SWITCHING FROM A CESIUM-137 BLOOD IRRADIATOR TO AN X-RAY IRRADIATOR Experience at a Community-based Hospital in the Northeastern U.S.

M. HERNANDEZ

Morristown Medical Center – Atlantic Health System Morristown, New Jersey, U.S.A. Email: marissa.hernandez@atlantichealth.org

Abstract

Blood irradiators are often used to irradiate blood and blood components prior to transfusion to prevent the proliferation of certain types of T lymphocytes that can inhibit the immune response and cause graft-versus-host disease. Morristown Medical Center, which is part of Atlantic Health System based in the northern part of New Jersey, USA, employed a cesium-137 blood irradiator for about 20 years. The Security enhancements and response protocols were set in place, in order to comply with the USNRC Increased Control Orders, as well as 10 CFR 37. The facility eventually came to the decision to replace the caesium irradiator with an X-ray irradiator. Factors such as irradiator performance, prohibitive regulations, security issues and cost savings, that affected the decision, will be discussed. Finally, a visual description of the day when our caesium irradiator was picked up for disposal, will be presented. It is hoped that our experience will engage other facilities to do the same in terms of replacing their Cs-137 irradiators with technologies that yield better performance and result in much less vulnerability from theft & sabotage involving high-activity radioactive materials.

1. INTRODUCTION:

The paper aims to describe the experience of Morristown Medical Center (MMC) with the disposal of its caesium blood irradiator and replacing it with an X-ray irradiator. It is hoped that other facilities will be engaged & inspired to do the same and subsequently replace their own cesium-137 irradiators with technologies that yield better performance and result in much less vulnerability from theft & sabotage involving high-activity radioactive materials.

Blood irradiators are often used to irradiate blood and blood components prior to transfusion to prevent the proliferation of certain types of T lymphocytes that can inhibit the immune response and cause graft-versus-host disease. Morristown Medical Center, which is part of Atlantic Health System (AHS) based in northern New Jersey, employed a cesium-137 (Cs-137) blood irradiator for about 20 years.

On November 14, 2005, the U.S. Nuclear Regulatory Commission (NRC) issued Order EA-05-090, imposing increased controls for certain high-risk radioactive materials such as those contained in the blood irradiators. On December 5, 2007, the NRC issued Order EA-07-305, imposing fingerprinting and criminal history records check requirements for unescorted access to certain radioactive material. These increased control (IC) requirements were imposed on radioactive materials of concern such as cesium-137 (Cs-137) with activities greater than or equal to 27 Ci (1 TBq).

During the time of the IC orders, MMC had a blood irradiator that contained approximately 1400 Ci (52 TBq).

The Blood Bank policies, Security enhancements, and response protocols were set in place, in order to comply with the USNRC IC Orders.

In February 2011, the National Nuclear Security Administration (NNSA/U.S.DOE) visited MMC to assess the security of radioactive materials - specifically the blood irradiator.

AHS/MMC volunteered to participate in NNSA's Global Threat Reduction Initiative (GTRI) program, which is now referred to as the Office of Radiological Security (ORS). The goal of the program is to bolster the security of radioactive materials, both nationally and globally. NNSA agreed to cover 100% of the costs for numerous necessary systems/installations to enhance security. The security enhancements were incorporated into the existing site access control system: intrusion detection system, CCTV system, installation of a remote monitoring system (RMS)

U.S.NRC Title 10 CFR Part 37 took in effect on March 19, 2016 in New Jersey. It superseded the previous IC orders. It imposed further requirements on security protocols & procedures such as:

- Reinvestigation every 10 years for any individual with unescorted access (fingerprinting and an FBI identification and criminal history records check);
- Establishment of "Security Zones" as well as "continuous physical barriers" involving access via established control points or direct control by approved individuals;
- Maintaining capability to continuously monitor & detect without delay, all unauthorized entries into Security Zones;
- Appropriate Security training, both initial and annually, not to exceed 12 months

2. RATIONALE BEHIND THE DECISION TO REPLACE THE CESIUM IRRADIATOR AND SUBSEQUENT EXPERIENCES WITH USING THE X-RAY IRRADIATOR

MMC eventually came to the decision to dispose the caesium irradiator and replace it with an X-ray irradiator as part of the ORS Caesium Irradiator Replacement Project (CIRP). Factors such as irradiator performance, prohibitive regulations, security issues and cost savings, affected the decision.

2.1. Increased efficiency and throughput from x-ray irradiators

Switching to an X-ray irradiator increased efficiency and throughput at MMC, as shown in Table 1.

TABLE 1.	EFFICIENCY	& THROUGHPUT	COMPARISONS	BETWEEN A	A CESIUM	IRRADIATOR	₹ & AN
X-RAY IRRA	ADIATOR						

	Caesium Irradiator (IBL-437C) (~1100 Curies at disposal date)	X-ray Irradiator
Turnaround Time	12 minutes / cycle	< 5 minutes / cycle
Cycle Time	Increases every month due to decaying radioactive source	Never changes
Workload	Can irradiate 1-2 products/units at a time	Can irradiate up to 6 products/units at a time
Product Types	Cannot combine different blood products	Can do multiple types of products at a time

The quicker turnaround time as well as the ability to irradiate up to 6 products/units at a time yielded improved patient care, especially in the Outpatient areas as well as the Neonatal Intensive Care Unit (NICU) at MMC.

The following feedback were expressed by various laboratory personnel in the Blood Bank at MMC, when asked how their x-ray irradiator compared with their former caesium irradiator:

— "There is no comparison"

— "Minimal maintenance on the x-ray irradiator"

- "Higher throughput"
- "No separate water hook-up needed"
- "One day during the first week of use, the x-ray irradiator faulted 4 times only happened that time no other instances; if it happens again, we simply call the vendor and they will deploy service personnel"
 "No security issues"

From the time the X-ray irradiator was operational at MMC, from August 2017 to the present, there have only been:

- Three corrective services performed by the vendor. These included replacements of a control board and an HV cable and yielded a total downtime of less than 45 minutes.
- Two annual preventive maintenance services, at approximately 2.5 hours each time, yielded a total downtime of less than 30 minutes. During such maintenance periods, the service technician can allow interruptions to let the staff perform irradiations, if necessary. In addition, when such services are anticipated, the facility is able to irradiate products ahead of time.

2.2. More prohibitive and costly regulatory requirements on caesium irradiators

Based on our experience at MMC, the regulatory requirements for caesium irradiators are more prohibitive and costly than those for X-ray irradiators, as described in Table 2.

TABLE 2. REGULATORY REQUIREMENT COMPARISONS BETWEEN A CESIUM IRRADIATOR & AN X-RAY IRRADIATOR

Caesium Irradiator (IBL-437C)	X-ray Irradiator	
(~1100 Curies (41 TBq) at disposal date)	must comply with	
must comply with 10 CFR 37:	NJ Department of Environmental Protection	
(T&R requirements, Security, etc.)	(NJDEP) Cabinet X-ray Regulations:	
T&R Background Checks by HR	Annual Physics Testing	
Fingerprinting – initially & every 10 years	Semi-annual Door Interlock checks	
Annual Refresher Training – Security Program		
Annual Review of the Access Authorization		
Program		
& the Security Program		
Local Law Enforcement Agency (LLEA) -		
Annual Training; Annual signed agreement;		
Facility Security updates; Incident notifications		
Quarterly RMS testing by Security & the Alarm		
Co.		
24/7 Security Surveillance of the Irradiator		
(Redundant Systems); High-level Security		
Measures		

We had a total of almost 300 staff & contractors who were required to meet the Trustworthiness & Reliability (T&R) requirements of 10 CFR 37, 75% of which were required to be fingerprinted, as well as undergo FBI background checks.

The manufacturer's specifications on our X-ray irradiator requires:

— Monthly door interlock checks, instead of the semi-annual frequency that the NJDEP requires.

- Semi-annual dosimetry phantom test an irradiation cycle is run on a phantom that is sent to our facility; we in turn, send the phantom to a calibration facility in Texas for dosimetry readings.
- As needed, a condition cycle is run whenever the irradiator is not used during an entire work shift, causing the condition light to illuminate. No conditioning required if the irradiator is used constantly.

2.3. Issues and protocols related to security requirements

In order to remain in compliance with the 10 CFR 37 requirements, there were several issues and protocols related to Security, as shown in Table 3.

TABLE 3. SECURITY ISSUES AND PROTOCOLS ON A CESIUM IRRADIATOR

Caesium Irradiator (IBL-437C)		
(~1100 Curies (41 TBq) at disposal date)		
Facility/Community vulnerability to terrorism (cesium-137 is an attractive radioactive source candidate		
for WMDs)		
Conduct Fingerprinting		
Attend Annual Refresher Training – Security Program		
Perform Annual Review of the Access Authorization Program & the Security Program		
LLEA Coordination – Coordinate annual training; Site tours; Annual signed agreement; Updates		
Conduct Quarterly RMS testing; Coordinate with Alarm Co.		
Ensure 24/7 Security Surveillance of the Irradiator (Redundant Systems); High-level Security Measures		

Medical facilities such as MMC are a vulnerable target for terrorist infiltration involving radioactive materials. They are typically open-access facilities with limited security measures.

2.4. Considerable expense reduction when an x-ray irradiator is employed instead of a caesium irradiator

Cost is another imperative deciding factor for switching to an alternative technology for blood irradiation. Table 4 shows that doing so can yield considerable savings.

TABLE 4.EXPENSES/SAVINGS – CESIUM IRRADIATOR VS. X-RAY IRRADIATOR

Caesium Irradiator (IBL-437C) (~1100 Curies (41 TBq) at disposal date)	X-ray Irradiator
10 CFR 37 Requirements:	Caesium Irradiator Replacement Project (CIRP):
HR Staff hours for T&R Background Checks	50% reimbursement on X-ray irradiator Cost (Total cost (including 1-year warranty) ~ US\$250k)
Fingerprinting – Security staff hours; NRC processing charges US\$26/fingerprint card Security staff hours for Quarterly RMS testing, other periodic testing High cost of security enhancements; Periodic maintenance cost on security equipment after the federal contract period runs out	100% coverage of caesium irradiator Pick-up & Disposal

2.5. Requirements and expectations from ORS CIRP participation after x-ray irradiator installation

As part of the ORS CIRP participation, upon installation of the new X-ray irradiator, Pacific Northwest National Laboratory (PNNL) requires that the facility submit a report in Excel format, specifying the amount and type of product irradiated, cycle time of irradiation, and any issues that arise. This can be done by collecting daily irradiation statistical user and product data. The report shall be supplied on a quarterly basis for a period of one year, together with all manufacturer and/or contractor service/repair reports, if any.

The reimbursement check for 50% of the X-ray irradiator cost, was received from PNNL, one month after the caesium irradiator pick-up.

3. TIMELINE AND DESCRIPTION OF THE EVENTS ON THE DAY OF THE CESIUM IRRADIATOR DISPOSAL PICK-UP

Overall, the preparations for and execution of the irradiator disposal pick-up, were carried out accordingly. As shown in Table 5, preparations and pick-up occurred within 8 hours as expected.

TABLE 5.TIMELINE FOR THE DISPOSAL PICK-UP OF THE CESIUM IRRADIATOR AT MORRISTOWNMEDICAL CENTER BY IDAHO NATIONAL LABORATORY (INL)

7.00 11.00 a m	Removal company staff prepared the caesium blood irradiator, located in the
7.00-11.00 a.m.	Blood Bank
7:30 a.m.	Crane arrival
8:00 a.m.	Arrival of trailer/cask and INL personnel
11.00 a m	Removal company staff wheeled out the irradiator from the Blood Bank, out to
11.00 a.m.	the parking lot area next to the trailer.
11:00 a.m3:00	INL prepared the irradiator for transport – including leak tests and radiation
p.m.	surveys.
3:00 p.m.	Trailer transporting the cask containing the irradiator, left MMC.

Finally, a visual description of the day when the caesium irradiator was picked up from MMC for disposal, is shown below.



FIG. 1. Caesium irradiator with the cover removed



FIG. 2. Disposal Preparation of the caesium irradiator



FIG. 3. Caesium irradiator being transported out of the Blood Bank



FIG. 4. The Crane and the Cask in the parking lot behind the hospital



FIG. 5. Caesium blood irradiator being hoisted into the cask



FIG. 6. Trailer hauling the cask containing the irradiator, as it leaves the facility

4. FACTORS THAT DETER FACILITIES FROM SWITCHING TO ALTERNATIVE TECHNOLOGIES

Facilities that are considering switching from a caesium irradiator to an X-ray irradiator, may be having some notions or perceiving certain drawbacks that would deter them from doing so:

- Resistance to change
- Possible loss of research grant funding from agencies such as the NIH note that it is said that the NIH is technology agnostic so long as the researcher demonstrates the effectiveness of the irradiator; in any case, the importance of this consideration varies from user to user.
- X-ray irradiator performance issues note that generally, these no longer apply to the newer units
- X-ray irradiators generate heat; however, this can be solved by adequate ventilation and alleviated by a highperformance chiller.
- Cost for service contract is approximately \$17,500 per year per irradiator
- Cost of x-ray tube replacement is approximately \$20,000; note that irradiator x-ray tubes can typically last up to 7-10 years

All things considered, the author believes that switching from a caesium irradiator to an X-ray irradiator, yields benefits which far outweighs the drawbacks, if any.

5. CONCLUSIONS

The deciding factors discussed in the paper prove to be compelling reasons to dispose of a caesium blood irradiator and replace it with an alternative technology which yields better performance and results in much less vulnerability from theft & sabotage involving high-activity radioactive materials. It is hoped that our experience in doing so will engage and inspire other facilities to do the same.

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