Project to Replace A Cesium-Based Blood Irradiator with X-Ray Technology at Makassed General Hospital in Beirut, Lebanon

Tamima Jisr
Makassed Hospital
P.O. Box 11-6301 Riad El-Solh Beirut 1107 2210 Lebanon
tamimajisr@hotmail.com

Jodi B. Lieberman
Sandia National Laboratories
P.O. Box 5800 MS 1359
Albuquerque, New Mexico 87185-0722
505-382-1959
jbliebe@sandia.gov

Michael Itamura
Sandia National Laboratories
P.O. Box 5800 MS 1359
Albuquerque, New Mexico 87185-0722
505-284-4815
mtitamu@sandia.gov

ABSTRACT
In its efforts to reduce the risk of civilian-use, high-activity radiological materials, the U.S. Department of Energy's (DOE) National Nuclear Security Administration (NNSA) Office of Radiological Security (ORS) helps reduce the global reliance on high-activity radioactive sources by leading efforts to support the development and adoption of non-radioisotopic alternative technologies. Under the auspices of its "Reduce" program, ORS funded replacement of four Cesium-137 blood irradiators for four x-ray irradiators in Beirut, Lebanon: at the Lebanese Red Cross, the Hotel-Dieu de France, Makassed General Hospital, and the American University of Beirut Medical Center . The ongoing economic and political challenges in Lebanon, the emerging COVID pandemic, and August 2020 explosion at the Port of Beirut presented significant potential obstacles to successful delivery, installation, and commissioning of those replacement irradiators. However, with significant planning, coordination among the relevant stakeholders, and a commitment to the success of the project, all four x-ray irradiators were successfully delivered, installed, and commissioned. There was, however, some delay due to acquisition of the requisite approvals for Customs clearance.

The project's success was dependent on a number of factors, including the participation and agreement of the relevant in-country regulatory agencies. It was important to work with the site facilities and medical personnel to establish clear requirements for infrastructure modifications required to install the x-ray irradiator. The existence of a safe and secure disposition pathway for the existing cesium unit prior to the shipment of the new unit was also required.

INTRODUCTION

This paper will discuss the U.S. Department of Energy's (DOE) National Nuclear Security Administration (NNSA) Office of Radiological Security (ORS) -funded international alternative technology project at Makassed General Hospital (Makassed) in Beirut, Lebanon. It will review the full process including site identification, machine selection, licensing and approvals for use of a new device, contracting, infrastructure modifications, installation, and commissioning. The paper will also highlight challenges encountered along the way and how Sandia National Laboratories worked with partners at Makassed, the medical equipment distributor, the freight forwarder, and the Lebanese Atomic Energy Commission (LAEC) to resolve those issues.

The Risk of High-Activity Radiological Sources

The ingredients for a radiological "dirty bomb" are located at thousands of sites in more than 150 countries. Prior to inception of efforts to secure and replace these high-activity radiological sources, many of them were vulnerable to theft and misuse. As a result, many believe that the probability of a terrorist detonating a dirty bomb is much higher than that of an improvised nuclear weapon. The vulnerability of these radiological sources, particularly the Cs-137 used in blood irradiators in hospitals and other "soft target" environments, has historically been a concern. However, following the attacks of September 11, 2001, concern over the malicious use of high-activity sources escalated as new adversaries became a threat.

Although radioactive isotopes also are used for various purposes at universities and research centers, in agriculture, industry, and by governments, they are considered most vulnerable in often less secure medical settings where staff turnover can be high and many people have access to the machines housing the isotopes.[1]

NNSA/ORS Program to Reduce the Risk of High-Activity Sources

The NNSA ORS established a program to enhance global security by preventing high-activity radioactive materials from being used in acts of terrorism. To accomplish these tasks, ORS works with U.S. and international partners to reduce these risks through a three-pronged strategy

- Protect radioactive sources used for vital medical, research, and commercial purposes
- Remove and dispose of disused radioactive sources
- Reduce the global reliance on high-activity radioactive sources by promoting the adoption and development of non-radioisotopic alternative technologies

Because non-radioisotopic technologies have matured in recent years, viable alternatives to cesium and cobalt irradiators are now available and have proven, in many cases, to be comparable or even more effective than gamma irradiators for both research and blood irradiation. These alternatives have already been adopted and are in use by many facilities throughout the U.S. and other countries. Benefits of non-radioisotopic irradiators include:

- Mitigation of security risks, hassles, and licensing and security costs associated with cesium-137 devices
- Elimination of the terrorism and liability risks associated with cesium-137 devices

- Consistent throughput over the lifetime of the device (no source decay)
- Additional capabilities with some alternative technologies

Blood Irradiation to Prevent TA-GvHD Using X-Ray Devices

Gamma-based blood irradiators are commonly used to irradiate cellular blood components (i.e. whole blood, red blood cells, platelets and granulocytes) prior to transfusion to prevent the proliferation of viable T lymphocytes which are the immediate cause of Transfusion Associated-Graft Versus Host Disease (TA-GVHD). TA-GVHD, a rare complication, has a fatality rate greater than 90%. High risk TA-GvHD patients include newborns, immuno-compromised patients, and patients receiving transfusion from a relative. The disease occurs when donor lymphocytes engraft in a susceptible recipient. These donor lymphocytes can proliferate and damage target organs, especially bone marrow, skin, liver and gastrointestinal tract.[2] Blood and blood products are therefore irradiated, while packaged in transfusion bags, to inactivate T-lymphocytes for the prevention of TA-GvHD.

There are a number of x-ray-based blood irradiators on the market and approved for use in the U.S., the European Union, and/or China, including:

- Best Theratronics MK1 and MK2 (Canada)
- RadSource RS 3400 (U.S.)
- Hitachi Sangray (Japan)
- Gilardoni RadGil (Italy)
- Actemium NDT BloodXrad (France)
- Livzon X-Rad 3000 (China)

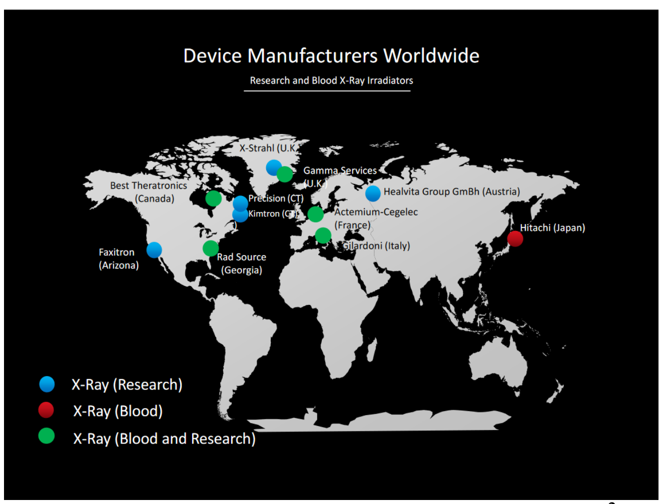

Figure 1. Device Manufacturers Worldwide[3]

Makassed General Hospital

Founded in 1930 in Beirut, Makassed General Hospital is a 230-bed institution that serves approximately 15,000 inpatients and more than 50,000 outpatient visits per year. The current six-story main building and its adjacent clinics are now equipped with the service capabilities needed to support a staff of 250 medical specialists and other licensed physicians, 400 nurses and 350 administrative staff.

Prior to its engagement with ORS and Sandia, Makassed was using a Cs-137 based MDS Nordion Gammacell 1000, which it procured in early 1997. It was used to process 93 units per month of platelets and 86 units per month of packed red blood cells (RBC).

Figure 2. Photo of MDS Nordion Gammacell 1000[4]

Replacement of the Makassed General Hospital Blood Irradiator

In 2018, at the request of ORS, Sandia National Laboratories engaged with Makassed General Hospital, one of four hospitals in Beirut using Cs-137 based blood irradiators, to discuss the possibility of replacing its Gammacell 1000 with a comparable x-ray-based blood irradiator. The principal concern for such sites is the comparability of the replacement technology, its throughput, and its reliability.

In 2018, the environment in Beirut was unstable. Years of conflict, government instability, civil war and economic stagnation created security concerns around the use of high-activity radioactive sources. Specifically, there were concerns that the sources being used at Makassed, in addition to the three other hospitals in Beirut, could be stolen and used by adversaries in a radiological terrorism event. With the advent of viable replacement technology, use of Cs-137 became unnecessary.

The site agreed to participate in the program and ultimately chose the RadSource RS3400 x-ray irradiator to replace its GC1000.[5] The RS3400 is FDA approved for use in the U.S. and CE marked for use in the European Union. Key features of the RS3400 include:

- A Dose Uniformity of 1.6 to ~ 1.35
- A cycle time for 25Gy center dose is less than 5 minutes
- Holds up to (6) 1 L canisters
- Can process blood bags, platelet bags, and drawn syringes of up to 60 mL (e.g. aliquots) in the cycle

Irradiation guidelines for irradiation of blood components using the RS3400 are:

- U.S. (FDA) 25 Gy min/ 50 Gy max dose rate: 5.5 – 6.5 Gy/min
- EUROPE (EDQM) & UK (BCSH) 25 Gy min./ 50 Gy max dose rate: 25 Gy/min. Dose rate: 5.5-6.5 Gy/min

Processing volume/cycle are:

- Blood Bags – Up to (6) 600 mL bags
- Platelet Bags – Up to (6) 500 mL bags
- Syringes – Up to (18) 60 mL syringes

The x-ray irradiator was installed and commissioned at Makassed in April 2020, in the midst of the global pandemic. The irradiation time for the GC 1000 was roughly 12 minutes for blood components versus 280 seconds for the new x-ray irradiator, a significant improvement that allowed for a higher throughput for the x-ray irradiator when compared to the GC 1000.

Financial Strain, the COVID-19 Pandemic and Port Explosion

Compounding the already difficult security environment, by 2020, hospitals in Beirut were struggling with country's financial collapse which stressed the already precarious healthcare system, the COVID-19 pandemic and damage resulting from the August 4 port explosion.

The onset of the COVD-19 pandemic forced medical facilities to reprioritize their needs based on the massive influx of COVID patients needing care, shortages in personal protection equipment and staffing and other funding needs to contend with the pandemic. As of July 13, 2021, the Government of Lebanon has confirmed over 547,961 cases of COVID-19, with 14.91% of the population having had at least one dose of a COVID-19 vaccine.[6]

Amid the global COVID-19 pandemic, a large amount of ammonium nitrate stored at the port in Beirut exploded on August 4, 2020, causing at least 207 deaths, 7,500 injuries, and US$15 billion in property damage, and leaving an estimated 300,000 people homeless. Makassed Hospital is less than 4 km from the explosion. Three hospitals in the vicinity of the port were damaged, including Makassed General Hospital. "Emergency medics in Al Makassed Hospital in Beirut had to treat the injured on the floor, Lebanese newspaper An Nahar quoted a witness as saying."[7]

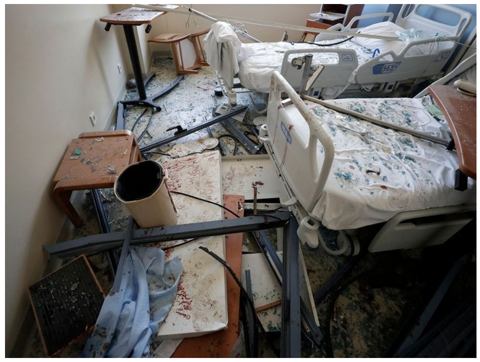

Figure 3. Image Credit: AP

The port of Beirut serves as the main maritime entry point into Lebanon and a vital piece of infrastructure for the importation of scarce goods. The large number of injuries placed an additional strain on the local hospitals as the need for irradiated blood product also markedly increased.

According to an August 4 account, "The Lebanese Red Cross said that every available ambulance from North Lebanon, Bekaa and South Lebanon was being dispatched to Beirut to help patients. Hospitals were so overwhelmed that they were turning wounded people away, including the American University Hospital. Patients were transported to hospitals outside Beirut because those in the city were at capacity."[8] [9]

All these developments underscored the need for 1) a steady and reliable supply of irradiated blood components and 2) prompt removal of the existing GC 1000 blood irradiator at Makassed. Given the supply chain interruptions due to the security environment, the port explosion, and economic disruption, re-sourcing the GC 1000 would continue to be difficult, making x-ray irradiation a better and safer choice.

Licensing and Regulatory Approvals

According to government decree law No. 15512/2005, the Lebanese Atomic Energy Commission (LAEC) is responsible for regulating radiation safety in Lebanon. The LAEC provides authorization for all activities that are pertinent to the use of radiation sources, including use, import, export, transport, handling, storage, and waste. Among other tasks, this includes assessment of the authorization applications, periodic inspections of related facilities and issuance of certificates for authorization that entitles an entity to possess a license from the Minister of Public Health.

For use of the x-ray blood irradiator, Makassed was required to fill out the appropriate license application form associated with the relevant use (www.laec-cnrs.gov.lb) and had to include all needed technical information, licensee information, description of location for use of the technology and classification of areas, academic and expertise of workers, adopted emergency plan, records and documentation. The license was issued by the Minister of the Public Health, based on the certificate of authorization issued by the LAEC. As Makassed already had a license for the use of radioactive sources, they needed to have their existing license amended to account for the new x-ray irradiator.

Removal of Gammacell 1000

Before the RadSource RS3400 could replace the existing GC 1000, a disposition pathway for permanent disposal of the GC1000 had to be determined. Options included permanent storage and disposal at an existing secured in-country facility or return to the manufacturer, which, in this case, was Best Theratronics in Ottawa, Canada. Given the unstable environment in Lebanon, the LAEC stated that they wanted to have the GC1000 removed from the country and sent back to Best for permanent disposal.

For this to occur, Sandia had to work with Best to make the appropriate arrangements for the dismantlement, packaging, transport and export of the irradiator. The in-country company assisting Best with the removal, Tanit Paramedic, had to apply for an export license from the LAEC that included all relevant information, including technical specifications of the item and radioactive material to be exported, transport security arrangements, and information pertaining to Best's authorization to transport and dispose of radioactive materials. They also had to provide a copy of the valid license for the facility receiving the radioactive material issued by the Canadian Nuclear Safety Commission (CNSC). Depending on the category of the radioactive source, additional requirements in the authorization/license process that are related to nuclear security, will be requested by LAEC for the transport and the use of the radioactive material.

Upon dismantlement, the GC1000 at Makassed was packaged in a Type B (U)[10] transport container certified by the CNSC for safe and secure transport of radioactive material. Upon arrival in Canada, Best transported the source to its disposal facility.

Type B

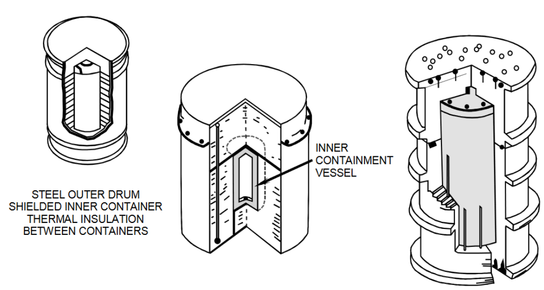

Figure 4. Type B Shipping Container for Radioactive Material

Figure 5. Putting Source "Pig" into Shipping Container

Figure 6. Makassed GC-1000 packaged for transport

CONCLUSION

The project's success was dependent on a number of factors, including the participation and agreement of the relevant in-country regulatory agencies and the need to satisfy regulatory requirements for licensing and operation of the medical device, establishment of procurement contracting requirements and expectations for reporting of technical results with the sites' use of the x-ray technology equipment. It was also important to work with the site facilities and medical personnel to establish clear requirements for infrastructure modifications required to install the x-ray irradiator, including installation of power drops and ensuring operational temperature requirements were met. The existence of a disposition pathway for the existing cesium unit prior to the shipment of the new unit ensured safe and secure transport and disposal of radioactive material.

REFERENCES

[1] Preventing a Dirty Bomb, Effective Alternative Technologies for Radiological Security, NTI, https://media.nti.org/documents/Preventing_a_Dirty_Bomb_FINAL.pdf, accessed July 13th, 2021

[2] "Why is blood irradiated?", American Association of Blood Banks (AABB), https://www.aabb.org/regulatory-and-advocacy/regulatory-affairs/regulatory-for-blood/irradiation, accessed July 11, 2021

[3] X-Ray Device Manufacturers Worldwide (2019), Nuclear Threat Initiative, https://media.nti.org/documents/Map_of_X-Ray_Manufacturers_2019.pdf, accessed July 13, 2021. **Not pictured**: Livzon Blood Irradiator, Zhuhai, Guangdong, China (http://www.livzondiagnostics.com/en-us/info/35.html)

[4] "Counterterrorism and Law Enforcement Preparedness Conference: The RDD Threat", September 29, 2010, Heather M. Pennington, Sandia National Laboratories

[5] The ORS Reduce program is "device agnostic"; the site selects the x-ray irradiator that best suits its needs.

[6] https://pandemic.internationalsos.com/2019-ncov/covid19-locations-with-cases, accessed July 13, 2021

[7] "Beirut blast: Lebanese hospitals struggling to help the injured after port explosion", August 5th, 2020, Ramadan Al Sherbini, Gulf News, https://gulfnews.com/world/mena/beirut-blast-lebanese-hospitals-struggling-to-help-the-injured-after-port-explosion-1.72996653, accessed July 13, 2021

[8] "Deadly Explosions Shatter Beirut, Lebanon", Ben Hubbard and Maria Abi-Habib, August 4th, 2020, https://www.nytimes.com/2020/08/04/world/middleeast/beirut-explosion-blast.html, accessed July 13, 2021

[9] Along with Makassed General Hospital, ORS funded replacement of Cs-137 blood irradiators at the Lebanese Red Cross and the American University of Beirut Medical Center.

[10] A Type B package may be a metal drum or a huge, massive shielded transport container for radioactive material. Like Type A packages, Type B packages must pass certain tests. However, the Type B tests are considerably more rigorous than those required for Type A packages. Transportation of Radioactive Material, Reactor Concepts Manual, USNRC Technical Training Center, https://www.nrc.gov/reading-rm/basic-ref/students/for-educators/11.pdf, accessed July 29, 2021

SAND2021-9111 C