



1

Learning Objectives

- Recognize the differences between cesium and X-ray irradiators and their impacts on TA-GVHD prevention, blood center operations, regulatory requirements, security requirements, blood product throughput and patient care, and lifecycle costs.
- Realize the importance of planning for the logistics, operational adjustments, and financial incentives associated with transition to an FDA-cleared X-ray irradiator.
- Summarize the Cesium Irradiator Replacement Project, discuss how it assists blood centers to replace cesium irradiators and know where to find more information.
- Describe how to participate in the Cesium Irradiator Replacement Project.



2

Faculty

Director/ Moderator:

Lance Garrison, PhD, Domestic Alternative Technologies Manager, National Nuclear Security Administration, DOE, Washington, DC

Presenters:

- Patricia M. Kopko, MD, Professor of Pathology, Director of Transfusion Medicine, Associate Director, Immunogenetics and Transplantation Laboratory, Associate Director, Pathology Residency Training Program, University of California San Diego, San Diego, CA
- John J. Svagr, CIH, RSO, ASA, Director of Environmental Health & Safety, Corporate Radiation Safety Officer, New York Blood Center, New York, NY
- Mark Georgescu, Regulatory Compliance Manager, Vitalant, Phoenix, AZ



3

The logo for the National Nuclear Security Administration (NNSA), featuring the letters 'NNSA' in a bold, blue font with a stylized atomic symbol to the right, and the text 'National Nuclear Security Administration' below it.

Radiological Security through Irradiator Replacement

Lance Garrison
November 5, 2019


A realistic image of the Earth showing the Americas, set against a background of yellow, glowing atomic orbits.The logo for Global Material Security, featuring a green shield with a white border and a central emblem.The logo for the Office of Radiological Security (ORS), featuring a stylized orange atomic symbol and the text 'ORS Office of Radiological Security Protect - Remove - Reduce'.

4

NNSA
National Nuclear Security Administration

Learning Objectives

- Recognize the differences between cesium and X-ray irradiators and their impacts on TA-GVHD prevention, blood center operations, regulatory requirements, security requirements, blood product throughput and patient care, and lifecycle costs.
- Realize the importance of planning for the logistics, operational adjustments, and financial incentives associated with transition to an FDA-cleared X-ray irradiator.
- Summarize the Cesium Irradiator Replacement Project, discuss how it assists blood centers to replace cesium irradiators and know where to find more information.
- Describe how to participate in the Cesium Irradiator Replacement Project.



5

NNSA
National Nuclear Security Administration

Consequences of Radiological Terrorism








6

NNSA
National Nuclear Security Administration

Office of Radiological Security

Enhance global security by preventing high-activity radioactive materials from being used in acts of terrorism.



 Global Material Security  **ORS**
Office of Radiological Security
Protect - Remove - Reduce

7

7

NNSA
National Nuclear Security Administration

Office of Radiological Security (ORS)


MISSION: The Office of Radiological Security enhances global security by preventing high activity radioactive materials from use in acts of terrorism.

PROTECT	REMOVE	REDUCE
PROTECT radioactive sources used for vital medical, research, and commercial purposes	REMOVE and dispose of disused radioactive sources	REDUCE the global reliance on radioactive sources by promoting the adoption and development of non-radioisotopic alternative technologies
		

 Global Material Security  **ORS**
Office of Radiological Security
Protect - Remove - Reduce

8

8



What Are “Alternative Technologies”?

Technologies which do not contain radioactive materials that perform an equivalent (or better) function as a comparable device

Alternative technologies may emit ionizing radiation, like **x-ray irradiators**, or they may not, like **UV pathogen reduction systems**




Application Examples

- Blood Irradiation
- Research Irradiation
- Sterile Insect Technique
- Food/Phytosanitary Irradiation
- Radiotherapy
- Medical Device Sterilization
- Plastic polymerization


Alternative Technology Examples

- Self-shielded X-ray Irradiators (generators)
- Industrial E-Beam & X-ray Conversion
- Linear Accelerators (LINAC)
- UV Pathogen Reduction
- Neutron Generators

New applications & technologies yet to emerge...





7

9




ORS Reduce Strategy

Seeks to convert and replace radiological devices to achieve **permanent risk reduction** by reducing the footprint of risk-significant radiological materials.




Policy Engagement

- Explore policies to incentivize the long-term transition to alternative technologies




Device Replacements

- Implement activities to facilitate the voluntary transition to alternative technologies by incentivizing adoption and removing barriers




Outreach & Education




- Information-sharing and outreach efforts to different stakeholder groups via educational tools and events




Research

- Address gaps, improvements, and analytical support for adoption of technology through support for studies & other collaboration with NNSA and DOE research & development offices






10

10



ORS Device Replacements

Cesium Irradiator Replacement Project

A voluntary initiative offering financial incentives to U.S. licensees who choose to replace Cs-137 self-shielded irradiators with alternative technologies.


Sites Receive:


- Removal of the Cs-137 device through the Off-Site Source Recovery Project (OSRP)
- A financial incentive toward the purchase price of an X-ray machine (typically 50%)

Initiative	Irradiator Application	Irradiators to be Replaced
University of California	Mostly research	90%
New York City	Blood & Research	75%
Atlanta	Blood & Research	66%
Vitalant	Blood	100%


Progress to Date

- 113** irradiators replaced
- 30%** of the U.S. inventory currently being replaced






Office of Radiological Security
Protect - Remove - Reduce


19


11




Congressional Support


H.R. 5515 – John S. McCain National Defense Authorization Act for Fiscal Year 2019

- To meet the goal of eliminating the use of blood irradiation devices in the United States that rely on cesium chloride by December 31, 2027 through a **voluntary** program (Cesium Irradiator Replacement Project) that:
 1. is voluntary for owners of blood irradiation devices;
 2. allows for the United States, subject to the review of the Administrator, to pay up to 50 percent of the per-device cost of replacing blood irradiation devices covered by the programs;
 3. allows for the United States to pay up to 100 percent of the cost of removing and disposing of cesium sources retired from service by the programs; and
 4. replaces such devices with x-ray irradiation devices or other devices approved by the Food and Drug Administration that provide significant threat reduction as compared to cesium chloride irradiators.





Office of Radiological Security
Protect - Remove - Reduce


12

12



ORIS Contacts

Lance Garrison
Domestic Alternative Technology Portfolio Manager
lance.garrison@nnsa.doe.gov
Office: 202-586-7449

Nan Silverman-Wise (CONTR)
Alternative Technology Program Support
Nan.Silverman-Wise@nnsa.doe.gov
Office: 202-854-2013



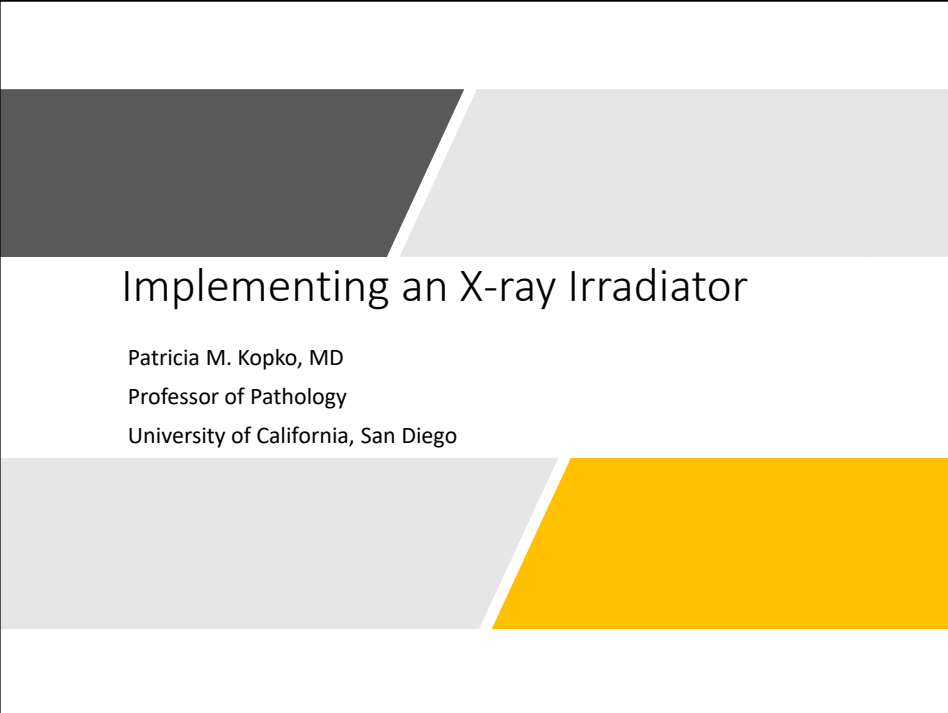
Global
Material
Security



ORIS
Office of Radiological Security
Protect - Remove - Reduce

13

13



Implementing an X-ray Irradiator

Patricia M. Kopko, MD
Professor of Pathology
University of California, San Diego

14



15



16



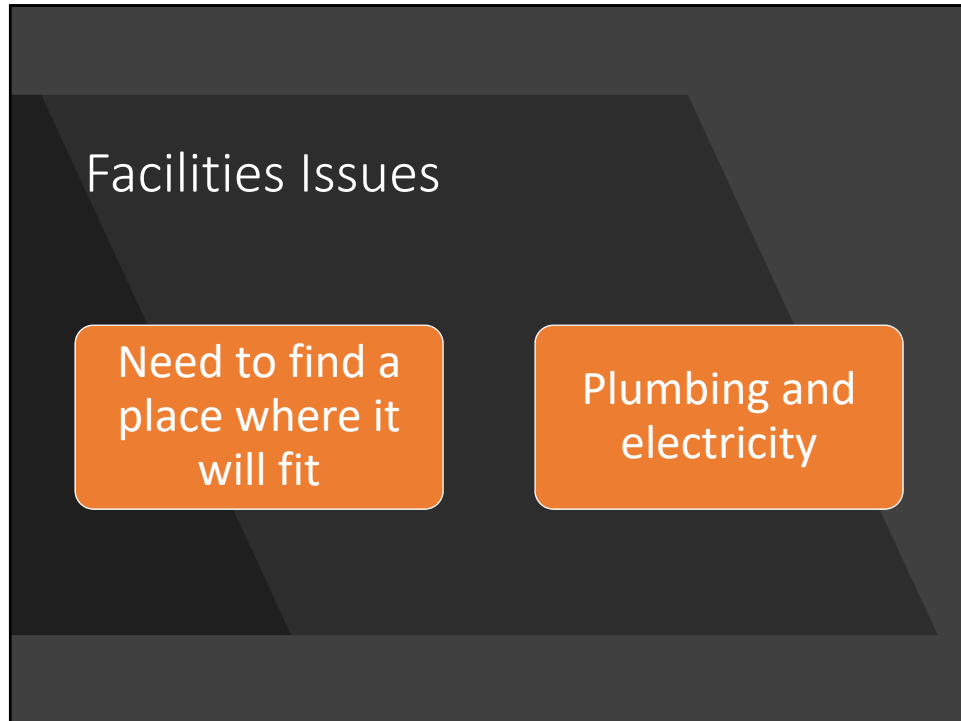
17

Implementing an X-ray Irradiator

- Issues
 - Facilities
 - Access
 - Reliability
 - Validation
 - Transition
 - Decommission

18

Facilities Issues

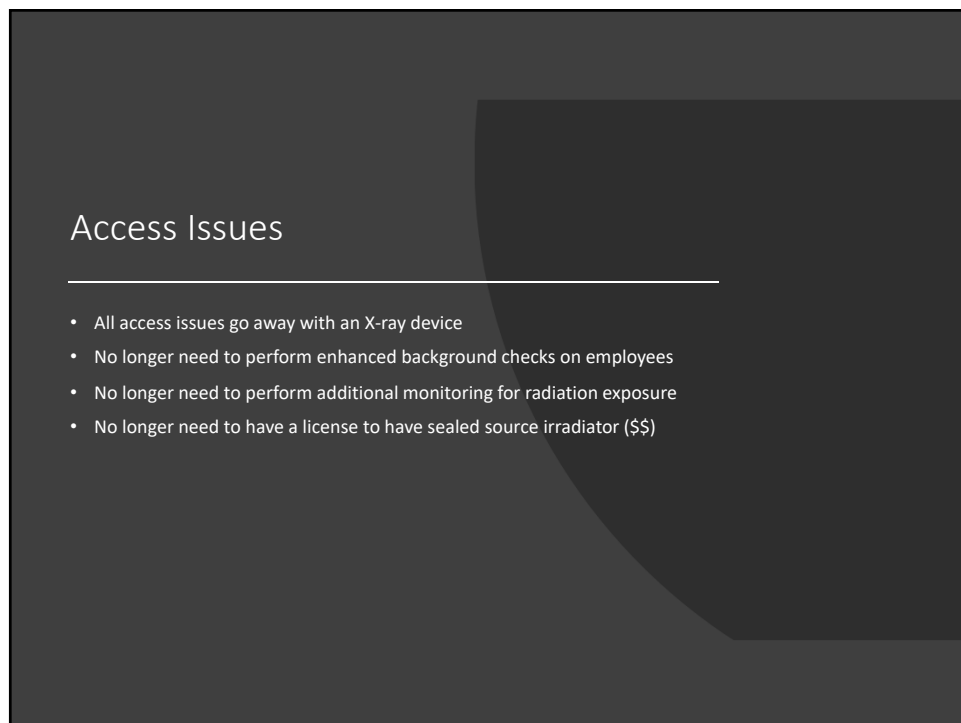
A dark grey slide with a white title 'Facilities Issues' at the top left. Below the title are two orange rounded rectangular boxes with white text. The left box contains the text 'Need to find a place where it will fit' and the right box contains 'Plumbing and electricity'.

Need to find a place where it will fit

Plumbing and electricity

19

Access Issues

A dark grey slide with a white title 'Access Issues' at the top left. Below the title is a horizontal white line. Underneath the line is a bulleted list of four items.

- All access issues go away with an X-ray device
- No longer need to perform enhanced background checks on employees
- No longer need to perform additional monitoring for radiation exposure
- No longer need to have a license to have sealed source irradiator (\$\$)

20

Reliability Issues

- The reliability of X-ray devices has improved significantly since the machines were first introduced
- UCSD has not experienced the machine out of service in more than one year
- Blood banks still need a back up plan in case the machine is out of service
 - Blood services provider
 - Access to an alternate machine
- Replacing the X-ray tube is expensive

21

Validation Issues

Not difficult

Somewhat
time
consuming

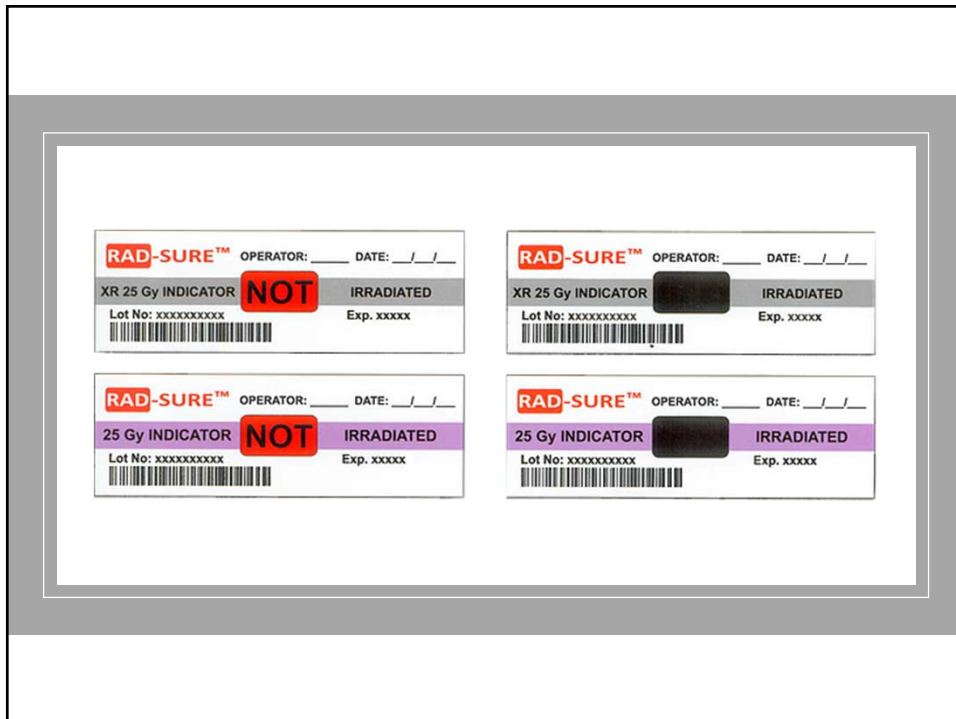
Can use
expired units

22

Transition Issues

- Can't usually place the new irradiator where the current machine already resides
- The old machine will need to be used until the new machine is validated
- Need to purchase the radiation indicators for X-ray irradiation

23



24


Decommission Issues

- You own the sealed source cradle to grave
- The sealed source needs to be safely decommissioned
- Work with your facility Radiation Safety Officer
 - There may be ways to decommission the source with little or no cost to your laboratory


25

pkopko@ucsd.edu


26



New York Blood Center



A Journey from Cesium 137 to X-Ray Technology
By: John Svagr, CIH & RSO
Director of Environmental Health and Safety




27

27

2005 – 2009

- **November 2005 NRC Issues Security Requirements for Self-Shielded Irradiators:**
 - Access Controls
 - Monitor, Detect, Assess & Respond
 - Information Protection and Document Retention
- **On December 5, 2007, the Nuclear Regulatory Commission (NRC) issued Order EA-07-305:**
 - Require fingerprinting and a FBI identification and criminal history check to ensure the trustworthiness and reliability of staff who grant access for and who have unescorted access to irradiators.
 - Company needed to appoint T&R Official
 - Local Law Enforcement Agreement



28

28

2005 – 2009

• NYBC moved processing operations to Long Island City:

- Need to decide: X-Ray or Cesium Irradiator
- X-Ray Case:
 - No security Issues,
 - Costly X-Ray tubes,
 - Large voltage power requirements,
 - Need for Cooling System, and
 - Maintenance Downtime.
- Cesium Case:
 - Familiar with Technology
 - Only need 110-volt outlet
 - Long Lasting Isotope



2010 – 2015

• NYBC moves IBL – 437 Cs137 to Long Island

- Only two trucks in USA can do it
- Need to coordinate police coverage at both locations
- Riggers to lift cask parts and irradiator core
- NRC + NJ and NY State Regulatory Agency notifications
- Weather has to cooperate
- Transport Cost = \$40,000

• Cs 137 Irradiator Suppliers Harden Equipment:

- Source access is hardened
- Irradiator is bolted to the floor
- Other proprietary delay techniques



2010 – 2015

- NYBC accepts additional controls
 - Tamper cords added to outer shell
 - Cameras that activate NYPD direct view
 - Iris Pattern Door Access
 - US Government funding = \$210, 000
- New X-Ray Device – Self Contained
 - 5-minute Irradiation Time for 25 gy dose
 - Up to 6 Blood Products per cycle
 - Self-Cooling via “On-Board” water system
 - Tube operates at 40% of maximum power
 - Unit on Wheels for Cleaning Access
 - No NRC license




New York Blood Center **Community Blood Center** **IBR INNOVATIVE BLOOD RESOURCES** **Rhode Island Blood Center** **Blood Bank of Delaware** 31

31

2015 – 2019

- Research Group Purchases a 320 X-ray Unit
 - Self Cooling Oil System
 - Real-Time Video monitoring of X-Ray Chamber
 - User programable settings – Password Protected
- NYBC & NYPD attend Y-12
 - US Government Facility in Tennessee
 - Develop Emergency Response Plan Document
 - ER Plan includes “safe distance” from exposed source tables
 - Live action simulation of theft of source



New York Blood Center **Community Blood Center** **IBR INNOVATIVE BLOOD RESOURCES** **Rhode Island Blood Center** **Blood Bank of Delaware** 32

32

2015 – 2019

- Congressmen Luncheon - NYC:
 - Introduces Removal & Replacement Initiative
 - Encourages participation via Financial Incentives
- NYBC Enters into agreement to remove all CS-137 Devices:
 - ORNL 50 Research Irradiator
 - Elan 3000 Blood Irradiator
 - IBL 437c Blood Irradiator x 2



33

33

2015 – 2019

- Research Irradiator Removal – 7/2018
 - Prep Team Removes Irradiator to street
 - Rigger and Contractor handle core removal
 - Core loaded into transport cask
 - NYPD provides security



34

34

2015 – 2019


- November 2018 to August 2019:
- NYBC removes all remaining Blood Irradiators (3 events)
- X-ray Units (Installed 2017) are validated and able to replace the removed Cs-137 devices
- NYBC avoids the cost of up to \$200,000 disposal cost per CS-137 source equipment (= up to \$800,000)
- NYBC receives 50% of the cost of two X-ray Source Blood Irradiators.



Logos for New York Blood Center, Community Blood Center, IBF INNOVATIVE BLOOD RESOURCES, Rhode Island Blood Center, and Blood Bank of Delaware. The number 35 is visible in the bottom right corner of the footer area.



Logos for New York Blood Center, Community Blood Center, IBF INNOVATIVE BLOOD RESOURCES, Rhode Island Blood Center, and Blood Bank of Delaware. The number 36 is visible in the bottom right corner of the footer area.




Vitalant Blood Irradiators /
Office of Radiological Security
Cesium Irradiator Replacement Project

Presented by:
Mark Georgescu, Regulatory Manager

37

Safety, Security, Liability of Cs-137

- Sealed source irradiators containing Cs-137 or Co-60 require compliance with 10 CFR Part 37
- Security enhancements have on-going maintenance and testing costs
- Licensees may be held liable for clean-up costs if a source was stolen and a malevolent actor successfully detonated a radiological dispersal device (RDD)
 - Clean-up costs can run into the **\$\$\$billions\$\$\$** of dollars
 - Many licensees' insurance policies do not cover damage from radioactive material



38

38

Why Change / Consider the CIP

- Operational SME attended a workshop which highlighted the terrorism risk and Security, Safety, & Liability of Cs/Co irradiators
- Terrorist activities continue to increase
- Improvements in x-ray irradiators result in higher levels of “up time”
- Need an equivalent replacement – numerous studies show x-ray irradiation is equivalent
- Gamma irradiators security requirements are necessary, but rather onerous
- Aging existing equipment
- Biggest reason: Had a very positive prior experience with ORS under the “PROTECT” program formerly known as GTRI.

39



39

Vitalant Enterprise Irradiator Strategy

Connie Morris – Corporate VP, Manufacturing/Laboratory Services
Frances Scher – RSO, Northeast Division
Susan Noone – RSO, West Division
Brian Landeck – RSO, West Division
Fran Milner – RSO, North Division
Ysela Gonzalez – RSO, Southcentral Division
Terri Poulin – Southwest Division
Brad Keffalas – Corporate Supply Chain
Mark Georgescu – Corporate Compliance & Regulatory Affairs
Brenda Heiman – Corporate Operating Systems

Several RSOs from our blood center divisions and Corporate Office departments were represented

5

40

Change to WHAT?

- Current irradiator inventory
 - Cesium-137: 22
 - Cobalt-60: 2
 - X-ray: 6
- Had two equipment vendors present their x-ray devices to the strategy team
- Polled internal customers who currently used their x-ray devices
- Selected a standardized piece of equipment to be rolled out across the enterprise
- Vitalant chose a single piece of equipment as the replacement device of choice

41



41

Remove & Replace up to 24 devices

- Each irradiator was ranked on a scale of 1 to 5 for the following categories:
 - Cycle time (40% weight)
 - Backup availability (15%)
 - Unscheduled downtimes (25%)
 - Geographic location (15%)
 - Volume of product irradiated daily (15%)
- 6 irradiators not enrolled in the PROTECT program.
- Also needed to take into consideration some planned facility moves... can we remove/replace at the same time as a planned move?
- Determined 3 devices could be removal only and did not need replacement
- Ranking results and other factors determined the "order" of remove/replace

42



42

Cost of Compliance with Part 37

- RSO: # of staff with unescorted access (completed T&R/Fingerprinting)?
- RO: # of staff you process for unescorted access annually?
- RO: Amount of time to clear staff for unescorted access??
- RSO: If a contract RSO, what is the cost per year?
- RSO: Annual fee to maintain/renew your radioactive materials license?
- RSO: Amount of staff time it takes to maintain licensure?
- RSO: Amount of your time (annually) it takes to maintain NRC Procedures Manual documents.
- RSO: Amount of staff time it takes (annually) to host external inspections and prepare any responses to citations?
- Time spent annually for Corporate Office staff (Regulatory & Operational subject matter experts) on NRC-related issues/questions

43



43

Now that we have a plan...

- Presented the strategy to Executive Leadership: All approved
- Presented the strategy team's work and information on the CIRP program to all RSOs. We shared:
 - The proposed order of replacement and how we came to this decision
 - The proposed replacement choice and how we came to this decision
 - The cost of Part 37 compliance and the ROI
 - The cost of purchasing 21 new x-ray devices and the expected reimbursement from the CIRP program
- Response to pursuing x-ray technology as an enterprise-wide strategy was very positive.

44



44

CIRP Program Experience

- Project Manager chosen
- Began contracting process for all our sites
 - Had to split out one site from the rest due to time constraints – site is physically moving.
- Ask LOTS of questions – they are there to help
- Created Excel spreadsheet to track all steps for all sites
- Created a very tentative schedule of replacements based on our remove/replace order

45



45

Lessons Learned (Tips & Tricks)

- Allow time for the contracting process
- Have the attorneys from both sides speak directly to each other
- If you are located in a cold, snowy climate, do not schedule a removal during the winter months!
 - It is easier to delay your removal once scheduled than to move it to an earlier date... it may be impossible to move it up.
- Consider space & workload when thinking about if you need to decommission the current device before taking possession of a new x-ray irradiator.
- There are excellent checklists for removal and preparing for your new irradiator (at least for the one we chose)

46



46



47