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Stakeholder Mapping Project

International Stakeholders Involved in the Adoption of Alternative Technologies to Radioactive Sources within the Medical Sector

November 2022

Jennifer Hart

U.S. DEPARTMENT OF ENERGY

Prepared for the U.S. Department of Energy
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Richland, Washington 99354

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1.0 Background

Radioactive sources are used in a variety of applications in the medical, industrial, and agricultural industries. In the medical field, most uses of radioactive sources involve low-activity amounts of radionuclides. However, some applications, like cancer therapy and blood irradiation, involve high-activity Category 1 and 2 sources. High-activity sources have the potential to cause significant damage and injury if they are mishandled, whether accidentally or maliciously. Accidental dispersal and malicious use can cause severe societal consequences and the cleanup of such events could cost billions of dollars.[1] Radioactive sources are categorized based on their ability to harm human health. This report uses the International Atomic Energy Agency's (IAEA) *Categorization of Radioactive Sources*, which aims to provide an internationally harmonized basis for risk-informed decision-making.[2]

Licensees who possess high-activity sources are responsible for their safety and security. However, sources can be located in locations—recognized as soft targets—that have limited security and protective measures, making them vulnerable to attack, especially because these locations are easily accessible to large numbers of people. For instance, in the medical field, sources are stored in hospitals and blood banks, both of which are recognized as soft targets. One effective option for reducing the risk posed by high-activity sources at medical facilities is to replace them with non-radioisotopic alternative technologies that perform the same function(s), but the adoption of certain non-radioisotopic technologies also involves challenges. Furthermore, some widely used and accepted alternatives are perceived to be difficult to acquire in certain regions of the world due to the initial cost and the infrastructure and personnel needed to run the equipment.

In December 2020, the World Institute for Nuclear Security (WINS) organized a roundtable discussion about Strengthening the Coordination of International Programs and Organizations involved in the Adoption of Alternative Technologies to Radioactive Sources in Support of Radiological Security. During the roundtable, participants noted that a variety of organizations and programs are involved in the adoption of alternative technologies, but information regarding their activities is fragmented and not easily accessible. Information about their activities is important to ensure coordination between stakeholders and avoid duplication of efforts or conflicting priorities. Therefore, WINS developed an Action Plan to support and structure efforts related to the adoption of alternative technologies to radioactive sources.

The Action Plan identified the following next steps:

1. Map out the international stakeholders (i.e., organizations and programs) involved in the manufacture, procurement, and development (outside of mainstream manufacturer development) of non-radioisotopic or alternative technologies, capacity-building initiatives, and end-of-life management of disused sources.
2. Review and assess stakeholder coordination and cooperation to identify potential issues and suggest solutions that can help avoid duplication of initiatives or conflicting objectives.

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[1] For more information about cost estimates, see https://www.gao.gov/products/gao-19-468

[2] For the IAEA's *Categorization of Radioactive Sources*, see https://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf

1.1 Report Purpose and Scope

This report addresses the first objective under the Action Plan by consolidating information regarding various international stakeholders involved in the adoption of alternative technologies to high-activity Category 1 and 2 sources. Due to the large number of stakeholders involved in the adoption of alternative technologies within the medical, industrial, and agricultural industries, this report focuses on stakeholder involvement in the medical sector. Future reports may address the adoption of alternative technologies by industry and agriculture. Table 1 includes the alternative technologies discussed in this report, their source-based counterparts, and their global prevalence.

Table 1. Description of Select Alternatives to IAEA Category 1 and 2 Sources Used in the Medical Field

Possible Alternative Technologies Used in Medical Applications	Typical Source-based Equipment Used in Medical Applications	Global Prevalence of Alternative and Source-based Equipment
Category 1		
Medical Linear Accelerators (LINACs)	Teletherapy Units (Co-60)	LINACs are common in high-income countries, while many Co-60 teletherapy units remain in use in low- and middle-income countries.
LINAC-based Stereotactic Radiosurgery Equipment	Stereotactic Radiosurgery Equipment (Co-60)	LINAC-based stereotactic radiosurgery equipment is becoming more prevalent in high-income countries. However, source-based equipment is still operational. The ratio of LINAC-based stereotactic radiosurgery equipment to cobalt-based equipment in low- and middle-income countries is unclear.
X-ray Blood Irradiators **AND** Ultraviolet Pathogen Reduction Technology (UV-PRT)	Irradiators (Cs-137)	X-ray blood irradiators are prevalent in high-income countries. Middle-income countries have also made efforts to transition to X-ray blood irradiators. The number of irradiators in low- and middle-income countries is unclear. UV-PRT is regulated and available in select markets. UV-PRT is used in high-income countries but cannot fully replace Cs-137 irradiators to prevent against Transfusion-Associated graft vs. host disease until systems are approved for treating red blood cells. Use of UV-PRT in low- and middle-income countries appears to be uncommon.
Category 2		
X-ray Devices	High **or** Medium Dose Rate Brachytherapy (Co-60, Cs-137, and Ir-192)	External beam therapy has largely replaced brachytherapy when treating cancers of the esophagus, lung, breast, and skin. Additionally, countries often use high-dose rate with Co-60 sources in place of Ir-192 because of the longer half-life and lower frequency of source replacement. Electronic brachytherapy, as an alternative to conventional brachytherapy, is of interest due to the potential to address feasibility issues associated with use of radioactive sources. However, further clinical research and research and development efforts are needed confirm and improve efficacy.

CS = cesium; Co = cobalt; Ir = iridium.

This report does not evaluate or offer suggestions for improved collaboration; instead, its sole purpose is to shed light on existing stakeholder involvement, recording their missions and contributions to provide an accessible picture of stakeholder involvement. While the report aims to be comprehensive, gaps are unavoidable. Readers are encouraged to reach out to WINS with additional information as applicable. Further research is needed to evaluate the effectiveness of stakeholder involvement to offer suggestions about how to improve and better coordinate stakeholder engagement.

1.2 Report Content and Organization

This report has six ensuing sections and one appendix:

- Section 2.0 describes the methodology used to complete this report.
- Section 3.0 is dedicated to categorizing international stakeholders into groups and providing general insight into their objectives and missions.
- Section 4.0 is organized by alternative technology type and includes a more in-depth look at stakeholders and their involvement in current and past projects.
- Section 5.0 focuses on stakeholders involved in capacity-building initiatives, offering insight into various engagements.
- Section 6.0 considers organizations and programs involved in end-of-life management of disused sources.
- Finally, conclusions are drawn and areas that may benefit from further research are discussed in Section 7.0.

The appendix includes information regarding the various stakeholders discussed and other stakeholders that are not mentioned in the body of the report. It also includes information regarding various past, present, and future projects related to the adoption of alternative technologies. At the end of the appendix, Figure A.1 shows all the identified international stakeholders in their respective stakeholder groups.

2.0 Methodology

To compile this report, the author reviewed the current literature available, conducted open-source research, and engaged with several stakeholders through interviews and email correspondence. The purpose of this data collection phase was to

- understand what information was already consolidated and available, and
- determine the key international stakeholders involved in the adoption of alternative technologies and gather information regarding the missions and contributions of the identified organizations and programs.

3.0 International Stakeholders

Many different stakeholders are involved in the adoption of alternative technologies to Category 1 and 2 sources within the medical field. In general, stakeholders can be classified into two large groups: international and national stakeholders. At the national level, national governments, government agencies, regulators, and end-users all play an essential role. Generally, end-users engage directly with government agencies, regulators, and device manufacturers to procure equipment. However, when states lack the infrastructure, workforce, and/or finances needed to procure and operate technology, international stakeholders may become involved. For the purpose of this report, international stakeholders include intergovernmental organizations (IGOs); non-governmental organizations (NGOs); government support programs; manufacturers, vendors, and developers; and sponsors and funders that transcend national boundaries. Although referenced occasionally, domestically focused organizations and programs are not considered in the overall mapping process because such organizations are beyond the scope of this report.

International stakeholders directly engage national cancer-care providers or end-users, regulators, and often the Ministry of Health, although the specific government agency involved in therapeutic goods (including medical device regulation) varies from state to state. These stakeholders often have different objectives and missions and their primary focus is rarely radiological security.[1] In fact, most stakeholders—specifically in the area of oncology—are focused on increasing the global capacity for cancer care, which in certain areas of the world is inadequate.[2] For these organizations, alternative technologies to high-activity radioactive sources, like linear accelerators (LINACs), may offer superior treatment capability and are therefore of interest. It is important to note that this interest stems from the equipment's treatment capability and not from a security standpoint. Figure 1 depicts international and national stakeholders, and this section provides general insights into each of these stakeholder groups. Note that although this report divides stakeholders into groups based on a single criterion, many organizations and programs often fit into more than one category. For instance, the IAEA is an IGO, but it also assists in mobilizing funding for the adoption of alternative technologies and the disposal of disused sources. Therefore, some organizations may be discussed under multiple categories.

[1] For instance, development banks play a key role in the adoption of alternative technology because they often provide loans to end-users and without such financing some alternative technologies would be too expensive. However, development banks do not focus on the adoption of alternative technologies as a focus area; instead, adoption often falls under a larger health initiative.

[2] The IAEA recommends 250,000 people per megavoltage machine. In 2018, only three countries in Latin America and Africa met this recommendation. See https://www.sciencedirect.com/science/article/pii/S0360301618310472?via%3Dihub.

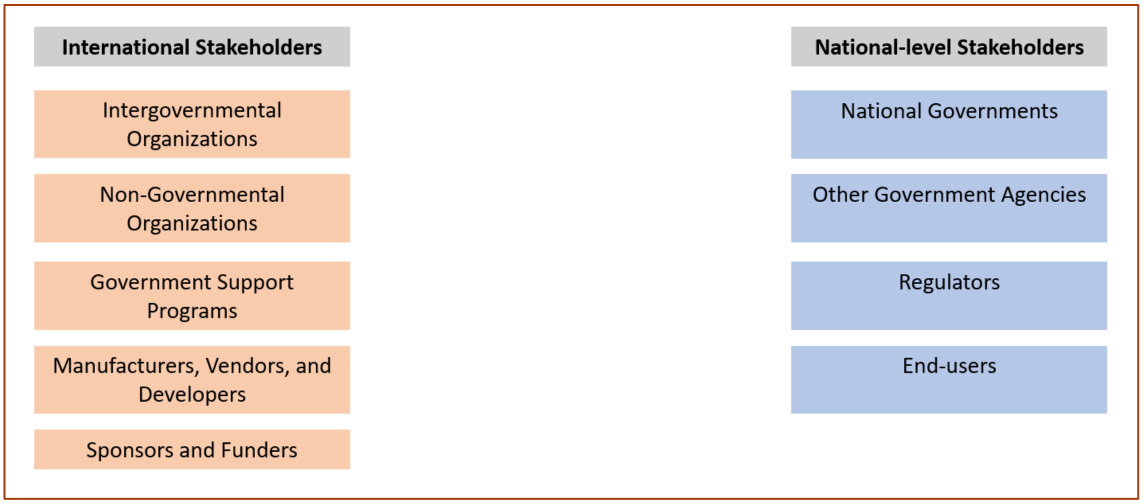

Figure 1. International and National-level Stakeholders

3.1 Intergovernmental Organizations

IGOs are multilateral forums that generally involve two or more nations and are formed on the basis of a treaty. IGOs are typically organized by their membership and purpose. As nations become more interdependent, IGOs play an increasingly vital role in global governance. IGOs, such as the IAEA, play an important role in the adoption of alternative technologies because they mobilize support for low- and middle-income countries (LMICs) that need additional assistance. However, IGOs (including the IAEA) do not encourage an alternative technology over source-based equipment solely from a security standpoint. The IAEA is mandated to "…accelerate and enlarge the contribution of atomic energy to peace, health and prosperity."[1] Therefore, decisions regarding equipment procurement are made by Member States and factors such as security, infrastructure, and personnel requirements are all considered.

In addition to the IAEA, two groupings of states should be noted for their contributions to the adoption of alternative technologies to radioactive sources: the Global Partnership against the Spread of Weapons and Materials of Mass Destruction's Nuclear and Radiological Security Working Group (NRSWG) and the Ad Hoc Working Group on Alternatives to High-Activity Radiological Sources. The NRSWG is an informal working group guided by several principles, including being a tool for matchmaking or identifying potential partnerships to promote work in nuclear and radiological security.[2] The Ad Hoc Working Group provides a forum for states to share information about and experiences with alternative technologies.[3]

3.2 Non-Governmental Organizations

NGOs are typically formed by two or more individuals or private organizations rather than by nations. NGOs are therefore typically independent of governments, are usually nonprofit organizations, and receive at least a portion of their funding from private sources. NGOs have a

[1] For more information, see https://www.iaea.org/about/statute.

[2] For more information about the NRSWG, see https://www.gpwmd.com/nrswg.

[3] The Ad Hoc Working Group hosts an annual meeting for stakeholder states involved with technological alternatives to high-risk radioactive sources. During the meeting, states and other stakeholders gather to share their experiences with transitioning to alternative technologies among other relevant topics. For more information about the Ad Hoc Working Group, see https://alttechwg.org/.

range of operating models, different levels of funding, and a range of policy objectives. Several NGOs play a role in the adoption of alternative technologies in the medical field by providing training to essential staff, including but not limited to radiation oncologists, medical physicists, radiation therapists, and radiotherapy nurses. One NGO, Radiating Hope, also assists in the procurement of radiation-generating technologies, by providing donated equipment to facilities in need. However, similar to IGOs, NGOs do not generally encourage the use of alternative technologies. They also often provide training on source-based equipment. Due to budget constraints, NGOs often contribute on an ad hoc basis. Unlike IGOs, NGOs tend to engage directly with end-users, although there may be some interaction with various government agencies. (See the appendix for a more comprehensive list of NGOs involved in the adoption of alternative technologies.)

3.3 Governmental Support Programs

While many government organizations engage in radiotherapy capacity-building, government support programs for alternative technologies that transcend national boundaries are limited; the major contributor is the United States' National Nuclear Security Administration Office of Radiological Security (NNSA-ORS). Japan's International Cooperation Agency (JICA) has also provided ad hoc assistance in the adoption of alternative technologies. JICA has been involved in training initiatives and procurement, and in funding an initiative covered in Section 4.4 of this report. That said, most government encouragement or support of alternative technologies occurs domestically; generally, policy is directed at reducing the amount of radioactive material in the country under risk reduction efforts. Governments may introduce policy changes or impose new restrictions on the acquisition or use of high-activity radioactive sources in certain applications, making it difficult for end-users to continue operating source-based equipment when viable alternatives are available. Due to the chemical properties of cesium-137 (Cs-137), most domestic government initiatives focus on its replacement. For example, France encouraged end-users to choose alternatives to Cs-137 blood irradiators through their licensing process under the French Nuclear Safety Authority. The Norwegian government, in partnership with the Norwegian Radiation Protection Authority, replaced all Cs-137 irradiators in 2015, and other countries, such as the United States (US), Japan, and Switzerland, have all replaced or made significant strides toward replacing all Cs-137 blood irradiators.[1]

3.4 Manufacturers, Vendors, and Developers

Manufacturers, vendors, and developers play a key role in the adoption of alternative technologies to radioactive sources. Large manufacturers of alternative technologies create equipment such as LINACs, provide training to staff on how to use their purchased equipment, and provide servicing for the equipment. Additionally, large manufacturers are putting effort into researching and developing alternatives to radioactive sources within the medical field. However, the process of research and development can take several years and is often opaque due to its sensitive business nature.[2] Vendors are sometimes separate from the manufacturer and can also be secondhand sellers of equipment. This report includes information regarding

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[1] For more information about the US and Japan, see
https://media.nti.org/documents/NTI_INMM_Alternative_Technology_Paper_Jul2017_oDGeMET.pdf.
For more information about Switzerland's efforts, see Ad Hoc Working Group on Alternatives to High-Activity Radioactive Sources. 2021. *Ad Hoc Meeting of Stakeholder States Involved with Technological Alternatives to High-Activity Radioactive Sources*. Virtual.

[2] National Academies of Sciences, Engineering, and Medicine. 2021. *Radioactive Sources: Applications and Alternative Technologies*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26121.

various vendors of used LINACs. These vendors play an important role in the adoption of alternative technologies because used machines tend to be less expensive. This report also includes several developers of alternative technologies to radioactive sources that are outside of mainstream manufacturers, including universities, small companies, and—in one effort—a grouping of various organizations led by the International Cancer Expert Corps (ICEC). These developers represent an important part of stakeholder involvement in the adoption of alternative technologies because they tend to be more transparent in their research and development efforts and may contribute to market competition if their development is successful. In the US, some companies receive funding through the NNSA's Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs to explore and develop new technologies, including alternative technologies to radioactive sources.[1]

Finally, manufacturers and vendors of radioactive sources also play an important role in the adoption of alternative technologies because they are key to end-of-life management. This report covers source manufacturers' and vendors' roles in the adoption of alternative technologies in Section 6.0. The appendix also provides the names and descriptions of several source manufacturers, vendors, and companies that advertise their ability to remove and recycle or dispose of disused sources. Although some of these disposal companies operate regionally, the IAEA, NNSA-ORS, and others may use their services to accomplish specific projects. These relationships are also covered in Section 6.0 of the report. Due to the number of entities falling into the manufacturers, vendors, and developers stakeholder group, the manufacturers of alternatives and sources have their own respective sections in this report and in the appendix.

3.5 Sponsors and Funders

National governments and end-users can finance themselves or, alternatively, acquire funding through development banks, charities, fundraisers, and grants. However, outside of development banks and other financial institutions, alternative funding avenues typically occur on an ad hoc basis. Although the IAEA is characterized as an IGO and NNSA-ORS is a government support program, both are instrumental in securing funding for the adoption of alternative technologies. As such, both organizations are discussed in this section in addition to their other respective groups.

The IAEA's Programme of Action for Cancer Therapy (PACT) supports Member States by directly engaging other Member States, development banks and financial institutions, the private sector, NGOs, and philanthropic foundations to mobilize financial support.[2] PACT also provides indirect support by helping Member States create project proposals or "bankable documents" to procure financing. The funds acquired are used for a variety of activities, including—but not limited to—procuring LINACs and other vital medical equipment.[3] Outside of the IAEA, NNSA-ORS provides financial and technical support internationally to switch from Cs-137 to X-ray blood irradiators.

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[1] For more information, see https://www.sbir.gov/about.

[2] For more information about IAEA resource mobilization, see https://www.iaea.org/services/key-programmes/programme-of-action-for-cancer-therapy-pact/resource-mobilization.

[3] The IAEA may help a Member State create a "bankable document," but the financial agreement is between the state and the financial institution. Therefore, the agreement can contain funding for items/services outside of the IAEA's scope, including funding for infrastructure to house radiation-generating equipment.

4.0 Stakeholder Involvement by Technology Type

International stakeholders assist states and/or end-users within the state that do not have the elements (infrastructure, finances, and personnel) needed to procure, operate, and maintain equipment. As such, stakeholder involvement varies by technology type because suitability and viability vary. In general, international stakeholders are heavily active in supporting the procurement of LINACs and associated capacity-building initiatives. This support is most likely because over half of cancer patients need radiotherapy at some point during their treatment. Technologies such as X-ray irradiators and stereotactic radiotherapy (SRS) equipment are more specialized and are less of an immediate need, especially for poorer countries. This section describes stakeholder involvement in the manufacture, procurement, and development (outside of manufacture development) of the alternative technologies described in Table 1.

4.1 Medical Linear Accelerators

In general, LINACs have become the backbone of radiation therapy in high-income countries because of their associated better patient outcomes. As such, the transition, in high-income countries, from cobalt-60 (Co-60) teletherapy units to LINACs generally occurred naturally without government incentives. This transition is contrary to X-ray irradiators, which are largely purchased because of government incentives due to security concerns regarding Cs-137. These concerns are covered in more depth in Section 4.3. LMICs still operate many Co-60 teletherapy units and many face challenges in transitioning to LINACs because of the initial cost and the infrastructure and personnel needed to run the equipment. Furthermore, some countries do not have any radiotherapy equipment—neither radioisotope- nor non-radioisotope-based equipment. International stakeholders often become involved when a LMIC or end-user within a LMIC desires a LINAC. This is due to the initial cost of the equipment, the training to use the equipment safely and effectively, the high cost of required ongoing service and maintenance contracts, and the infrastructure necessary to run the machine.

4.1.1 Manufacturers

Varian and Elekta are the dominant LINAC manufacturers, while others such as Accuray, Panacea Medical Technologies, RadiaBeam, and Shinva are also providers.[1] Additionally, resellers buy and sell used LINACs. At least two companies are selling used medical LINACs worldwide: Radiation Oncology Systems and Avante Health Solutions.[2] Manufacturers play a large role in the life of LINACs because they require maintenance throughout their lifecycles. Most manufacturers offer an initial 1-year warranty and then provide several service and software support contracts for purchase. However, service contracts may not have been procured and technicians are not always within an accessible distance to the machine in LMICs. This results in a need to fly service technicians in from neighboring countries or regions. Such arrangements can result in added costs and significant downtime of the machine, as seen in Zimbabwe.[3]

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[1] Siemens Healthineers recently acquired Varian.

[2] For more information regarding vendors of used LINACs, see the appendix.

[3] Zimbabwe does not currently have engineers in-country to fix their LINACs when they break down. Therefore, the country must fly in engineers from South Africa. The lack of trained personnel in-country can result in significant downtime of the machine. For more information, see https://www.zimlive.com/2021/05/26/mpilo-cancer-machines-break-down-and-nearest-engineers-in-south-africa/. For a broader understanding of the issues associated with the maintenance and repair of LINACs and potential solutions in African countries, see https://www.sciencedirect.com/science/article/pii/S0936655516302734?via%3Dihub.

4.1.2 Procurement

The IAEA appears to be the only organization mobilizing financial and technical support to procure medical LINACs on a somewhat regular basis. Through PACT's relationships with international financial institutions (IFIs), PACT supports Member States in receiving funds (grants and/or loans) from IFIs like the Islamic Development Bank (IsDB). Member States can then transfer funds to the Agency for procurement (e.g., Nigeria).[1] In the past, PACT also facilitated the donation of equipment (e.g., Jordan).[2] Other organizations and programs have also assisted in the procurement of LINACs on an ad hoc basis.

Some examples include:

- Washington University in St. Louis MO, USA (WUSTL) led an effort to transition La LIGA Nacional Contra el Cáncer's hospital Instituto de Cancerología (INCAN) to LINAC-based intensity-modulated radiation therapy in Guatemala. Organizations involved included WUSTL, Varian Medical Systems, Rayos Contra Cancer, and NNSA-ORS. The equipment purchase, installation, and commissioning, disused source removal, conversion of the treatment room, regulatory approval, and staff training were financed in part by the US Agency for International Development's Office of American Schools and Hospitals Abroad.[3]
- The Radiating Hope and the Global Access to Cancer Care Foundation installed two LINACs, a stereotactic radiosurgery device, a computed tomography (CT)-scan device, and X-ray machines in a Bolivian hospital.[4] The equipment was procured partly by a donation from Dr. Ed Hughes, the founder of First Dayton Cancer Care in Ohio.[5]

Due to the initial cost of LINACs, it appears the most common financing avenue (outside of government or end-user self-funding) is through development banks. The IAEA assists Member States in developing a "bankable document" to facilitate the process. Nigeria received 3.46 million euros in funding from IsDB in 2014. Prior to receiving the funding, the IAEA and partners conducted an imPACT review in 2010.[6] imPACT reviews are conducted by the IAEA, World Health Organization (WHO), and the Interagency for Research on Cancer to assess a country's current cancer control capacities, identify needs, and provide recommendations. The 2010 review revealed the need to develop a training plan for cancer specialists and to establish radiotherapy services.[7] The funding received from IsDB financed the acquisition of a LINAC and training for medical oncologists, radiotherapists, and radiophysicists in Morocco and Tunisia.[8] In the past, bankable documents have also been used to acquire funding through a country's Ministry of Finance or to obtain grants from various other institutions.[9]

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[1] Correspondence with a subject matter expert, 8/27/2021.

[2] Ibid.

[3] For more information, see https://www.sciencedirect.com/science/article/pii/S036030162030986X.

[4] For more information, see http://blacktiemagazine.com/society_2019_november/Global_Access_to_Cancer_Care_Foundationl.htm and/or https://rasmuspreston.dk/a-gift-of-hope-ohio-to-bolivia.

[5] Ibid.

[6] For more information about imPACT reviews, see https://www.iaea.org/services/review-missions/impact-reviews.

[7] Ibid.

[8] For more information about Nigeria's experience, see https://www.iaea.org/sites/default/files/publications/magazines/bulletin/bull60-3/6031819.pdf.

[9] Correspondence with a subject matter expert, 8/27/2021.

Financial support (such as grants) and equipment donations (such as those facilitated by Radiating Hope) also occur without IAEA assistance.[1] However, funding through grants tends to be on an ad hoc basis and such funding avenues do not seem to benefit multiple end-users. For instance, the US Agency for International Development's Office of American Schools and Hospitals Abroad did not necessarily intend for their grant to be used to procure a LINAC. The LINAC procurement was a benefit of the WUSTL and La LIGA/INCAN partnership.

4.1.3 Development

Outside of manufacturer development, multiple ongoing efforts are being made to develop a LINAC that may better suit the needs and constraints of LMICs. Examples of these efforts include those led by ICEC, the University of Sydney, and RadiaBeam.

- ICEC leads Project STELLA: Smart Technology to Extend Lives with Linear Accelerators. Project STELLA seeks to transform radiation therapy to significantly improve treatment for millions of cancer patients around the world, particularly in underserved LMICs and underserved areas in high-income countries. Project STELLA serves as the umbrella program for ITAR—Innovative Technologies toward building Affordable and equitable global Radiotherapy capacity—the goal of which is to develop a more robust LINAC for LMICs.
- The University of Sydney is developing the Nano-X gantry, a modified gantry that is fixed to the floor to reduce the shielding requirement and lower staff-to-patient ratios. The system is undergoing testing.[2]
- RadiaBeam is working on developing a LINAC that consumes less power and is more affordable. To minimize the potential for downtime, the LINAC's collimator uses eight metal leaves controlled by larger sturdier motors to form one single aperture.[3]

4.2 Stereotactic Radiosurgery Equipment

Stereotactic radiosurgery (SRS) equipment is relatively new compared to external beam radiotherapy. SRS is increasingly common in high-income countries. The ratio of alternative SRS to cobalt-based equipment in LMICs is unclear. In high-income countries, the decision between radioisotope- or non-radioisotope-based SRS equipment is largely based on user preference. Although LINAC-based SRS is becoming more widely accepted as being equivalent to source-based SRS, radiotherapy centers tend to only offer one or the other (non-radioisotopic or radioisotopic) due to the high cost of the machine. Institutes that have both machines tend to be specialized cancer facilities.[4]

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[1] Radiating Hope has donated several LINAC and Co-60 machines since their founding in 2009. For more information regarding past, current, and future projects, see https://cdn.agilitycms.com/applied-radiation-oncology/PDFs/issues/ARO_06-19_Shah_special.pdf.

[2] For more information, see https://image-x.sydney.edu.au/nano-x-2/ and https://www.lindau-nobel.org/blog-tackling-the-silent-crisis-in-cancer-care-with-innovation/.

[3] For more information, see https://www.lindau-nobel.org/blog-tackling-the-silent-crisis-in-cancer-care-with-innovation/.

[4] Subject matter expert interview, 6/17/2021.

4.2.1 Manufacturers

SRS can be administered with a standard isocentric LINAC, a dedicated isocentric LINAC, or a miniature LINAC on a robotic arm.[1] Systems that have a dedicated LINAC include Varian's Edge and HyperArc, ViewRay's MRIdian, Zap Surgical System's Zap-X, and Elekta's Axesse. Devices equipped with a miniature LINAC on a robotic arm include Accuray's CyberKnife.[2] This section does not cover standard isocentric LINACs that can be used for SRS because LINACs are covered in Section 4.1.

4.2.2 Procurement

Users of SRS equipment are highly concentrated in high-income countries. Thus, stakeholders involved in the procurement of such equipment tend to be end-users, manufacturers, and national regulators. Additionally, user and patient preferences tend to play a large role in deciding which equipment should be used in SRS. Notably, Swiss regulators have pushed back on institutes asking for gamma-based equipment. The Swiss regulator asks the end-user if there is an equally effective nonradioisotopic alternative and if there is, the regulator may ask that such an alternative be purchased.[3]

4.2.3 Development

Recently, ZAP Surgical Systems released Zap-X, which is designed specifically for cranial radiosurgery. The platform received US Food and Drug Administration (FDA) clearance in 2017, Japan Shonin clearance in 2020, and European Union Conformitè Europëenne (CE) clearance in 2021 but it is not currently available to all markets.[4]

4.3 X-ray Blood Irradiators

Irradiated blood protects against Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD), a rare complication occurring in fewer than 1 per million transfusions. X-ray blood irradiators are commonly used to replace Cs-137 irradiators in high-income countries. This is largely due to the security risk associated with Cs-137 and the commitment of several national governments and NNSA-ORS to reduce the use of Cs-137. National governments, such as those of France, Japan, Norway, Switzerland, the United Kingdom, and the US, have taken steps to reduce the number of Cs-137 blood irradiators used within their respective borders. National approaches to eliminating Cs-137 blood irradiators differ from state to state.[5]

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[1] National Academies of Sciences, Engineering, and Medicine 2021. *Radioactive Sources: Applications and Alternative Technologies*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26121.

[2] Accuray recently released the new Cyberknife S7. For more information, see https://www.accuray.com/cyberknifes7/

[3] Ad Hoc Meeting of Stakeholder States Involved with Technological Alternatives to High-Risk Radioactive Sources. "Swiss initiatives in Support of Alternative Technologies" (06/15/2021).

[4] For more information, see https://zapsurgical.com/.

[5] Case studies have been written documenting some of the approaches taken and can be found at https://media.nti.org/documents/NTI_INMM_Alternative_Technology_Paper_Jul2017_oDGeMET.pdf and here: National Academies of Sciences, Engineering, and Medicine. 2021. *Radioactive Sources: Applications and Alternative Technologies*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26121.

4.3.1 Manufacturers

Manufacturers of X-ray blood irradiators include Rad Source, Gilardoni, FUJIFILM Healthcare Asia Pacific (formerly known as Hitachi Medical Systems Singapore), and Best Theratronics.[1] X-ray blood irradiators are considered as effective as Cs-137 blood irradiators for the prevention of TA-GVHD and may be priced lower with similar or better throughput, typically selling for around $270,000 and featuring blood exposure times of around 5 minutes.[2]

4.3.2 Procurement

NNSA-ORS aids organizations interested in transitioning from Cs-137 blood irradiators to X-ray blood irradiators. NNSA-ORS assists with X-ray device procurement, infrastructure modifications, and radioactive source end-of-life management. NNSA-ORS will provide an X-ray blood irradiator of the licensee's choice. NNSA-ORS recipients develop their own operational requirements for their X-ray blood irradiators and select an X-ray make/model, and NNSA-ORS provides financial support, connection with subject matter experts, and other support services throughout the transition.[3] While the IAEA does not actively promote non-radioisotopic technology, the Agency has stopped supplying developing states with Cs-137 sources in this application space.[4]

Given that TA-GVHD does not affect nearly as many people as cancer, the demand for X-ray irradiators is less than that for external beam radiotherapy. X-ray irradiators require modifications to the physical space but are not as expensive or as difficult to operate as LINACs, resulting in less of a barrier to their procurement. States may use the money acquired from development banks and other financial institutions to procure X-ray irradiators, but such procurement is not advertised as LINAC procurement. Funds have also been raised using other means. For example, Costa Rica held a telethon to raise money to procure an X-ray blood irradiator in 2020.[5]

4.3.3 Development

There is at least one irradiator in development—a self-contained blood/biological irradiator—by Stellarray. The irradiator has a solid-state cooling and insulation system and high-voltage power sources built within the same casings as the flat panel X-ray sources. The instrument can also use standard wall power sources, thereby improving its resiliency.

4.4 Ultraviolet Pathogen Reduction Technology

Ultraviolet Pathogen Reduction Technology (UV-PRT) can prevent TA-GVHD by inactivating lymphocytes in whole blood and/or platelets. Unrelated to the prevention of TA-GVHD, UV-

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[1] For more information about the listed manufacturers, see the appendix. Also, for a comparison of select X-ray blood irradiators, see https://media.nti.org/documents/Non-uc_xray_irradiator_comparison_chart_-_Blood_05_15_2018_non-UC.pdf.

[2] The estimated price is from 2017. For more information about the estimated price and technical capabilities of X-ray blood irradiators, see https://www.nti.org/analysis/articles/Cs-137-blood-irradiator-replacement/.

[3] For more information about NNSA-ORS, see https://www.energy.gov/nnsa/office-radiological-security-ors and https://www.wins.org/wp-content/uploads/2018/03/ORS_WINS-RRM-Workshop-2March18.pdf.

[4] For more information, see Recent Achievements on Irradiation Facilities at http://www-naweb.iaea.org/napc/iachem/working_materials/Report%20IF.pdf.

[5] For more information about Costa Rica's telethon, see https://www.telediario.cr/nacional/teleton-dona-equipo-hospital-ninos-garantizar-transfusiones-seguras.

PRT's ability to reduce bacteria and certain other pathogens decreases the likelihood of transfusion-transmitted infections (TTIs) caused by the introduction of certain pathogens (e.g., bacteria, viruses, and parasites) into the blood stream during transfusion. Blood components that have been pathogen reduced are also tested for evidence of TTIs. Under certain circumstances, testing for certain pathogens may not be required for UV-PRT treated components, which may be a useful option for cost-saving purposes.[1]

In high-income countries, the procurement of UV-PRT is driven by national governments and end-users. However, until UV-PRT is approved by regulators for use with red blood cells, the use of X-ray and Cs-137 blood irradiators is still necessary to prevent TA-GVHD. That said, whole blood transfusions are higher in LMICs than in high-income countries; only 37 percent of blood is separated into blood components in low-income countries and 69 percent of blood in middle-income countries.[2] Therefore, X-ray and Cs-137 blood irradiators may be required less to prevent TA-GVHD in these countries if UV-PRT is approved for use on whole blood. Furthermore, TA-GVHD is a rare but fatal complication of transfusion, making the high number of TTIs more of a risk in LMICs.

4.4.1 Manufacturers

Two currently used UV-PRT methods use ultraviolet light and a photoactive compound to prevent TA-GVHD. Cerus Corporation manufactures the INTERCEPT Blood System for Platelets using ultraviolet A light (UVA) and Amotosalen. Terumo Blood and Cell Technologies (BCT) also manufactures a system (Mirasol) that uses ultraviolet B light (UVB) and Riboflavin. However, UV-PRT availability depends on the end-user's geographic location because not all devices are available or approved for use in all markets.

Cerus Corporation received the CE marking for their INTERCEPT Blood System for Platelets in 2002.[3] The US Food and Drug Administration (FDA) approved the Cerus system in 2014.[4] Terumo's system received the CE marking for platelets in 2007, and whole blood in 2015.[5] Terumo's system also received approval from Ghana's Food and Drugs Authority in 2016.[6] Terumo's system is currently not available in the US. Cerus and Terumo systems are not approved for use on red blood cells.

4.4.2 Procurement

There do not appear to be any international stakeholders assisting with the procurement of UV-PRT on a regular basis. That said, there is one example of assistance funded through a grant provided by JICA. Terumo Corporation applied and received funding ($500,000) through JICA's *Collaboration Program with the Private Sector for Disseminating Japanese Technology for the*

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[1] For more information, see https://www.cisa.gov/sites/default/files/publications/19_1211_cisa_non_radioisotopic_alternative_technologies-white_paper.pdf and https://pubmed.ncbi.nlm.nih.gov/25989465/

[2] For more information, see https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability

[3] The CE Mark is the European Union's mark of approval and allows for a medical device to be placed on the market. For more information about Cerus Corporation's approvals, see https://www.biospace.com/article/releases/cerus-corporation-s-intercept-blood-system-receives-ce-mark-label-expansion-for-treatment-of-previously-frozen-plasma-/

[4] For more information, see https://www.cisa.gov/sites/default/files/publications/19_1211_cisa_non_radioisotopic_alternative_technologies-white_paper.pdf

[5] For more information, see https://www.terumobct.com/mirasol.

[6] For more information, see https://openjicareport.jica.go.jp/pdf/12322772.pdf

Social and Economic Development of Developing Countries.[1] Following Terumo's selection, Terumo BCT, JICA, the Japanese Red Cross Society, the Association for the Advancement of Blood and Biotherapies (AABB, formerly the American Association of Blood Banks), and several agencies in Ghana—the Ministry of Health, Teaching Hospitals of Ghana, and National Blood Bank Service (NBSG) —partnered to bring Mirasol and a haemovigilance (HV) program to Ghana.[2,3] Following the program, the Ministry of Health committed to continue funding ($20,000 in 2018 and $300,000 to $400,000 over the next 5 years [2018–2023]) to continue the project. It is unclear to the author of this report whether the additional Mirasol systems were procured; if they were, three additional systems were installed in Ghana. In 2018, Terumo BCT opened a branch office in Kenya in preparation for business developments in sub-Saharan Africa.[4]

4.4.3 Development

There is at least one UV-PRT system using ultraviolet C light under development—Macopharma's THERAFLEX UV-Platelets.[5] This system is not yet available in any markets.

4.5 Electronic Brachytherapy

Studies with large patient numbers and long-term follow-up are needed to demonstrate the suitability of electronic brachytherapy as an alternative to conventional brachytherapy.[6] Currently, electronic brachytherapy is not widely used in high-income countries or LMICs. If long-term studies confirm the efficacy of electronic brachytherapy, miniature X-rays could replace high-activity Category 2 sources, such as Co-60, used in high-dose rate (HDR) brachytherapy. This is noteworthy because countries often substitute HDR with Co-60 for low-dose rate with iridium (Ir)-192 because of the longer half-life and lower frequency of source replacement. However, stakeholder involvement in electronic brachytherapy is limited due to the current lack of data and guidelines on standard practice.[7]

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[1] For more information about the Collaboration Program implementation in Ghana, see https://www.modernghana.com/news/716692/jica-invests-in-ghanas-health-sector.html and/or https://openjicareport.jica.go.jp/pdf/12322772.pdf. For more information about JICA's Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries, see https://www.mofa.go.jp/policy/oda/white/2017/html/honbun/b3/s2_3_3.html

[2] HV is the "systematic surveillance of adverse reactions and adverse events related to transfusion." For more information about HV, see https://www.transfusionguidelines.org/transfusion-handbook/5-adverse-effects-of-transfusion/5-1-haemovigilance

[3] Prior to this partnership, Terumo BCT funded a study, the African Investigation of the Mirasol System (AIMS) conducted by Agility Clinical Inc at the Komfo Anokye Teaching Hospital in Kumasi, Ghana, to test whether Mirasol-treated whole blood would prevent transfusion-transmitted malaria in patients with anemia. The results of the study concluded that treated whole blood reduced the incidence of transfusion-transmitted malaria. For more information about the AIMS study, see https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00581-X/fulltext

[4] For more information, see https://openjicareport.jica.go.jp/pdf/12322772.pdf

[5] For more information, see https://www.macopharma.com/theraflex-uv-platelets/.

[6] For more information, see https://pubmed.ncbi.nlm.nih.gov/30497939/ and/or https://consultqd.clevelandclinic.org/electronic-brachytherapy-is-it-a-viable-option/ .

[7] The American Association of Physicists in Medicine (AAPM) released a 2019 report to serve as a training document for medical physicists aiming to design a quality management program for electronic brachytherapy. The report specifically focuses on the Xoft and INTRABEAM systems. For more information, see https://aapm.onlinelibrary.wiley.com/doi/epdf/10.1002/mp.13910

4.5.1 Manufacturers

Currently, at least seven devices on the market provide electronic brachytherapy. Of these seven, four devices are capable of intraoperative radiotherapy: the Xoft Axxent System, the INTRABEAM system, the Papillon, and the Sculptura.[1]

4.5.2 Procurement

Currently, no international stakeholders are assisting in the procurement of electronic brachytherapy. This is most likely due to the fact that it cannot fully replace traditional HDR brachytherapy at this time. However, international stakeholders do assist in the procurement of afterloaders and applicators to perform traditional HDR brachytherapy. The IAEA includes HDR brachytherapy in their recommendations for essential equipment in a basic radiotherapy center.[2] As such, HDR brachytherapy afterloaders and applicators are typically procured through the same means as external beam radiotherapy (radioisotope or non-radioisotope).

4.5.3 Development

RadiaBeam recently received funding through NNSA's SBIR/STTR programs to establish the technical merit, feasibility, and commercial potential of their proposed electronic brachytherapy system.[3] The project aims to replace radioactive sources by developing a system that delivers energetic electron beams for brachytherapy. The IAEA and the WHO have also showed interest in electronic brachytherapy as a potential avenue for lessening the burden associated with replacing radioactive sources and dealing with regulatory issues concerning the safety and security of radioactive sources.[4]

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[1] A 2015 analysis found three devices capable of intraoperative radiotherapy; see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5415885/. Since 2015, Sensus Healthcare received FDA approval for Sculptura, a robotic intraoperative radiation therapy system; see https://www.prnewswire.com/news-releases/us-fda-grants-market-clearance-to-sensus-healthcares-new-sculptura-radiation-oncology-system-300801774.html?tc=eml_cleartime&fbclid=IwAR3sUsFbhzzyig89PGmvMGcbfxA1w-OqjRnEMp3SRt8e50mxAvZODe4kR8A

[2] For more information about the IAEA recommendations for a basic radiotherapy center, see page 30 at https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1462_web.pdf.

[3] As mentioned earlier, NNSA awards funding through their SBIR and STTR programs to encourage small businesses to take part in federal research and development. To learn more about the SBIR/STTR programs, see https://www.sbir.gov/about. For more information about RadiaBeam's electronic brachytherapy project, see https://www.sbir.gov/node/2073929.

[4] For more information, see page 76 at https://apps.who.int/iris/bitstream/handle/10665/339912/9789240019980-eng.pdf.

5.0 Capacity Building

Qualified professionals are needed to ensure effective and safe radiation treatments. However, personnel are often limited in LMICs and the recommended levels of staff are not always available. A 2015 report, *Expanding Global Access to Radiotherapy,* projected the number of personnel needed by 2035 for high-income countries, upper-middle income countries, and low-income countries. The report estimated lower-middle income countries would need to train 9,900 radiation oncologists, 7,200 medical physicists, and 24,900 radiation technologists to meet the demand in 2035. [1] The procurement of new technology and the expansion of services may also require additional training and/or additional staff members. Therefore, capacity-building initiatives are necessary to ensure that staff can effectively and safely administer treatments.

The IAEA works with the WHO and the International Agency for Research on Cancer to conduct imPACT reviews. During an imPACT review, a country's cancer control capacities and needs are assessed, and interventions are identified to improve the country's cancer burden. The IAEA has conducted more than 100 imPACT reviews since 2005.[2] The IAEA has also conducted follow-up meetings (virtual during COVID) with Member States who had an imPACT review in the past 5 years. There has also been an increase in the number of Member States requesting support in developing National Cancer Control Plans (NCCPs).[3] NCCPs can serve as critical policy documents assisting with the effective integration of radiation medicine into comprehensive cancer control. The IAEA also helps countries around the world adapt to changing technology and security needs. To accomplish this mission, the IAEA publishes guidelines and information booklets, organizes seminars, and partners with professional communities. The IAEA also supports the training overseas of candidates from low-income countries and shares the cost of professionals from middle-income countries.

In 2019, the IAEA and IsDB launched the *Partnership Initiative to Increase Access to Diagnostics and Treatment of Women's Cancers in Low- and Middle-Income Countries* to raise funds for projects supporting countries in addressing cancers that mainly affect women. The funds raised will aid projects in 17 countries that are members of the IAEA and IsDB. Projects aim to expand breast and cervical cancer control programs by upgrading cancer facilities through equipment procurement, training and education, and by strengthening quality assurance.

Outside of the IAEA, many other organizations and programs are assisting in training essential personnel, including NNSA-ORS, Rayos Contra Cancer, Radiating Hope, the Global Access to Cancer Care Foundation, the ICEC, and many more.

- Rayos Contra Cancer (RCC) is a relatively new nonprofit organization that focuses on supporting existing radiotherapy clinics in resource-limited settings around the globe. RCC specializes in providing training during a transition to new equipment. RCC recently worked with WUSTL and LIGA/INCAN in Guatemala.[4]

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[1] For other projections or more information about these estimates, see Table 5 at https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00222-3/fulltext.

[2] For more information about imPACT reviews, see https://www.iaea.org/services/review-missions/impact-reviews.

[3] Correspondence with a subject matter expert, 8/27/2021.

[4] For more information about RCC's involvement in Guatemala, see https://www.sciencedirect.com/science/article/pii/S036030162030986X.

- Radiating Hope was founded as an NGO in 2009. Radiating Hope facilitates the donation of equipment (radioisotope and non-radioisotope based) and provides education and training to end-users. Radiating Hope has donated equipment and provided training to end-users in Senegal, Ghana, Honduras, Guatemala, and Nepal.[1] Radiating Hope recently entered a strategic partnership with the Global Access to Cancer Care Foundation.[2]
- The ICEC aims to reduce mortality and improve the quality of life for people with cancer in LMICs, as well as the indigenous and geographically underserved populations in high-income countries and regions worldwide. The ICEC addresses this mission through a mentoring network of cancer professionals who work with local and regional in-country groups to develop and sustain expertise for better cancer care. ICEC facilitates capacity-building through their twinning programs. ICEC's twinning programs connect university departments, cancer programs, and/or private practices in high-income countries (ICEC Hubs and ICEC Experts) with cancer programs, facilities, or individuals in LMICs. These long-term sustainable mentoring partnerships facilitate the transfer of information and technology with the end goal of the LMIC partner becoming an ICEC Hub for other cancer facilities in their region.[3]
- Most capacity-building initiatives identified during the research for this report involve personnel in cancer treatment. That said, there is one example of capacity-building involving the use of UV-PRT and the creation of a HV program. This example is briefly mentioned in Section 4.4 and involves AABB Consulting Services, Terumo BCT, and the Japanese Red Cross Society as a part of the *Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries*.[4] AABB Consulting Services developed and supported the training and implementation of the HV system employed in Ghana. The Japanese Red Cross Society provided HV training to doctors and nurses from the hospitals and the National Blood Service in Japan, and Terumo BCT supported the training of Mirasol operators and provided training on how to train future operators.[5]

Although not specifically covered in this report, professional associations and organizations also contribute to capacity-building. A few examples include initiatives through the Radiological Society of North America (RSNA), the International Organization for Medical Physics (IOMP), and a recent initiative to develop an international radiation oncology association.

- RSNA launched the *Global Learning Center (GLC)* program to improve radiology education and patient care around the world in 2019. Through the program, RSNA members work with universities or hospitals to develop curriculum that is tailored to the institution's needs. RSNA launched the first GLC in South Africa in 2019. Shortly after this launch, NNSA awarded RSNA a grant to address radiologists' needs in Sub-Saharan Africa. In 2020, RSNA opened its second GLC in Tanzania, funded in part by NNSA's contribution.[6]

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[1] For more information, see https://cdn.agilitycms.com/applied-radiation-oncology/PDFs/issues/ARO_06-19_Shah_special.pdf.
[2] For more information, see https://markets.businessinsider.com/news/stocks/global-access-to-cancer-care-foundation-and-radiating-hope-announce-strategic-partnership-to-treat-cancer-globally-1028625276.
[3] For more information about ICEC's twinning programs, see https://www.iceccancer.org/early-career-leaders-twinning-programs/.
[4] For more information, see https://openjicareport.jica.go.jp/pdf/12322772.pdf
[5] For more information about the Japanese Red Cross Society, see https://www.jrc.or.jp/english/activity/blood/ and for more information about Terumo BCT's training, see https://openjicareport.jica.go.jp/pdf/12322772.pdf
[6] For more information about the GLC in Tanzania and NNSA's contribution, see https://www.rsna.org/news/2020/September/Global-Learning-Center-Virtual-Education.

- IOMP offers education and training resources, medical physics equipment donation, and works with international organizations and medical physicists worldwide to enhance patient treatment.
- Several regional and state-specific oncology societies—including the European Society for Therapeutic Radiology and Oncology, the Royal Australian and New Zealand College of Radiologists, the Royal College of Radiologists, African Organization for Research and Training in Cancer, and several others—are working with the IAEA's Division of Human Health to develop an international radiation oncology society.[1]

This section provided a sample of the current capacity-building initiatives; the appendix provides further insights. Due to the sheer magnitude of initiatives, describing all possible pathways is not feasible within the scope of this report.

[1] Subject matter expert interview; 5/26/2021

6.0 End-of-Life Management

For source users seeking to transition from a radioisotope-based technology to an alternative technology, providing end-of-life management of the radioactive source is a crucial aspect of achieving security risk reduction. At the time of purchase, source users can include source return to supplier agreements with manufacturers, but these agreements typically do not contain an agreement that the manufacturer will pay the shipping costs, which vary depending on the location and thus can be high. Due to the high cost of safe disposal in line with regulatory guidelines, users may abandon their disused sources or store them in unsafe and insecure locations. Current end-of-life management options for disused sources include reuse or recycling, long-term storage and disposal, and return to the supplier. When end-users cannot afford end-of-life management services or end-users do not have the technical expertise required, international stakeholders may become involved. While several services exist for end-of-life management that operate internationally, there are few stakeholders who financially contribute to international end-of-life management projects. The IAEA and NNSA-ORS appear to be the predominant players.

The IAEA, through the Division of Nuclear Fuel Cycle and Waste Technology's Waste Technology Section, assists Member States in effectively handling all forms of radioactive waste. The Waste Technology Section assists Member States across a variety of radioactive management topics, including predisposal management and the development of policies, strategies, and technical solutions for radioactive waste disposal programs. The Section also works with the Division of Nuclear Security to secure sources. Projects between the Section and the Division of Nuclear Security are financed through the Nuclear Security Fund, which is based on voluntary contributions from Member States. These projects consist of securing and removing the source. One example of the Waste Technology Section's involvement is the borehole disposal concept that is being piloted in Ghana and Malaysia.[1]

NNSA-ORS also aids in end-of-life management.[2] NNSA-ORS assists with the packaging, transportation, and emplacement of disused sources into secure storage and/or disposal in partner countries. On a case-by-case basis, they also repatriate US origin sources from international locations through the Off-Site Source Recovery Program (OSRP). According to publicly available fact sheets, NNSA-ORS has recovered 45,000 sources from the US, Puerto Rico, and 28 foreign locations since 1997.[3] Both the IAEA and NNSA-ORS hire regional and/or domestic companies capable of end-of-life management to physically handle the source(s), while they provide the funding and technical supervision. (A preliminary list of regional and domestic companies offering end-of-life management services is included in the appendix). Outside of the IAEA and NNSA-ORS, there do not appear to be any significant organizations and/or programs involved in supporting the end-of-life management of disused sources, although some countries—such as Canada, France, and Germany—assist with the removal of sources from LMICs on an ad hoc basis.

[1] The IAEA hopes to employ the borehole concept in countries that do not have a large-scale waste facility. Ghana and Malaysia are both currently using a borehole to dispose of sources.

[2] For more information about NNSA-ORS removals abroad and within the US, see https://osrp.lanl.gov/ and/or https://osrp.lanl.gov/Documents/Brochure.pdf

[3] Ibid.

7.0 Conclusion

This report addresses challenges noted during the 2020 WINS roundtable discussion by consolidating information regarding various organizations and programs involved in the adoption of alternative technologies to high-activity Category 1 and 2 sources within the medical field. The purpose of this report is to shed light on existing stakeholder involvement, recording their missions and contributions within one document.

The information included in this report was acquired through open-source research and stakeholder interviews and correspondence. In-country news articles proved to be a helpful source for collecting information about past, present, and future alternative technology projects. However, data availability is largely dependent on the alternative technology involved. For instance, information about stakeholder involvement in the adoption of LINACs proved more readily available than information about X-ray blood irradiator procurement.

In the future, further transparency in the adoption of alternative technologies would be beneficial to those working to understand the overarching landscape and the stakeholders involved. Undoubtedly, some past, present, and planned activities involving alternative technologies are not captured in this report. Readers are encouraged to reach out to WINS with information regarding such stakeholder engagement. Furthermore, additional research is needed to evaluate the effectiveness of stakeholder involvement. Such research may identify gaps and opportunities for enhancing coordination and cooperation between various organizations and programs.

The author does not endorse any technologies mentioned in this report. The author attempted to include all technologies currently available as alternatives to high-activity Category 1 and 2 sources within the medical sector.

Appendix A – International Stakeholders Involved in the Adoption of Alternative Technologies

This appendix includes information about various international stakeholders, their overall missions, and their past, present, and/or future projects related to the adoption of alternative technologies. The appendix is organized by stakeholder groups.

- The first section covers intergovernmental organizations (IGOs).
- The second section covers non-governmental organizations (NGOs).
- The third section covers government support programs.
- The fourth section covers manufacturers, vendors, and developers.
- The fifth section covers sponsors and funders.
- The sixth section covers original source manufacturers and companies involved in end-of-life management.

A large part of the first section is dedicated to the International Atomic Energy Agency (IAEA) because several different divisions, sections, and programs within the agency play a vital role in the adoption of alternative technologies. At the end of this appendix, Figure A.1 provides a picture of all the identified international stakeholders in their respective stakeholder groups.

Note that although this appendix divides stakeholders into groups based on a single criterion, many organizations and programs often fit into more than one category. For simplicity, organizations are not listed twice; instead, their contributions are all listed within their selected category. Finally, while the report aims to be comprehensive, gaps are unavoidable. Readers are encouraged to reach out to the World Institute of Nuclear Security (WINS) with additional information as applicable. Further research is needed to evaluate the effectiveness of stakeholder involvement to offer suggestions about how to improve and better coordinate stakeholder engagement.

A.1 Intergovernmental Organizations

The Ad Hoc Working Group on Alternatives to High-Activity Radiological Sources was established at the 2016 Nuclear Security Summit. The Working Group provides a forum for states to share information and experiences with alternative technologies. The Working Group hosts an annual meeting to bring together states and other stakeholders to share information about alternative technologies.

The European Organization for Nuclear Research (CERN) was established in 1951 and is run by 23 Member States. Many non-European countries are also involved in different ways. CERN's mission is to provide a range of particle accelerator facilities for research purposes, conduct world-class fundamental physics research, and to bring people together from all over the world to push scientific frontiers. Relevant to this report, CERN is involved in the ITAR (Innovative Technologies toward building Affordable and equitable global Radiotherapy capacity) project, which aims to develop a more robust linear accelerator (LINAC) for low- and middle-income countries (LMICs).

The Global Partnership Nuclear Radiological Security Working Group (NRSWG) is an informal working group of the Global Partnership Against the Spread of Weapons and Materials of Mass

Destruction. The working group aims to follow several principles related to nuclear and radiological security. Relevant to this report, NRSWG works to identify potential partnerships to promote work under several thematic areas that fall under nuclear and radiological security.[1]

The IAEA was created in 1957 after the discovery of nuclear technology. It is mandated to work with Member States to promote peaceful uses of nuclear technology. The IAEA includes six departments and several divisions, sections, and programs. The departments, divisions, sections, and programs playing a role in the adoption of alternative technology are described below.

The Department of Technical Cooperation (TC) helps Member States address specific needs within the following topic areas: health and nutrition, food and agriculture, water and the environment, industrial applications or radiation technology, safety and security, and energy planning and nuclear power. To accomplish this task, the TC Department helps connect more advanced Member States with less advanced Member States. The Department includes four divisions to support its four geographic regions of operation (Africa, Asia and the Pacific, Europe, and Latin America and the Caribbean). Each division works with Member States within their region to address their specific needs. In addition to the region-specific divisions, the Department is also home to the Division of Programme of Action for Cancer Therapy (PACT).

- Division for Africa
- Division for Asia and the Pacific
- Division for Europe and Central Asia
- Division for Latin America and the Caribbean
- The Division of Programme of Action for Cancer Therapy (PACT) was established in 2004 to foster collaboration with other international organizations and ensure that radiotherapy is included in national cancer control plans. PACT supports Member States by conducting imPACT reviews with the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC), assisting in the development of Comprehensive National Cancer Control Plans, and assists in mobilizing resources, including funds, by assisting Member States in developing bankable documents.

The Office of Procurement Services is within the Department of Management. The Office procures a variety of goods and services (including isotopes and radiotherapy equipment) in support of the IAEA. Many of the goods and services procured are delivered to Member States in Africa, Asia, Europe, and Latin America.

The Division of Human Health (NAHU) is within the Department of Nuclear Sciences and Applications. The Division aims to assist Member States in addressing needs related to the prevention, diagnosis, and treatment of diseases using nuclear techniques.

- The Nuclear Medicine and Diagnostic Imaging Section (NMDI) is within NAHU. The Section provides a variety of services to Member States related to enhancing Member States' abilities to address health needs using nuclear medicine techniques in both imaging and therapeutic applications. The Section also maintains the Nuclear Medicine Database (NUMDAB) that contains information about the status of nuclear medicine practices worldwide with the aim to facilitate quality management and professional development.[2]

[1] For more information about the NRSWG's principles and thematic areas, see https://www.gpwmd.com/nrswg.
[2] For more information about NUMDAB, see https://www.iaea.org/resources/databases/numdab.

- The Applied Radiation Biology and Radiotherapy Section (ARBR) is within NAHU. The Section aims to improve the availability and safe use of radiation for effective cancer management. The Section accomplishes this mission by helping establish and enhance existing radiotherapy centers and equipment by introducing resource-sparing protocols, organizing teaching and training courses for medical personnel, and designing effective treatments for different types of cancer based on radiobiological principles and studies.
- The Dosimetry and Medical Radiation Physics Section (DMRP) is within NAHU. The Section is responsible for the quality assurance aspects of the use of radiation-generating equipment to ensure safety and effectiveness.
- Medical physicists monitor the radiation dose delivered during procedures using dosimetric tests. The IAEA partners with the WHO to provide a gateway to the international measurement system or the International System of Units (SI) through the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories. [1]

The Division of Nuclear Fuel Cycle and Waste Technology (NEFW) is within the Department of Nuclear Energy. The Division develops and executes the IAEA's activities concerning the nuclear fuel cycle, waste management, and research reactors.

- The Waste Technology Section is within NEFW. The Section assists Member States in effectively handling all forms of radioactive waste by applying safe, prompt, and cost-effective solutions. The Section accomplishes its mission by Member States on radioactive management topics, including predisposal management and the development of policies, strategies, and technical solutions for radioactive waste disposal programs. Most relevant to this report, the Section assists Member States with improving their management of radioactive sources by improving their capacity to recover, condition, store, recycle, repatriate, and dispose of disused sources.

The Division of Nuclear Security is within the Department of Nuclear Safety and Security. The Division aims to prevent, detect, and respond to acts and threats of nuclear terrorism. The majority of sections under the Division of Nuclear Security are beyond the scope of this report. However, the Division does work with the end-of-life management of disused sources with the Division of Nuclear Fuel Cycle and Waste Technology.

The Office of Safety and Security Coordination is within the Department of Nuclear Safety and Security. The Office ensures the IAEA's coordination across activities in nuclear, radiation, transport, and waste safety and security programs.

The Division of Radiation, Transport and Waste Safety (NSRW) is within the Department of Nuclear Safety and Security. The Division assists in the development and implementation of safety standards for radiation protection, radioactive waste, and transport.

- The Waste and Environmental Safety Section is within NSRW. The Section develops the IAEA's Safety Standards concerning radioactive waste management, decommissioning, remediation, and environmental releases and assists Member States in implementing policies and strategies regarding the safety of radioactive waste. The Section also provides input to the Secretariat on the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management. Finally, the Section provides ARTEMIS—a peer

[1] The IAEA maintains a database (DOLNET) of all of the laboratories involved in the network. For more information, visit https://ssdl.iaea.org/Home/AboutDOLNET

review service that provides expert opinion and advice about radioactive waste and spent fuel management, decommissioning, and remediation programs.[1]

The International Agency for Research on Cancer (IARC) is an autonomous agency of WHO that aims to promote international collaboration in cancer research. IARC also offers free learning materials and delivers international training courses held at the IARC and at diverse locations worldwide through collaborative research projects. The IARC is also involved in imPACT reviews.

The World Health Organization (WHO) is the United Nations agency that connects nations, partners, and people to promote health. WHO develops normative guidance, monitors global health data, performs health technology assessments, and provides advice to countries regarding the prioritization of medical devices for cancer management. WHO also works directly with the IAEA and the IARC on imPACT reviews, and also co-publishes guidelines and supplementary material with the IAEA. Additionally, WHO also partners with the IAEA on the IAEA/WHO Network of Secondary Standard Dosimetry Laboratories to provide Member States with the International System of Units used for dosimetric tests. *Please note, the above description is by no means comprehensive of all WHO's efforts. It is merely meant to provide a snapshot of the initiatives relevant to this report. For more information about WHO and the organizations mission, please visit their website.* Several WHO Teams of relevance to this report are also listed below.

- Health Product and Policy Standards assists Member States in developing evidence-based polices and verifying that best practices and good governance are present throughout the supply chain.
- Noncommunicable Diseases Surveillance, Monitoring, and Reporting aims to improve public health policy through the collection, analysis, and dissemination of country-level risk factor information.
- Noncommunicable Diseases leads, coordinates, and monitors global efforts to provide access to health services, medicines, vaccines, and diagnostic and health technologies to prevent and treat noncommunicable diseases. The team also supports those living with noncommunicable disease-related disabilities.
- Radiation and Health works to improve radiation protection for the public, patients, and workers worldwide. The team provides evidence-based guidance, tools, technical advice, and capacity building related to ionizing and non-ionizing radiation, including planned exposures such as medical uses of radiation.

A.2 Non-Governmental Organizations

The African Organization for Research and Training in Cancer (AORTIC) is an NGO dedicated to cancer control and palliation in Africa. AORTIC offers training through workshops and an online education platform. At the time of this report (11/23/2022), AORTIC was conducting a needs assessment of the online courses offered and indicated that available courses will be published soon.

AABB (Association for the Advancement of Blood and Biotherapies) is an international not-for-profit association that represents individuals (e.g., nurses, physicians, medical technologists,

[1] For more information about ARTEMIS, see https://www.iaea.org/services/review-missions/integrated-review-service-for-radioactive-waste-and-spent-fuel-management-decommissioning-and-remediation-artemis.

etc.) and institutions involved in transfusion medicine and biotherapies. The association focuses on the development and delivery of standards, accreditation, and educational programs that focus on patient and donor care and safety. AABB is in over 80 countries and accredits institutions in more than 50 countries. (AABB was formerly known as the American Association of Blood Banks).

- AABB Consulting Services offers consultations, interviews, and gap analysis consultative services to assist blood, plasma, and tissue collection and/or management facilities; transfusion services; clinical laboratories; and cellular and related biological therapy facilities. The consultative services provide assistance in the improvement of quality management and process improvement systems. AABB Consulting Services developed and supported the training and implementation of the haemovigilance (HV) system employed in Ghana as a part of the *Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries*.[1]

Bio Ventures for Global Health (BVGH) is dedicated to solving global health issues by connecting people, resources, and ideas. BVGH runs the African Access Initiative, which is a public-private partnership dedicated to increasing access to cancer treatment. Through this initiative, BVGH helps to expand access to cancer medicines and technologies, strengthen the health care infrastructure, build the clinical oncology capacity, and address the cancer data gap through clinical trials.[2] BVGH has connected the Rayos Contra Cancer (RCC) to institutions in Africa that may benefit from RCC's training initiatives.[3]

The City Cancer Challenge Foundation (C/CAN) supports cities around the world in improving access to cancer care. C/CAN accomplishes this mission by transforming the way stakeholders from the public and private sector design, plan, and implement cancer solutions. C/CAN was launched by the Union for International Cancer Control at the 2017 World Economic Forum Annual Meeting. The organization has been a standalone foundation since 2019.

The Global Access to Cancer Care Foundation (GACCF) supports clinical training programs on radiotherapy with the aim of creating a local base of experts. GACCF works specifically with LMICs in South America, Africa, and South and East Asia. The Foundation's cancer-care professionals work with in-country partners to improve radiotherapy treatment through training courses and workshops. In-country partners include universities, hospitals, and/or government institutions involved in the treatment of cancer through radiotherapy. Recently, GACCF and Radiating Hope entered a partnership.[4]

The International Cancer Control Partnership (ICCP), created in 2012, is a group of international organizations that joined forces to minimize duplication of efforts in cancer control and publish resources and available national cancer control plans. After nearly a decade of operation, ICCP has grown to also provide technical assistance (proactive and reactive).[5]

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[1] For more information about AABB Consulting Services efforts in Ghana, see https://openjicareport.jica.go.jp/pdf/12322772.pdf

[2] For more information about the AAI, see https://bvgh.org/african-access-initiative/.

[3] Subject matter expert interview, 6/17/2021.

[4] For more information about the strategic partnership, see https://www.prweb.com/releases/global_access_to_cancer_care_foundation_and_radiating_hope_announce_strategic_partnership_to_treat_cancer_globally/prweb16664775.htm.

[5] Correspondence with a subject matter expert, 8/27/2021.

The International Cancer Expert Corps (ICEC) is an NGO registered in the United States (US), developed in response to the United Nations and WHO's recognition that LMICs frequently suffer the burden of noncommunicable diseases.

- ICEC leads the *Smart Technology to Extend Lives with Linear Accelerators* (Project STELLA), which seeks to transform radiation therapy to significantly improve treatment for millions of cancer patients around the world, particularly in underserved LMICs and underserved areas in high-income countries. Project STELLA is an ongoing collaboration of ICEC, CERN, the United Kingdom (UK) Science and Technology Facilities Council (STFC) and its Daresbury Laboratory and Hartree Centre in association with Lancaster University (UK).
- Project STELLA serves as the umbrella program for ITAR—Innovative Technologies toward building Affordable and equitable global Radiotherapy capacity—the goal of which is to develop a more robust LINAC for LMICs. [1]
- Through ICEC's network-oriented global trusted partnerships, ICEC's Twinning programs provide sustainable and continuing education, training, and mentoring to professionals in resource-poor countries and to underserved regions in high-income countries.[2]
- ICEC encourages and supports interested practitioners early in their careers in participating in sustainable global cancer-care initiatives and provides senior cancer and health care professionals and retirees opportunities to engage and serve as mentors.[3]

The International Network for Cancer Treatment and Research (INCTR) is an international nonprofit NGO whose mission is to address the burden of cancer in developing countries. INCTR operates several programs that involve cooperation between their regional branches and offices (located in Brazil, Canada, Egypt, France, Nepal, and the US and offices in Cameroon, India, Tanzania, and the UK) and institutions in LMICs. INCTR's programs include adult oncology, cancer registry, clinical research, foundation-building, palliative care, pathology, and pediatric oncology.

Medical Physics for World Benefit (MPWB) supports activities to ensure the safe and effective use of physics and technology within the medical profession. The organization provides support on an as-needed basis to various entities, especially those in LMICs. For instance, MPWB[4]

- Provides training, in-person and online, for various medical physics activities.
- Provides educational webinars on issues of relevance to medical physicists.
- Provides online mentoring support to medical physicists.
- Provides an online forum to connect medical physicists from around the globe.
- Provides support for under-resourced medical physicists in attending professional meetings.
- Assists by responding to specific requests. Examples of support include the following:
  - the development of education programs such as master's degrees in medical physics;

[1] For more information about STELLA and ITAR, see https://www.iceccancer.org/innovative-radiotherapy-technologies/.
[2] To learn more about ICEC's Twinning Programs, see https://www.iceccancer.org/early-career-leaders-twinning-programs/.
[3] For more information about Senior Mentoring, see https://www.iceccancer.org/programs-grants/senior-healthcare-professionals-and-retirees/
[4] Correspondence with a subject matter expert, 8/30/2021.

- advising on the recruitment process for temporary or full-time medical physics staff; and
- advising on technical concerns in the purchase of new technologies, quality assurance or quality control of existing technologies, or on radiation safety-related issues.

The Nuclear Threat Initiative (NTI) supports activities to raise awareness, improve security, and strengthen global standards to prevent dirty bombs. NTI accomplishes this mission by working globally with governments and industry to bolster security for and eliminate dangerous radiological materials. Within the US, NTI supported efforts to convert all New York City hospitals from using cesium-137 (Cs-137) irradiators to using X-ray irradiators and convert the University of California Cs-137 to X-rays irradiators. NTI has also published several reports and other resources about radiological security and alternative technologies:

- Case Study: An Analysis of Several National Approaches to Alternative Technologies for Radioactive Sources
- Preventing a Dirty Bomb: Case Studies and Lessons Learned
- Preventing a Dirty Bomb: Effective Alternative Technologies for Radiological Security
- NTI Nuclear Security Index.

Radiating Hope works to provide radiation machines to underserved populations with the overarching goal of improving radiation oncology care around the globe. Radiating Hope accepts used LINACs. The organization also provides education and training to the medical teams receiving donated equipment. Radiating Hope also organizes medical symposia, including the Greater Horn Oncology Symposium in Eastern Africa, to share best practices and new research.[1] Recently, the GACCF and Radiating Hope entered a partnership.[2]

Rayos Contra Cancer (RCC) is a 501(c)3 nonprofit organization that aims to support existing radiotherapy clinics in resource-limited settings around the globe. RCC specializes in providing training during a transition to new equipment (e.g., transitioning from using a teletherapy unit to using a LINAC). Their training model has been reported and involves weekly remote sessions with multiple clinics over a longitudinal 3- to 4-month curriculum at a time.[3] RCC has supported partner efforts among academic and professional institutions in different regions, including Washington University St. Louis (WUSTL) in Guatemala.[4] RCC reaches most participating clinics through word of mouth, predominantly through its network of local professionals and regional radiation oncology professional associations.[5] BVGH has also connected RCC with institutions in Africa that may benefit from the organization's training initiatives.[6]

The TreatSafely Foundation aims to provide educational opportunities to radiation medicine professionals related to patient safety, error management, and quality improvement. The Foundation operates a vetted peer-to-peer website (i.treatsafely) that provides both general education and application-specific training.

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[1] For more information about Radiating Hope, see https://cdn.agilitycms.com/applied-radiation-oncology/PDFs/issues/ARO_06-19_Shah_special.pdf

[2] For more information, see https://www.prweb.com/releases/global_access_to_cancer_care_foundation_and_radiating_hope_announce_strategic_partnership_to_treat_cancer_globally/prweb16664775.htm.

[3] For more information, see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7713515/.

[4] https://www.sciencedirect.com/science/article/pii/S036030162030986X?via%3Dihub.

[5] Subject matter expert interview, 6/17/2021.

[6] Subject matter expert interview, 6/17/2021.

The Union for International Cancer Control (UICC) implements convening, capacity-building, and advocacy initiatives that bring together the cancer community to reduce the global cancer burden, promote equality, and ensure that cancer control continues to be a priority on the world health and development agenda.

A.3 Government Support Programs

The Japan International Cooperation Agency (JICA) provides development assistance to developing countries around the world. For example, JICA provided training through short courses to Nigerian staff in radiation oncology.[1] JICA also provided funding to Terumo Corporation, AABB Consulting Services, and the Japanese Red Cross Society through their *Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries* to assist in bringing Mirasol and an HV program to Ghana.[2]

The Japanese Red Cross Society (JRCS) is the Japanese affiliate of the International Red Cross. The JRCS works both domestically and abroad. Most notable to this report, JCRS participated in JICAs' *Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries* to provide training in HV to doctors and nurses from Ghana.

The National Cancer Institute (NCI) is the US government's main organization for cancer research and training. NCI's mission is to lead, conduct, and support cancer research across the US. Notable for this project, NCI established the Center for Global Health in 2011 to reduce the global burden of cancer.

- The Center of Global Health (CGH) works with other NCI divisions, designated NCI cancer centers, and countries to support cancer control planning capacity, cancer research, and cancer research networks in LMICs. [3]

The National Nuclear Security Administration's Office of Radiological Security (NNSA-ORS) works with domestic and international partners to prevent radiological terrorism by securing risk-significant radioactive materials, removing and disposing of disused sources, and reducing reliance on high-activity sources through the adoption of non-radioisotope-based alternative technologies.

The author of the report based this list on publicly available English-language information. There may be other government support programs that contribute to capacity-building initiatives like Japan's JICA that are not captured in this report. However, this report was unable to document specific cases of such involvement. The author also acknowledges that numerous countries contribute to IAEA projects related to the use of radiation in health care.

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[1] For more information about JICA's support in Nigeria, see https://www.wajradiology.org/article.asp?issn=1115-3474;year=2013;volume=20;issue=2;spage=84;epage=88;aulast=Nwankwo

[2] For more information about JICA's involvement in Ghana, see https://openjicareport.jica.go.jp/pdf/12322772.pdf For more information about JICA's Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries, see https://www.mofa.go.jp/policy/oda/white/2017/html/honbun/b3/s2_3_3.html

[3] For additional information regarding CGH, see https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-nci#cgh

A.4 Manufacturers, Vendors, and Developers

A.4.1 Medical Linear Accelerators

Accuray is based in the US and specializes in developing and manufacturing alternative cancer treatments.

- TomoTherapy (LINAC)
- Radixact System (LINAC)

Elekta is a medical device company focused on providing equipment for radiotherapy treatments.

- Synergy (LINAC)
- Infinity (LINAC)
- Harmony (LINAC as of (11/2022) it is not available to all markets)

Panacea Medical Technologies is based in India and was founded to improve global access to cancer care.

- Siddharth II (LINAC)

RadiaBeam is based in the US and provides design to delivery service of high-energy e-beam sources, LINAC components, and turnkey systems.

- RadiaBeam develops custom LINACs and accelerator hardware components as well as systems for any application, including medical.[1]
- Radiabeam is also working to develop an affordable LINAC that uses less power but delivers the same high-quality treatment using a concept developed at the University of California, Los Angeles.[2]

Shinva is based in China and offers a variety of medical devices and equipment, pharmaceutical machinery, and air purifiers, including the following:

- Digital XHA1400 (LINAC)
- High Energy Medical Electron Linear Accelerator (LINAC)
- Digital XHA600E (LINAC).

The University of Sydney is developing the Nano-X gantry, a modified gantry that is fixed to the floor to reduce the shielding need for the walls and ceiling of the radiation room. Conventional gantries rotate around the patient's tumor, while the University's modification allows the patient to rotate and the gantry to stay fixed.[3]

Varian, recently acquired by Siemens Healthineers, offers a variety of medical equipment for radiosurgery, radiotherapy, proton therapy, and brachytherapy, including the following:

- Halcyon (LINAC)

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[1] For more information, see https://radiabeam.com/applications/medical/.

[2] For more information, see https://www.lindau-nobel.org/blog-tackling-the-silent-crisis-in-cancer-care-with-innovation/.

[3] For more information, see https://www.lindau-nobel.org/blog-tackling-the-silent-crisis-in-cancer-care-with-innovation/.

- TrueBeam (LINAC)
- VitalBeam (LINAC).

A.4.2 Used Medical Linear Accelerators

Avante Health Solutions sells refurbished used LINACs, LINAC parts, and also provides service plans to buyers.

Radiation Oncology Systems (ROS) provides refurbished and used radiation oncology and diagnostic imaging equipment solutions to facilities. ROS sells a variety of used LINACs and LINAC parts, provides service and warranty contracts, and also provides for the removal and disposal of radioactive materials.

A.4.3 Stereotactic Radiosurgery (SRS) Equipment

Accuray is based in the US and offers products from oncology to neuro-radiosurgery.

- CyberKnife S7 (miniature LINAC on a robotic arm)

Elekta is a medical device company focused on providing equipment for radiotherapy treatments.

- Versa HD (dedicated LINAC)

Varian, recently acquired by Siemens Healthineers, offers a variety of medical equipment for radiosurgery, radiotherapy, proton therapy, and brachytherapy.

- Edge (dedicated LINAC)
- HyperArc (dedicated LINAC)

ViewRay is based in the US and offers a magnetic resonance-guided LINAC.

- MRIdian (dedicated LINAC)[1]

ZAP Surgical Systems is based in the US~~,~~ and was formed by Dr. Adler, a professor of Neurosurgery and Radiation Oncology at Stanford University. Adler also founded Accuray and invented the CyberKnife System.

- Zap-X (dedicated LINAC)[2]

A.4.4 X-ray Blood Irradiators

Best Theratronics is a Canadian subsidiary of TeamBest. Formerly part of MDS Nordion, the company became part of the Best family in 2008.

- Raycell Mk1 (X-ray blood irradiator)
- Raycell Mk2 (X-ray blood irradiator)

[1] Not all products and features are available in all markets. For more information, see https://viewray.com/discover-mridian/

[2] The platform received FDA clearance in 2017, Japan Shonin clearance in 2020, and E.U. CE clearance in 2021. However, as of 11/23/2022 it is not available to all markets.

Gilardoni, an Italian company, manufactures X-ray and ultrasound equipment in the medical, security, and non-destructive testing sectors.

- RADGIL2 (X-ray blood irradiator)

FUJIFILM Healthcare Asia Pacific, formerly known as Hitachi Medical Systems Singapore, develops new solutions in diagnostic imaging, ultrasound, neurosurgery, and digital health.

- Sangray (X-ray blood irradiator)

Rad Source is a US-based company that was founded in 1997 to create non-gamma irradiation alternatives. The company's vision is to solve environmental and related issues associated with source-based equipment.

- The RS 3400 (X-ray blood irradiator)

Stellarray has received funding from the National Institutes of Health and the Department of Energy as well as an investment from the Texas Emerging Technology Fund to develop a new kind of self-contained blood/biological irradiator. Stellarray was developed out of the Stellar Micro Devices (SMD) and builds on research that was conducted by SMD for the US Air Force.

Stellarray's Self-Contained Blood/Biological Irradiator is not yet cleared for sale on the market but has the following characteristics:

- A solid-state cooling and insulation system.
- High-voltage power sources built into the same casings as the flat panel X-ray sources, thereby eliminating high-voltage cables.
- Standard wall power sources are sufficient because the irradiator uses less energy than X-ray tube irradiators.

A.4.5 Ultraviolet Pathogen Reduction Technology

Cerus Corporation is headquartered in the US and manufactures:

- INTERCEPT Blood System for Platelets (ultraviolet A light and amotosalen).

Terumo Blood and Cell Technologies (BCT) is headquartered in Japan and manufactures:

- Mirasol (ultraviolet B light and riboflavin).

Macopharma is headquartered in France and is developing:

- THERAFLEX UV-Platelets, which is not yet for sale because regulatory clearances for the system are pending. The system uses ultraviolet C light and no photoactive compound.

A.4.6 Electronic Brachytherapy

Ariane Medical Systems was incorporated in the UK in 2005. Since its incorporation, Ariane has worked with clinical partners to produce devices to deliver low-energy X-rays to tumors.

- Papillon (X-ray device)

Elekta is a medical device company focused on providing equipment for radiotherapy treatments.

- Esteya (X-ray device)

RadiaBeam

- RadiaBeam received funding through NNSA's Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Programs to establish the technical merit, feasibility, and commercial potential of their proposed electronic brachytherapy system.[1]

Sensus Healthcare is a medical device company specializing in minimally invasive and cost-effective treatments for oncological and non-oncological conditions.

- SRT-100 VISION (X-ray device)

Xoft is a subsidiary of iCAD and is headquartered in the US. Xoft developed a miniaturized X-ray source to treat skin, gynecological, and breast cancer.

- Xoft Axxent System (X-ray device)

Xstrahl provides medical and research systems to advance X-ray technology and its treatment options.

- RADiant (X-ray device)

Zeiss supports health care professionals in ophthalmology, ophthalmic surgery, and visualization systems.

- Intrabeam (X-ray device)

A.5 Sponsors and Funders

The Arab Bank for Economic Development in Africa aims to strengthen economic, financial, and technical cooperation between the Arab and African regions.

- The Arab Bank for Economic Development in Africa partnered with the OPEC Fund for International Development to provide funding to upgrade and strengthen radiotherapy and nuclear medicine services in Ghana. Specifically, two LINACs replaced two cobalt-60 (Co-60) machines and an additional Co-60 machine was also provided.[2]

The Islamic Development Bank (IsDB) works to improve lives by promoting social and economic development in Member States and Muslim communities worldwide.

- IsDB provided a loan that contributed to the acquisition of LINACs for oncology centers in Uzbekistan.[3]
- IsDB provided a loan to Niger that resulted in the procurement of a LINAC and the training of medical oncologists, radiotherapists, and radiophysicists on the operationalization of the radiotherapy unit in Morocco and Tunisia.[4]

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[1] For more information about RadiaBeam's electronic brachytherapy project, see https://www.sbir.gov/node/2073929.
[2] For more information, see https://humanhealth.iaea.org/HHW/RadiationOncology/ICARO2/E-Posters/04_FIAGBEDZI.pdf.
[3] For more information, see https://www.iaea.org/sites/default/files/19/11/uzb6008_success_story_2019.pdf.
[4] For more information, see https://www.iaea.org/newscenter/news/from-plans-to-funding-bankable-documents-and-nigers-first-radiotherapy-unit

- The IAEA and IsDB launched the *Partnership Initiative to Increase Access to Diagnostics and Treatment of Women's Cancers in Low- and Middle-Income Countries* to raise funds for projects supporting countries to address cancers that mainly affect women. The funds raised will aid projects in 17 countries that are members of the IAEA and IsDB.[1]

The OPEC Fund for International Development aims to stimulate economic grown and social progress in low-and middle-income countries around the world.

- Uruguay acquired a LINAC in 2014 thanks to funding from the OPEC Fund for International Development and their own government funds.[2]
- The OPEC Fund partnered with the Arab Bank for Economic Development in Africa to provide funding to upgrade and strengthen radiotherapy and nuclear medicine services in Ghana. Specifically, two LINACs replaced two teletherapy machines and an additional teletherapy machine was also procured.[3]

The US Agency for International Development (USAID) Office of American Schools and Hospitals Abroad aids schools, libraries, and medical centers outside of the US that serve as study and demonstration centers for American ideas and practices.

- Partnered with WUSTL, Varian Medical Systems, and NNSA-ORS to transition a Guatemalan hospital from a teletherapy machine to a Halcyon radiation system.[4]

The Qatar Fund for Development (QFFD) is a public development institution that assists in implementing external aid projects. QFFD's main goal is to achieve inclusive and sustainable development by providing assistance for issues related to education, health, and economic empowerment. QFFD delivers financial assistance through a variety of instruments including grants, soft and commercial loans, guarantees, and development investments.

- QFFD is funding the development of a radiotherapy center in Burkina Faso. The Center will be equipped with all the necessary medical equipment and training will be provided to ensure safe and effective treatments. However, it is unclear what medical equipment was procured for this center and if the devices are radioisotope or non-radioisotope based.[5]

The UK Research and Innovation Science and Technology Facilities Council (UKRI STFC) aims to promote and support high-quality scientific and engineering research by developing and/or providing facilities and expertise to support basic to advanced applied research programs in the UK and elsewhere.

- STFC is one of the four collaborating entities of Project STELLA that includes the ICEC, CERN, STFC (Daresbury Laboratory), and Lancaster University. STFC has funded portions of the project's research and development work including ITAR (Innovative Technologies toward building Affordable and equitable global Radiotherapy capacity).
- The ITAR project, a critical part of the larger international project, Project STELLA, is led by Lancaster University and Oxford University with partners from the Cockcroft Institute, STFC's

[1] For more information, see https://www.iaea.org/newscenter/pressreleases/iaea-and-islamic-development-bank-launch-womens-cancers-partnership-initiative
[2] For more information, see https://www.iaea.org/sites/default/files/documents/tc/URU6032.pdf.
[3] For more information, see https://humanhealth.iaea.org/HHW/RadiationOncology/ICARO2/E-Posters/04_FIAGBEDZI.pdf.
[4] For more information, see https://www.sciencedirect.com/science/article/pii/S036030162030986X.
[5] For more information, see https://qatarfund.org.qa/en/launching-of-qatar-cancer-treatment-center-in-burkina-faso-funded-by-qatar-fund-for-development/.

Accelerator Science and Technology Centre (ASTeC), John Adams Institute, Swansea University, King's College London, ICEC, and CERN.[1]

The World Bank comprises 189 member countries and includes 5 institutions, 1 of which is the International Finance Corporation. The World Bank provides a variety of financial products and technical assistance. Since 1947, the World Bank has funded more than 12,000 development projects. An example of the World Bank's involvement in the adoption of alternative technology is included below.

- Serbia procured six LINACs using money from a World Bank loan. The purchase supported the Serbian government's achievement of international standards on radiotherapy coverage.[2]

The International Finance Corporation (IFC) is one of the five institutions within the World Bank Group. IFC is the largest multilateral investor in health care in developing countries.

Funds from IFC will go to finishing the construction of a new full-service hospital in Iraq and purchasing necessary medical equipment. The type of equipment is not specifically mentioned but the article mentions brachytherapy and other radiotherapy services.[3]

The following multilateral development finance institutions may also be involved, but this report has yet to find documented cases of their involvement.

- *African Development Bank (AFDB)*
- *Asian Development Bank (ADB)*
- *European Bank for Reconstruction and Development (EBRD)*
- *European Investment Bank (EIB)*
- *Inter-American Development Bank (IDB).*

Other organizations/programs may provide financial assistance that are not captured in this report, including but not limited to government agencies providing official development assistance to promote economic development and welfare in developing countries. However, the author of this report was unable to find documented cases of other agencies' involvement.

A.6 End-of-Life Management

Gamma Service supplies, removes, recycles, and transports high-activity Co-60 and Cs-137 sources as well as depleted uranium. The company also sells source-based irradiators.[4]

The Board of Radiation & Isotope Technology (BRIT) is based in India and supplies products for applications in health care, agriculture, and research and industry. BRIT supplies Co-60 sealed sources, but their transportation and installation are the responsibility of the end-user.[5]

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[1] For more information, see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7316442/.

[2] For more information regarding Serbia's World Bank loan, see https://ewsdata.rightsindevelopment.org/files/documents/25/WB-P166025.pdf and/or https://projects.worldbank.org/en/projects-operations/project-detail/P166025.

[3] For more information, see https://disclosures.ifc.org/project-detail/ESRS/39533/seema-hospital.

[4] For more information, see http://www.gammaservice.co.uk/products.html.

[5] For more information, see https://britatom.gov.in/sealed-sources/cobalt-teletherapy-sources.

Dioxitek is based in Argentina and is dedicated to producing uranium dioxide dust and sealed Co-60 sources. Dioxitek produces Co-60 sealed sources for medical and industrial purposes.[1]

Isotope Technologies (IT) provides a full range of services in the field of radioactive materials, including the manufacture, export, and import of sealed sources. IT was formed by the Belarussian Joint Institute for Power and Nuclear Research and Russian Joint Stock Company State Scientific Center – Research Institute of Atomic Reactors (JSC NIIAR) in 1998. IT also assists in the end-of-life management of disused sources.

JSC Isotope is the sole supplier of Russian isotope products manufactured by the State Atomic Energy Corporation Rosatom. JSC Isotope produces and sells both Co-60 and iridium (Ir)-192.[2]

Nordion, a Sotera Health company, is the leading provider of Co-60 to global customers. Nordion offers source supply, recycling, and transportation services.[3]

The Nuclear Energy Corporation of South Africa (NECSA) was established by the Republic of South Africa Nuclear Energy Act in 1999. It is a state-owned company. NECSA encompasses many South African enterprises including NTP Radioisotopes. NECSA is mandated to undertake and promote research and development in nuclear energy and radiation sciences and technology. NECSA also assists in the end-of-life management of disused sources.

- NTP Radioisotopes, based in South Africa, is a leading international supplier of industrial and medical radioisotopes. NTP Radioisotopes is a part of the Nuclear Energy Corporation of South Africa (NECSA Group). NTP produces and supplies high-activity Ir-192 and equipment as well as transport, storage, safety, and disposal services.[4]

Mayak PA is the leading Russian producer and one of the world's largest manufacturers of radionuclide ionizing radiation sources and other isotope products. Mayak produces more than 200 types of sources of alpha, beta, gamma, and neutron radiation, including Cs-137, Co-60, and Ir-192.[5]

The author does not endorse any technologies mentioned in this report. The author attempted to include all technologies currently available as alternatives to high-activity Category 1 and 2 sources within the medical sector.

As mentioned above, Figure A.1 provides a picture of all the identified international stakeholders within their respective stakeholder groups. Note that although Figure A.1 divides stakeholders into groups based on a single criterion, many organizations and programs often fit into more than one category.

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[1] For more information, see https://dioxitek.com.ar/productos/.

[2] For more information, see http://www.isotop.ru/en/production/medical/439/.

[3] For more information, see https://www.nordion.com/services/source-supply-recycling-service/ and https://www.nordion.com/services/source-containers-and-transport-services/

[4] For more information, see https://www.ntp.co.za/iridium-192/.

[5] For more information, see https://www.po-mayak.ru/en/products_services/products/radioisotope_products/.

A.7 International Stakeholders

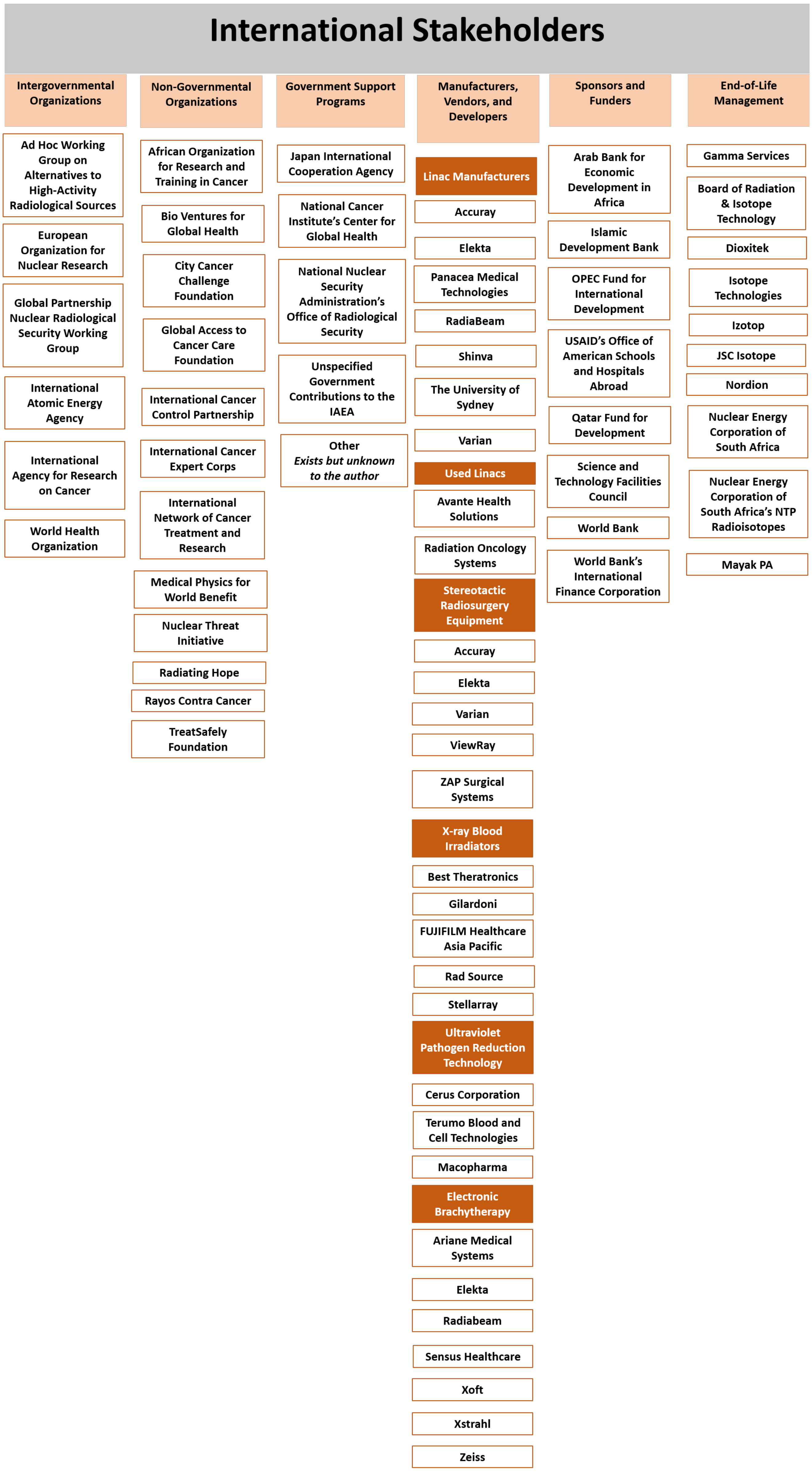

Figure A.1. International Stakeholders

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