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OVERVIEW AND STATUS OF THE DOE-NNSA OFFICE OF RADIOLOGICAL SECURITY REDUCE PROGRAM

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ABSTRACT

The National Nuclear Security Administration's Office of Radiological Security (ORS) works to enhance global security by preventing the use of high activity radioactive materials in acts of terrorism. ORS accomplishes this mission through three strategies: Protect, Reduce, and Remove. The ORS Reduce mission utilizes a holistic approach to achieving permanent risk reduction through the implementation of non-radioisotopic alternative technologies for both U.S. and international partners. ORS promotes this approach through policy development; education, and outreach on the status of cutting-edge technologies; research, development, testing, and evaluation of non-radioisotopic technologies; and direct replacement programs where possible through the Cesium Irradiator Replacement Project and international partnerships.

This paper will describe the current landscape for common alternative technologies to radioisotopic sources, including linear accelerators for oncology, X-ray blood and research irradiators, X-ray and electron beam irradiators for food and medical device sterilization, and alternatives to radioisotopic well logging and radiography devices. This paper will further outline ORS's efforts in promoting alternative technologies through the four strategies noted above, through international and regional subject matter expertise, end-of-life planning and interim storage of disused sources, the development of local and international partnerships, targeted financial assistance and cost sharing arrangements, guidance for International Atomic Energy Agency (IAEA) support, analyzing regulatory requirements, and development of sustainable implementation plans. Finally, the paper will address gaps and future areas of potential growth in the alternative technology space.

INTRODUCTION

While radioactive materials play a critical role in commercial, medical and research facilities worldwide, these materials are vulnerable to theft. Due to the widespread availability and less stringent security of radioactive material in a variety of fields, including medicine, construction, food processing, and oil and gas, high-activity radioactive sources are at risk of falling into the wrong hands. Recognizing this growing radiological risk, world leaders at the 2016 Nuclear Security Summit made a commitment to strengthen radioactive source security, acknowledging that "the threat of nuclear and radiological terrorism remains one of the greatest challenges to international security, and the threat is constantly evolving."[i]

ISOTOPES OF CONCERN

Thousands of devices across the country and world contain dangerous amounts of radioactive material. These devices provide many benefits, but their use must be balanced against sufficient security to prevent these materials from being used maliciously. This radioactive material, if stolen, could be incredibly dangerous in the hands of a terrorist seeking to make a radiological dispersal device or "dirty bomb." There are thousands of radioactive isotopes, but most are uncommon or poorly suited to use in a dirty bomb. The Office of Radiological Security (ORS) has identified four isotopes that pose the greatest risk: cesium-137 (Cs-137), cobalt-60 (Co-60), iridium-192 (Ir-192), and americium-241 (Am-241).

Of these, Cs-137 is of particular concern. According to a 2021 National Academy of Sciences (NAS) report, "cesium-137 in irradiators and calibration devices is in the form of a compressed cesium chloride powder, which is soluble in water and can be dispersed relatively easily" [ii] Because of this, Cs-137 is considered to have the most devastating consequences if misused. The original 2008 NAS report recommended the elimination of "all Category 1 and Category 2 cesium chloride sources in the United States and, if possible, elsewhere."; while much progress has been made in removing and replacing Cs-137 devices, they remain in use in the U.S. [iii] Cs-137 is used in the irradiation of blood components to prevent transfusion associated graft vs. host disease (TA-GvHD), a rare, and usually fatal disease in which white blood cells from a donor's blood attack host tissues in a recipient patient. This radioisotope is also used in biological research, including cancer studies.

Co-60 is highly radioactive and is the most used radioisotope globally. Co-60 is most often used in facilities that conduct industrial sterilization (of medical supplies, cosmetics, food, etc.) and in clinical settings with devices that conduct external beam radiotherapy for cancer treatment. The industrial sterilization facilities represent most Co-60 usage – often millions of curies per facility – but at a much smaller number of facilities worldwide. In comparison, radiotherapy devices use less Co-60, but thousands of them can be found in hospitals and universities around the world.

WHAT ARE ALTERNATIVE TECHNOLOGIES?

ORS defines alternative technologies as those that do not contain radioactive materials and are able to perform an equivalent (or better) function compared to radioactive source-based devices. Alternative technologies may emit ionizing radiation, like x-ray irradiators, or they may not, like ultraviolet pathogen reduction technology (UV-PRT) pathogen reduction systems. ORS encourages the adoption and development of non-radioisotopic alternative technology to permanently reduce the risk of terrorism by eliminating risk-significant radioactive materials. This is a key ORS strategy to

fulfill the office's mission to enhance global security by preventing high-activity radioactive materials from use in acts of terrorism.

However, equally important to the security of these sources are the functions these devices provide. For example, cesium irradiators that are being replaced serve vital functions in the blood processing and medical research fields, and the quality of services they provide must be maintained for current and future patient health. The table below summarizes available alternatives for each application. Viable alternative technologies are available for most radioactive source-based devices.

Application	Typical Isotope	Commercially Available Alternatives?
Blood Irradiation	Cs-137	Yes: X-ray—5 FDA approved devices Partial: UV Pathogen Reduction—FDA approval for platelet & plasma systems, ongoing R&D for red blood cell systems
Research Irradiation	Cs-137 & Co-60	Partial: X-ray Irradiators for most research applications
External Beam Radiotherapy	Co-60	Yes: Linear Accelerators (LINACs)
Industrial Sterilization	Co-60	Yes: X-Ray, E-beam, LINACs
Well Logging	Am-241 & Cs-137	Incomplete: Am-241 - alternatives available, Cs-137 – ongoing R&D
Radiography	Ir-192, Cs-137, Co-60, Se-75	Yes: X-ray

TRENDS IN ALTERNATIVE TECHNOLOGIES

In recent years, there has been an increased recognition of alternative technologies as part of a comprehensive approach to radiological security. Many leading healthcare and research facilities are already using or transitioning to non-radioactive source-based alternative technologies.

Trends continue to show increasing use of medical linear accelerators (LINACs) worldwide relative to Co-60 machines for radiotherapy. LINACs can provide more sophisticated and precise treatment capabilities, in addition to their benefits of reduced security procedures, requirements and costs for the facility operating them[iv]. For blood and research applications, X-rays have been able to maintain and even exceed performance standards offered by older Cs-137 devices, and their use as a replacement for cesium continues to increase. Additionally, there is strong interest in UV pathogen reduction technology, which is not yet Food and Drug Administration (FDA)-approved for use on all blood products (though one company's devices have received a CE mark in Europe). While Co-60 remains the most common irradiation-based modality for phytosanitary, food, and medical device sterilization, the usage of electron beam and X-ray continues to grow, with several new accelerator-based facilities under construction as of July 2021. X-ray use is growing in the sterile insect technique user field given the lessened security costs, and validation work on many prominent insects is continuing. X-rays are in use for radiography in all but the most challenging environments. Accelerators are also in use in many new applications, including plant mutagenesis and waste treatment.

Despite these positive trends in alternative technology availability, some users continue to prefer radioactive sources for their applications. Other factors such as maintenance requirements, technical capabilities, infrastructure reliability, and resources for implementation within an organization may make a site reconsider transitioning to alternatives. For example, while Am-241 alternatives are available for well logging, they are not widely used due to operational, technical, and economic challenges.

U.S. GOVERNMENT MOMENTUM ON ALTERNATIVE TECHNOLOGIES

In the late 1990s, as a result of incidents involving radioactive sources and devices that were lost, abandoned, or lacking regulatory control ("orphaned"), the Nuclear Regulatory Commission (NRC) and other domestic and foreign regulatory organizations recognized the need to improve the control over high-activity radioactive sources. Prior to the events of September 11, 2001, the NRC's regulations focused on the safe use, transportation, and control of licensed radioactive material. The events of 9/11 heightened concerns about the use of high-activity radioactive sources as a radiological dispersal device (or "dirty bomb") or radiological exposure device in an act of terrorism. As a result, the United States implemented an increased physical security program for radioactive materials that included the existing regulations to maintain the safe use of radioactive materials with enhanced security requirements for those materials deemed "highly risk-significant."

The Energy Policy Act of 2005 (Public Law 109-58) directed the NRC to work with the National Academies of Sciences, Engineering, and Medicine (NAS) to review current industrial, research, and commercial uses of radiation sources and to identify technically and economically feasible replacements for these sources.[v,vi] In 2008, the National Research Council of the National Academies' Committee on Radiation Source Use and Replacement released its report concluding that the U.S. Government should consider factors such as potential economic consequences of misuse of the radiation sources into its assessments of risk. The committee found that replacing most sources is technically possible, but not necessarily economically feasible.[vii] The committee also recommended that the U.S. Government take steps in the near term to replace cesium chloride radiation sources, a potential "dirty bomb" ingredient, with lower-risk alternatives, and that longer-term efforts be undertaken to replace other sources. Additionally, the 2008 National Academies report found that neither sealed source licensees nor manufacturers "bear the full life-cycle cost, including disposal costs, of some of these radiation sources".[viii] Moreover, some Federal agencies are bearing the cost of voluntary additional security, transportation, disposal, and environmental remediation of the commercial sector's use of high-activity radioactive sources.

The NAS released an updated report in 2021. This report found that since 2008, the US government and the international community have taken meaningful steps to improve the security of Category 1 and 2 radioactive sources, particularly in the field of replacement of Cs-137-based blood and research irradiators.[ix] The committee noted that alternative technologies have developed at different rates and their implementation has not been uniform across applications or geographies, but efforts are underway to meet many of the challenges to more widespread acceptance; the report notes the importance of funding research and development to continue this process.[x] The Energy Policy Act of 2005 also established the Radiation Source Protection and Security Task Force to "evaluate, and provide recommendations relating to, the security of radiation sources in the United States from potential terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiological dispersal device."[v] The 2014 Radiation Source Protection and Security Task Force Report noted that

"all members support efforts to further reduce security risks by developing alternative technologies as replacements."[vi] In the 2018 report, the Task Force noted its ongoing efforts to "investigate options such as voluntary, prioritized, incentivized, programs for the replacement of Category 1 and 2 radioactive sources with effective alternatives" and to "lead by example in the consideration of and transition to alternative technologies that meet technical, operational, and cost requirements".[xi]

The "United States National Progress Report" delivered at the 2016 Nuclear Security Summit highlighted "minimizing nuclear and other radioactive materials" as one of six key focus areas of the United States in strengthening nuclear security implementation. According to the report, the United States will "continue to develop initiatives for reducing the number of vulnerable high-activity radioactive sources through continued research and development on non-radioisotopic alternative technologies, international workshops and collaboration, and direct site engagement," and "partner with industry to replace 34 cesium-137 blood irradiators with non-radioisotopic alternative technologies by 2020."[xii] This goal was met in 2018. Several Federal Government entities have taken initiatives to encourage U.S. commercial users of radioactive source-based technologies to transition to commercially available alternatives or, where commercially available alternatives do not exist, to develop new technologies. These initiatives include a working group of the Department of Homeland Security (DHS) Critical Infrastructure Partnership Advisory Council and an International Atomic Energy Agency (IAEA) ad hoc working group on alternatives to high-activity radiological sources.

In 2015, the Interagency Working Group on Alternatives to High-Activity Radioactive Sources (GARS) was chartered and began an assessment of Federal agency involvement with high-activity radioactive sources and development of best practices on how agencies can incorporate the transition to alternative technologies into their strategic plans. The final report, "Transitioning from High-activity Radioactive Sources to Non-radioisotopic (Alternative) Technologies: A Best Practices Guide for Federal Agencies" was published at the end of 2017 and includes the following recommendations for agencies with a direct role in funding or procuring source-based devices for medical applications:

- Look for opportunities where possible to lead by example on the utilization and promotion of alternative non-radioisotopic technologies.
- Set internal policies to no longer purchase source-based devices, discontinue the use of, or terminate provision of grant funds for their purchase.
- Institute internal protocols or policies to phase out the use of an existing device(s).
- Expedite, where possible, approvals of new non-radioisotopic devices.
- In cases where devices using high-activity sealed sources are favored, the supporting agency should ensure that end-of-life management plans are in place to cover costs associated with source disposition.

OFFICE OF RADIOLOGICAL SECURITY

The Department of Energy's National Nuclear Security Administration (NNSA) Office of Radiological Security (ORS) works with domestic and international partners to enhance the security of high-activity radioactive sources worldwide. This initiative helps prevent unauthorized access to materials for use in a radiological dispersal device or other acts of terrorism.

ORS collaborates with a broad range of stakeholders including government regulatory authorities, responders, operators, industry, and international organizations to enhance the security of medical devices containing high-activity radioactive sources. ORS uses three strategies under this approach:

- *Protect* high-activity radioactive sources in use, storage, and transit;
- *Remove* and dispose of disused radioactive sources; and
- *Reduce* the global reliance on high-activity radioactive sources by promoting the adoption and development of non-radioisotopic alternative technologies.

ORS is leading efforts to reduce the reliance on high-activity sources by supporting viable non-isotopic alternative technologies to replace the most common devices that use high-activity sources. This strategy works toward permanently reducing the terrorism risk through the elimination of risk-significant radioactive materials. To achieve this goal, ORS enables the exchange of information on the status of technology, invests in and encourages the improvement of new technologies, reduces the obstacles preventing the use of alternative technologies where they are technically and operationally feasible, and provides financial support for removal and replacement of radioisotopic sources where possible. ORS, and NNSA more broadly, additionally funds research, development, testing, and evaluation in alternative technological solutions where no commercial product exists through its national laboratory and Small Business Innovation Research programs. This approach is complemented by other ORS strategies, including the voluntary removal of disused sources and physical security enhancement at sites with high-activity radioactive material.

STRATEGIC APPROACHES FOR ALTERNATIVE TECHNOLOGY

Through education, outreach, policy analysis, and device replacement initiatives, ORS works with partners to advance understanding and adoption of alternative technologies. Through technical cooperation and research, ORS also encourages the development of new technologies and addresses barriers preventing implementation. Together, these initiatives create a holistic approach to fostering the growth of alternative technologies.

Research, Development, Testing, and Evaluation

ORS collaborates closely with NNSA's Defense Nuclear Nonproliferation Office of Research and Development, who manages alternative technology research and development (R&D) projects at the DOE national laboratories, universities, and small businesses, among other R&D mission areas. Current or recent NNSA R&D projects include novel technologies in all major radioactive source applications: blood irradiation, research irradiation, industrial sterilization, external beam radiotherapy, industrial radiography, and well logging. For example, several NNSA R&D projects are funding the development of novel X-ray sources for blood irradiation, research irradiation, and Sterile Insect Technique that will provide a more robust and reliable alternative to standard X-ray tubes. Another project is working to answer challenges faced by medical LINACs in low- and middle-income countries by designing a simpler, easier to repair LINAC system.

ORS manages testing and evaluation projects and supports the development of analytical tools or products that help allow users to compare their needs across both radioactive source-based technology and alternative technology. In the above examples, ORS either has funded or will consider funding the testing and validation of the technology. Furthermore, there are many independent operators, non-

governmental organizations, , and universities that are conducting their own research on alternative technology to meet their specific needs. ORS partners with these institutions to identify the research that is currently being conducted in these corners and highlight it for interested parties across the field.

Outreach & Education

ORS partners with DOE national laboratories and NGOs to organize workshops for users of high-activity radioisotopic sources who are considering converting to non-radioisotopic alternatives. These workshops provide information on available technologies, replacement considerations, the experiences of source users who converted previously, and ORS programs that may offer replacement assistance. ORS also engages with industry, NGOs, and key countries by presenting at regional workshops, webinars, technical information exchanges, and professional society meetings to ensure high-activity radioisotopic source users are aware of the current capabilities and availability of alternative technologies, as well as the pros, cons, and logistical considerations for replacement. ORS also utilizes these opportunities to engage with industry directly to understand market considerations that may drive alternative technology-related decisions (along with challenges faced in these transitions) to better help partners in their efforts to switch.

The IAEA and NGO's (including the World Institute for Nuclear Security (WINS)) are key partners for ORS. Both seek to convene stakeholders in applications of radiation technology, discuss challenges faced by prospective users, and utilize lessons learned to help develop solutions. Both have also helped build networks for new application spaces, including the sterile insect technique and wastewater treatment.

One key ORS partner is the state of California (CA), which has replaced many of its high-activity Cs-137 irradiators over the last several years. The state is encouraging all CA medical and research facilities to transition to non-radioisotopic alternative technologies where economically and operationally feasible. In 2018, the University of California hosted technical sessions in Los Angeles and San Francisco. These sessions were organized in partnership with ORS, the California Department of Public Health, and the Nuclear Threat Initiative (NTI). The sessions provided facilities with an opportunity to interact with technical experts and X-ray manufacturers and learn more about device capabilities and experiences in converting to alternative technologies in blood and research applications. The sessions also facilitated dialogue on how transitioning to alternative technologies can contribute to the permanent reduction of radiological security risk. Similarly, in Atlanta, NTI and Emory University hosted a two-day workshop on radiological security in February 2018, and Memorial Sloan Kettering Cancer Center hosted a workshop for New York City institutions in June 2017.

The Cesium Irradiator Replacement Project

The Office of Radiological Security is working with domestic users of Cs-137 based irradiators who are interested in converting to viable non-radioisotopic alternatives. The Cesium Irradiator Replacement Project (CIRP), offered by ORS, provides qualified sites that are interested in making the switch with a financial incentive towards the purchase price of a new non-radioisotopic device, as well as the removal and disposal of the cesium irradiator. The Project was launched in 2015 and

was the foundation of the United States Government's successful efforts to facilitate the replacement of 34 Cs-137 irradiators with non-radioisotopic alternatives two years earlier than planned.[xiii]

Qualified participants receive:

- Removal and disposal of the Cs-137 irradiator, saving the site approximately $100–$200k per irradiator. Irradiator removal timing can be scheduled to align with delivery of the new device with some parallel/overlap operations possible.
- A limited financial payment towards the purchase of the new non-radioisotopic device, up to 50% of the purchase price. The payment will be disbursed once the cesium device has been removed and the non-radioisotopic device has been installed.

Due to the limited funding provided to support CIRP conversions each year, ORS prioritizes sites based on several considerations – including the interest level and feasibility of site engagement, the expected impact on national security, the number and types of devices to be replaced, and the timeline of procurement and/or disposition. As of July 14, 2021, 180 devices have been replaced through CIRP, with pledges made to replace 170 additional irradiators in the United States by 2023.

ORS also understands that not all users will choose these alternatives. For those facilities that prefer to use high-activity radioactive sources, ORS offers security equipment and training, including training local law enforcement to better prepare them to respond to any attempted theft of the radioactive material. In the last ten years, ORS has worked with nearly 1,700 hospitals, universities, research institutes and private companies who have chosen to improve their security footprint beyond what is required by regulations.

NEW YORK CITY CASE STUDY

New York City is currently leading in the field of radiological security with the first city-wide initiative in the United States to replace Cs-137-based irradiators with alternatives that do not contain radioactive sources. New York City medical facilities and universities have partnered with ORS, the New York City Department of Health and Mental Hygiene (DOHMH), and NTI to consider replacements for all of the irradiators containing high-activity Cs-137 sources (around 5% of the U.S. Cs-137 irradiator inventory). As of July 2021, 66% of NYC's irradiators have been replaced, and 80% are expected to be replaced by 2024. This combined effort will reduce the risk of a terrorist acquiring this material for a radiological dispersal device. ORS is playing a pivotal role in this replacement effort through its Cesium Irradiator Replacement Project.

New York City is a national leader in radiological security. The city has been targeted for terrorism in the past and continues to be considered a major target now and for the foreseeable future. As a result, the New York Police Department (NYPD) has taken an extensive and proactive approach to security against terrorism, including radiological terrorism, earning recognition as having one of the best law enforcement organizations on radiological threat matters in the country. In addition to the CIRP initiative, New York City users of high-activity radioactive sources, the New York City DOHMH, and the NYPD have partnered with ORS over the past 11 years to enhance the physical security of the sources and ensure that law enforcement is well prepared to respond to any attempted theft of this material.

NNSA's Acting Deputy Administrator for Defense Nuclear Nonproliferation David Huizenga; DOHMH Commissioner Dr. Mary Travis Bassett; and former Senator Sam Nunn, NTI co-chairman, announced the initiative to transition from blood and research irradiators using high-activity sources to alternative technologies that do not use radioactive materials. "We applaud New York City's effort to work together to phase out high activity radioactive sources," Huizenga said. "It has been at the forefront of U.S. efforts to enhance radiological security and serves as an example for other major cities. We are proud to support the city's permanent threat reduction effort and we greatly appreciate its leadership in the prevention of radiological terrorism."[xiv]

ORS continues to work with similar sites around the country to replace Cs-137 irradiators through CIRP and will use the New York City initiative as a model for engagement in other regions, including in California. In support of the California risk-reduction effort described in the Outreach and Education section, the University of California system is participating in a system-wide replacement and disposal effort for their high-activity Cs-137 irradiators.

INTERNATIONAL ALTERNATIVE TECHNOLOGY PROGRAM

ORS works with global partners on a broad range of activities to encourage the replacement of devices that utilize Cs-137, Co-60, Am-241 and Ir-192 sources. ORS supports capacity building, technical exchanges, and, on a case by case basis, the removal of radioactive-source based devices and installation of alternative technology replacements. Since the start of the international alternative technologies program in 2016, ORS has removed 26 devices in support of alternative technology transitions, and has installed 30 x-ray devices globally.

In addition to bilateral partnerships, ORS works to build capacity with other stakeholders, like WINS and the IAEA. ORS supports IAEA activities relevant to the selection of radiation-based technology, including by acting as a resource for Member States to exchange technical information, improving and developing new technologies, and addressing barriers hindering the adoption of non-radioisotopic technologies. ORS also works with subject matter experts from around the world to identify new areas where radioactive sources may have viable alternative technology replacements and develop strategies to further the permanent risk reduction mission.

Case Study: Sixth Annual Meeting of the Ad Hoc Working Group of Stakeholder States Involved with Technological Alternatives to High-Risk Radioactive Sources

In 2015, the first meeting of the Ad Hoc Working Group of Stakeholder State Involved with Technological Alternatives to High Activity Radioactive Sources met on the margins of that year's IAEA Radiological Source Security Working Group meeting. Since then, the working group, co-chaired by United States, France, and Germany, continues to be convened annually in Vienna – except in 2020, when the group did not convene due to the COVID-19 pandemic. In 2021, co-chairs convened the first-ever virtual meeting of the working group, which saw participation numbers more than triple that of previous years. The goal of the meeting is to provide a forum where users, regulators, subject matter experts, industry, NGO's, governments, and international organizations can exchange views and ideas on the development and use of alternatives to high activity sealed radioactive sources.

The 2021 meeting, held from June 14-18, 2021, brought together a diverse group of attendees to discuss a wide range of alternative technology topics, including national initiatives and policies in support of alternative technologies, how public-private partnerships and unique financing models can be utilized for alternative technologies, and addressing gaps in the alternative technology space. Attendees also heard presentations on the National Academies of Sciences' 2021 update to their 2008 study and Information Circular (INFCIRC) 910 (Joint Statement on Strengthening the Security of High Activity Sealed Radioactive Sources). WINS managed one day of the event and led discussions that highlighted key lessons learned from the wide range of speakers. The event brought together stakeholders from most alternative technology sectors, including radiation oncology, blood irradiation, sterilization, SIT, and research. At the end of the event, participants showed substantial interest in learning about new technology developments and end-of-life management, as well as alternative technologies for non-destructive testing, well logging, and industrial sterilization. A website is being developed that will serve as a repository for published research, past Ad Hoc meeting materials, and other resources.

CONCLUSION

ORS continues to promote the adoption of alternative technologies with the goal of permanently reducing the terrorism risk of the highest risk sources, including cesium-137, cobalt-60, americium-241, and iridium-192. In addition, ORS partners with NGOs on a broad range of activities to promote viable replacements for devices that utilize these sources. It remains clear that users require support – analytical tools, training, capacity building, expert resources, professional studies, etc. – to make informed decisions between radioactive sources and alternative technologies. ORS will continue finding opportunities to highlight new technologies, research, and user experiences across the field. ORS will continue supporting projects that support the development of alternative technologies that are robust, economical, compact, easily operated, and sustainable

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