Sandia National Laboratories

“Radiological Risk Reduction in Uruguay: An International Alternative Technology Pilot”

NAS Albuquerque Meeting

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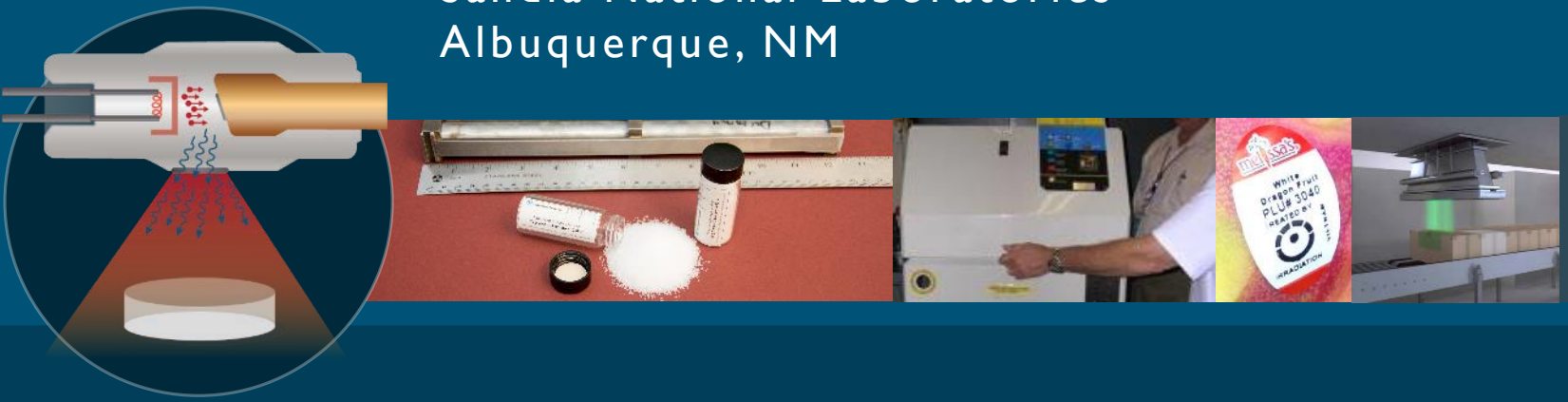

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International Reduce

- Pilot projects started in 2016
- Begun in earnest in 2018
- The International Reduce program currently operates in 20 countries
- International partners include the WINS and IAEA

Six X-ray irradiator designs approved for use around the world

Many countries accept either European Union CE mark or U.S. FDA approval for blood irradiation, which facilitates adoption around the world.

Considerations

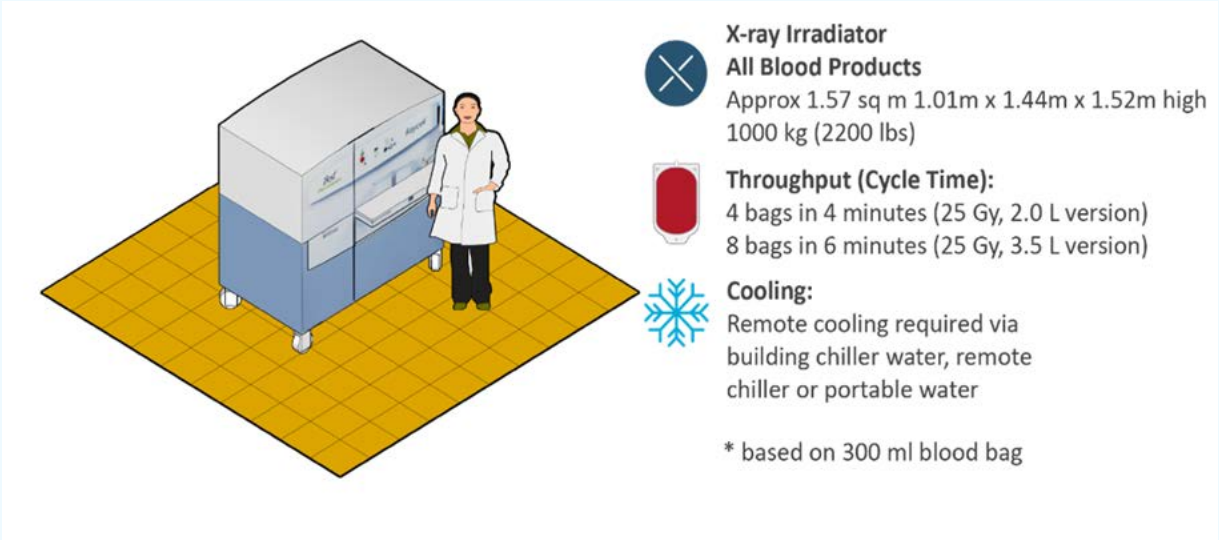
These projects are often more complex than domestic CIRP projects

- Regional nuances
- Different in-country rules/regulations
- Ambiguous lines of authority regarding licensing/regulation of alternative technologies
- Commissioning processes can differ in substance and amount of time
- Disused source removals can be complex and differ by country
  - i.e. Is there a secure in-country storage facility?
- Infrastructure constraints
  - i.e. cooling water, electricity, adequate trained staff
- Financial considerations over the long term
  - i.e. cost of maintenance beyond warranty period
- International contracting

Asociación Española Primera de Socorros Mutuos
a Private Hospital in Montevideo, Uruguay

- First International Alt Tech project piloted in 2016-18
- One of two facilities in Uruguay that can irradiate blood
- Selected the 2 liter, Best Theratronics, Raycell Mk2 to replace its Gammacell 1000 Cs-137 irradiator

Gammacell 1000



Raycell Mk2

Preparation for the Raycell Mk2 Installation

- **Infrastructure Modifications** – new machine was placed in a wing of the hospital undergoing major renovations. Old equipment had to be removed. New electrical hookups and plumbing for the heat exchanger needed to be installed before the new irradiator could be installed.

- **Company Qualification Certificate** – documentation needed to be secured from Ministry of Public Health to import the irradiator.

- **Import Authorization** – needed to be secured from the National Directorate of Nuclear Technology, Ministry of Industry, Energy and Mining to import the irradiator.

- **Certificate of Registration and Authorization of Sale of Medical Products License** – needed to be secured from the Ministry of Public Health before operating the irradiator.

Validation of Irradiator

Fig. 1 Unirradiated Blood Bag

Fig. 2 Irradiated Blood bag

Installation of the Raycell Mk2 and Unexpected Issues

- ✓ Best Theratronics engineers travelled from Canada to Uruguay to install the machine
- ✓ Staff were trained on the operation of the machine and how to diagnose problems
- ✓ Representative from a local equipment importer was trained in Canada on how to maintain and repair the machine

Operational Raycell Mk2

- **Installation was delayed due to renovation work taking longer than expected and raised a concern over air leakage into the X-ray vacuum tubes. Additional seasoning runs were required before it could be used to irradiate product.**
- **The heat exchanger was damaged during transport and had to be replaced.**

Results and Lessons Learned

Hospital staff are happy with the operation of the machine and run the machine 10- 14 times per week. At present, they only irradiate blood for their own use, but are considering doing so for other organizations given the higher throughput.

For future projects, it important considerations include:

Understanding regulatory requirements for licensing and operation of a new medical device

Site is prepared to install the new machine

Identify paperwork needed to import device

Establish disposal path

Develop long term maintenance strategy

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