Strengthening the Coordination of International Organisations and Programmes involved in the Adoption of Alternative Technologies to Radioactive Sources

**Report of a Series of Virtual Roundtables** 



December 2022

### 1. Background

Developing a comprehensive and sustainable approach to radioactive source security requires the proper management of these sources and their protection by adequate security arrangements throughout their lifecycle. Although radioactive sources clearly have multiple benefits, they also have the potential to cause significant harm to people, property and the environment should they be lost or stolen and fall into the wrong hands. They could not only cause bodily harm and significant social disruption, but an incident could lead to significant economic consequences (e.g., medical costs for employees and members of the public, radiological clean-up costs, loss of the use of facilities, lost business, recovery costs, replacement costs, etc.) and damage the reputation and credibility of any organisation involved.

To increase security resilience, strict control over the radioactive sources in use and in storage must be enforced, a strong security culture must be fostered, and careful planning and security exercises must take place to ensure an effective response should a security event occur.

An important way to reduce radiological security risks is to decrease the total amount of radioactive material in circulation by using radioactive source-free technologies, when possible, effective, and economically feasible. Ongoing research, new technology, and improvements in existing technologies have made many alternatives to radioactive sources attractive and cost effective. If properly implemented, the transition towards alternative technologies can have a significant impact on improving radiological security, since these technologies are far less attractive for malicious use and cannot be used, for instance, in a radiological dispersal device. To ensure the full radiological security benefits, replaced sources need to enter an effective end-of-life management process.

A large group of stakeholders is involved in the decision-making process for the kind of radiation-generating devices—radioactive source-based or non-isotopic—that are selected and operated for a particular application in medicine, industry, agriculture or research. Decisions about which device to use are based on various factors such as available resources, technical requirements and user preferences. Stakeholders outside the operating organisation (end users)—such as those in government agencies (e.g., the ministry of health) or financing organisations, including international programmes—are also an integral part of the process.

Experience has shown that some end users may select a device without a complete and comprehensive assessment of all related opportunities and challenges (e.g., long-term costs associated with certain devices; funding opportunities for a specific technology; the need to manage disused sources; security requirements; etc.). In many cases, the assessment of radiological security concerns comes as a secondary review after the technology has been selected or is being readied for operation and licensing.

At the international level, multiple efforts support the safe and secure use of radioactive sources through a range of activities aimed at strengthening the competencies of the organisations using or regulating these sources. International efforts also include programmes, especially in the healthcare sector, that support the purchase, delivery and commissioning of sources and associated devices and technologies in low- and middle-income countries (LMICs). More recently, some of these international initiatives have included programmes to support the development of non-isotopic alternative technologies to radioactive sources in order to incentivise LMICs and their end users to adopt such technologies and ensure the proper end of life management of disused sources.

However, experience also shows that international efforts might not yet be fully coordinated and that some overlap, duplication of efforts, or conflicting priorities exist. In some cases, a sponsor has funded the replacement of radioactive sources and associated devices with an alternative technology while another sponsor was funding the purchase of a new, similar source-based device in the very same country. In addition, there are still some coordination challenges regarding IAEA activities in this regard. While some IAEA activities clearly support the adoption of non-radioisotopic technologies in the long term, there are still some projects that try to deal with short-term needs, which can sometimes lead to countries acquiring high-activity radioactive sources through its technical cooperation programme, as long as they meet the required safety standards and security recommendations.

### 2. Objectives of the report

The core objective of this report is to review and discuss the status of and challenges to coordination and cooperation between international stakeholders involved in the adoption of alternative technologies to radioactive sources with the specific aim of proposing mechanisms to avoid duplication of initiatives or conflicting objectives.

Achieving this objective requires first developing a comprehensive and global picture of the international stakeholders. This global picture is not available today, and no organisation seems to have taken the lead on developing such a comprehensive picture. It is recognised that there are many international actors, but the available information is fragmented and not easily accessible.

For medical applications, this gap was partially addressed in November 2022 by the publication of the Stakeholder Mapping Report,<sup>1</sup> prepared by Pacific Northwest National Laboratories (PNNL) of the United States. The PNNL publication maps out the international stakeholders involved in the manufacture, procurement, and development (outside of mainstream manufacturer development) of non-isotopic alternative technologies, capacity-building initiatives, and end-of-life management of disused sources. Extracts of the PNNL report are included here and the full version is available on the WINS website. The Stakeholder Mapping Report, co-authored by WINS, should be read in conjunction with this WINS report.

Information contained in this report comes mostly from a series of virtual roundtables and in-depth follow-up interviews with experts that were conducted between December 2019 and January 2022. The main objective of these virtual roundtables was to bring together influential international stakeholders and individual experts involved in the development, procurement, commissioning and end of life management of radiation equipment to review ongoing activities in order to better understand their respective missions and contribution to the topic. Another objective of the roundtables was to demonstrate the diversity of parties involved and how decision makers can influence which equipment or which technology will be used. Finally, these roundtables were an opportunity for participating organisations and experts to better know each other and identify gaps and opportunities for enhancing their respective coordination and contributions.

This series of roundtables gathered more than 60 international experts representing a diverse range of stakeholders involved in the development or adoption of alternative technologies or in activities supporting the safe and secure use of radioactive sources. For practical reasons, the last two roundtables focused on alternative technologies for medical applications. A similar process could be followed for exploring other applications of radioactive sources and alternative technologies, in particular in the industrial area.

# 3. Alternative technologies in medical applications

Some alternative technologies, such as linear accelerator (LINAC)-based radiotherapy systems, are already in wide use and possess distinctly superior features compared to some systems using Cobalt-60 (Co-60) sources. However, alternative technologies have their own requirements in terms of necessary infrastructure, regulations, safety and maintenance.

In addition, there is a growing trend of new electronic applications for some important techniques, such as brachytherapy. In the past there were not a lot of viable alternatives to radioactive sources, but more and more electronic clinical treatments are being used to treat different cancers, such as breast, skin,

<sup>1</sup> Hart, J. (November 2022). Stakeholder Mapping Project – International Stakeholders Involved in the Adoption of Alternative Technologies to Radioactive Sources within the Medical Sector. Pacific Northwest National Laboratory (PNNL) – 33700.

keloids, spinal metastasis, GI, endometrium, cervix, and rectum<sup>2</sup>. Concerted efforts are thus needed to continue the development of alternative technologies and to support their wider adoption and sustainable use in all countries and regions of the world.

Despite the existence of many fora on the topic, comprehensive, reliable and up-todate information on available alternative technologies is still difficult to access and further attention should be given to this area. End users do not always take fully informed decisions, prompting the question of where end users go to find answers to their questions. Providing data on technology performance (and other issues) is essential in supporting the decision-making process. In this matter, it is important to highlight that professional associations are seen as a good support opportunity.

Discussions held during the roundtables demonstrated the complexity of the topic and highlighted the fact that there are no clear-cut divisions between those favouring and opposing certain technologies. Some participants believed that the primary decision criteria should not be radiological security but rather providing the best quality treatment for cancer patients or delivering cost-effective sterilisation or irradiation services. Others reminded the group of the security risk associated with radioactive sources and of the importance of using all available means to reduce that risk. It was finally noted that we should not talk about alternative technologies as a new solution. Quite a few experts stressed that in most cases isotopic and non-isotopic technologies have been working in parallel for years, especially in the medical area. It was agreed that both types of technologies will remain in use in the near future.

### 3.1 Availability of alternative technologies in medical applications<sup>3</sup>

### **3.1.1 BLOOD IRRADIATORS**

#### 3.1.1.1 X-ray Blood Irradiators

Irradiating blood protects against transfusionassociated 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.

While there are operational benefits, one other consideration has been the security risk associated with Cs-137, the commitment of several national governments (such as France, Japan, Norway, Switzerland, the United Kingdom and the United States) to reduce the use of high activity Cs-137, and the international efforts in this area of the National Nuclear Security Administration's Office of Radiological Security (NNSA-ORS). National approaches to reduce the use of Cs-137 blood irradiators nevertheless differ from State to State.

### 3.1.1.2 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-PRT's ability to reduce bacteria and certain other pathogens decreases the likelihood of transfusion-transmitted infections caused from 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 transfusion-transmitted infections. Under certain circumstances, testing for certain pathogens may not be required for UV-PRT treated components, which may save costs.

<sup>2</sup> www.ncbi.nlm.nih.gov/pmc/articles/PMC5415885

<sup>3</sup> For further information, please also read Section 4.0: Stakeholder Involvement by Technology Type of the PNNL Stakeholder Mapping Project report and the WINS Special Report on Considerations for the Adoption of Alternative Technologies to Replace High Activity Radioactive Sources.

### **3.1.2 RADIOTHERAPY**

LINACs are generally associated with better patient outcomes than radioisotope-based radiotherapy, and as a result have become standard throughout high-income countries. As such, the transition in high-income countries from Co-60 teletherapy units to LINACs generally occurred naturally, without government incentives, because stakeholders in these countries understand the benefits of the transition and, most importantly, have the resources to afford it. This transition differs from that of X-ray irradiators, the transition to which has been required or incentivised by some governments.

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-based nor non-radioisotopic. 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 higher cost of required ongoing service and maintenance contracts, and the infrastructure necessary to run the machine.

#### The Growing Need for Radiotherapy

The world is facing a growing need for multiple cancer treatment options, including radiation therapy. According to the World Cancer Research Fund International, in 2020 there were more than 18 million cancer cases in the world. Other data suggest that nowadays more than 1% of the population has cancer.

This reality creates multiple challenges around the world, but especially in LMICs. These usually do not have sufficient diagnostic and therapy equipment and resources to deal with increasing demand. Hence, significant gaps in radiotherapy equipment have been identified in these countries, and research shows that alternative technologies could play an important role in addressing these gaps.

### 3.1.3 ELECTRONIC BRACHYTHERAPY

Studies with large patient numbers and longterm follow-up are needed to demonstrate the suitability of electronic brachytherapy as a broad alternative to conventional brachytherapy. 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 brachytherapy. This is noteworthy because countries often substitute high-dose rate equipment using Co-60 for low-dose rate equipment using Ir-192 because of Co-60's longer half-life and the 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.

### 3.1.4 STEREOTACTIC RADIOSURGERY

Radiosurgery is a technique designed to treat brain tumours and other intracranial abnormalities with a high dose of radiation instead of with standard neurosurgical techniques. Stereotactic radiosurgery (SRS) equipment is relatively new compared to external beam radiotherapy. SRS delivers a precisely targeted dose in fewer high-dose treatments than traditional therapy. SRS is increasingly common in high-income countries. Users, clinicians and regulators consider different factors when deciding between a LINAC-based SRS treatment or a Co-60-based SRS treatment depending on the specific clinical needs of the patient, availability of published research, and operational requirements. As the clinical evidence base grows, the case for new modalities will strengthen. Although LINACbased SRS is becoming more widely accepted as equivalent to source-based SRS, radiotherapy centres tend to only offer one or the other (nonradioisotopic or radioisotopic) due to the high cost of the machine. Institutes that have both machines tend to be specialised cancer facilities.

### 4. Experience transitioning to LINACs and lessons learned for improving the contribution of international stakeholders

# 4.1 The process for deciding what technology to procure

For many LMICs, the decision to use alternative technologies involves both national and international stakeholders, such as the end users/operators, regulators and other governmental entities, the IAEA and funding organisations. As was stated before, one of the key findings of this report is the fact that comprehensive information on alternative technologies is not yet accessible to all practitioners. Also, there were concerns about the possible lack of awareness among key decision makers.

It is also important to understand the interconnection and impact of any decision regarding the choice of a technology. End users are not always aware of the consequences of a technological choice on other aspects of a practice (e.g., downtime) or on the management of the replaced source. For instance, the decision to move from Co–60 to LINAC machines is often made by doctors, who may not consider other issues, such as security, end of life management or repatriation of the old source, in their planning.

Another important topic to consider is the role of regulatory bodies and donors. Regulators must be fully informed and educated to effectively regulate and monitor the acquisition of any technology and the safe and secure removal and end of life management of disused sources. An important discussion involves if regulators must also decide if are going to remain neutral regarding technology options, or if they can or should encourage the adoption of less-risky technologies. Some regulatory authorities have required users to justify not only their use of radiation, but the use of radioactive sources, if alternatives are available. Technology and other considerations may be secondary for donors, since they mainly need to be convinced that they are investing their money logically, effectively (e.g., treating the maximum number of patients; developing a competent local workforce) and in a sustainable manner (e.g., the technology will remain in use for the expected period and will benefit from proper maintenance programmes).

Alternative technologies should be promoted in a balanced manner. The recipients must be ready to use them. When alternative technologies are deemed not viable, it can be helpful to assess the root causes of *why*. While answering the immediate technology needs is important in the near-term, there is an opportunity for national and international stakeholders to discuss how to address local challenges hindering the adoption of alternative technologies in a more long-term strategy.

Successful technology adoption requires the appropriate operational knowledge, a developed regulatory framework, effective and efficient local technical support. It is important to ensure sustainability of the practice since operators need to understand how to use a new machine and incorporate potential new updates/upgrades it may require. Also, alternative technologies need to ensure the proper legal framework to legitimately operate and guaranteeing a safe practice to the public. Finally, it is important to establish a proper, efficient, and available technical support and suppliers network.

For years and within multiple forums, several countries, especially LMICs, are reporting challenges in adopting alternative technologies and expressing the need for external assistance. There is a clear understanding that international and bilateral programmes cannot provide full support to all entities requiring assistance, and therefore there is a need to explore mechanisms that can facilitate coordination and sharing of lessons learned between various stakeholders and support global efforts to adopt alternative technologies.

## 4.2 Good practices for successful national projects

Roundtable participants have shared several good practices that new users or parties interesting in transitioning to alternative technologies might need to consider implementing in order to be more successful:

- → First figure out needs, then get funding, not the other way around.
- → Determine your technical requirements and establish a dialogue with industry and suppliers to identify the technology that meets your requirements.
- → Develop realistic, customised and detailed planning process documents. These documents should include clear objectives and a reasonable timeline. They should also consider possible challenges, risks and contingencies and possible ways to overcome them.
- → Establish a project implementation entity to act as liaison between the various stakeholders who might be involved.
- → Multiply dialogue opportunities and open new channels of communication to more comprehensively address the national needs.
- Prepare bankable documents in order to get funding. Take everything into account from the training to the equipment. International stakeholders can help to make these bankable documents.
- → Ensure early engagement with regulator. As independent bodies, regulators have a limited role in promoting alternative technologies, but they can facilitate and encourage access to relevant information, in particular as it relates to the pros and cons of each technology. They also play an essential role in any move to alternative technologies as the use of ionising radiation is subject to appropriate regulation and control, and new ionising radiation device often must be approved before use is permitted.

- → Identify the competence needs and initiate actions to fill the gaps. It is important to invest in training and develop comprehensive programmes that will help address new technologies. This will also ensure sustainability of practices by ensuring local knowledge transfer mechanisms.
- → International cooperation is key to success. That is why it is important to establish and maintain a dialogue with international stakeholders that includes the right mixture of experts, vendors, and funders to meet national needs to ensure constant and fluent engagement with multiple national and international stakeholders. Cooperation is key to success. Consider that international stakeholders might have an agenda that is not aligned with national plans.
- → Ensure a clear path for the end-of-life management of replaced radioactive materials. Work with national regulators and international partners to explore ways to ensure secure and safe final management.

During the roundtable discussions, it was noted that the option of consolidating and disseminating these best practices into guidelines supporting the coordination of national stakeholders could be beneficial. These guidelines could be inspired and complement the LINAC transition "Planning Guide" published by Lawrence Livermore National Laboratory. The LLNL guide identifies the major stakeholders in the management of the transition process: government, policy, administrative, management, clinical, physics, regulatory, diagnostics, IT, financial, nursing, and pathology.

# 4.3 The importance of effectively addressing the end-of-life of radioactive sources

For source users seeking to transition from a radioisotope-based technology to an alternative technology, providing end-of-life management of the replaced radioactive source is a crucial aspect. Radiological security benefits will only be demonstrated if proper security arrangements are implemented during the process, in particular during the transport and storage of the disused source.

At the time of purchase, source users can include 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 end-of-life management in line with regulatory guidelines, there are multiple cases of users that have abandoned their disused sources or stored them in unsafe and insecure locations. These negligent actions could create a major incident. Therefore, current end-of-life management options for disused sources should be considered. These include reuse or recycling, long-term storage and end of life management, 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, national, regional and international stakeholders may become involved. While several services for end-of-life management operate internationally, few stakeholders financially contribute to international end-oflife management projects.

National stakeholders, such as the nuclear regulator or the national atomic commission, play an essential role in the high-activity disused source management. Countries need to have regulations, procedures and mechanisms in place to ensure a safe and secure management of disused radioactive sources. Roles and responsibilities should be clearly identified and there should be enforcement mechanisms in place to guarantee compliance. In some instances, LMICs adopting alternative technologies count on international organisations or programmes to help manage the disused sources. The IAEA and US NNSA-ORS appear to be the predominant players at the international level. These partners can provide experiences and lessons learned on the effective management of disused sources. They can also help national partners overcome challenges or provide a wide range of support opportunities such as funding, human resource development, regulatory infrastructure reviews, technical expertise, etc.

# 5. International stakeholder engagement<sup>4</sup>

### 5.1 Map out international stakeholders

A variety of international organisations, programmes and stakeholders are able to assist with the adoption of alternative technologies in the medical sector, but the lack of consolidated information about them makes coordination mechanisms more difficult, allowing potential duplication of activities and efforts.

The roundtable discussions highlighted the need to identify major international organisations and programmes (including their roles, responsibilities and achievements) that are interested and can contribute to different aspects of radioactive source replacement and alternative technologies. It was suggested to identify and consolidate the work already conducted in this area to avoid duplication of efforts. To facilitate the research and reporting, it was proposed to group programmes and organisations by topical areas (e.g., medical applications, industrial applications), stakeholder groups (e.g., funders, vendors, etc.) or any other commonalities.

As mentioned above, PNNL took the lead and initiated a task to map out the international stakeholders 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. For practical reasons, these efforts were focused on medical

<sup>4</sup> For further information, please reference Section 3.0: International Stakeholders of the Stakeholder Mapping Project report. Pacific Northwest National Laboratory (PNNL) - 33700.

applications. As a result of these efforts, a report was published in November 2022. The information contained in Section 5 is mostly derived from this report.

### 5.2 Different types of international stakeholders

International stakeholders—intergovernmental organisations (IGOs); nongovernmental organisations (NGOs); government support programmes; manufacturers, vendors, and developers; and transnational sponsors and funders—become involved in States that lack the infrastructure, workforce, and/or finances needed to procure and operate technology.

### 5.2.1 IGOS

IGOs provide support for LMICs in procuring both source-based and alternative medical equipment, without encouraging alternative technology over source-based equipment solely from a security standpoint.

The International Atomic Energy Agency (IAEA) is the predominant IGO in this area. It plays a central role in supporting its Member States benefiting from radiation technologies. IAEA assistance is essential for many countries, in particular in human health matters.

The IAEA also works with multiple external organisations and programmes, including the WHO, FAO, UNICEF and other UN bodies; funders such as the Islamic Development Bank; and more developed Member States that provide technical resources and extra budgetary support.

IAEA support in planning upgrades, training and capacity building is very extensive, but supply of sources by the IAEA seems to be limited. There are, however, few statistics on the number of sources replaced or supplied each year by vendors, the IAEA or through bilateral agreements between countries. There are limited international mechanisms to oversee the supply of Category 1 and 2 sources. It is challenging to anticipate the magnitude of the radiological security risk in the medium and long term.

Another notable support to the adoption of alternative technologies is the *Ad Hoc Working Group on Alternatives to High–Activity Radiological Sources (AHWG).*  France, the United States and then Germany established the AHWG in 2015 to provide an open forum for States to share information, ideas, views, and experiences on the use of alternatives to technologies that use highly radioactive sources. Discussions are informal and nonbinding. The outcomes of the Working Group should at no point be interpreted in a way that would affect States' sovereign choices regarding the use of radioactive materials. Along with other IAEA guidance, the Group also helps to support the IAEA Information Circular (INFCIRC) 910 on the Joint Statement on the Security of High Activity Radioactive Sources, signed by 32 States and Interpol.

The AHWG provides a forum that highlights the benefits of alternative technologies. These are: reducing security procedures, requirements and costs; eliminating radiological terrorism risk and potential liabilities; avoiding costly end-of-life management for radioactive sources; potential expanded capabilities or technical performance; and steady device throughput, since there is no source decay or reload requirements.

The group focuses on blood irradiation, research irradiation, radiotherapy, industrial sterilisation, phytosanitary and food safety, the sterile insect technique, well logging and radiography. (More information can be found at <u>www.alttechwg.</u> org.)

### 5.2.2 NGOS

NGOs do not generally encourage adoption of alternative technologies. Several NGOs assist with alternative technology adoption by training essential staff as well as providing training on source-based equipment. NGO support is often limited to an ad hoc basis due to budget constraints. While IGOs tend to provide support through local governments, NGOs usually engage end users directly.

Some notable NGOs supporting the implementation of alternative technologies include the Vienna Center for Disarmament and Non-Proliferation (www.vcdnp.org) and the World Institute for Nuclear Security (www.wins.org).

### 5.2.3 GOVERNMENT SUPPORT PROGRAMMES

Few government programmes support alternative technology adoption abroad; most work only domestically. NNSA-ORS is the main exception. Japan's International Cooperation Agency has also occasionally provided training and procurement for the adoption of alternative technologies.

### 5.2.4 MANUFACTURERS, VENDORS AND DEVELOPERS

Manufacturers, vendors and developers have a vital role in alternative technology development and training, the resale of used equipment, and end-of-life management. It is important to find ways to include them in different activities to raise awareness of the benefits of alternative technologies. They can also play a significant role in promoting an effective transition to alternative technologies and can be key partners by providing experience dealing with the usual challenges.

### 5.2.5 SPONSORS AND FUNDERS

While many national governments and end users finance themselves, development banks, charities, fundraisers, and grants also provide funding but only on an ad hoc basis. The IAEA's Programme of Action for Cancer Therapy supports Member States by directly mobilising funders. NNSA-ORS offers international financial and technical support to replace Cs-137 with X-ray blood irradiators. These are key partners to guarantee a successful and effective transition from high-activity sources, and it is important to understand that there are multiple channels of funding available for source transition.

# 5.3 International stakeholders' contribution by technology type

International stakeholders are most active in LINAC procurement and related capacitybuilding. Only the IAEA appears to regularly arrange financial and technical support to procure LINACs. Other organisations and programmes do so on an ad hoc basis. It is also worth noting that multiple efforts are underway to develop a LINAC more suited to the needs of LMICs. SRS equipment is newer than external beam radiotherapy and increasingly common in high-income countries. The rate of adoption of SRS to replace cobalt-based equipment in LMICs is unclear. Since SRS is mainly used in high-income countries, procurement usually involves end users, manufacturers and national regulators.

X-ray blood irradiators commonly replace Cs-137 irradiators in high-income countries to eliminate the security risk of Cs-137. As mentioned earlier, NNSA-ORS provides support to replace Cs-137 irradiators with X-ray blood irradiators. The IAEA no longer supplies developing States with Cs-137 sources but does not yet supply alternatives. It is possible that States use the money acquired from development banks and other financial institutions to procure X-ray irradiators, but this is not publicised as widely as LINAC procurement.

In LMICs whole blood transfusions are more common, so fewer X-ray and Cs-137 blood irradiators may be required if UV-PRT is approved for use on whole blood. Currently, no international stakeholders appear to regularly support the procurement of UV-PRT.

Electronic brachytherapy is not widely used in high-income countries or LMICs. If long-term studies confirm it is effective, miniature X-rays could replace the high-activity Category 2 sources used in high-dose-rate brachytherapy. Currently, no international stakeholders assist in the procurement of electronic brachytherapy, but they do support the procurement of afterloaders and applicators to perform traditional high-dose rate brachytherapy.

# 5.4 The role of international stakeholders in capacity building

It is estimated that LMICs need to train 9,900 radiation oncologists, 7,200 medical physicists, and 24,900 radiation technologists to meet demand in 2035<sup>5</sup>. The IAEA, WHO and International Agency for Research on Cancer conduct imPACT reviews, assessing a country's cancer control capacities, needs and required interventions. More IAEA Member States have requested support in developing national cancer control plans as well. The IAEA publishes guidelines and information booklets, organises

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seminars, and partners with professional communities to promote effective integration of radiation medicine into comprehensive cancer control, as well as supporting the overseas training of candidates from low-income countries and sharing the cost of professionals from middle-income countries. Many other organisations and programmes, as well as professional associations and organisations, assist in training essential personnel, mostly for cancer treatment.

# 5.5 The role of international stakeholders in supporting effective end-of-life management

The IAEA, through the Division of Nuclear Fuel Cycle and Waste Technology's Waste Technology Section, assists Member States with radioactive waste. These projects, financed by the Nuclear Security Fund, consist of securing and removing the source. NNSA-ORS also aids in end-oflife management through the packaging, transportation and emplacement of disused sources into secure storage in partner countries. They also repatriate US-origin sources from international locations on a case-by-case basis. Both the IAEA and NNSA-ORS provide the funding and technical supervision for regional and/or domestic companies to physically handle the source(s).

### 6. Mechanisms for coordination and cooperation among international stakeholders

### 6.1 The need for coordination

There are many international actors working on technology transition, but, as mentioned earlier, the available information about various programmes is fragmented. Before discussing the effectiveness of coordination, there is a need to map out all international programmes, consolidating their main missions and contributions under a single framework. It is important to consolidate this information and make it public to avoid overlap of functions, tasks and assistance programmes. This will help embarking players understand the process and ease their transition to alternative technologies. There are shortcomings in coordination among the known international programmes, and it is important to encourage coordination among them. Also, existing networks and fora should and could play a more active role. Individuals participating in them are key to a successful process.

It is also important to develop coordination mechanisms within the international community to prevent and avoid duplication of efforts. Organisations working in the same field of expertise and delivering the same service/ product should find ways to combine their efforts. At the same time, in order to increase knowledge and understanding of alternative technologies, access to information should be easy. Awareness campaigns and distribution of information should be encouraged at all levels.

In order to have an efficient process and successful results, it is always important to smooth and ease coordination among national, regional and international stakeholders. This is not a task that can be achieved alone. In this scenario, the IAEA plays a central role coordinating players, distributing information, and helping overcome challenges and issues. This will also promote the optimal use of resources available internationally.

### 6.2 Examples of Coordination

### 6.2.1 THE IAEA COORDINATION APPROACH

The IAEA promotes a one-house approach with Project Management Officers (PMOs) in the Technical Cooperation Department acting as the main vector of assistance, supported by subject matter experts from across the agency. The IAEA has multiple opportunities for information exchange amongst its various departments and divisions. Within the IAEA, internal coordination between departments on project review, design, approval and implementation appears strong. However, some participants in the WINS roundtables believe there are opportunities to enhance coordination on alternative technologies as a security strategy. The IAEA usually applies the following steps to coordinate its support activities:

- → Identifying stakeholders: The IAEA identifies stakeholders (through stakeholder analysis) and their involvement, roles and responsibilities (e.g., national counterparts, national liaison officers), as well as the promotion of cooperation, coordination, and communication among them.
- → Conducting coordination meetings with project partners: The IAEA regularly conducts coordination meetings with key project stakeholders from the recipient country, sometimes including representatives of donor countries as well.
- Establishing a mechanism to ensure that projects do not overlap. The IAEA has arrangements in place to facilitate close internal coordination in the design and implementation of complementary projects, which in turn contributes to enhancing effectiveness and efficiency in the delivery of IAEA assistance to Member States, while allowing diversification of funding mechanisms and sources. This is, for instance, the case for largescale IAEA flagship projects such as **Regulatory Infrastructure Development** projects, which support Member States in creating an enabling regulatory infrastructure for the safe, secure and peaceful application of radiation technology and are deliberately designed to complement other IAEA initiatives in the overall context of promoting sustainable socio-economic development.

Case Study: Assessing Cancer Control Gaps and Needs in Collaboration with International Stakeholders<sup>6</sup>

In cooperation and coordination with its internal and external partners, the IAEA Programme of Action for Cancer Therapy (PACT) conducts imPACT reviews (107 reviews conducted since 2005) to help governments and local stakeholders to prioritise investments and interventions in cancer control (the reviews could help, for instance, to prioritise cancer screening programmes and could even be the trigger to initiate the development of strategic plans to acquire or improve radiotherapy services).

One example of successful coordination with external partners at the country level is ongoing work between PACT and Uzbekistan, where an initial imPACT review led to longer term engagement. This included PACT and partners' support for a needs assessment, planning to address the gaps, resource mobilisation, and more recently a request for a follow-up imPACT review to evaluate progress.

PACT acts as a platform for coordination internally and externally (both at the national and international levels). Additionally, a mechanism such as an imPACT review, which is a gap analysis methodology involving all key players, creates a roadmap for establishing a cancer control plan and the introduction or upgrading of cancer care services as needed. Such a roadmap is an essential requirement to engage in resource mobilisation. The three pillars for resource mobilisation and outreach for PACT support projects are traditional donors (Member States), international financial institutions, and the private sector and foundations.

### 6.2.2 THE CONTRIBUTION OF THE AHWG TO COORDINATION NEEDS

The AHWG, co-chaired by France, Germany, and the United States, is a forum for participants to exchange experiences, improve cooperation and, when appropriate, promote alternative technologies. Discussions include, for instance, exchanges on assistance programs for education and training opportunities and on criteria for assessing the adequacy of a given technology. They also cover technical and financial issues, but also on how to involve governmental officials and other decision makers in the process of adopting alternative technologies.

Before 2016, many international programmes concerning the security of radioactive sources or alternative technologies were being implemented without coordination. Some national campaigns to replace certain devices, such as CsCl blood irradiators, were underway in countries such as France and Norway. Nevertheless, the coordination of these projects was limited, and the lessons learned were not really shared. A gap and an urgent need to strengthen the coordination of efforts and sharing of experience was existing.

The creation of the AHWG has been a clear success. It proved useful for raising global awareness about technology options, alternative technology as a security strategy, the various benefits of using alternative technologies, national approaches to these alternatives, and available international activities and incentives. It has also been key for information exchange between users, high income and LMIC countries, and industry.

Essential topics for the AHWG in the coming years will include providing an open forum for widespread information dissemination on achieved national/international transition results (e.g., feedback, success stories); connecting countries and users with questions on the adoption of alternative technologies with subject matter experts; and identifying gaps, for example in training and education, that countries, international organisations, and non-governmental organisations can use as a starting point to develop solutions.

### 6.2.3 EXAMPLE OF COORDINATION OF MULTIPLE SUPPORT PROGRAMMES FROM THE SAME COUNTRY: THE US WORKING GROUP ON MEDICAL LINAC

The US Working Group on Medical LINAC is intended to improve coordination within the US government on strengthening global capacity for safe, secure and effective cancer treatment through LINACs. Participants in the working group include the US/DOE/NNSA, the National Institutes of Health/National Cancer Institute, the Department of State and the Nuclear Regulatory Commission, as well as other entities and sub-organisations.

The working group is informal and can be convened by any member, which allows for flexibility. It was founded in 2021 and has already made progress by producing a white paper on considerations when evaluating medical LINAC requests, including procurement and sustainability considerations. The working group has been vital in helping to widen the understanding of options for allocating funding as well as taking other interests into consideration (for instance, not making decisions based solely on security concerns). The upcoming objectives of the working group include:

- → Continuing to coordinate on device procurement requests for medical LINACs
- → Continuing to share information on contributions and engagements with international organisations
- → Considering combined efforts to address sustainability challenges.

### 6.3 Potential coordination gaps

During our round table discussions we have identified many challenges and potential gaps regarding alternative technologies and its adoption and operation. Most of the challenges are associated with some lack of proactive actions towards taking initiative to enhance coordination. Also, another major challenge is associated with sustainability and how to make sure that an alternative technology remains available after the installation and implementation phase. This is even more challenging in LMICs. Another major challenge has to do with the fact that different organisations feel limited by their mission and scope of work, and within their expected role, to reach out and work with different stakeholders involved in adopting alternative technologies. This means that some organisations are willing to start a transition but do not feel entitled or "allowed" to do it on their own.

# 7. Opportunities for improvement

### 7.1 Prerequisites to effective coordination

Effective coordination requires a comprehensive, flexible and functional communication strategy. Also, in engagement that involves multiple stakeholders, it is vital to know the audience and how they perceive the common goals. It is important to use strategies and terminology that can be understood by everybody. One way to measure this is through self-assessment and asking whether efforts are effective.

Another important prerequisite is to continue mapping stakeholders at the national, international and peer levels and updating their roles and responsibilities as well as adding potential new relevant actors (or eliminating others). This is an important step in ensuring that all necessary stakeholders and interests are being addressed. Additionally, it is key to always understand who is the contact point and be clear on organisations' roles and responsibilities within this map.

It is important that coordination efforts are seen as central to guaranteeing an effective process. Therefore, it is important to understand the diversity of stakeholders involved, as well as their missions, structure and tasks. Also, many stakeholders are limited by their mission and might not make coordination a priority. That is why organisational or political leadership should encourage working-level professionals to explore outside their mission role, and guidance could be provided to help such organisations to reach out beyond their traditional networks. That is why forums for information exchange are so important; they bring together a diverse set of stakeholders and help them break down barriers, engaging stakeholders outside of any one organisation's mission space.

In addition, it is important to have a comprehensive, flexible, modular and concrete development strategy at the national level. Local planning and coordination are mandatory to transition to alternative technologies in an efficient and successful way. This should include a coordinated national strategy towards the management of disused and replaced radioactive sources as well. This cannot be considered only at the end of the process, when it is too late. In order to maintain radiological security, any given country or stakeholder should plan for radioactive source end-oflife management before or in parallel to transitioning to an alternative technology.

Good practices for effective coordination should be incorporated as early as possible into any project plan. This will allow all partners to understand the coordination that will be needed at various points throughout the project lifecycle. Coordination efforts should be specific, practical and action oriented.

Also, there should be more outreach and coordination meetings to bring together different stakeholders during early stages of projects, in order address all the prerequisite needs for the successful adoption of technologies. Stakeholder lists or best practice guides can help confirm that project planners/ counterparts are engaging the correct and complete group of relevant stakeholders for a given project. It is also important for stakeholders to continue conversations, have regular coordination meetings throughout the project lifecycle, and have actionable plans.

Additionally, organisational leaders should encourage non-mission-oriented coordination in order to enhance technology project success and sustainability. It is important that there are clear incentives for organisations to coordinate aspects of a project's lifecycle that are outside of their mission spaces, and for non-traditional partners to partake in coordination meetings.

In this regard it is essential to ask project planners/counterparts from the start what their priorities are and design the whole programme considering those priorities. This will help address more realistic national needs and encourage sustainability. Failing to do this might lead to conflicting goals and potential operational hurdles.

#### 7.2 Possible follow-up actions

### 7.2.1 CONTINUE TO RAISE AWARENESS ABOUT ALTERNATIVE TECHNOLOGIES AND SHARE LESSONS LEARNED

It is important to continue the consolidation of information on available alternative technologies and offer further opportunities to discuss experiences and lessons learned from adopting alternative technologies, so that end users can find answers to their questions on the availability of alternative technologies and best practices for adopting them.

Because of this, WINS will continue to implement a set of activities to consolidate and share information on alternative technologies. In particular, WINS will continue to invite stakeholders involved in this area to share their experiences and lessons learned during workshops and other international events. These discussions will review the current availability of, feasibility of and possibilities for replacement. Among others, these exchanges will include information on new devices under development, incentives for replacement, risk assessment and efficacy of replacement techniques, regulatory changes required, the role of suppliers, international collaboration etc. Based on these discussions, WINS will periodically review and revise its series of publications, such as its Best Practices Guides and Special Reports. All presentations, reference materials and findings will be made available and shared with the community on the WINS website.

Many countries, organisations and working groups are also conducting efforts to consolidate information on available alternative technologies and offer further opportunities to discuss experiences and lessons learned from adopting these technologies. The AHWG has already taken steps to enhance the exchange of information between these various parties.

### 7.2.2 ORGANISED MEETINGS DEDICATED TO COORDINATION MATTERS

International organisations, such as the IAEA, could hold meetings aimed at increasing stakeholder coordination (for example, donor coordination meetings, where both traditional stakeholders like Member States and nontraditional stakeholders such as development banks are present). Other organisations or forums, such as WINS or the AHWG, can play a complementary role by having regular meetings and agenda items on alternative technologies and coordination issues. All of these meetings should be coordinated to harmonise messages.

### 7.2.3 STRENGTHENING THE IAEA'S CONTRIBUTION

The IAEA could be encouraged to establish a working group within the agency to provide guidance on transitioning to alternative technologies from radioactive source use. This group, e.g., the Alternative Technologies Support Group, could be similar to the Nuclear Power Support Group established in 2006. It would serve as a base for information sharing and coordination opportunities for all IAEA activities related to various applications of radioactive sources and alternative technologies, their implementation, and their impact on other IAEA programmes.

In addition, IAEA Member States could be encouraged to request the Secretariat take further actions to support effective external coordination. For example, the IAEA could host coordination meetings, invite experts with proper credentials to attend these events, and ensure practical follow up on the main conclusions. The IAEA is encouraged to explore all opportunities, including taking initiatives, to support better external coordination based on its current mandate.

Another improvement opportunity regards recovery, repatriation and end of life management of disused high-activity sources. In many LMICs, end of life management options may not exist, and the cost of disused source removal and return to a supplier can be prohibitive. Funding is an issue and causes serious delays in moving from Co-60 to LINACs in the medical sector. Case studies from some LMICs have been shared, detailing a desire to transition to alternative technologies but are prevented from doing so by the absence of necessary funding to effectively address the end of life management of the sources to be replaced. To increase the IAEA's potential to address this issue, the appropriate IAEA Divisions could consider hosting donor roundtable meetings, similar to how PACT has done in recent years.

### 7.2.4 STRENGTHENING THE ROLE OF THE AHWG

The AHWG could be encouraged to initiate a discussion on its terms of reference and assess their adequacy based on the experience gained since 2016. The AHWG could also consider further developing its contribution by publishing or endorsing selected documents and establishing exchange forums for each stakeholder groups.

The AHWG could also encourage the development of regional reference centres that would consolidate the information and experience related to this region and would support the implementation of alternative technologies taking into account the specific needs and constraints on the countries from the region.

### 7.2.5 THE ROLE OF NGOS IN IMPROVING COLLECTIVE EFFICIENCY

NGOs can play a key role in improving collective efficiency by providing free, open and nonbinding spaces for relevant stakeholders to meet and discuss issues and challenges. NGOs can help overcome these challenges by facilitating discussions that may not happen naturally. They can also help to raise awareness, set agendas, clarify roles and responsibilities, and better frame communication to decision makers, stakeholders and even the public. They can also connect national players with vendors and help overcome challenges along the supply chain. They can also secure multiple and permanent spaces to encourage dialogue and coordination and, in this way, help achieve an effective transition to alternative technologies.

As identified in PNNL's Stakeholder Mapping Report, NGOs can play a key role in providing technical training and education in underserved communities. As noted in the report, when it comes to medical applications, "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."

In the medical area, WINS could convene a series of events with relevant radiotherapy– focused NGOs and radiological security–focused organisations to discuss possible opportunities for collaboration and exchange good practices for improving efficiency of individual support project and collective support.

### 7.2.6 THE ROLE OF MANUFACTURERS

A comprehensive supplier services network should be developed for regions where demand is increasing. These networks will help achieve the highest rates of awareness, implementation success and sustainability of the practice.

In addition, concerted efforts should be implemented to continue the development of electronic brachytherapy and support their wider adoption and sustainable use in all countries and regions of the world.

### References

- Cybersecurity and Infrastructure Security Agency. (September 2019). *Non-radioisotopic alternative technologies white paper*. US Department of Homeland Security.
- Enwerem–Bromson, N., & Abdel–Wahab, M. (2015). *Expanding global access to radiotherapy: The IAEA perspective*. The Lancet Oncology Commission. <u>www.thelancet.com/pdfs/journals/lanonc/</u> <u>PIIS1470–2045(15)00287–9.pdf</u>
- Hart, J. (November 2022). Stakeholder Mapping Project International Stakeholders Involved in the Adoption of Alternative Technologies to Radioactive Sources within the Medical Sector. Pacific Northwest National Laboratory (PNNL) 33700.
- IAEA. (2010). IAEA Human Health Series No. 14: *Planning national radiotherapy services: A practical tool.*
- IAEA. (2017). Radiotherapy in cancer care: Facing the global challenge. <u>www.iaea.org/publications/10627/</u> radiotherapy-in-cancer-care-facing-the-global-challenge
- IAEA. PACT. <u>www.iaea.org/services/key-programmes/programme-of-action-for-cancer-therapy-pact</u>
- National Academies. (2022). Radioactive sources: Applications and alternative technologies.
- WINS. (December 2019–January 2022). Roundtable meeting reports.
- WINS. (January 2021). Considerations for the adoption of alternative technologies to replace high activity radioactive sources.

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