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Promoting Alternatives to High-Risk Radiological Sources: The Case of Cesium Chloride in Blood Irradiation

Miles Pomper, Egle Murauskaite, Tom Coppen

Middlebury Institute *of* International Studies at Monterey

James Martin Center for Nonproliferation Studies

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James Martin Center for Nonproliferation Studies
Monterey Institute of International Studies
CNS Washington, DC, Office

1400 K Street, NW, Suite 1225
Tel: 202-842-3100
Fax: 202-842-0556
http://www.cns.miis.edu

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Miles Pomper

Egle Murauskaite

Tom Coppen

James Martin Center for Nonproliferation Studies

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ABOUT THE AUTHORS

Miles Pomper

Miles Pomper is a Senior Research Associate in the Washington DC office of CNS and a well-known expert on nuclear security issues. He serves as co-chair of the Fissile Materials Working Group, a coalition of more than 70 nongovernmental organizations worldwide working on nuclear security issues and has published widely on issues related to the minimization of nuclear and radiological materials. He holds a master's degree in international affairs from Columbia University and a master's degree in journalism from Northwestern University. Before joining CNS he served as Editor-in-Chief of *Arms Control Today* (2003-2009). Previously, he was the lead foreign policy reporter for *CQ Weekly* and *Legi-Slate News Service*, where he covered the full range of national security issues before Congress, and a Foreign Service Officer with the U.S. Information Agency.

Egle Murauskaite

Egle Murauskaite is a Research Associate in the CNS Washington DC office. She specializes in trends of WMD-specific and dual-use technology transfers, with the focus on the Middle East and South Asia. Her work regularly appears in a number of professional publications, and is presented at international academic and policy conferences; recently she also co-edited a volume on the insights for the Middle East peace process. Prior to joining CNS, Murauskaite has been working as a research assistant with Ambassador Fahmy at the American University in Cairo, and has also taught a short course "Introduction to Politics and Negotiations" at Vilnius Satrija Youth Center. She holds an MA (Summa Cum Laude) in International Security Studies from Sciences Po Paris, and a BA in Economics from the Stockholm School of Economics in Riga.

Tom Coppen

Tom Coppen is a Fulbright Fellow with CNS and a PhD candidate at the Centre for Conflict and Security Law at Utrecht University, the Netherlands. He specializes in the role of international law in matters of arms control and non-proliferation. He has published a number of academic pieces on nuclear non-proliferation, presented his work at various conferences and served as a Special Advisor to the delegation of the Netherlands at the 2010 NPT Review Conference, as well as the 2012-2014 NPT Preparatory Commissions. He holds a Master's degree in Public International Law and teaches International and European Conflict and Security Law in Utrecht.

EXECUTIVE SUMMARY

In 2008, the U.S. National Academy of Sciences published a landmark report *Radiation Source Use and Replacement*, which examined the feasibility of replacing high-risk radioactive sources with less risky (and most likely non-isotopic alternatives) in order to forestall an act of radiological terrorism. The report expressed particular concern about the threat posed by the continued use of one isotope—cesium chloride—whose unique characteristics make it especially susceptible to be being used by terrorists. The report recommended that government policies be enacted that would lead to the substitution of less hazardous technologies.

The Academy's conclusions were only partially embraced by the United States government. In 2010, an interagency Task Force on Radiation Protection and Security submitted its quadrennial report to the President and Congress. The report emphasized the security measures that had been implemented to protect existing risk-significant radiological sources. It concluded that for cesium chloride, "immediate phase-out would not be feasible because the sources are extensively used in a wide range of applications in medicine, industry, and research."[1] However, it concluded "That a gradual stepwise phase-out could be feasible as alternatives become technologically viable and if disposal pathways are identified." It also noted that "While alternatives exist for some applications, the viability, relative risk reduction achievable, and state of development of these alternatives vary greatly."[2]

The area where an alternative to cesium chloride is considered most viable in the short term is its use in blood irradiation. The Task Force report noted that for blood irradiation, "x ray technologies were cost competitive with radionuclide technologies on an annualized basis" although concerns remained about their throughput and reliability. Other technologies, such as linear accelerators (LINACs), could be used for blood irradiation in addition to their principal use in cancer treatment. Replacing cesium chloride in blood irradiators would be particularly useful because the irradiators are primarily used in hospitals and blood banks, which are by necessity publicly accessible facilities, raising security concerns.

Indeed, while U.S. efforts have generally stalled, awaiting further technological, commercial, and waste disposal developments, foreign governments, industry, and some U.S. state authorities have taken steps to encourage the use of alternatives to cesium chloride in blood irradiation. They have demonstrated that with the proper

[1] U.S. Radiation Source Protection and Security Task Force 2010 Report, August 11, 2010, p.ii.
[2] Ibid.

incentives such conversions should be feasible for the United States—the world's largest market for cesium chloride—as well as for other countries. In the United States, given its diverse needs and large number of sources, such changes are likely to have to be made slowly and carefully in order to ensure the protection of patient health. Like the current program of converting research reactors to use low enriched uranium, a strong and consistent government commitment to the conversion is essential if any progress is to be made.

To chart a strategy for shifting to alternatives to cesium chloride, the James Martin Center for Nonproliferation Studies (CNS), with the support of the Foreign and Commonwealth Office of the United Kingdom, held a workshop in January 2014 among relevant stakeholders from domestic and foreign governments, industry, health care providers, security experts, and the nongovernmental community. The workshop helped generate recommendations in this domain and in the broader area of replacements for radiological sources.

Following the workshop discussions, the CNS team conducted a substantive review of the state of scholarly and policy best practices to date, consulting with relevant experts, and subsequently recommends the following steps:

International

- Supportive states, particularly the United Kingdom and the United States, should offer a "gift basket" at the 2014 Nuclear Security Summit (NSS) in the Netherlands, related to high-risk radiological sources. The states should announce the launch of an international coalition to research the feasibility of alternative non-isotopic technologies and the intention to provide the 2016 NSS with a roadmap for the conversion to such sources, in a phased manner and where technically and economically feasible. Ending the civil use of cesium chloride, particularly its use in blood irradiators, should be a priority for this coalition. However, the coalition should also examine the possibility of promoting alternatives to similar practices using other high-risk sources, such as cobalt-60 and cesium-137, in teletherapy devices.[3] The U.S. government (specifically the Department of Energy's National Nuclear Security

[3] See Charles Ferguson, "Ensuring the Security of Radioactive Sources: National and Global Responsibilities," 2012, US-Korea Institute at SAIS, Table 1: Radioisotopes of Security Concern on p. 6 and Table 3: High-Risk Radioactive Sources on p. 10. Also see DOE/NRC Interagency Working Group on Radiological Dispersal Devices, Report to the Nuclear Regulatory Commission and the Secretary of Energy, "Radiological Dispersal Devices: An Initial Study to Identify Radioactive Material of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition," May 2003.

Administration) and the Global Partnership should support annual technical and policy conferences akin to the RERTR conferences in HEU conversion to push this initiative forward. Caution should be exercised in extending new licenses for high-risk sources and governments should consider ending the issuance of new licenses, particularly for cesium chloride. At the very least, this should be a declared policy goal. Any new licenses should require a written justification on the part of the licensee as to why they are not using non-isotopic technology. Licensees should also be required to provide financial assurance to cover the costs of disposal.

- The role of International Atomic Energy Agency (IAEA) technical cooperation programs should be reviewed to ensure that the agency provides non-isotopic alternatives to high-risk radiological sources when technically and economically feasible and appropriate for meeting public health needs. The IAEA should continue its efforts to ensure that each Member State has an up-to-date registry of sources.

- Discussions with the public health and medical communities need to be broadened to ensure their concerns are addressed. Similarly, health regulators, such as the Food and Drug Administration, should be encouraged to consider first-of-a-kind alternatives to radiological sources on an expedited basis. FDA expedited approval several years ago in another anti-terrorism effort when South Africa and Australia shipped the first batch of a new variety of the medical isotope molybdenum-99 (Mo-99 that was derived from safer low enriched uranium targets rather than nuclear-weapon-usable highly enriched uranium).

- Governments should seek mechanisms to increase cooperation among facilities that use X-ray blood irradiators so as to have back-up capacity when one of the X-ray machines is temporarily out of commission, and promote cost-sharing. In the United States, Center for Medicare and Medicaid Service should be asked to explore options in this regard.

- The United States and other countries need to move forward expeditiously to find pathways for long-term disposal of high-risk sources. When necessary, disposal costs should be subsidized to ensure safety and security is not compromised by cost factors.

United States

All High-risk Radiological Sources

- Congress should pass legislation, or the White House should set a policy, directing the interagency Task Force to prepare within one year a proposed roadmap for the substitution of non-isotopic alternative technologies for high-risk radiological sources in a phased manner and where technically and economically feasible, both in the United States and for recipients of U.S. technology overseas. The emphasis should first be on slowing and eventually ending the introduction of new high-risk sources, and then accelerating the decommissioning and replacement of existing sources, consistent with public health and industry requirements and the need for a pathway towards disposal. A particular focus should be placed on ending the use of cesium chloride, especially in blood irradiators.

- This roadmap should provide an estimate of where and how non-isotopic alternatives might best be substituted for radiological sources overseas, the estimated costs for doing so, and how existing U.S. funds, such as the Peaceful Uses Initiative with the International Atomic Energy Agency, might be allocated to this purpose, including training in the use of alternatives. This roadmap should also propose how the costs of this initiative might be shared with other members of the Global Partnership.

- The roadmap should direct the NRC to:

    - Discontinue licensing for each application of new high-risk radiation sources as soon as practicable, but in any event no later than 2024, unless it can be demonstrated that technologically and economically feasible alternatives are not available.

    - Immediately initiate a program to require all new licensees wishing to replace a high-risk radiation source with another one of similar kind to conduct an internal feasibility review and produce justification for this choice**.**

    - Immediately establish a new license fee structure, or other means of providing financial assurances that funds will be available for the disposal of high-risk sources, including their transportation to the designated disposal area and their storage while they await disposal.

- Prohibit the export of high-risk radiation sources to other countries as soon as practicable, but in any event no later than 2024, unless it can be demonstrated that technologically and economically feasible alternatives to maintain adequate public health standards are not available.
- The United States government should heed the advice of the 2010 Task Force report to enhance short- and long-term research and development for alternative technologies, and Congress should direct funding to this effort. One of the priorities should be advancing technologies that adapt well to developing country conditions, including limited electricity and water supplies, and shortages of trained workers, particularly health physics specialists. Another priority area should be the development of appropriate shipping containers for disused sources. A third important issue to address would be conducting a more rigorous assessment of various alternative technologies.
- Congress needs to take steps to support the continuous search for sustainable solutions to dispose of "Greater than Class C" radioactive waste, and assess the prospects for putting together an incentives package for supporting secure storage of such disused sources at licensee sites.
- Independent scholars should assess:
    - The role that insurance and liability issues might play in influencing the choice between high-risk sources and non-isotopic alternatives;
    - Developing country use of radiation sources and alternatives;
    - Medical effectiveness of various technologies.

Cesium Chloride-specific

Consultations should be carried out with other countries to draw on their best practices of blood irradiation and challenges they've encountered in using different types of technology. In addition, the interagency task force in relation to cesium chloride should:

- Propose a plan for rigorous evaluation of alternatives from a both a medical and technical standpoint, including patient outcomes in the case of medical

technology and systematic collection of hard data about the performance of different technologies employed by the facilities.

- Encourage more competition in the market for X-ray devices through incentives, such as government purchases, in order to lower the cost of the devices to end-users.
- Provide estimates for the costs of phase out of cesium chloride, including any incentives needed to maintain the operating costs for non-profit end users at current levels and ensure the same level of medical outcomes for patients.
- Ensure that cesium chloride customers have sufficient credible and reliable information about the range of alternatives potentially available to them before making a buying decision. As part of this effort, develop a spreadsheet to allow end users to input the various costs for gamma versus X-ray devices in order to compare lifecycle costs.

RISKS AND BENEFITS OF CESIUM CHLORIDE IN BLOOD IRRADIATION

Characteristics

The only stable isotope of cesium (Cs) is Cs-133, which occurs naturally. There are a number of radioactive cesium isotopes that are produced when uranium or plutonium undergoes fission. Commercially useful radioactive cesium is produced by chemical separation of cesium from other fission products. Radioactive Cs-137, which is about 25-32% of the cesium yield, is a very useful radionuclide due to its long half-life (just over 30 years) and the fact that its beta decay produces a single relatively high-energy (~662 keV) gamma ray. Its many applications include blood irradiation, cancer treatments (e.g., radiotherapy, teletherapy, brachytherapy), irradiation of small animals used in research studies, seed irradiation, food irradiation, oil well logging, and a wide variety of industrial applications, such as moisture-density gauges, thickness gauges, etc.

The only location where Cs-137 is currently separated and produced for commercial purposes is at the Production Association (PA) Mayak in Chelyabinsk, Russia. It is adapted for use in blood irradiators by REVISS, a UK-based company, which manufactures the source casings and provides technical support, including arranging for special containers to transport the radioactive sources.

Cs-137 is typically produced, stored, and used in devices in the physical form of cesium-chloride (CsCl), a salt with chemical properties (including total solubility in water) similar to those of sodium chloride (NaCl), or common table salt. Moreover, Cs-137 is one of the most commonly used radioactive materials. When it is present in large amounts in a device, such as a medical blood irradiator, it is classified as an IAEA Category 1 source.[4] These properties of CsCl raise extreme concerns when accidental or intentional misuse scenarios are considered.

CsCl is commonly used for blood irradiation prior to blood transfusions to prevent Graft-Versus-Host-Disease (GVHD) – an immuno-related complication caused by white blood cells in donor blood attacking tissues in the body of the recipient, which nearly always proves fatal. GVHD poses a risk for recipients whose immune system is weakened, suppressed, or defective, including neonatal patients; in addition, there is a heightened risk of GVHD in blood transfusions where donor and recipient share close genetic ties (i.e. family members or members of a particularly homogenous population). Blood irradiation using CsCl is carried out with self-shielded or self-contained irradiators, which typically weigh around 1,000 kg. There are around 530 such CsCl irradiators in the U.S., mainly in hospitals and blood banks.[5]

Advantages

CsCl lends itself particularly well for use in self-shielded blood irradiators. First, its half-life of just over 30 years means one source of CsCl can usually last through the lifetime of any device that it is used in, reducing the possible transportation-associated risks with such infrequently required replacements. Second, its moderate level γ-ray energy emissions mean that the shielding requirements for Cs-137 irradiators are not so thick as to become impractical. The third advantage of the use of CsCl in blood irradiators is the relatively low price of purchasing such a source. Fourth, the costs of operating a CsCl blood irradiator are also low: it requires little electricity and is fairly uncomplicated to use, thus not requiring specially trained personnel and typically requiring little maintenance throughout its useful life.

[4] Category 1 source category is the most dangerous in IAEA classification set out in Safety Guide RS-G-1.9 "Categorization of Radioactive Sources." Exposure to such a source for periods as brief as minutes or a few hours can cause permanent injury or death.

[5] U.S. National Academy of Sciences, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement," 2008, p.35.

Disadvantages

The downside to the use of CsCl, and the rationale for this report, is its suitability as a source material for use in radiological dispersal devices (RDDs). Such weapons could couple CsCl with different means of dispersal (e.g., conventional explosives—a "Dirty Bomb") to cause significant adverse health effects or death to those exposed to it, contaminate large areas, and cause public panic. Belligerent actors could obtain this material from operating devices in hospitals or other facilities, which often by their nature have limited security due to the necessity for public access. They could also take advantage of the fact that many countries—including the United States—lack a mechanism for disposing of disused sources - therefore these are often stored without proper security measures, or sometimes even abandoned.

The latter concern was amply illustrated by the Goiania incident: in 1985, two persons broke into a former radiotherapy institute in Goiania, Brazil, taking a Cs-137 teletherapy unit with them. Not realizing what material the unit contained, the thieves attempted to dismantle it in order to sell it for scrap; in the process, they accidently damaged the Cs-137 container, which led to the eventual unwitting dispersal of the radioactive material inside it.[6] The health effects of the incident were severe. Four people died of radiation sickness. In total, 249 persons were contaminated, internally or externally, of which twenty needed hospitalization. Overall, 112,000 persons had to be monitored for possible adverse health effects; those highly exposed required long-term monitoring. In terms of clean-up costs, decontamination alone cost tens of millions of U.S. dollars; the effort took three years. For other negative effects, such as the social stigma and harm to agricultural production in the affected region, the total material and immaterial damages are immeasurable. It is no stretch to conclude that these effects, in case of a purposeful dispersion of cesium chloride in densely populated areas or key economic or industrial zones could be even worse, making an attack with a Cs-137-based RDD a legitimate national and international security threat.

This threat is exacerbated by a number of other characteristics of CsCl. The fact that it is supplied in the form of a salt, or a talc-like powder, makes it easy to handle and disperse, therefore enlarging the potential area that would be affected by an RDD. CsCl is, moreover, easily soluble in water, which creates further opportunities for the belligerents to spread the material; it also means that upon entering the human body, CsCl will disperse quickly throughout the whole body. When dispersed, CsCl easily

[6] See, for example, IAEA, "The Radiological Accident in Goiania", STI/PUB/815, Vienna, 1988, http://www-pub.iaea.org/mtcd/publications/pdf/pub815_web.pdf.

binds itself to surfaces and migrates into concrete, further complicating the task of decontaminating an environment affected by a CsCl-based RDD.[7] A final factor relating to the potential security threat posed by CsCl is its wide availability: as mentioned above, there are around 530 CsCl-based blood irradiators in the U.S. alone; in addition, the U.S. houses 490 research irradiators and an unknown number of additional CsCl sources.[8] In general, such sources are not located in secure areas, but are rather 'soft targets,' such as hospitals, clinics, blood banks, or universities. In other words, CsCl is not only a potentially harmful radioactive source, but it is easily dispersible, difficult to clean up, and relatively accessible.

ALTERNATIVE BLOOD IRRADIATION TECHNOLOGIES

Are there alternative technologies that might provide the public health benefits of CsCl for blood irradiation, while lowering the security risks? And are these alternative technologies sufficiently robust, reliable, and economically attractive to be commercially viable? In this section we examine the most widely accepted alternatives to CsCl for this purpose, building on the discussions among international medical practitioners and scientists using this technology, as well as manufacturers, regulators, and independent experts.

The primary focus is X-ray technology, presently the most common alternative to CsCl for blood irradiation in the U.S. We discuss the benefits of switching to this technology, as well as the challenges associated with such a transfer. Other alternatives to CsCl include the use of cesium sources in a non-powdered form, cobalt sources, linear accelerators (LINACs), and photochemical treatment. These will be briefly considered at the end of the section.

It is worth noting that cesium and X-ray irradiators are devices dedicated to blood irradiation, usually operated by specialized institutions or departments external to the healthcare facilities that are actually using the irradiated blood (and thus have to purchase it from the irradiation service providers); in contrast, many user facilities already have LINACs and cobalt sources for cancer therapy and other treatments. These units, although they are designed for other purposes, can be used for blood irradiation on a limited basis. For example, a blood bag holder can be placed where a patient would be exposed and the LINAC operated to irradiate the blood instead of a person.

[7] U.S. National Academy of Sciences, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement," 2008, p.28.
[8] Ibid.

Such use involves a tradeoff of patient treatment time for blood irradiation time, using a far more expensive machine and more highly skilled operators - therefore it is typically not thought of as a high capacity system, but one that has a useful side benefit for limited blood irradiation usage on demand.

The location of irradiators is important to take into account when considering the additional costs and delivery time aspects under each method. In addition, while views of appropriate cost assessment and technical and public health feasibility of various alternatives are often colored by the public-private sector divide, presently one of the most serious problems is the limited availability of objective medical and other assessments - and the general lack of awareness about the range of alternatives.

X-ray Blood Irradiators

This technology, based on a non-radioactive source, comes in two forms: either a machine where a drawer holding blood bags is irradiated between two opposable X-ray tubes, or a design where the blood bags are placed on a carousel and a single tube emits X-rays in a 360 degree output to irradiate them (see Figures 4 and 5 in the Appendix). In many ways the performance of X-ray technology closely matches that of gamma blood irradiators using cesium-137 (CsCl) as the source (see Figures 2 and 3 in the Appendix), but the issue of comparability of costs, reliability, and additional resource requirements has thus far prevented a consensus on the feasibility of conversion.

Effectiveness

No identifiable medical or scientific study has been conducted to directly compare the effectiveness of X-ray and gamma irradiators in preventing GVHD,[9] partially because of the extreme rarity of the disease (estimated at less than 1 per million). Among medical researchers, there does not seem to be a consensus as to whether gamma rays and X-rays produce the same biological impact on blood cells,[10] but most note that both have the capacity to effectively prevent GVHD. Notably, Japan with its particularly

[9] Radiological Devices Advisory Panel, "Blood Irradiators – Unclassified: Executive Summary," April 12, 2012, p. 17.

[10] Advisory Committee on the Medical Uses of Isotopes, "Report on 137CsCl Irradiators," October 13, 2008 (based on Brian Dodd and Richard J.Vetter, "Replacement of 137Cs Irradiators with X-Ray Irradiators," *Health Physics*, June 17, 2008; Jenny Trelevean et al., Guidelines on the Use of Irradiated Blood Components prepared by the British Committee for Standards in Haematology Blood Transfusion Task Force, British Journal of Haematology, 2011, Vol. 152 No. 1, pp. 35-51.

homogenous population, subsequently deemed to be at a higher risk of GVHD,[11] is one of the most prominent advocates for the use of X-ray based irradiators, with no reported GVHD cases since 2000, when the technology was introduced.

Prevalence

In order to prevent GVHD, the American Association of Blood Banks (AABB) recommends a radiation dose of 25Gy (minimum 15Gy) for treating blood.[12] However, many countries recommend a dose of around 20-35Gy.[13] British Guidelines, meanwhile, set the maximum at 50Gy to avoid damage to blood cell components.[14] The only X-ray blood irradiators presently meeting the 25Gy standard and approved by the U.S. Food and Drug Administration (FDA) for human use are Raycell, manufactured by Best Theratronics (also the manufacturer of the most popular Cs-137 irradiator series Gammacell), and Rad Source's RS3400.

Countries presently using these X-ray irradiators include Canada, France, Germany, Italy, Norway, Sweden, the United Kingdom, and some U.S. states (a majority of blood irradiators in the U.S. are still based on radioactive sources). Meanwhile, Japanese X-ray irradiators made by Hitachi Medical Corp. deliver a radiation dose of 15Gy (and up to 35Gy), but have not yet been approved by FDA. Although developing countries represent a large market for blood irradiation, most tend to rely on LINACs, rather than blood irradiators.[15]

The American Association of Physicists in Medicine (AAPM) surveyed its members (mostly working at hospitals and blood banks) in 2008 about their use of blood irradiators:[16] 81% of the 363 respondents had an irradiator at their facility, and of those 85% were Cs-137 units, 9% - X-ray units, and 6% used LINACs. However, only 40% of CsCl or LINAC units were used to irradiate blood, with X-ray irradiators used for that purpose approximately half the time - other, more frequent, uses of irradiators include animal and material irradiation for research purposes. A similar 2008 survey by

[11] Franz F. Wagner and Willy A. Flegel, "Transfusion-Associated Graft-Versus-Host Disease: Risk Due to Homozygous HLA Haplotypes," *Transfusion*, 1995, Vol. 35 No. 4, pp. 284-291.
[12] Radiological Devices Advisory Panel, 2012.
[13] Alison Sinclair, "X-ray Versus Gamma Irradiation of Blood Components for Prevention of Transfusion-Associated Graft Versus Host Disease," Technology Assessment Unit of the McGill University Health Center, Report No. 51, April 12, 2011.
[14] Jenny Trelevean et al., Guidelines on the Use of Irradiated Blood Components prepared by the British Committee for Standards in Haematology Blood Transfusion Task Force, January 2013.
[15] Charles Ferguson, "The Threat (and Benefit) of Cesium Chloride," Presentation at Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.
[16] Results reported by Advisory Committee on the Medical Uses of Isotopes, 2008, p. 4.

American Association of Blood Banks (AABB), focusing specifically on hospitals, showed that of the 345 respondent facilities, just over half irradiated blood products in-house, with 80% using Cs-137 and 14% using X-ray blood irradiators.

Table 1: Prevalence of Cs-137 and X-ray Blood Irradiators in Selected Countries.

	Number of Cs-137 irradiators	Number of X-ray irradiators	Share of Cs-137
U.S.	300-1,000	Data not available	Data not available
Japan	120	280	30%
France	12	17	41%
Norway	14	3	82%

Sources: World Institute for Nuclear Security, Workshop Report "Alternative Technologies to Radioactive Sources," October 8-9, 2013, Brussels, pp. 5, 9; Brian S. Kirk, "Decommissioning and Disposal Options for Cesium-137 Blood Irradiators," *Rad Journal*, 28 September 2001; Gregory J. Van Tuyle et al., "Reducing RDD Concerns Related to Large Radiological Source Applications," Los Alamos National Laboratory, 2003, p. 23.

Throughput

The number of blood bags that can be processed during one operation cycle ranged from 5 to 7 in CsCl machines, with newer X-ray irradiators able to treat up to 7 bags at a time. Both Gammacell and Raycell machines can irradiate 4 units of blood per cycle.

The Best Theratronics X-ray machine takes around 4min to deliver 25Gy, compared to approximately 7min cycles of Cs-137 based machines by the same manufacturer. The second-generation Japanese X-ray machines take around 5min to deliver 15Gy.

However, whereas the X-ray irradiation times stay constant throughout the lifetime of a machine, irradiators using Cs-137 require increasingly longer times to deliver the necessary charge as the radioactive source ages (e.g., a machine using a 29 year old source requires 12 minutes to irradiate a single blood bag).[17]

In terms of demand for irradiated blood and blood products, hospitals tend to use their irradiators for emergencies, when small quantities of blood are needed rapidly, and rely on regional or national blood centers for regular, larger volume supplies of irradiated blood. For instance, Montreal General Hospital, which is one of the two Level-1 trauma

[17] Sinclair, 2011, pp. 3, 5.

centers in Montreal, has estimated its urgent demand for blood units at 1148 annually, implying the need for up to 140 hours of blood irradiator machine operation per year.

Maintenance and Operability

The X-ray blood irradiation machines have no special requirements for environments in which they can be located or requirements on the qualifications of their users. An average X-ray irradiator weighs about 710kg (1,565lb), and is around 1.5m (4.9ft) high, 1.2m (3.9ft) wide and 0.5m (1.6ft) deep.[18] That compares favorably with many Cs-137 irradiator models, where an average machine weighs over 1,500kg (3307lb), and is sized at approximately 1.5m (4.9ft) high, 0.75m (2.5ft) wide and 0.9m (3ft) deep.[19]

Respondents to the 2008 AAPM survey indicated that 25% of CsCl irradiators had malfunctioned during the year and most had been repaired within 7 days, whereas X-ray irradiator malfunction was reported in 35% of the cases, with repairs within 7 days made available in 44% of those instances. The AABB survey of the same year suggests the annual downtime for 92% of CsCl irradiators lasted fewer than 2 days, whereas X-ray irradiators were reported non-operational for under 2 days in 79% of cases and over 30 days in one-fifth of cases. Other countries currently using X-ray irradiators reported downtimes ranging from 2 days to 2 weeks.[20]

The costs of purchasing an X-ray blood irradiator stood at approximately $250,000 in 2008,[21] while the price of an average CsCl irradiator purchased in the mid-1990s was $107,272[22] (approximately $160,454 in 2013 dollars). However, the maintenance service contracts for Cs-137 irradiators were considerably cheaper for most AABB-surveyed facilities: three-quarters of them paid under $10,000 annually with the rest paying between $10,000 and $25,000; meanwhile X-ray irradiators cost under $10,000 in maintenance for 61% of survey participants, with nearly 39% paying between $10,000 and $25,000. In addition, 85% of X-ray irradiator maintenance contracts did not include the replacement of X-ray tubes – the parts most prone to break and most expensive to replace ($10,000-40,000). Indeed, the X-ray tubes of these irradiators have a 2,000-hour warranty period (implying they would need replacement about every 3.7 years),[23] but

[18] U.S. National Academy of Sciences, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement," 2008, p. 92.
[19] Ibid, p. 89.
[20] Tadokoro et al., "Problems with Irradiators," Vox Sanguinis, Vol. 98 No. 1, 2010, pp. 78-84.
[21] Advisory Committee on the Medical Uses of Isotopes, 2008. It is believed, however, that this cost could decrease with increased competition in the industry.
[22] Celso Bianco and Ruth Sylvester, "Blood Irradiators in ABC [*American Blood Centers*] Member Centers," http://pbadupws.nrc.gov/docs/ML0827/ML082770826.pdf.
[23] Advisory Committee on the Medical Uses of Isotopes, 2008.

in practice, users have found the need to replace them around every two years, with the estimated lifespan of the machine averaging six to ten years.[24] The CsCl based irradiators tend to have a much longer average lifespan, with the half-life of Cs-137 being approximately 30 years. Furthermore, maintenance contracts for X-ray irradiators do not include physics services required to calibrate the device, and if such a specialist is not available on-site, calibration costs stand at up to $10,000 per year per device.[25]

On the other hand, the need to institute additional security measures to protect Cs-137 irradiators (e.g., installing physical barriers and adding surveillance) can cost the facilities $20,000-$25,000 up front,[26] with further costs potentially associated with maintaining security. Moreover, these expenses do not take into account hidden costs related to liability. Presently, none of the institutions operating blood irradiators that use radioactive sources carry, or are required to carry, insurance coverage for risks associated with those materials (e.g., in case they are stolen and/or used in an act of terrorism). Standard liability insurance policies available to medical facilities exclude CBRN-related events, and measures available for nuclear power plant operators do not apply in this case.[27] Indeed, in the absence of such coverage, licensees, operators, or manufacturers could be liable for massive damages in the event of a terrorist attack involving cesium chloride from blood irradiators.[28] Moreover, there is the cost (and the complex burden) of disposal, discussed further below, which to date is often borne by the government, not the user.

Finally, it is worth noting that in the 2008 AABB survey, 74% of respondents stated that they use another facility as a back-up for blood irradiation services, with only 14% of facilities admitting to having no back-up. Subsequently, irradiator downtime would likely not be a factor threatening the lives of emergency patients – whether they are being treated in a facility that uses X-ray or Cs-137 irradiators.

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[24] Susan F. Leitman, "The Role of Cesium-137 Irradiators in Transfusion Medicine," NRC CsCl Public Meeting, November 8-9, 2010, http://pbadupws.nrc.gov/docs/ML1031/ML103190184.pdf.
[25] Advisory Committee on the Medical Uses of Isotopes, 2008.
[26] World Institute for Nuclear Security, Workshop Report "Alternative Technologies to Radioactive Sources," October 8-9, 2013, Brussels, p. 5.
[27] George Moore, "Liability Issues for Use of Radionuclides," Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.
[28] Ibid.

Retirement Costs

One of the challenges in replacing or retiring radioactive source based blood irradiators is the extremely limited number of containers (less than 1% of containers currently in circulation) suitable for transporting them from the facilities that own them. Although the cost of such a shipment averages around $100,000, in early 2014 the Los Alamos National Labs backlog list for pick-ups in the U.S. stood at 48 Cs-137 based devices (64 radioactive sources) and 30 sites using Co-60 (1,154 sources).[29] International shipping is further complicated by the limited number of ships and ports that are not only able, but also willing to handle such cargo. In addition, the U.S. Nuclear Regulatory Commission (NRC) has noted that since most hospitals and blood centers are not-for-profit entities, it is highly problematic for them to be compensated for these technology retirement costs, complicating the practicalities of designing a Cs-137 phase-out incentive scheme even if there was political will to do so.[30] In contrast, the Japanese manufacturer Hitachi estimates that the costs for disposing of an X-ray irradiator at the end of its lifecycle would be under $10,000.[31]

Resource Intensity

X-ray irradiators require large amounts of electricity (approximately 13kW), in contrast to Cs-137 based machines (1-2kW), and approximately 20 liters (5.3 gallons) of water per minute to cool down the X-ray tube.[32] This can substantially increase the utility bills for facilities using X-ray irradiators, and some experts have indicated that resource intensity constitutes a significant barrier for developing countries to acquire this technology.[33] In addition, the availability of a consistent stream of electricity, to ensure delivery of sufficient and even doses of radiation to all parts of the blood bag in the irradiator, was another related concern.

[29] Abigail Cuthbertson, "Global Threat Reduction Initiative," Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.
[30] U.S. Nuclear Regulatory Commission, Public Meeting on Cesium Chloride Uses, Including Blood Irradiators, 2008.
[31] Hitachi Medical Corporation, Presentation at Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.
[32] Ibid.
[33] Charles Fergusson, Comments at Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.

Alternative Forms of Cesium

In light of increasing awareness of the potential risks associated with having radioactive sources on the grounds of accessible public facilities like hospitals or blood centers, the U.S. Departments of Homeland Security and Energy instigated an irradiator hardening program during the period of 2007-2008.

It is also worth recalling that all Cs-137 used in the U.S. comes from a single provider – Russia's Mayak industrial complex.[34] Such source dependency is not uncommon in radiological medicine and thus ought not to be a cause for additional concern. At the same time, if an attempt was made to convert to alternative, less dispersible, forms of cesium for blood irradiation, the implementation process would be somewhat simplified by working out the technical arrangement with only one manufacturer.

However, the alternative form of cesium (glass or ceramic) would be able to achieve only about half of the radioactivity as a source, compared to CsCl – meaning the doubling of irradiation cycle times or redesigning the current irradiators to hold two sources instead.[35] In addition, the high volatility of cesium in high temperatures, required to produce a solid cesium source, means such a source would pose a greater radiation hazard during the process, making it more complex and considerably more expensive to produce.[36]

Cobalt-60 Based Irradiators

Some of the U.S. industrial irradiators presently use Co-60 as a source, which typically comes in the form of a metal wire or a solid pellet, and is therefore considered to carry a considerably lower risk of dispersal. However, this technology is presently not available for blood irradiation, and would entail significant additional costs and security concerns, compared to Cs-137 machines. First, because the half-life of Co-60 is much shorter (just over 5 years), it would require more frequent replacement, creating not only the potential threat of diversion during transit, but also entailing the abovementioned high costs associated with obtaining a suitable container. Furthermore, accumulating backlogs of sources waiting to be moved imply a reasonable prospect of significant downtime if a facility would not be able to get a new Co-60 source shipped in and a used one shipped out synchronously. Second, the level of energy emissions of

[34] Isotop.ru (part of Rosatom), "Cesium-137," http://www.isotop.ru/en/production/Sterilization/476/.
[35] U.S. Nuclear Regulatory Commission, 2008.
[36] Advisory Committee on the Medical Uses of Isotopes, 2008.

Co-60 is around four times higher than that of Cs-137, which would require additional protective shielding for a machine using Co-60 as a source, meaning, in turn, larger and much heavier devices.

Linear Accelerators (LINACs)

Of all the blood irradiation techniques presently in use, LINACs are able to deliver the most uniform dose of radiation to blood bags.[37] The cost of a LINAC machine is approximately $2 million, with annual maintenance costs estimated at around $200,000.[38] Subsequently, only facilities that process particularly large volumes of blood could justify such a steep investment in a machine exclusively for blood irradiation purposes. However, the principle modes of employment for LINACs (as well as cobalt-60 irradiators) are their multiple radiotherapy applications for cancer treatment[39] (see Figure 6 in the Appendix), and dedicated cancer centers or hospital radiology departments might also be able to provide blood irradiation services. An acrylic box containing blood bags is placed on the table where a patient would normally lay, and it takes around 8 minutes to irradiate them to 25Gy or more (with some additional 9 minutes for set up).[40]

This practice is particularly common in the developing world, with blood banks unable to afford separate Cs-137 or X-ray machines, but can also be found in smaller communities in the U.S. For instance, Alabama's Montgomery Cancer Center, operating three LINACs, was able to irradiate nearly 600 blood bags per year in the time its radiology department could spare from using these LINACs for regular patient treatment.[41] Presently, linear accelerators suitable for blood irradiation are manufactured by Elekta (Sweden), Varian (U.S.), and Accuray (U.S.) companies.

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[37] Susan F. Leitman, 2010.

[38] Advisory Committee on the Medical Uses of Isotopes, 2008.

[39] Charles Fergusson, Comments at Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014; A. Wambersie and R.A. Gahbauer, "Medical Applications of Electron Linear Accelerators," http://cds.cern.ch/record/399430/files/p229.pdf?version=1.

[40] Paola Pinnaro et al., "Implementation of a New Cost Efficacy Method for Blood Irradiation Using a Nondedicated Device," *Journal of Experimental & Clinical Cancer Research*, Vol. 30 No. 7, 2011; Shamee Shastry et al., "Linear accelerator: a Reproducible, Efficacious and Cost Effective Alternative for Blood Irradiation," *Transfusion and Apheresis Science*, 2013, http://dx.doi.org/10.1016/j.transci.2013.03.007.

[41] G.A. Patton and M.G. Skowronski, "Implementation of a Blood Irradiation Program at a Community Cancer Center," Transfusion, Vol. 41 No. 12, January 2002, pp. 1610-6. Reportedly, the local blood bank

Photochemical Treatment

An alternative to treating blood components (platelets and plasma) to prevent GVHD is photochemical treatment using Amotosalen HCl solution activated by UV-A light, designed to inactivate pathogens in general, including GVHD.[42] It has been used by blood centers in European countries including Belgium, France, Norway, Slovenia, Spain, Sweden, and Switzerland, as well as the Middle East and Russia since 2002,[43] but has not been licensed for use in North America.[44] Presently, the company CERUS is the sole manufacturer of illuminators used for this treatment (Intercept), with each kit costing approximately $120.[45] The Intercept illuminator is 0.37 m (14.5 in) high, 1.15 m (45 in) wide and 0.74 m (29 in) deep, and weighs around 69 kg (152 lbs); it requires around 330W of electricity[46] (see Figure 7 in the Appendix). European blood centers using photochemical treatment for platelet concentrates usually install 2 Intercept illuminators, sufficient to treat the entirety of their annual intake ranging from 2,000 to 9,000 platelet concentrate units (the blood center in Alsace, France, has 4 illuminators, treating 17,000 platelet concentrate units and 18,000 units of plasma annually).[47] Some studies have indicated that Amotosalen HCl may actually be more effective in GVHD prevention than gamma irradiation.[48]

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recently purchased an X-ray blood irradiator and the Montgomery Cancer Center is no longer required to provide these services.

[42] Larry Corash and Lily Lin, "Novel processes for inactivation of leukocytes to prevent transfusion-associated graft-versus-host disease," *Bone Marrow Transplant*, Vol. 33 No. 1, 2004, pp. 1-7; P. Schlenke "Protection against transfusion-associated graft-versus-host disease in blood transfusion: is gamma-irradiation the only answer?" *Transfusion Medicine and Hemotherapy*, Vol. 31 Suppl. 1, 2004, pp. 24-31.

[43] INTERCEPT Use Overview, http://www.interceptbloodsystem.com/intercept-in-use/overview.

[44] It is the understanding of the author that the FDA has been presented with Phase 3 trial results of this procedure and the technology is undergoing FDA review: CERUS Corporation, "A Phase 3 Prospective, Randomized, Double-Blinded, Multicenter Clinical Trial to Determine Effectiveness and Safety of Platelet Components Prepared by Photochemical Treatment Compared to Conventional Platelet Components Processes," November 2009, http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandotherbiologics/bloodproductsadvisorycommittee/ucm189568.pdf.

[45] Akihiro Shimosaka, "Risk of Pathogen Transmission through Blood Transfusions and the Intercept Blood System," *Asia Biotech Publication*, Vol. 11, No. 5, 2007, http://www.asiabiotech.com/publication/apbn/11/english/preserved-docs/1105/0273_0278.pdf.

[46] Intercept Illuminator: Operator's Manual, http://www.interceptbloodsystem.com/documents/int100_english_operator_manual.pdf.

[47] INTERCEPT Customer Experience, http://www.interceptbloodsystem.com/intercept-in-use/experience/belgium/btc-mont-godinne.

[48] Jean-Pierre Cazenave, "Towards Universal Pathogen Inactivation in Blood Cells," in Transfusion Medicine: Looking to the Future, edited by Patrick Herve, Jean-Yves Muller, Pierre Tiberghien (Paris: John Libbey and Company, 2006), p. 38; Van Rhenen et. al, "Transfusion of pooled buffy coat platelet components prepared with photochemical pathogen inactivation treatment: the euroSPRITE trial," *Blood*, Vol. 101 No. 6, March 15, 2003, pp. 2426-2433.

U.S. POLICY ON CESIUM CHLORIDE (CSCL) SOURCES

Governance Framework

In 2005 the Energy Policy Act established a Task Force on Radiation Source Protection and Security (hereafter: "Task Force").[49] Its members represent 14 Federal agencies and two State organizations from various fields that are involved in matters of radiological security, and it includes experts in regulatory, intelligence, law-enforcement, security, foreign affairs, environmental protection, and emergency management; the Task Force is chaired by the Nuclear Regulatory Commission (NRC). Its main task is 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."[50] To this end, the Task Force is to provide a progress report every four years to the Congress and President, including recommendations for follow-up actions to be taken with respect to, among other issues, the secure storage of radiation sources, the availability of alternative technologies for functions that currently require radioactive sources, and/or the establishment of incentives to switch to such alternative sources. After the release of the report, the NRC has 60 days to take any action it deems appropriate in response to the recommendations of the Task Force. So far, the Task Force has published two such reports: on August 15, 2006 and on August 11, 2010. The authority to license and regulate radioisotopes lies with the NRC, but the Atomic Energy Act allows the NRC to transfer part of this mandate to State authorities, whereupon the NRC will provide assistance to that State. This transfer of powers is done by agreement between the State and the NRC chairman: currently, such agreements have been reached with 37 States.[51]

The 2006 Report and Its Implementation

The Task Force's 2006 report contained two notable recommendations relating to the replacement of Cs-137 and the search for alternative technologies. Firstly, the Task Force suggested that its Alternatives Technology Subgroup evaluate financial incentives, and research the needs for both, alternative technologies and designs. It also called for a cost-benefit analysis of potential alternatives for, among others, cesium

[49] Energy Policy Act (EPA) of 2005, 119 Stat. 594, sec. 651.
[50] EPA, sec.651, F.(3)(a).
[51] See the NRC website: http://www.nrc.gov/about-nrc/state-tribal/agreement-states.html.

chloride (CsCl).[52] This evaluation was completed in 2010. Rather than attempting to quantify the total costs of replacement, the Task Force came up with an assessment of financial incentives, research needs, and the life cycle costs of potential alternatives. It concluded that "alternatives exist for some of the seven applications but that the viability, relative risk reduction, and stage of development of these alternatives vary," and that the replacement of radioactive sources should be addressed per source individually, leading to different approaches and timetables depending on the application.[53] Moreover, the Task Force concluded that the availability of pathways for disposal must be considered before replacement can occur.

Secondly, the 2006 report recommended that priority be given to conducting a study on the feasibility of phasing out CsCl in a highly dispersible form, considering the availability of alternatives, options for disposal, and international safety and security implications.[54] This study was conducted over 2007-2009. It concluded that the immediate phase-out of the use of CsCl sources would not be feasible, because they are used in too wide an array of applications, but that, instead, a gradual phase-out could be an option, as alternatives become more viable with new technological and economic developments. Again, the safe and secure disposal of CsCl sources was highlighted as a necessary condition for such changes to occur. The study includes a five-part approach for improving security and reducing risks related to the use of CsCl. Rulemaking on the elimination of licensing and a ban on exports of CsCl is mentioned, but considered premature as it depends on the availability of reliable alternatives. The study does, however, recommend the consideration of the development of government-facilitated pathways for disposing of used sources, as well as of "prioritized Government-incentivized replacement of devices with existing, effective alternatives."[55] It also encourages the support of both short- and long-term research and development for such alternatives.

A number of other research studies and initiatives had been undertaken since 2006 to assess the feasibility of such technologies. In 2008, the U.S. National Academies of Sciences published a report on the *Radiation Source Use and Replacement*, which recommended replacing existing CsCl sources through a system of incentives, discontinuation of import and export licensing for CsCl, and stimulation of research

[52] 'The 2010 Radiation Source Protection and Security Task Force Report', submitted to the President and US Congress by the Chairman of the NRC on behalf of the Task Force on Radiation Source Protection, 08/11/2010 [hereafter: Task Force report 2010], p.43.
[53] Ibid.
[54] Task Force report 2010, p.44.
[55] Ibid.

into alternative technologies.[56] The NRC developed a policy statement, which maintained that while it was not *required* for adequate protection, the development of alternative technologies would be prudent. In 2009, the NNSA began to research CsCl alternatives in its applications for well logging (focusing on recent technical advancements in this domain), and the development of non-radionuclide-based sources of high-energy gamma rays and X-ray alternatives to the use of CsCl in blood irradiators.[57]

The 2010 Task Force Report

Apart from the implementation of the two recommendations from the 2006 report discussed above, the 2010 Task Force report listed a number of other key accomplishments in the context of improving the security of radioactive sources. These are:

- Increasing inter-agency preparedness and coordination;
- A re-evaluation of the list of risk-significant radioactive sources that need enhanced security and protection;
- Improving existing security at locations where radioactive sources are used by requiring fingerprinting and background checks on persons with access to the sources as well as by providing voluntary security enhancements and training;
- The development by the NRC of the National source Tracking System, which tracks the possession and transfers of over 70,000 radioactive sources; and
- Increasing adherence to international initiatives aimed at enhancing radiological security.[58]

The 2010 report further outlines a number of key challenges and recommendations. Special attention is given to the recovery and disposition of radioactive sources and the search for viable alternative technologies.

The 2010 report identifies access to disposal for disused radioactive sources as "the most significant" challenge in terms of radiological security.[59] In the U.S., radioactive sources, upon disuse, constitute low-level radioactive waste (LLRW), which is subdivided into Classes A, B, C, and greater than class C (GTCC) LLRW. The classes are

[56] Available at http://www.nap.edu/catalog.php?record_id=11976.
[57] Task Force report 2010, p.42.
[58] Task Force report 2010, pp. i-iii.
[59] Task Force report 2010, p.iii.

determined based on the concentrations of specific radionuclides, with the level of hazard posed by the waste going up with each letter.[60] Under U.S. law, commercial LLRW is the primary responsibility of States or State Compacts (partnerships based on agreements between two or more States). These entities are to provide options for disposal for Class A, B and C LLRW. When the radionuclide concentration of Cs-137 is larger than 4600 curies per cubic meter, however, it is classified as GTCC LLRW, and becomes a Federal responsibility.[61] Thus, it falls to the DOE to address the problem of such disused Cs-137 isotopes, but DOE has been stymied in these efforts. Current regulations require that GTCC LLRW be disposed of in geological repositories, yet there are currently no such facilities in the U.S. As there are no commercial disposal options for most CsCl users, they have to instead resort to long-term on-site storage of their disused isotopes.

To be sure, security-related regulations apply to these locations: the NRC conducts frequent inspections, and both Federal and State agencies have undertaken a number of actions to strengthen the security of sources in storage. Nevertheless, disposal is considered a more secure way of handling GTCC LLRW.

In response to this situation, the 2010 report formulates several general recommendations, among them that the DOE continue its ongoing efforts to develop GTCC disposal capability, and that the U.S. government and States continue to evaluate waste disposal options for disused radioactive sealed sources. CsCl sources are given particular attention in the report, as the Task Force recommends that "U.S. Government, regional compacts, and States continue to evaluate disposal options for disused radioactive sources, including options for handling a potentially large number of disused cesium chloride sources that may be replaced once viable alternatives are available."[62]

Concerning the introduction of alternative technologies to replace CsCl, the 2010 report offered several recommendations, reflecting the conclusions of the 2007-2009 study on the feasibility of phasing out CsCl use:

- **Recommendation 9**: The Task Force recommends that the U.S. Government enhance support of short-term and long-term research and development for alternative technologies;

[60] See http://www.gtcceis.anl.gov/index.cfm.
[61] CRS Report for Congress, 'Radioactive Waste Streams: Waste Classification for Disposal', updated 12/13/2006, available at https://www.fas.org/sgp/crs/misc/RL32163.pdf.
[62] Recommendation 4, Task Force report 2010, p.37.

- **Recommendation 10**: The Task Force recommends that the U.S. Government, contingent upon the availability of alternative technologies and taking into consideration the availability of disposal pathways for disused sources, investigate options such as a voluntary prioritized, Government-incentivized program for the replacement of Category 1 and 2 sources with effective alternatives, with an initial focus on sources containing CsCl;
- **Recommendation 11**: Contingent upon the availability of viable alternative technologies, the Task Force recommends that the NRC and the Agreement States review whether the licensing for new Category 1 and 2 CsCl sources should be discontinued, taking the threat environment into consideration.[63]

Actions since the 2010 Task Force report

The NRC developed its first implementation plan for the Task Force report in December 2010, followed by two more that were published in December 2011 and 2012 respectively.[64] On July 25, 2011, the NRC published a policy statement on the protection of CsCl sources. The NRC, in this statement, reaffirms that the primary responsibility for the security of CsCl sources lies with the licensees, and that adequate protection is ensured if sources are stored in accordance with regulations issued by the NRC and States under the abovementioned agreement. The statement further notes that design improvements could be made to further mitigate risks, and that the NRC maintains awareness of international and domestic security efforts.[65] The main focus of the policy statement, however, lies with regulatory requirements relating to the security and control of radioactive sources. These require licensees to comply with NRC standards to reduce the risk of abuse. Such standards relate to, for example, "access controls and background checks for personnel; monitoring, detecting and responding to unauthorized access; delay; advance coordination with local law enforcement; and the tracking of transfers and shipments." There are new license requirements for the import and export of radioactive sources, and the NRC supports the voluntary program of the NNSA to retrofit existing CsCl irradiators with additional physical security enhancements and to incorporate these improvements into the designs of newly manufactured units.

[63] Task Force report 2010, p.45.
[64] Available at the website of the Task Force, http://www.nrc.gov/security/byproduct/2010-task-force-report.pdf.
[65] NRC-2010-0209], Policy Statement of the US Nuclear Regulatory Commission on the Protection of Cesium-137 Chloride Sources, 76 FR 142 at 44378, 7/25/2011 [hereafter: NRC Policy Statement 2011].

The NRC policy statement pays special attention to the issue of ensuring secure disposal for disused CsCl sources. High costs and a lack of commercial facilities are listed as main challenges in this area. The NRC reaffirms that "used and unwanted CsCl sources are stored safely and securely at the users' sites under the applicable NRC and Agreement State control and security requirements until options become available"; it also points out that storage sites are routinely inspected, but nevertheless considers that it is necessary to develop a pathway for the long-term storage of CsCl sources, since storage at users' sites "increases the potential for safety and security issues."[66] Pending such developments, however, the DOE is not responsible for accepting used CsCl sources for storage or any other activity, except when such sources present a threat to public health, safety or national security. The NRC is monitoring the DOE as it further looks into options for disposal of GTCC LLRW. The DOE has published a draft Environmental Impact Statement on the disposal of GTCC LLRW in 2011, but a final version is expected in 2014.

The DOE also expects to submit its report on disposal pathways considered in the Environmental Impact Statement (EIS) to Congress in 2014. This report is intended to identify the waste involved; detail Federal and non-Federal disposal options; propose actions to ensure safe disposal of the waste; describe the projected costs; identify options for ensuring that those who benefit from activities associated with the generation of the waste bear all reasonable costs of disposing of the waste; and identify statutory authority required for disposal of the waste.[67] Furthermore, the 2012 implementation plan points out that the NNSA's Global Threat Reduction Initiative (GTRI) funded a working group to examine possibilities for expanding commercial disposal options for sources including CsCl.

Regarding alternative technologies for CsCl use, the NRC in its 2011 policy statement "supports efforts by manufacturers to develop alternate forms of Cs-137 and to strengthen device modifications that could further reduce the risk of malevolent use associated with CsCl."[68] It also considers, however, that "current security requirements and measures are adequate."[69] It concludes that instead of focusing on replacement technologies, it is "more appropriate to focus on continued enforcement of the United States security requirements and to mitigate risk through cooperative efforts and voluntary initiatives of industries that currently manufacture and use CsCl sources."[70]

[66] NRC Policy Statement 2011, p.44381.
[67] Ibid., p.44382.
[68] Ibid.
[69] Ibid.
[70] Ibid.

As a result, the 2012 implementation plan merely notes that the Task force has begun efforts to draft the next quadrennial report to the President and Congress, in the context of which it will examine any new developments in the area of alternative technologies. In relation to options for the replacement of CsCl sources, the implementation plan simply observes that there are currently no uniform alternatives available to replace CsCl in all its fields of application.

Evaluation

In terms of securing CsCl sources from abuse, the focus of the NRC is clearly on the physical security of the isotopes at the locations of operation. Yet, despite the achievements in this area, a 2012 GAO report concluded that there were still concerns remaining regarding the security of radiation sources.[71] More specifically, the report pointed out, the NRC requirements were inadequate, because of their breadth and non-prescriptive nature. This has produced a situation where licensees enjoy a margin of freedom to implement these regulations, and therefore security conditions differ from one location to another. This problem is further exacerbated by the fact there have been complaints that NRC training for personnel handling high-risk sources is insufficient.[72] Although the NNSA voluntary program to upgrade security arrangements at locations using high-risk sources has led to numerous improvements, the report further notes, the NNSA does not expect to complete its work until 2025. Other drawbacks are that not all facilities will cooperate since the program is voluntary; that facilities will have to maintain the upgrades beyond a three to five-year period in which NNSA is the warrantor; and that facilities are not required to sustain the upgrades.[73]

One can observe that some of the key recommendations of the 2010 Task Force report are not being implemented to their full extent. Progress on disposal options for disused CsCl is still insufficient, which means that the 'most significant challenge' identified in the 2010 report is not being addressed adequately. Moreover, regarding alternative technologies for CsCl use, the actions taken since 2010 do not match the ambitions reflected in the recommendations of the Task Force report. The NRC appears to have diverted its attention to more conventional, regulatory approaches to securing the sources instead of focusing on possibly reducing or phasing out their use.

[71] GAO report 12-925, 'Nuclear Nonproliferation: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities', September 2012 [hereafter: 2012 GAO report].
[72] 2012 GAO report, p.10.
[73] Ibid., p.23.

INTERNATIONAL PRACTICES FOR GVHD PREVENTION

In 2012, red blood cells constituted over three-quarters of all transfusions in the EU, with plasma and platelet transfusions accounting for 15% and 9% respectively.[74] Annual surveys of EU member states, conducted by the European Committee on Blood Transfusion between 2001 and 2008, indicate that most states use leukocyte-depleted blood components in transfusion, but the practice of further gamma irradiation[75] is not very common: in 2008, 19 of 23 reporting states were irradiating less than 10% of red blood cells, and not irradiating platelets at all.[76] This is not inconsistent with the approximate prevalence rates of immunocompromised patients that would require such additional precautions, although the share of blood donations by family members is not known. In addition, the 2010 Guide by the European Committee on Blood Transfusion on "the Preparation, Use and Quality Assurance of Blood Components," recommends irradiating all blood components for intrauterine and neonatal exchange transfusions. In 2011, one case of GVHD was reported in the EU, out of a total of 1,574 serious adverse reactions to blood transfusion.[77]

The trends in irradiation practices were not internally consistent within EU members, as illustrated by the schematic from countries that used leucocyte depletion for 100% of blood components to be transfused (see Table 2 below). Interestingly, France, which had declared intent to phase out all Cs-137 blood irradiators by 2016,[78] showed a systematic increase in irradiation practices. To be sure, the French phase out approach involves licensing the CsCl irradiators for 10 years only (less than the 30 years lifespan of its source), not re-licensing old irradiators, and not issuing new licenses – as the availability of this technology declines, a gradual decline in the practices of irradiation using radioactive sources will occur, but the data indicates that effect has not been observed thus far. In Germany, a survey of 35 transplant centers (out of existing 47)

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[74] European Commission, Health and Consumers Directorate General, "Summary of the 2012 Annual Reporting of Serious Adverse Events and Reactions (SARE) for Blood and Blood Components (data collected from 01/01/2011 to 31/12/2011)," Brussels, August 13, 2013, p. 2, http://ec.europa.eu/health/blood_tissues_organs/docs/blood_sare_2012_en.pdf.

[75] The cause of GVHD is residual leucocytes; common leucocyte-depletion methods presently in use (blood filtration or centrifugation) may not be sufficient to prevent GVHD in imunocompromised patients (see, e.g. Nihon Rinsho, "Prevention of Posttransfusion Graft-Versus-Host Disease by Leukocyte Depletion Filter," September 1997, Vol. 55 No. 9, pp. 2282-9.

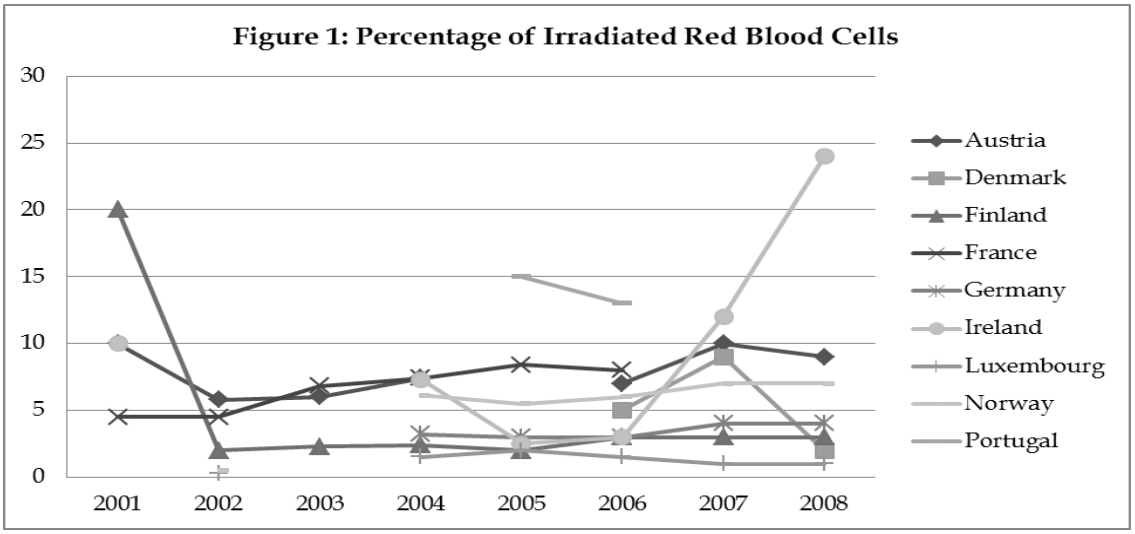
[76] See, e.g. European Committee on Blood Transfusion, "The Collection, Testing and Use of Blood and Blood Components in Europe," 2008, p. 26.

[77] European Commission, "Summary of the 2012 Annual Reporting of SARE," pp. 4-6.

[78] Anita Nilsson, "Replacing CsCl as the prevailing method for blood irradiation," Presentation at Workshop Examining Alternatives to Cesium Chloride in Blood Irradiators, James Martin Center for Nonproliferation Studies, Washington, DC, January 8, 2014.

indicated that over 90% of them transfuse irradiated blood to prevent GVHD in stem cell transplant patients, and gamma irradiation was the method used uniformly in all reporting institutions.[79]

Slovenia reported looking to avoid blood irradiation of platelets, turning to alternative methods of preventing GVHD: the decision was made in 2007, and by 2009 the Intercept system was in place instead;[80] however, Slovenian establishments continued the practice of irradiating a portion of red blood cells before transfusion (16% in 2007 and 5% in 2008).[81]



Source: European Committee on Blood Transfusion, Annual reports on "The Collection, Testing and Use of Blood and Blood Components in Europe," 2001-2008.

Denmark has taken perhaps the strictest approach in the EU, outlawing gamma-based blood irradiation.[82] The laxer French approach of gradual phase-out of Cs-137, adopted in 2005, has met with limited success as noted above. Other approaches, based on national promotion of best practices rather than formal policy requirement, were adopted in Czech Republic, Finland and Sweden, while Belgium and Norway opted for asking facilities to provide a formal justification if they wished to replace one radioactive source based blood irradiator with another.[83]

[79] B. Weiss et al, "Gamma-irradiation of blood products following autologous stem cell transplantation: surveillance of the policy of 35 centers," Annals of Hematology, Vol. 83 No. 1, 2004, pp. 44-49.
[80] European Committee on Blood Transfusion, "Symposium on Implementation of Pathogen Reduction Technologies for Blood Components: Executive Summary," 2-3 September 2010, Strasbourg, France, p. 39.
[81] European Committee on Blood Transfusion, 2007, p. 26; 2008, p. 26.
[82] Anita Nilsson, January 8, 2014.
[83] Ibid.

Curiously, while U.S. experts seem to view X-ray irradiators as the most plausible alternative to cesium based ones for blood processing, European Good Manufacturing Guidelines list electron accelerators, producing Beta radiation, next to Gamma radiation-producing machinery that uses radioactive sources as equally acceptable options.[84] A recent study at Italy's Regina Elena National Cancer Institute, which uses over 2000 irradiated blood bags annually, found that it could irradiate blood and blood components using the three LINACs it had for one-fifth of the price it was paying to purchase the Cs-137 irradiated blood from the blood center in Rome.[85]

CONCLUSION: LEARNING FROM EFFORTS TO MINIMIZE HIGHLY ENRICHED URANIUM

A radiological terrorist attack—particularly one involving high-risk sources such as cesium chloride— represents an important security risk and one whose potential costs have not been internalized by most current end-users of the material. As a result, the U.S. National Academy of Sciences 2008 Task Force, as well as other U.S. and international experts, have suggested a number of incentives to encourage the replacement of cesium chloride blood irradiators with non-isotopic alternative technologies, and some governments have already begun to implement policies designed for this purpose.

For example, the NAS 2008 report includes a fairly comprehensive list of tools (Table 10-1, p. 161), which governments could wield. These are grouped into prohibitions and push incentives, which one can view as two types of government policies: one designed to force end users to shift to new technologies through punitive measures (i.e. "sticks"), and another one nudging them in the same direction through positive incentives (i.e. "carrots").

In deciding which tools to use, and how and when to employ them, governments can learn from the decades-long effort of the United States, Russia, and other countries to phase out the use of highly enriched uranium (HEU) in civilian applications, particularly in research reactors and medical isotope production. HEU is one of two

[84] EudraLex, Vol. 4 Good manufacturing practice Guidelines, "Annex 12: Use of Ionizing Radiation in the Manufacture of Medicinal Products," (Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively).
[85] Pinnaro et al., 2011.

fissile materials commonly used in nuclear weapons and is viewed as the material that would be particularly easy for terrorists to fashion into a crude explosive device. As a result, following India's detonation of a "peaceful nuclear explosive" in the 1970s, the United States and then Soviet Union launched programs to convert research reactors to use safer low enriched uranium (LEU). These efforts took on increased urgency after the 9/11 terrorist attacks.

Just like the current pursuit to phase out high-risk radioactive sources, the efforts to phase out HEU initially faced considerable resistance on technological, economic, and political grounds. Initially, current users and producers both claimed the absence of a credible threat. Then, when headway was made in educating the producer and user communities about the risks involved, their first instinct was simply to increase security measures for existing technology, claiming the lack of technologically or economically feasible alternatives. Now, as technology has advanced and is becoming increasingly economically competitive (especially once a way was found to effectively incorporate additional costs related to security risks into operating costs), many obstacles to change have subsided. To be sure, some obstacles remain, but these are often proxies for broader international political struggles or narrow political self-interest rather than substantive and specific technical or economic concerns related to real scientific or commercial need to use HEU.

The HEU experience teaches us that the most important factor for making progress is a belief that governments have the political will to carry it forward, namely the belief of those participating in the market in question that relevant governments are intent on changing end-user behavior and will keep coming up with incentives and rules to do so until change is accomplished. The clarity and certainty of government commitment and the direction and goal of change is more important than the form it takes. This truism is particularly applicable to the U.S. government. The U.S. global leadership position, and the fact that in areas such as medical isotopes and blood irradiation the United States is the primary customer, often dominating with half or more of global demand, puts Washington in a unique position to shape global rules.

Still, properly mixing and timing the four types of incentives outlined by NAS can practically demonstrate this commitment, mitigate political turbulence, and affect the pace and scope of progress. Experience with HEU, for example, has shown that supply incentives, such as assistance with research and development of new technologies, are an essential first step and does not tend to generate significant political backlash. On the other hand, such supply incentives are best coupled with push restrictions or even limited prohibitions that impose some kind of penalty (regulatory and/or financial) and

signal that governments look with disfavor upon the current more dangerous technology. Government support is also important for helping generate and propagate models that show end users, particularly medical practitioners, that they can adapt less dangerous technologies without reducing the quality of care received by their patients. Finally, once the process has generated some momentum, broader incentives can help provide the final impetus for change.

In the realm of high-risk radiological sources, governments first need to set a general goal of phasing out such sources, when feasible from the points of view of technology, economics, and public health and then take the steps needed to meet this goal, including research and development programs. They then need to take immediate steps to impede the introduction of additional high-risk sources, such as cesium chloride blood irradiators, where feasible alternatives already exist. Such steps need not begin with an immediate outright ban on replacing such sources; instead, governments can employ the financial and procedural tools (such as requiring written justification for not using alternative technologies or better utilizing existing resources at other facilities) to force operators of such technologies to internalize the full costs of continuing to use a technology that poses security risks to society as a whole. Such an approach should preserve public health while improving public security.

APPENDIX

Figure 2: Typical self-shielded Cs-137 blood irradiator.

Source: U.S. National Academy of Sciences, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement," 2008, p. 88.

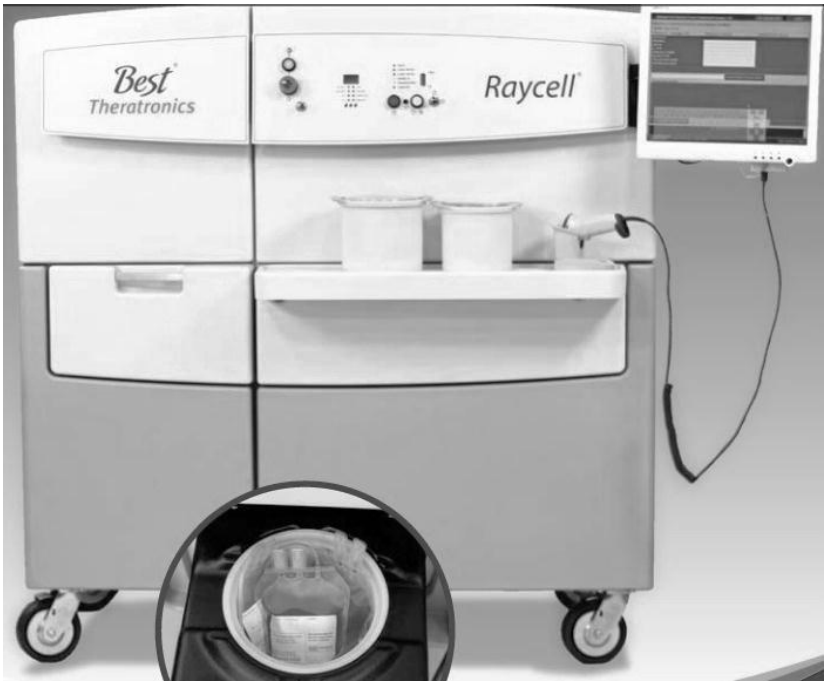
Figure 3: Cs-137 blood irradiator Gammacell, Best Theratronics.

Source: Best Theratronics, http://www.theratronics.ca/product_gamma.html.

Figure 4: X-ray blood irradiator, Radsource.

Source: U.S. National Academy of Sciences, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement," 2008, p. 88.

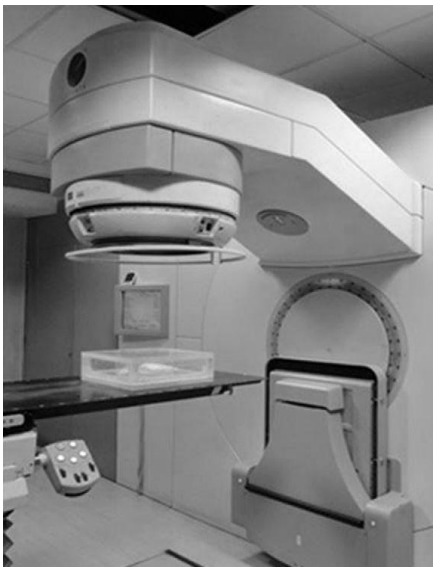
Figure 5: X-ray blood irradiator Raycell, Best Theratronics.



Source: Best Theratronics, http://www.theratronics.ca/product_raycell_mk2.html.

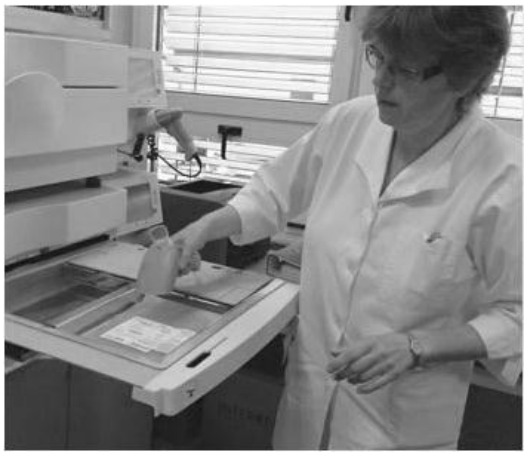
Figure 6: Standard Linear Accelerator (LINAC), Elekta Precision.

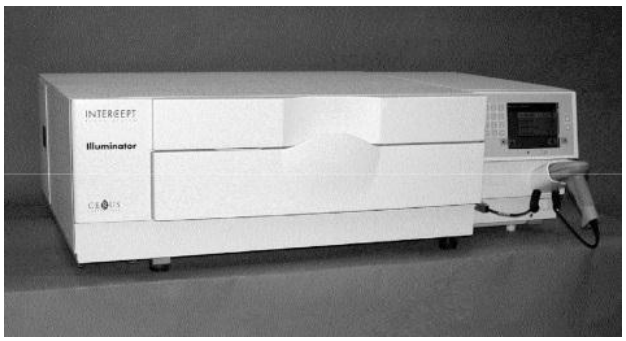
Blood bags for irradiation are to be placed in an acrylic box designed for that purpose



Source: Shamee Shastry et al., "Linear accelerator: a Reproducible, Efficacious and Cost Effective Alternative for Blood Irradiation," *Transfusion and Apheresis Science*, 2013, http://dx.doi.org/10.1016/j.transci.2013.03.007.

Figure 7: Illuminator for Photochemical Treatment of Blood Products Intercept, CERUS.





Sources: Intercept, http://www.interceptbloodsystem.com/intercept-in-use/experience/slovenia/btc-slovenia;
http://www.interceptbloodsystem.com/documents/int100_english_operator_manual.pdf

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