussions, project teams work with partner sites to design and install security systems that achieve optimal security with intrusion detection hardware, hardened doors and other barriers that slow an adversary’s progress, and effective alarm components that will alert responders to an adversary’s presence, while affording efficient use of the cesium device. New developments in the area of physical security that have become a central component of GCSI are the IDD kit and response-force integration [2]. DOE has funded the development of IDD kits for various cesium based irradiator devices. The IDD kit, when installed on a device, significantly increases the adversary task time necessary to successfully remove the cesium source from the device. When available, the IDD kit is central to the GCSI “protect” strategy’s objective of optimizing source security commensurate with the risk posed by the cesium sources [2]. In addition to enhanced security measures, ORS has conducted multiple training courses and workshop with site personnel and law enforcement agencies to improve awareness and increase capabilities to respond to an attempted malicious act.

In Poland, a number of the cesium irradiators are nearing end of life, with an average age of approximately 18 years. Therefore, many of the regional blood centers are in the procurement window for the replacement of these blood irradiators. ORS and its partners in Poland see this as a unique opportunity to discuss alternatives to the old cesium-based irradiation practices. To accomplish this, a number of outreach workshops have taken place to discuss the advantages and disadvantages to alternatives such as X-ray for blood irradiation. A number of regional blood centers and hospitals have declared their intention to switch from Cs-137 to X-ray. The adoption of X-ray by the first Polish site is fairly new, but through the GCSI, ORS is working to transition at least six volunteer sites by 2020 from cesium-based irradiation to X-ray based blood irradiation. This momentum can be attributed in part to the age of the cesium devices and the procurement decision timeframe, but also the ability of the regulator to discuss the full cost of ownership for radioisotopic devices, such as security systems and disposition costs. The costs associated with the security of radioactive sources can be significant. As regulators begin to enact legislation that requires sites to ensure the safe and secure disposal of old cesium-based irradiators, and as sites consider the costs of potential liability that may arise from a malicious act involving radioactive sources, they have begun to realize the true cost of securing cesium for use, and become more amenable to exploring other methods such as X-ray based irradiation.

## gcSi iMPLEMENTATION

With the absence of regulatory drivers, radioactive source security becomes a voluntary endeavour for many potential ORS partners. The voluntary nature of radioactive source security is precisely the reason that some sites have not received security upgrades to protect their cesium devices. In addition, operators often lack knowledge of the risks, threats, and consequences that could drive a willingness to voluntarily adopt security measures for radioactive sources, motivate a state to develop legislation to establish security requirements, or prioritize the allocation of scarce resources to security rather than to other competing needs [2].

ORS with its partners are discovering that combining the conversation of threat and regulations with the opportunities to adopt alternatives has been very successful during outreach engagements. This has resulted in exploration of new focus areas in regulatory development support, including the incorporation of requirements to justify selection of isotopic technologies instead of other alternatives, as well as requirements to provide for source disposal at the end of its service life [4]. For example, some countries have regulations that require the use of cesium-based blood irradiators, preempting any discussion of permanent risk reduction using an alternative technology. Other regulations may not provide a mechanism for licensing alternative technologies for use [2]. It is for these reasons that multiple stakeholders are engaged in these GCSI meetings. In the case of Poland, radioactive source licensees must provide financial resources in the form of an “escrow” to ensure the safe and secure disposition of disused sources at end of life. The focus on enhancing security regulations and lifecycle management of radioactive sources, coupled with technical exchanges, is leading licensees to evaluate the complete cost of ownership and operation of radioisotopic devices.

### Transition to Alternative technology

When addressing the security risk associated with these cesium-based devices, ORS cooperates with partners to install a range of security enhancements consistent with IAEA recommendations and national-level regulations and licensing language to meet physical security requirements. These security upgrades include motion detection sensors, door locks and alarms, access control systems, reinforced doors and access points, combined with mechanisms to ensure the initiation of an effective law enforcement response as key elements to this security strategy. Taken holistically, a sufficiently robust system based on these elements can achieve containment of adversaries attempting to steal a radioactive source. This enhanced security profile along with consideration of long-term disposal or secure storage of cesium irradiators at end of life add to the cost of ownership. In addition, the goal of containment implies an acceptance of some level of risk, as containment can never be a certainty, and security systems are designed based on assumptions that may not ultimately reflect the reality of an adversary attack. Cost along with the residual liability associated with the risks, has been leading the conversation towards adopting alternative technology. The progression of technologies that can replace radioisotopic devices in performing many functions, such as blood irradiation, has made a strategy of replacing the radioisotopic device not only viable but desirable in many cases. This alternative technology strategy allows for the complete and permanent elimination of the threat posed by the deployment and use of the radiological device and ensures the achievement of permanent risk reduction.

The primary use for cesium irradiators is for either research or blood irradiation to prevent TA-GvHD. Although rare, TAGVHD has an extremely high mortality rate (87-100%). In 2011 the UK guidelines by the British Committee for Standards in Hematology Blood Transfusion task force, concluded that blood X-ray irradiation was recommended as a suitable safe alternative to gamma ray irradiation [3]. The British Committee for standards in Haematology Blood Transfusion gives clear guidelines on when the use of irradiated blood components are appropriate and documents that the major technology to prevent TA-GvHD is through irradiation of blood components to inactivate residual lymphocytes. The guidance goes on to state that Gamma rays and X-rays are similar in their ability to deactivate T lymphocytes in blood components at a given absorbed dose [5]. Photons used to irradiate blood components are typically generated by two methods, using either a gamma photon source or an X-ray photon beam. Gamma rays are generated by cesium, and in rare cases, cobalt 60 sources. X-rays are photon beams generated electronically by devices that accelerate electrons at a very high speed, directing them to a metallic target such as tungsten and generating a X-ray photon beam as the result of the collision. Both modalities damage the lymphocytes in a similar manner [6]. Within the United States, X-ray based blood irradiation has been FDA approved since 1998 [7]. This filing was approved based on both devices capable of delivering 2500cGy of ionizing radiation to containers filled with blood and blood products [8]. As of 2017, the number of companies selling devices globally with the CE marking for European use is at least five; Gilordoni, Hitachi, RadSource, Cegelec, and Best Theratronics. [9]. With many new vendors seeing growth in the X-ray based irradiation market, this number is anticipated to grow significantly.

The increase in quality and number of companies providing X-ray blood irradiators globally has provided real alternatives to cesium for blood irradiation. Along with availability, many of these new X-ray blood irradiators come with options that blood transfusion centers are finding desirable to meet transfusion guidelines. Current guidelines state that irradiation of blood components constitutes a manufacturing process. The responsible department is therefore expected to comply with relevant aspects of the EC Guide to Good Manufacturing Practices [5]. Because of these expectations, blood centers are required to document blood irradiation with barcodes and radiation label indicators. Some sites go as far as to require temperature monitoring of the blood while being processed. In order to maintain this level of good manufacturing processes, some sites are turning to newer X-ray based systems to have tracking and monitoring capabilities that are rare in older cesium based irradiators.

### Decision making process for X-ray based blood irradiators

In order to participate in the ORS Alternative Technology transition under GCSI, ORS and ZUOP require each site to sign a disposition letter stating the commitment to 1) operate the ORS-funded alternative technology equipment appropriately and incorporate operational and maintenance procedures into their regular routine, 2) allow their cesium irradiator to be removed to a secure storage facility after full transition is complete, and 3) not make future plans to obtain a cesium-137 blood irradiator. This initiative does not specify what device is procured for the partner site. This decision is left up to the site. ORS views the sites to be the primary subject matter expert in their blood processing and relies on the site to make procurement decisions based on site-derived technical requirements for irradiating blood within their facility. ORS requires the site to assume full responsibility for the operation, testing, and maintenance of the alternative technology at the close of the ORS-funded maintenance and warranty period as specified in the contract. Although the initiative provides financial resources required for the removal of the cesium source, the site is required to facilitate scheduling and logistics for this removal.

## conclusion

As a result of the effort to advance the security of Cs-137 through enhanced physical protection measures, increased response capabilities or through permanent risk reduction by replacing cesium devices with non-radioisotopic alternatives, ORS and its Polish partners are starting to see a transition towards alternatives such as X-ray based irradiation at its hospitals and blood banks. Drivers in this decision stem from supporting regulations, new understanding of X-ray based irradiation capabilities and the ORS effort through the GCSI to provide outreach and financial assistance for device procurement and training. Although the first site to adopt X-ray based irradiation is fairly new, there are currently six more transitioning by May 2020. This momentum can be attributed in part to the age of these devices and procurement decision timeframe but also the ability of the regulator to discuss the full cost of ownership for radioisotopic devices. In addition, new X-ray devices have many new options and accessories that allow for high throughput of blood and automated advanced tracking of blood bags and documentation for good laboratory QA practices. X-rays typically have a set irradiation time and do not suffer from the decay process seen in cesium-based devices. As cesium decays, users are faced with increasing irradiation time and at some point, reloading the device with new cesium to increase the activity. Although cesium has a fairly long life, decreasing activity levels nevertheless result in longer irradiation times over the lifetime of the device. In addition to advanced capabilities with these new devices, X-ray devices have no inherent security risks with regards to theft. This allows the user the ability to install devices closer to the other blood donation and processing areas within the hospital/blood bank. Many of the older cesium irradiators demanded security measures that resulted in limited accessibility to the device. These security enhancements, although warranted, increased time in the blood irradiation process and often resulted in devices installed away from the blood donation center within the hospital. The long transit time and delayed access resulted in longer times for blood irradiation and blood residing at room temperature for a longer period of time. As Poland and other countries adopt stronger regulations around the use and security of radioisotopic sources, there will be increased momentum towards adoption of alternatives to these isotopic sources. ORS is already observing global trends in adopting alternative technologies in other countries who are moving in this direction on their own.

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