Case Study: An Analysis of Several National Approaches to Alternative Technologies for Radioactive Sources[1]

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Abstract

The ingredients for a radiological dirty bomb—the very same isotopes that can make life-saving blood transfusions and cancer treatments possible—are located at thousands of sites in more than 150 countries, many of them poorly secured and vulnerable to theft. The vulnerability of these radiological sources, such as cesium-137, has caused concern for years, but today the risk is growing. Although many types of isotopes are dangerous, many technical experts have concluded that cesium-137 poses the greatest danger and should be considered the top priority. Cesium is the most attractive and dangerous isotope from a terrorist perspective because it is very difficult to clean up, contains a substantial level of dangerous radiation, and has a long half-life (30 years). World leaders at the 2014 and 2016 Nuclear Security Summits recognized the growing threat and put an important spotlight on the issue of radiological security. Several countries, such as Japan, France, Norway, and the United States have

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advanced well beyond advocacy for and implementation of efforts to switch to non-isotopic alternatives. In some countries where the devices are government owned, x-ray units have entirely replaced devices using cesium-137 and other high-risk radioactive materials. While non-radioactive replacement technology readiness time-tables differ across isotopes and applications, the replacement of cesium-137 (particularly in blood sterilization) should be one of the highest priorities for implementing the use of alternative technologies. The replacement of this isotope with x-ray based technology would achieve the greatest risk reduction. In the United States, the U.S. Food and Drug Administration has approved the use of x-ray devices for blood sterilization. This reflects significant technology advances over the past several years that has resulted in mature replacement technologies. This paper explores the various "case studies" based on the national experiences of Japan, France, Norway, and the United States in support of alternative technologies, and provides several key recommendations for other governments to consider in their national approaches to alternative technologies. These "case studies" reflect a growing global trend that should be part of a broader initiative to achieve permanent threat reduction by replacing cesium with effective alternative x-ray technologies in as many countries as possible.

Introduction

The ingredients for a radiological dirty bomb are located at thousands of sites in more than 150 countries, many of which are poorly secured and vulnerable to theft. The vulnerability of these radiological sources, such as cesium-137, has caused concern for years, but today the risk is growing. Cesium-137 is commonly used in medical facilities and blood banks around the world to irradiate blood prior to transfusion in order to prevent graft-versus-host disease. The cesium used in blood irradiators is classified by the International Atomic Energy Agency (IAEA) Code of Conduct on Safety and Security of Radioactive Sources as either Category I or Category II, given the high level of radioactivity. Cesium blood irradiators in hospitals and blood centers commonly contain between 2,000-3,500 curies of cesium. Cesium is the most attractive and dangerous isotope from a terrorist perspective, because it can easily be dispersed with high explosives. If stolen and used by terrorists to detonate a large dirty bomb in a major world city, this amount of cesium could result in massive clean-up costs on the order of hundreds of billions of dollars. Several countries, such as France, Norway, and Japan have taken significant steps to phase-out cesium use in blood irradiators and replace these units with an alternate x-ray device that cannot be used to make a dirty bomb. The replacement x-ray equipment provides the same medical benefits in terms of sterilizing blood and eliminates the dirty bomb threat.

Alternative Technologies

Unlike gamma radiation that is produced by high-activity cesium radioactive sources that requires heavy shielding and high levels of security to protect, x-ray radiation is produced by an x-ray tube that can be turned off when it is not being used and it requires much less shielding. Also, since the source of irradiation is not radioactive material, the radioactive material license is not required for x-ray irradiators. At the end the of unit's life-cycle, the unit does not have

any radioactive source and therefore does not require expensive disposal costs associated with sources that remain radioactive for hundreds of years. X-rays have equivalent medical outcomes, do not require a license, their safety and security requirements are less onerous, and they eliminate burdensome security considerations and requirements. Other advantages are that x-ray irradiators are typically much lighter in weight than gamma irradiators so they have fewer structural limitations and they provide a relatively quick irradiation cycle capacity. More importantly, this represents permanent risk reduction and can be achieved by the replacement of these devices. In 2012, the U.S. Food and Drug Administration (FDA) approved the use[5] of ionizing radiation devices (x-ray) for sterilizing blood prior to a transfusion to prevent graft-versus-host disease. As of 2015, two manufacturers are selling these devices in the United States. The typical cost for a replacement x-ray device in the U.S. is approximately $270,000, which includes preventative maintenance and warranty coverage.[6]

International Case Studies

International interest in, and support for, replacing high-activity radioactive sources has been increasing over the past several years, in part due to the Nuclear Security Summit (NSS) process. In particular, given the concern regarding cesium-137 use in blood irradiators and the availability of effective alternative technologies that cannot be used to make a dirty bomb, several countries have already taken steps to phase out the use of cesium in blood irradiators in their countries. Below are case study analyses based on the national experiences of France, Norway, and Japan to replace all their cesium blood irradiators with alternative x-ray equipment. These countries should be commended for their efforts, and their actions should spur other countries to take similar steps to completely phase-out the use of cesium blood irradiators.

[5] In 2012, the FDA approved the equivalency (510k certification) of x-ray devices.

[6] Some consideration has been given to the use of linear accelerators (LINACs) to irradiate blood units, which would provide a homogeneous dose distribution. However, this application has not been widely adopted because the blood units must leave the blood bank for an indeterminate length of time, where they are subject to uncertain temperature control. Facilities that use LINACs for irradiation either are part of larger processing facilities or find time between patient treatments in a radiotherapy clinic. Due to their high costs (above $2 million for the LINAC unit and approximately $200,000 per year for maintenance), LINACs are not a viable replacement for cesium blood irradiators due to lifetime costs and primary application of this device. Therefore, they are typically not a direct replacement for these technologies. Another emerging technology procedure for sterilizing blood is the use of pathogen inactivation, which has an advantage because it abolishes lymphocyte mitotic activity and inactivates T-cells. In addition, this technique does not require a radioactive material license. The treatment causes pathogen inactivation, meaning that harmful bacterial and other viral infections are eliminated from the blood components (e.g., hepatitis B and C, HIV, west nile virus and bacteria, as well as emerging pathogens such as chikungunya, malaria, and dengue). Further, the use of wavelength range of illumination with the molecule Amotosalen interacts with nucleic acids to inhibit pathogen and leukocyte replication. Another system uses a combination of Riboflavin (vitamin B2), a non-toxic, naturally occurring compound, and a specific spectrum of ultraviolet (UV) light to inactivate viruses, bacteria, parasites, and white blood cells that may be present in collected blood products. Although one pathogen inactivation system was FDA approved to treat plasma and platelets for pathogen and bacterial reduction, it is not yet approved for irradiating whole blood in the U.S.

France

The Government of France has been a strong advocate for alternative technologies to radioactive sources. During the 2014 NSS, President Hollande announced that France would strengthen its international radiological efforts by 1) strengthening the implementation of the international framework applicable to sources; 2) promoting international exchanges on the development and use of alternative technologies to high-activity sources when technically and economically feasible; and 3) deepening further the cooperation between source supplier states to improve the security of disused sources. Following this announcement, France has continued to promote the exchange of information on alternative technologies through many forums, such as the IAEA General Conference, United Nations General Assembly, as well as through a co-sponsored Technical Working Group with the United States.[7] At the final NSS held in March 2016, the Government of France also led a Joint Statement on Strengthening the Security of High Activity Sealed Radioactive Sources (HASS). This Joint Statement was signed by 28 countries (and Interpol) and has contributed to raising political awareness on actions needed to strengthen global radiological security while providing a platform for states to initiate and sustain substantive work on source security and alternative technologies through the auspices of the IAEA.[8]

France's promotion of alternative technologies on the international scene mirrors its domestic policies for moving away from cesium, particularly in blood sterilization. In 2006, France instituted a ten-year plan to replace all 30 cesium-based blood irradiators with x-ray devices at all national blood transfusion centers. Implementation of this national directive was completed at the end of 2016, and France has now completely replaced all of its cesium blood irradiators with x-ray devices.[9] The implementation of this directive was overseen by the French Nuclear Safety Authority (ASN), an independent authority that oversees radiation protection requirements for authorized manufacturers, holders, users, suppliers, importers, and exporters of all ionizing radiation sources. In compliance with this policy, ASN put in place a "justification principle" in its licensing process, placing the burden on operators to make the case for continued use of cesium irradiators for blood sterilization.[10] This policy contributed to the

[7] France committed to co-chair with the United States an ad hoc working group of stakeholders involved with alternative technologies. Although the working group has no official mandate, it has a Terms of Reference and has served as a technical platform for building an international roadmap on alternative technologies.

[8] Recommendations for international engagement in support of alternative technologies and calls on the IAEA to focus on three key areas: Encouraging the IAEA and Member States to promote and support research efforts on the development of technically and economically realistic and acceptable non-HASS technologies, incorporating in these efforts the manufacturers, end-users, standards-setting bodies, and technical experts; Encouraging the IAEA and Member States to initiate discussions on how to take into consideration radiological security implications in their regulatory arrangements for HASS-based technologies; Encouraging the IAEA and Member States to exchange on the barriers that limit or could limit the spread of non-HASS technologies and on possible ways to tackle them.

[9] Presentation at the NTI Global Dialogue Meeting, Airlie Center, 15-16 November 2016 by Mr. Phillippe Delaune, Deputy Director for International Affairs at the French Alternative Energies and Atomic Energy Commission (CEA).

[10] Operators are responsible for implementing the justification principle. Additionally, operators are required to consider new ways to reduce risks associated with their practices given the existing knowledge and the available

replacement of all cesium blood irradiators and the identification of alternative technologies and practices to reduce the risks associated with cesium devices.[11] Prior to the national decision, ASN conducted several outreach meetings with the main users of cesium irradiators, including the French National Blood Service and other research institutes. The discussions concluded that that x-ray blood irradiators could replace cesium blood irradiators without detriment to patient safety or security of supply and at an acceptable cost.

Norway

The Norwegian National Statement presented at the 2016 NSS called for the prevention of unauthorized personnel from having access to high-activity radioactive sources. In addition, Prime Minister Solberg made the following statement: "…we need to adopt alternative technologies that do not rely on radioactive material. Preventing unauthorized personnel from having access to high-activity radioactive sources reduces the risk of terrorism involving radiological material. In 2015, Norway finished phasing out the use of high-activity sources in blood irradiators, having gradually replaced them with x-ray based irradiators. These are no longer a security concern."[12]

The Norwegian Radiation Protection Agency (NRPA), a directorate under the Ministry of Health and Care Services responsible for matters concerning nuclear security and radiation use, indicated that their decision to phase out all cesium devices was informed by an internal government study on the economic impacts of a radiological dispersal device (RDD), the 2011 Andres Breivik terrorist incident and his manifesto (which had references to the utility, use, and delivery of an RDD),[13] and Norway's overarching security concerns with increasing the physical protection of all high-activity radiological sources. This achievement was directed and carried out in partnership with NRPA, the public hospitals, and the medical institutions that formerly used cesium devices to sterilize blood. By 2015, all 13 blood irradiators containing high-activity cesium were replaced with x-ray devices, and the cesium sources were returned to their Canadian manufacturer. The NRPA is continuing to encourage its industry to use alternative

technological options. They should also encourage further progress by stimulating the development of new techniques or the sharing of good practices.

[11] ASN's "Principles of Nuclear Safety, Radiation Protection and Protection of the Environment" is based on the three overall principles of radiation protection: Justification, Optimization, and Dose Limitation. ASN requires that users of gamma irradiators prove that the use of cesium sources is still justified, given the availability of x-ray irradiators. This justification provision is thoroughly assessed through the French licensing process (for new licenses or the renewal of existing licenses).

[12] The Norwegian National Statement at the 2016 NSS can be found here: http://www.nss2016.org/document-center-docs/2016/4/1/national-statement-norway.

[13] The Anders Breivik terrorist incident led to reports recommending enhanced security for critical infrastructure with an emphasis on security (his manifesto can be found here: https://publicintelligence.net/anders-behring-breiviks-complete-manifesto-2083-a-european-declaration-of-independence/).

technologies to radioactive sources,[14] and the Norwegian government continues to be a strong advocate for alternative technologies.

Japan

At the 2014 NSS, Japan was one of 23 countries that signed the NSS Joint Statement on Enhancing Radiological Security. In 2016, Japan became Chair of the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (Global Partnership), and also Chair of the Global Partnership's Nuclear and Radiological Security Sub-Working Group.[15] The Global Partnership Action Plan contains a specific reference that supports alternative technologies for radioactive sources: "Provide assistance to and coordinate programs and activities on enhancing nuclear security, exploring the development of alternative technologies, and end-of-life management for radioactive sources – especially high activity ones."[16] Japan's support for alternative technologies was based on a "bottom-up" approach and left to the discretion of the operator and user. Although the Japanese National Regulatory Authority did not introduce a regulatory requirement for the introduction of alternative technologies, Japan has been phasing out cesium for the past twenty years and has replaced more than 80% of their cesium blood irradiators with x-ray devices. Several factors have also played a key role in Japan's decision: (1) cesium devices required extensive safety regulations and special handling qualifications, which are costly for users, whereas x-ray devices do not; (2) cesium devices must be contained in a controlled area and x-ray devices do not; (3) the disposal of x-ray equipment is safer, easier, and less expensive than cesium devices; (4) there is no risk of radioactive contamination due to a disaster or theft of materials; and (5) fear of radioactivity by the Japanese public in the aftermath of the Fukushima incident. Additionally, the Hitachi Medical Corporation has conducted comparison studies[17] and concluded that x-ray irradiators have equivalent effects and performance as cesium devices, and it reduces the risks associated with radioactive materials. Of the five factors mentioned above, Hitachi Medical Corporation noted that both the burden of regulations and the fear of radiation were significant factors that accelerated the use of x-rays to sterilize blood instead of the use of cesium, and that the general trend is that the number of operators with licenses of blood irradiators using radioisotopes is significantly declining.

Status of Alternative Technologies in the United States

[14] The National Paper of Norway on the Implementation of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and its associated Supplemental Guidance on the Import and Export of Radioactive Sources. Next in line are radiography sources and control sources, for which they are currently making sure the national source registry is updated.

[15] The Global Partnership seeks to fund and coordinate projects and activities in the areas of chemical, biological, nuclear, and radiological security. The Global Partnership is one of five organizations or initiatives for which the participating NSS countries agreed upon an Action Plan to build on the achievements and carry forward the goals of the NSS process.

[16] See paragraph 4 of the 2016 NSS Global Partnership Action Plan: https://static1.squarespace.com/static/568be36505f8e2af8023adf7/t/56feeef34d088e7781f9e5ef/1459547891584/Action+Plan+-+GP_FINAL.pdf.

[17] This is based on conversations between the authors of this report and the Hitachi Medical Corporation.

In 2008, the U.S. National Academy of Sciences (NAS) published a landmark report, "Radiation Source Use and Replacement", which examined the feasibility of replacing high-risk radioactive sources with less risky alternatives. One of the report panel's primary recommendations was to eliminate use of cesium devices entirely and transition to alternatives such as x-ray irradiators. Furthermore, they contended that the government would have to intervene because "the alternatives cost more and the liabilities or social costs of the sources currently are not borne by the end-users." The NAS report also suggested various avenues for achieving this outcome, including discontinuing licensing of new cesium irradiator sources, creating incentives for decommissioning existing sources, and prohibiting the export of cesium sources to other countries.

Domestically, the United States has not fully embraced this recommendation, as is made clear in both the 2010 and 2014 congressionally-mandated reports of the Radiation Source Protection and Security Task Force.[18] In particular, the transition to alternative technologies for the irradiation of blood products in the U.S. has been slow to materialize and are behind national efforts undertaken by other governments. Some experts argue that the current security measures are adequate and that alternative technologies are cost-prohibitive or not as effective as the existing methods. Others contend that the use of alternative technologies are the most promising way to achieve permanent threat reduction and that cost-effective x-ray alternatives to replace both cesium blood and research irradiators are already available. The Nuclear Regulatory Commission (NRC), an independent agency established to ensure the safe use of radioactive materials, has not encouraged or required (e.g., license condition or regulatory action) the replacement of cesium blood irradiator devices. Rather, the NRC has focused on upgrading and enforcing the physical protection of such devices from potential misuse or theft.

The U.S. holds the largest share of global inventory of radiological sources, by a wide margin. The American Association of Blood Banks (AABB)—an international, not-for-profit association representing individuals and institutions involved in transfusion medicine—reported its members managed almost 1.8 million irradiated blood products in 2013, representing almost 33% of all blood components transfused by blood banks reporting irradiated units. Given the large number of cesium devices in both the public and private sectors and the absence of any regulatory requirement to convert or to justify their continued use, the decision to move away from cesium sources and adopt alternative technologies will rely on decisions by the management of individual medical and research facilities. Further, even if all private sector operators agreed to convert, federal agencies would concurrently need to overcome national capacity obstacles related to the transportation and final disposal of cesium and other high-activity sources. There is currently no existing commercial disposal options available for high-

[18] The task force is headed by the U.S. Nuclear Regulatory Commission and includes 14 federal agencies and one state organization. The 2010 and 2014 task force reports and additional information on the task force and their implementation are available at www.nrc.gov/security/byproduct/task-force.html.

activity cesium sources and no current term limits or financial warranties for addressing end-of-life management. The U.S. Department of Energy's National Nuclear Security Administration (DOE/NNSA) Off-Site Source Recovery Project (OSRP) is the only program that provides waste disposal for these high-activity sources and devices.[19] OSRP has a mission to recover excess, unwanted, abandoned, or orphan high-activity radioactive sealed sources that pose a potential risk to national security, health, and safety. The NRC is also reviewing a scoping study to evaluate whether financial planning requirements for decommissioning and end-of-life management for some radioactive materials are necessary, but no decision has been reached.

However, the NNSA Office of Radiological Security has established a new program called the Cesium Irradiator Replacement Program (CIRP) to partner with hospitals and other medical facilities to replace their cesium-137 irradiators with x-ray irradiators. Under this program, the U.S. government provides a financial incentive toward purchasing the replacement x-ray device up to a 50-50 cost-sharing model. In addition, DOE/NNSA will remove the cesium devices at no cost to the site as part of its long-standing program to permanently remove radiological sources that are no longer needed. These efforts support the U.S. Government's commitment at the March 2016 NSS to replace 34 cesium-137 devices with alternative technologies by the end of 2020. NNSA's Office of Radiological Security should be commended for its innovative and creative CIRP program.

In addition, the U.S. National Science and Technology Council formed the Interagency Working Group on Alternatives to High-Activity Radioactive Sources (GARS) to develop a set of best practices for federal agencies to help them transition to alternative technologies in a way that meets technical, operational, and cost requirements. Chartered through the end of 2016, GARS released a report on alternative technologies which outlined four key categories of possible action: federal procurement and grant-making; agency priorities; education and outreach; and research and development.[20] Congress should consider providing increased funding to DOE/NNSA's Office of Radiological Security so that they have sufficient funds for both their CIRP and OSRP programs. Currently, these programs are not sufficiently funded to implement a wide-scale national program, and funding for the CIRP and OSRP programs should be doubled.

Recommendations

A global effort is urgently needed to accelerate efforts to secure the highest risk radiological materials and to phase-out the use of cesium-137 in blood irradiators to achieve permanent

[19] This program is managed by NNSA's Off-Site Source Recovery Project (OSRP). See http://osrp.lanl.gov/.

[20] The United States is also evaluating alternative technologies through a Government Coordinating Council/Sector Coordination Council Working Group (GCC/SCC) led by the Department of Homeland Security. This Working Group, which allows for public and private sector engagement, is aiming to publish a report which will identify specific cases where further developing or adopting alternative technologies can benefit national security and radioactive waste disposal issues without affecting the efficiency of industrial, medical, and research applications. See final report, "Transitioning from High-Activity Radioactive Sources to Non-Radioisotopic (Alternative) Technologies: A Best Practices Guide for Federal Agencies: https://www.whitehouse.gov/sites/default/files/microsites/ostp/ndrd-gars_best_practices_guide_final-.pdf.

threat reduction. Despite increased focus on the issue of radiological security and the need to consider replacement technologies, only France, Norway, and Japan have made it a national priority to completely phase-out all of their cesium blood irradiators. In addition, only 28 countries out of the more than 50 countries that attended the NSS in March 2016 adopted the French-sponsored Joint Statement on Strengthening the Security of High Activity Sealed Radioactive Sources. This represents only 54% of NSS participating countries and reflects the need to draw much greater attention to this issue and accelerate efforts by other countries to follow the example set by France, Norway, and Japan, and move towards zero risk by adopting alternative technologies for cesium blood irradiators.

Develop a strong national strategy for disposal of cesium sources

The use of non-isotopic technologies negates the need for security and disposal requirements and eliminates the risk that radioactive sources will become orphaned. States should develop a strong strategy for disposal and "end-of-life management" of cesium sources, including financial assurances, return to original supplier, and term limits for interim or on-site storage. States should also consider a "justification" requirement in their licensing process, placing the onus on operators to make the case for the continued use of gamma irradiators for blood sterilization, given the availability of x-ray irradiators or other available and equivalent technologies.

The proper disposal of radioactive materials used by the private sector is the responsibility of the licensees who benefit from them commercially. However, commercial disposal access and security considerations related to high-activity sources has led to a temporary increase in government involvement, including the assumption of significant costs related to disposal. Most countries do not have a permanent waste disposal facility for high-activity cesium sources and other radionuclides, requiring users to send their material back to the original supplier, recycle or commercially dispose of these materials, or give it back to federal programs and facilities for appropriate disposal. If commercial disposal options for high-activity cesium devices are available, states should reduce and ultimately eliminate routine subsidized disposal and establish limits on the amount of time a source can be stored at a site. Such a change in national policy (if warranted) will significantly impact life-cycle costs, shifting costs back to commercial users. This action will likely affect future purchase and replacement decisions.

Promote an education campaign and data sharing to support wide-spread radioactive replacements and overcome barriers to industry acceptance

When a hospital or medical facility considers purchasing a cesium blood irradiator for the first time or considers buying a replacement for its existing cesium blood irradiator, replacement technology should be considered an available and equivalent option. The key to broader understanding and acceptance of cesium alternatives will require educating operators on alternative options. Industry acceptance may currently be hampered by information gaps such as life-cycle costs as well as a lack of technical or scientific data that compares performance applications or technical equivalency. This will require governments and operators to share

information on independent clinical comparisons and academic and technical literature reviews. Licensees should conduct outreach to users of alternative technologies and survey their experiences and challenges. This information should then be shared with the broader international community to assist other countries in making an informed decision to adopt alternative technologies. Information sharing could be achieved by creating online forums to facilitate knowledge exchange as well as conducting educational and social networking campaigns.

For research and medical facilities that are private and for-profit institutions, a strong business case template for alternative technologies should also be developed that provides a roadmap that would cover costs and operational and scientific considerations that need to be addressed to ensure a smooth transition. Elements of this roadmap should include life-cycle cost comparison of devices (lifetime maintenance and reliability costs), operational competency (training and certification), regulatory policies (financial and/or administrative burden), and infrastructure requirements (disposal capacity and associated costs). Operators should also consider other cost reductions, such as relief from regulatory burdens associated with radioactive material, and reduction in licensing activities, regulatory inspections, sealed-source inventory reporting, and mandatory security requirements. Although alternative technologies may be required to meet new regulations depending on the specifics of national regulatory policies, these regulations may be less onerous than those for radioactive sources.

For blood banks and operators, detailed throughput and reliability comparisons between cesium and current x-ray models would allow a blood bank to determine the feasibility of the switch based on the levels of normal blood demand for their facility and the operational constraints of the current x-ray device. If it is feasible to replace cesium blood irradiators with little or no reported loss of performance, contingency planning for the potential of being off-line for several days should be made for those with critical supply requirements.

Educate the private sector on liability and insurance implications for utilizing high-activity radiological sources

Although the liability and insurance regimes vary between states, the intentional misuse of radioactive sources could have significant effects on a global scale. The indirect liability costs related to possession and use of radiological sources should be considered when making source management and use decisions. In the United States, for example, the Terrorism Risk Insurance Act (TRIA) was established to manage liability claims resulting from acts of terrorism by providing government backstop on losses. However, this legislation has not been effective for addressing damages related to radiological source misuse because commercial liability insurance policies required to cover initial damages have typically excluded nuclear and radiological terrorism from coverage. Additionally, very few user facilities have insurance coverage for this contingency and are not aware that they potentially could be held liable for hundreds of billions of dollars in damages due to malevolent use of devices under their control. More should be done to educate senior level officials in medical and research facilities of their

potential liability from high-risk radiological materials so they can make risk informed decisions on the continued use of cesium devices.

Provide increased financial incentives for the use of alternative technologies

The regulator or other federal agencies have a key role to play in the adoption of alternative technologies by providing financial incentives for conversion, or more often disincentives for the continued use of radioactive sources. Disincentives could include increased requirements for security, financial guarantees, and obstacles to licensing radioactive sources. In some countries, regulators are now requiring licensees to provide a financial guarantee to ensure sufficient funds are available to address the decommissioning of their facility and the disposal of their sealed sources. The financial guarantee is intended to address the fact that neither licensees nor manufacturers currently bear the full life-cycle cost of such sources, including disposal costs. Incentivizing the move toward alternative technologies could include tax or financial drivers (e.g., federal subsidies or the establishment of a private sector fund) to incentivize operators to replace radioactive technologies with effective alternatives, where applicable, and lead by example in transitioning to alternative technologies that meet technical, operational, and cost requirements.

Identify and work towards solutions to national capacity challenges in support of a national phase-out

In many countries, the immediate phase out of cesium devices for blood irradiation will not be feasible until several pre-conditions become available. This may require states to evaluate phase-out strategies in stages to ensure that: (1) viable alternative technologies are available; (2) existing device manufactures can support the required surge capacity for alternative technologies; (3) disposal pathways, including transportation containers and the disposal sites, are established and available (if the return to supplier is not an option); and (4) sufficient time is scheduled for an orderly transition. States should fully evaluate these factors and develop both a timeline and strategy for working towards a national phase-out plan for cesium devices.

Accelerate regulatory approvals for new types of alternative technologies for medical applications

In many countries, obtaining the regulatory clearances and approvals for alternative technologies requires a very long and onerous process. In the United States, for example, the FDA 510K clearance and premarket notification requires that new devices must meet several conditions, including a demonstration that a device with different technological characteristics does not raise new questions of safety and effectiveness. Other countries may require similar reviews as well as year-long clinical studies for approval. Although these lengthy approval processes were put in place to ensure the highest level of safety of new devices entering the market for medical care, states should review their current requirements and determine if they can be assigned a higher priority or “fast track” review and certification. In several countries, priority reviews and accelerated approvals have already been established for break-through

therapies and drug treatment. A similar process should be established for the review of alternative technologies. This may encourage more domestic competition as well as spur international manufacturers to enter new geographic markets and make alternative technologies available to other countries and operators.

Encourage the IAEA to promote alternative technologies and provide guidelines for its use

In support of the 2016 NSS Joint Statement on Strengthening the Security of High Activity Sealed Radioactive Sources, IAEA Member States should encourage the IAEA to promote and support research efforts on the development of technically and economically realistic and acceptable non-HASS technologies, incorporating in these efforts the manufacturers, end-users, standards-setting bodies, and technical experts. In order to support international engagement on alternative technologies, the IAEA should consider formally adopting alternative technologies as part of its program mandate and play a coordination role in defining standards and guidance, providing assistance (whereby feasible), and facilitating access to information related to alternative technology to support the decision-making of operators, regulatory bodies, and other competent authorities. Within the IAEA, the Technical Cooperation (TC) Division may have to respond to a Member State request and provide a cesium or cobalt device instead of an alternative technology that cannot be used to make a dirty bomb because of (1) lack of sufficient funding, and (2) lack of a formal IAEA policy that requires them to take alternative technologies into consideration when responding to Member State requests for various types of medical equipment. The IAEA should also develop a program plan on alternative technologies with a defined scope and mission as well as establish a lead office to coordinate such an effort. The establishment of an IAEA Coordinated Research Project (CRP) to develop an open design that would be available for many states and involve R&D organizations, manufacturers, and suppliers should also be considered as a means for providing information and technology solutions to requesting Member States. The growing requests by Member States for improving access to effective cancer care must be balanced with the heightened concerns of radiological terrorism and the promotion of alternative technologies.

Ensure that end-users are afforded reliable, cost-effective service, maintenance, and replacement parts

To assist countries with their decision-making process related to adopting alternative technologies, providers of x-ray blood irradiation devices should ensure that users are provided with reliable, cost-effective, and timely delivery of services, maintenance, and replacement parts for devices. Supply chain execution is critically important, as many hospitals and medical facilities do not maintain a back-up supply of blood. It is imperative that device repairs and device down-time is limited to shortest amount of time as possible, and manufacturers provide full warranties that include preventative maintenance, dose mapping, and full and timely coverage.

Encourage users to put in place reciprocal arrangements to meet demands for blood product

Encourage blood bank facilities to develop a large network of reciprocal arrangements and exchanges with other blood bank centers for back-up sterilization services. This will ensure the continuity of services and patient care during the replacement, installation, downtime, calibration, and maintenance. The development of a relationship with one or more neighboring blood bank centers will greatly assist blood bank centers, especially those that only have one blood sterilization device, as they do not have a back-up service within their facility. Such a network can also assist in coordinating blood bank community resources for the purposes of decreasing the risk of interruptions, improving the quality of emergency services, and developing a comprehensive network of emergency medical services responsive to the blood supply and needs of the medical institution.

About the Authors

Andrew J. Bieniawski serves as Vice President for Material Security and Minimization after 25 years of serving in senior-level positions with the U.S. Department of Energy and the National Nuclear Security Administration. Bieniawski leads key NTI projects related to nuclear materials security and minimization, including the Global Dialogue on Nuclear Security Priorities, the International IAEA LEU Bank, and the International Partnership for Nuclear Disarmament Verification. He is also an expert in radiological threat reduction. Bieniawski has a bachelor's degree in Nuclear Engineering from Pennsylvania State University and Master of Arts degree from the Paul H. Nitze School of Advanced International Studies at Johns Hopkins University.

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About the Nuclear Threat Initiative

The Nuclear Threat Initiative works to protect our lives, environment, and quality of life now and for future generations. We work to prevent catastrophic attacks with weapons of mass destruction and disruption (WMDD)—nuclear, biological, radiological, chemical, and cyber. Founded in 2001 by former U.S. Senator Sam Nunn and philanthropist Ted Turner who continue to serve as co-chairman, NTI is guided by a prestigious, international board of directors. Ernest J. Moniz serves as chief executive officer and co-chairman; Des Browne is vice chairman; and Joan Rohlfing serves as president.