Preventing a Dirty Bomb:
Case Studies and Lessons Learned

BY IOANNA ILIOPULOS AND CHRISTOPHER BOYD
WITH FOREWORD BY LAURA S.H. HOLGATE

NTI
BUILDING A SAFER WORLD

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ABOUT THE NUCLEAR THREAT INITIATIVE

The Nuclear Threat Initiative (NTI) works to protect our lives, environment, and quality of life now and for future generations. We work to prevent catastrophic attacks with weapons of mass destruction and disruption—nuclear, biological, radiological, chemical, and cyber.

The views in this publication do not necessarily reflect those of the NTI Board of Directors or institutions with which they are associated.

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Foreword

By Laura S.H. Holgate, Ambassador (Ret.)

At the Nuclear Threat Initiative, we know that the radiological, or "dirty," bomb threat is urgent, and that a national effort is needed to address it. We support congressional efforts to phase out all cesium-137 blood irradiation devices in the United States by 2027—tracking international models in France, Japan, and Norway.

Fortunately, new technologies have eliminated the need for the use of radiological materials like cesium-137 in medicine and research; equally effective and safe, these technologies have been approved by the Food and Drug Administration and have made their way to market.

Already, NTI work at the state and local level—with Emory University in Atlanta, the University of California system, and New York City—has shown that there is a path forward that reduces risks and costs for everyone. In our work with these partner organizations, we explored issues around liability, lifecycle, and disposal costs of cesium-137, helped establish the viability and reliability of replacement technologies, and worked to bring stakeholders together to make these changes.

As a result, our partners have made remarkable progress. In New York City alone, 15 of the 32 irradiators in use as of 2014 have been replaced, and seven more are either under contract for replacement or have contracts pending.

In this report, we share lessons from those important efforts, also informed by international work in the United Kingdom and Central Asia.

This publication serves as a guide and a toolkit for those seeking answers about the threat, the technologies involved, and the process for reducing and eliminating the risk that a radiological device will be stolen and used to build a bomb.

We're hopeful that moving forward, other universities and municipalities will see this work as a blueprint for reducing radiological risks across America and the world.

Overview

Preventing a Dirty Bomb: Case Studies and Lessons Learned tells the stories of major urban areas and institutions in the United States that have made the decision to remove and replace medical and research devices containing cesium-137 with equally effective alternatives that do not pose the security risks associated with high-activity radiological materials. Although there is no regulatory mandate to achieve permanent threat reduction by removing these potentially dangerous sources, hospitals, research centers, and governments increasingly are recognizing the risks associated with radiological devices and are voluntarily removing and replacing them. This report outlines those risks and offers successful models for permanent risk reduction at a midsized research institution, Emory University; a very large, statewide university system, the University of California; and a major urban center, New York City.

The report identifies key roles played by federal, state, and local regulators, operators, and decision makers in implementing cesium-137 substitution strategies. It highlights the incentives, challenges, and information gaps that shape decisions to move away from cesium-137 irradiators. The report also is intended to:

A blood irradiator made by RadSource

- educate public health officials at the local and state levels, hospital chief operating officers and administrators, and other cesium-137 users about the advantages of alternative technologies: equivalent efficacy, improved security, reduced costs and liability, and more flexible research applications;
- identify and advocate for areas where adjustments to U.S. Nuclear Regulatory Commission (NRC) regulations and practices could do more to incentivize securing and replacing cesium-137 sources and devices; and
- foster a network of technical professionals to facilitate collaboration and experience sharing among users and regulators in the field.

The "lessons learned" in this report are based on consultations with stakeholders in New York City, Atlanta, and California. NTI also surveyed other officials and administrators directly involved in replacing cesium-137 devices about their experiences. These case studies offer a roadmap for successful consensus building around cesium-137 and can be replicated in a wide range of institutional settings and major metropolitan areas. In addition to providing security benefits, alternative technologies to cesium-137 also can provide long-term cost savings and operational benefits. Using x-ray irradiators reduces the need to maintain expensive surveillance systems and security procedures and eliminates the high costs of material disposal.

WHAT IS THE RISK?

The ingredients for a radiological "dirty bomb"—the very same isotopes that can make life-saving blood transfusions and cancer treatments possible—are located at hundreds of facilities across the United States, many of them meeting only basic security requirements and all too vulnerable to theft. As a result, experts believe that the probability of a terrorist's detonating a dirty bomb is much higher than that of an improvised nuclear weapon. The vulnerability of these radiological sources, particularly the cesium-137 used in blood and research irradiators in hospitals and other open environments, has caused concern for years, and the risk is growing.

Radical terrorist organizations have said they are looking to acquire and use radioactive material for a dirty bomb. In 2016, Belgian investigators discovered terrorists monitoring an employee at a highly enriched uranium reactor that produces medical isotopes for a large part of Europe. Although radioactive isotopes also are used for various purposes at universities and research centers, in agriculture and industry, and by governments, they are considered most vulnerable in busy—often unguarded—medical settings, where staff turnover can be high and many people have access to the machines housing the isotopes.

WHAT IS AT STAKE?

Unlike a nuclear weapon, a radioactive dirty bomb would not cause catastrophic levels of death and injury, but depending on its chemistry, form, and location, it could cause tens of billions of dollars of damage due to the costs of evacuation, relocation, and cleanup.

There are several radiological isotopes of concern, but a bomb that intentionally spreads cesium-137 would have the most devastating consequences. Some of the other potentially dangerous isotopes are hard metals that likely would be dispersed as fragments and could be picked up from the ground or extracted from buildings after a detonation. Cesium-137, however, is a highly dispersible powder, so exposed buildings might need to be demolished and the debris removed. Following that, access to the contaminated area likely would be denied for years while the site was cleaned up well enough to meet minimal environmental guidelines for protecting the public.

WHAT CAN BE DONE?

Cesium-137 blood irradiators once were regarded as the most effective technology for sterilizing blood. In recent years, however, there have been significant technological advances in developing effective and safe alternative technologies that do not use radiological isotopes and have equivalent medical outcomes. In the United States, for example, the U.S. Food and Drug Administration (FDA) in 2012 approved the use of nonradioactive x-ray devices

as a replacement for cesium-137-based blood irradiators. As of 2015, two types of these devices were available, with a typical cost between $200,000 and $270,000 per unit. In addition to being a relatively inexpensive replacement for cesium-137 blood irradiators, the x-ray units require far less security and shielding, eliminate liability, and entail no expensive disposal at the end of their life cycle. Those factors make replacement much more cost-effective than increasing security around radiological sources—and replacement completely eliminates the risk. Replacement also protects hospitals that don't have insurance to cover terrorism losses; otherwise, there is a possibility of financial devastation from having to pay huge damages in the wake of a dirty bomb attack using hospital materials.

Models for Action

NTI has worked with Emory University, the University of California, and New York City to encourage permanent risk reduction related to radiological materials. These case studies can guide other hospitals, research centers, municipalities, and regulators on key steps, such as selecting alternative technologies, following regulations, and identifying funding sources.

NEW YORK CITY

As security tightened throughout the United States following the September 11 terrorist attacks in 2001, New York City officials, with federal assistance, took significant steps to strengthen security at sites that used high-risk radiological sources. They understood that if high-activity radiological materials were stolen and detonated in a bomb in a city as densely populated as Manhattan, the public health consequences and environmental contamination would be severe, possibly requiring massive relocation of residents and indefinite quarantine of large areas pending lengthy cleanup efforts.

They understood that if high-activity radiological materials were stolen and detonated in a bomb in a city as densely populated as Manhattan, the public health consequences and environmental contamination would be severe.

By 2014, the U.S. Department of Energy's (DOE) National Nuclear Security Administration (NNSA) was expanding the focus of its federal efforts from encouraging voluntary—and often costly—physical protection measures to include promoting alternatives for cesium-137 irradiators that would result in permanent risk reduction. As a result, New York City's Department of Health and Mental Hygiene decided to apply a public health approach to radiation safety: to eliminate the risk first and take steps to minimize consequences only when risk elimination was not possible.

At the time, the New York City health care community, with its 32 cesium-137 irradiators, was undergoing significant change, with multiple mergers that brought new management teams into decision-making roles. In some ways, the mergers, which brought multiple independent research and health organizations together, made decision making more complex. In others, the mergers offered opportunities for change in institutional cultures.

Amid this changing business landscape, the city health department, with support from NTI, organized a symposium: "Moving Towards Zero Risk: Can We Eliminate the Risks from High-Activity Radioactive Materials through Adoption of Alternative Technologies?" The event brought together more than 130 security experts, federal officials, radiation safety regulators, medical physicists, and health and safety personnel. Participants agreed that the high cost of disposal and decommissioning of cesium-137 irradiators could drive the facilities toward

pursuing permanent risk reduction, and there was a shared sense that health and safety departments at health care facilities should work toward that end. The group recommended studies comparing the use of x-ray technology alternatives with medical equipment using radioactive materials as well as more programs and funding to facilitate replacement of irradiators with alternative technologies.

Left: Participants in a press conference for the New York City irradiator replacement effort that began in 2016. L–R: NTI Co-Chair Senator Sam Nunn; Dr. Jacob Kamen, Associate Professor of Radiology and Chief Radiation and Laser Safety Officer; Dr. Burton Drayer, Professor and Mount Sinai System Chair of Diagnostic, Molecular and Interventional Radiology; Maegon Barlow, Former Director, Office of Radiological Security (ORS), National Nuclear Security Administration (NNSA); David G. Huizenga, Principal Assistant Deputy Administrator for Nonproliferation, National Nuclear Security Administration.

Building on the success of that first symposium, the Department of Health and Mental Hygiene in 2016 took steps to promote cesium-137 replacement in New York City. Officials collaborated with NTI once again to sponsor a discussion about cesium-137 replacement at an annual meeting of state regulators of radioactive materials and to plan a second symposium focusing on the science of alternative technologies. In addition, health department officials conducted two workshops on cesium-137 replacement specifically geared toward radiation safety and security officers (RSOs). Last, the department surveyed RSOs on their views about permanent risk reduction and created tools to evaluate the viability of alternative technologies. The tools were designed to:

- examine the major concerns of RSOs in considering alternative technologies;
- allow licensees to make more informed decisions when purchasing radioactive sources versus non-isotopic alternatives;
- provide comprehensive analysis of the cost and performance data of both technologies, including the costly burden of regulatory requirements;

- inform RSOs and their health care facilities about the potential liability costs they could face if a radioactive source were stolen;
- assess which devices could be immediately replaced and which would take longer to be replaced; and
- collect data to enable the health department to support public- and private-sector stakeholders in applying for federal incentives to replace high-activity radiation sources.

All operators surveyed provided feedback using the audit tools.

On the basis of the discussions and data collected, the health department concluded that the leading factor for the decision not to switch to alternative technologies was cost—the costs of purchasing and maintaining new equipment, combined with the cost of disposing of the cesium-137 devices no longer needed. Another key finding was that many hospital administrators did not fully understand or appreciate their liability exposure should one of their cesium-137 devices be stolen or maliciously used. It was clear that creating financial incentives was the most important effective strategy to encourage the switch.

[M]any hospital administrators did not fully appreciate their liability exposure should one of their cesium-137 devices be stolen or maliciously used.

Lack of information also played a role in some RSOs' reluctance to consider alternatives. RSOs expressed unease about operational issues such as equipment downtime and malfunction, infrastructure considerations, and complications related to changing standard operating procedures. Most RSOs were not familiar with the recent FDA approvals for alternative x-ray technologies and their updated performance standards. Many referred to experiences with early devices that had not performed efficiently. Although most RSOs viewed x-ray technologies as viable replacements for blood irradiators, additional data were needed to drive action on research irradiators.

Once it became clear that most institutions with cesium-137 irradiators were willing to commit to replacing them, health department officials met with NNSA to review the logistics of a multi-device removal schedule for a defined geographic area. A second coordination meeting, with all committed institutions, allowed for a review of the application process for the NNSA Cesium Irradiation Replacement Project (CIRP), as well as scheduling vendor presentations for institutions to collectively review device pricing, specifications, warranties, customer support, and add-on equipment, and scheduling tours of facilities to see alternative technology devices already in use. A workshop in June 2017 focused on the comparability of x-ray and cesium-137 devices for a range of research purposes. This event provided an opportunity for researchers who had compared the devices to discuss their experiences with participants from across the United States. The workshop also included background on regulatory experiences in Norway, where all cesium-137 devices have been replaced with alternative technologies.

The New York City Department of Health and Mental Hygiene's efforts resulted in important risk reductions. Today, 15 of the 32 irradiators in use in 2014 have been replaced, and seven more either are under contract for replacement or have contracts pending. Of the remaining 10 devices, institutional commitments exist for the removal of eight, and NNSA and the health department are continuing to discuss the status of the two others.

Participants in the Emory University blood and research irradiator replacement effort. (L–R: Dr. Michael Zwick, Assistant Vice President for Research, Emory University; Patty Olinger, Assistant Vice President, Office of Research Administration and Executive Director, Environmental Health and Safety Office, Emory University; NTI Co-Chair Senator Sam Nunn; Maegon Barlow, Director, Office of Radiological Security (ORS), National Nuclear Security Administration (NNSA); Melanie Florez, ORS Project Lead, Sandia National Laboratories.)

EMORY UNIVERSITY AND ATLANTA

In Atlanta, Emory University decided to address its three devices and encourage other area facilities to do the same. In 2016, Emory University Hospital received the Medical Innovation Award at the Nuclear Industry Summit for its efforts to convert its blood irradiator and to highlight the achievement. In February 2018, Emory invited NTI to co-sponsor a workshop on radiological security to discuss the city's planning and preparedness programs for radiological emergencies and the steps that had already been taken to secure radiological sources. The workshop developed an action plan with steps to further reduce the risk posed by radiological sources, and Emory played a central advocacy role in encouraging the removal and replacement of 13 blood and research irradiators across six institutions in the Atlanta region. Emory was keen to reduce radiological risks throughput the city as Atlanta was host to a highly visible Super Bowl event in 2019.

Emory's decision to become cesium-137-free was informed by:

- advances in x-ray technologies that are safe and produce effective and equivalent medical and research outcomes;
- the elimination of regulatory requirements and associated costs of cesium-137-based devices—extensive security-alarm fingerprinting and background checks, drills and training with police, recordkeeping, and other administrative measures—the savings from which could be applied to future maintenance of x-ray devices;
- federal funding subsidies, through CIRP, for a portion of the purchase price of the replacement x-ray irradiators and the full cost of disposing of cesium-137 irradiators, which is $100,000 to $200,000 per device; and
- the elimination of liability—alternative technologies resulting in permanent risk reduction and the elimination of the possibility of irradiators' theft or sabotage and subsequent use in an act of terrorism.

Emory's successful transition also was made possible with the advocacy of NTI Co-Chair Sam Nunn and support from senior management at Emory, including former Vice President for Research Administration Dr. David Wynes, whose department provided the funding required to match the NNSA federal subsidy under CIRP for the replacement and the removal of cesium-137 devices, and Patty Olinger, Executive Director, Environmental Health and Safety Office, Emory University. Emory mandated a deadline for research departments to reach a decision on converting their cesium-137 devices and choosing an appropriate x-ray alternative. Emory health and safety staff encouraged x-ray manufacturers to meet with each department and provide information about their product lines, specifications, and device capabilities.

NTI in 2017 launched a new radiological effort with the State of California, which has the largest number of high-activity cesium-137 devices in the United States, estimated at more than 120.

UNIVERSITY OF CALIFORNIA AND THE STATE OF CALIFORNIA

Building on the success of the New York and Atlanta models, NTI in 2017 launched a new radiological effort with the State of California, which has the largest number of high-activity cesium-137 devices in the United States, estimated at more than 120. NTI built broad political stakeholder support for a radiological device replacement initiative by partnering with the Office of Governor Edmund G. Brown, Jr., the Office of Senator Dianne Feinstein, the California Department of Public Health, and the Office of the President of the University of California (UC)—which operates more than 30 percent of the state's cesium-137 devices across 10 institutions and five medical centers.

To encourage hospitals and research facilities within the UC system to consider converting to x-ray technologies, UC sponsored a series of workshops, facilitating technical dialogues and information exchanges for researchers

NTI and the State of California partnered to reduce radiological "dirty bomb" risks at a May 2017 workshop in Irvine, California. Governor Jerry Brown, on screen, and Deborah G. Rosenblum, NTI Executive Vice President, spoke about ways to reduce the risks posed by radiological materials.

to share experiences and lessons learned in making the technology switch. Representatives from state and city executive offices, regulators, operational decision makers, law enforcement and emergency response officials, and research and blood bank operators, along with senior leadership from NTI and NNSA's Office of Radiological Security, attended and contributed to these discussions. These meetings informed senior management at UC about the potential risk and liability of owning cesium-137 irradiators and prompted them to take action.

Scientific reference materials—including compilations of x-ray energies, distributions, and applications; radiological biological effectiveness variations among research modalities of the new x-ray technologies (Appendix 1 of this report); and manufacturer information—also were shared to help alleviate information gaps and perceived scientific uncertainty surrounding the effectiveness and comparability of the new x-ray technologies. The workshops also provided information about federal assistance programs and subsidies, associated costs of switching to new technologies, and manufacturer data, as well as the overall benefits of making the technology switch (e.g., decreased liability, relief from burdensome regulations and associated costs, and the opportunity to upgrade equipment capabilities for automated dosimetry and imaging systems).

UC medical center blood banks, in particular, were very receptive to switching to x-ray technology, given the clear demonstration of equivalent results for blood irradiation, and chief executives at the six medical centers supported [their] decision.

Following the workshops, UC President Janet Napolitano, who served as U.S. Secretary of Homeland Security from 2009 to 2013, provided top-level support for this institution-wide campaign. She requested a commitment from university chancellors, who were required to complete a Decision Worksheet regarding removal and replacement of the 42 cesium-137 irradiators within the UC

system. The Decision Worksheet (Appendix 2 of this report) required detailed information about each irradiator and whether the device would be removed, removed and replaced, or retained. To complete this task, the UC Office of the President created a faculty-led, system-wide Radioactive Source Replacement Working Group and appointed a full-time coordinator to lead the three-year, phased effort.

Key faculty as well as research and medical departments using cesium-137 irradiators reached a science-informed consensus on source equivalency for most applications, and a determination was made that replacing the irradiators would not adversely affect ongoing research. The approach was collaborative and inclusive, allowing the medical and research communities to discuss pros and cons and be involved in the decision-making process. The resulting report concluded that x-ray irradiators could effectively replace cesium-137 instruments in many applications on UC campuses, with some notable exceptions, and laid out scientific recommendations for users looking to make the switch.

UC medical center blood banks, in particular, were very receptive to switching to x-ray technology, given the clear demonstration of equivalent results for blood irradiation, and chief executives at the six medical centers supported the blood bank operators' decision to convert their sterilizing process. The single application, FDA approvals on equivalency, and increased throughput (blood volume may be up to six times higher for x-ray irradiators than cesium-137 blood irradiators) were the most persuasive reasons for the switch.

To ensure a smooth transition once the decision was reached, the university deployed several tools to support researchers and blood bank operators. The first was a system-wide contract to obtain funding under CIRP and identify additional funding resources through the Office

Support for Cesium-137 Phaseouts from the California Department of Health

Like New York and Georgia, California is a Nuclear Regulatory Commission Agreement State, meaning that NRC regulations are implemented and enforced by state authorities. In the California case study, the California Department of Public Health Radiological Health Branch played an important role in encouraging the use of alternative technologies. Working within the limits of the NRC's rules, the state regulator provided information on cesium-137 licensing requirements and x-ray machine registration requirements to make the switch (forms, fees, inspection frequency, etc.). Upon the launch of this initiative, the agency developed an internal tracking system for the number of cesium-137 devices to be permanently removed from California. If a new cesium-137 irradiator license application is received for regulatory approval or renewal, the state regulator (through the creation of a new licensing checklist) informs the licensee on available alternative technologies and requires a justification for use of cesium-137. When use of cesium-137 is considered to be justified, licensees are urged to participate in NNSA's Voluntary Security Program and receive additional physical protection upgrades (above and beyond what is required to meet federal and state requirements under Section 10 of the Code of Federal Regulations, Part 37) prior to approval.

of the Chancellors. It was important to convey that funding would not be taken out of individual research grants.

To streamline the purchasing process, the UC coordinator provided information on device options as well as maintenance and warranty costs and negotiated pricing with equipment vendors for multiple device purchases. A project manager and purchasing agent were designated for each research department involved in this process. A phased approach provided researchers with the flexibility to retain their cesium-137 irradiators for a limited period of time after the installation of the new x-ray equipment to empirically assess the effects on their studies of converting from cesium-137 to x-rays. In some cases, additional funding for the comparison studies also was offered by the campus or hospital. Researchers were advised that if comparison studies were not successful, they would be allowed to retain their cesium-137 irradiators but would not receive the incentive funding provided by CIRP.

This initiative has put in motion the removal and replacement of 90 percent of UC's 42 cesium-137 devices (36 research irradiators and six blood irradiators) with x-ray devices. The removal and replacement will be executed over a three-year period to minimize the impact on research and operations.

Lessons to Promote and Catalyze Cesium-137 Replacement

What does it take to successfully build consensus around replacing cesium-137 blood irradiators in hospital and research settings? Using the models in California, Georgia, and New York, the authors have developed five key lessons, which can be applied at the institutional, state, and federal levels for those interested in cesium-137 replacement.

IDENTIFY LOCAL ADVOCATES AND BUILD SUPPORT NETWORKS

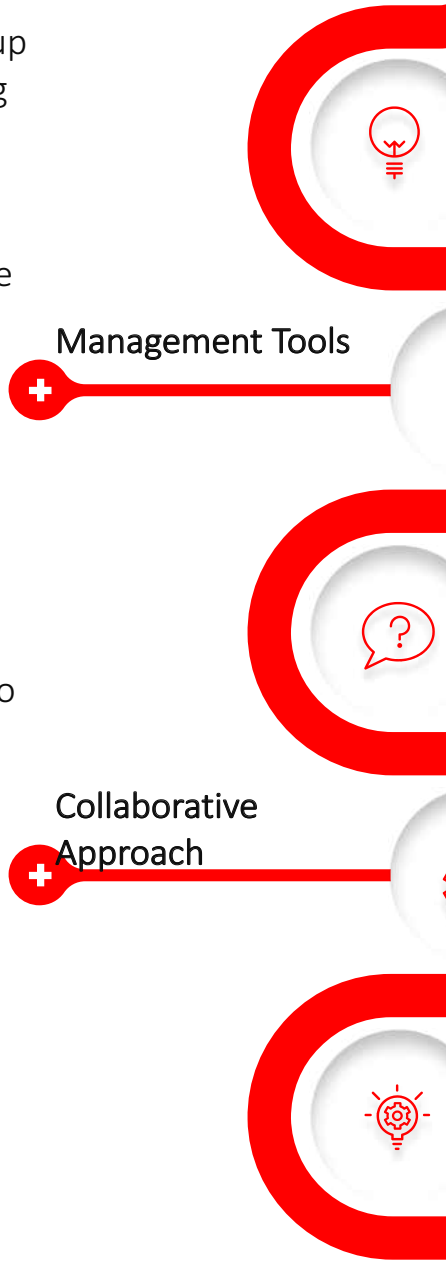
Government officials and institutional administrators often share concerns about malicious use of radioactive material and the long-term costs of sustaining the security of devices that use it. It is important to identify and support the efforts of those who are looking for ways to reduce their organizations' exposure to risk. As the case studies from New York City and California show, these advocates—whether state officials, hospital administrators, or institution leaders—often face significant challenges when trying to overcome institutional complacency or skepticism from operators who may not understand the value of making a change.

Supporting local advocates involves disseminating information about alternatives, exploring operational implications, finding and navigating funding options and sources, and offering examples of successful cesium-137 replacement.

One way to address challenges associated with replacement advocacy is to create a cesium-137 replacement advocacy network, which can be done at both the institutional and state levels. Leveraging the experiences of those who have already replaced radiological devices is invaluable for overcoming skepticism and institutional inertia. A network can be a powerful tool to amplify members' experiences and encourage peer-to-peer information sharing on the comparative research, equivalency, and application of alternative technologies. The New York City and Atlanta case studies show that leveraging the successes of premier hospitals or research facilities is key to influencing others to consider replacement. The long-term sustainability of a network will depend on identifying an advocate inside or outside the system to provide logistical and organizational support, to articulate the regulatory and policy changes required, and to communicate the opportunities to eliminate public health and security risks through permanent risk reduction.

University of California:

Establishment of faculty-led University of California (UC) working group and dedicated coordinator to assist with financial support, purchasing process, and getting to "yes":



- ✓ Centralized procurement for obtaining federal subsidies through NNSA's Cesium Irradiator Replacement Program (CIRP) and Off-Site Source Removal Programs (OSRP).
- ✓ Streamlined purchase of new x-ray irradiators by centralizing the process–identifying appropriate alternative manufacturers and equipment, developing cost comparison analysis to help with decisions on x-ray capabilities, pricing, maintenance, warranty and option costs.
- ✓ Created Cesium Irradiator Replacement Form to document decisions.
- ✓ Established website and shared published papers, conference video presentations, UC working group recommendations report, x-ray irradiator comparison data with manufacturer information, federal assistance programs (CIRP and OSRP), and regulatory implications for making the change.
- ✓ Raised awareness on risks and liabilities and communicated the benefits of alternative technologies.
- ✓ Involved researchers and medical practitioners in the decision-making process.
- ✓ Understood potential impacts of research and planned for exceptions.
- ✓ Instituted a phased approach, allowing practitioners to gain acceptance over time and conduct comparative studies.

Visible support from political leaders and elected officials is also important. In New York City, Atlanta, and California, high-level politicians and government officials helped attract support from top administrators and officials who would make institution- or region-wide replacement decisions.

Institutional Tools for Success

Stakeholder Involvement

- ✓ Sought high-level support from the Office of the President of the University of California.
- ✓ Established faculty-led UC working group and dedicated coordinator.
- ✓ Sought direct involvement of UC chancellors and subject matter experts (SMEs).
- ✓ Continued ongoing dialog and information exchange with researchers and medical practitioners

Getting to Yes—Informed Consent

- ✓ Sponsored multiple technical conferences to share experiences, scientific and comparative data on effectiveness and equivalency of alternative technologies, and lessons learned from users who have made the switch.
- ✓ Established conference website and information platform with video presentation and information resources.
- ✓ Established faculty working group to advise the UC on the best path forward and provide technical recommendations on how to proceed (Scientific Findings Report).
- ✓ Provided summary of existing biological data and recommendations.

Implementation

UC owns and operates 42 cesium-137 irradiators; 36 research and six blood irradiators. Ninety percent of these devices will be replaced with alternative technologies over the next two years.

IMPROVE THE DISSEMINATION OF INFORMATION

There are many benefits to replacing cesium-137 irradiators with alternative technologies, and the shift from security hardening to risk elimination through replacement makes even more sense when the enhanced capabilities of

There are many benefits to replacing cesium-137 irradiators with alternative technologies, and the shift from security hardening to risk elimination through replacement makes even more sense when the enhanced capabilities of alternative technologies are considered—among them, greater precision in dosing and imagery.

alternative technologies are considered—among them, greater precision in dosing and imagery. Regrettably, available information about alternative technologies is not always readily accessible to those contemplating the switch; studies on their performance should be made more accessible by public and regulatory health officials, manufacturers, and institutions that have already made the switch.

Meanwhile, vendors are best positioned to instruct potential customers and operators on the specifications and uses of their products. In Atlanta, officials at Emory requested that vendors meet individually with departments to introduce their x-ray devices. In New York, facility staff met with manufacturer representatives to obtain cost, performance, and warranty information. The UC system disseminated vendor-provided price quotes and comparison charts for all x-ray models to research departments.

Newly funded research with findings published in peer-reviewed journals would increase understanding of the benefits and limitations of conversion. Publishing comparative studies also would help overcome scientific uncertainty around alternative technologies. Both New York City and the University of California convened multiple meetings to discuss the technical issues involved in converting research and blood irradiators. UC established a faculty-led working group to provide technical recommendations and advise university leaders how to proceed. New York held numerous technical workshops and developed an analytic tool with a confidential survey to obtain information from its licensed community.

The University of California also built support by creating a phased approach, allowing users to keep both technologies for a brief period to validate their work and conduct their own side-by-side comparisons prior to removal of their cesium-137 irradiators. The data collected could be used to develop and publish standards for x-ray use.

SEEK CONSENSUS AMONG STAKEHOLDERS

Achieving consensus within and among institutions involving stakeholders at all levels was crucial to success in each case summarized here. In city and state governments, stakeholders include state regulators, representatives from the governor's offices, officers of local and state departments of health, and representatives from health commissioners' offices. At institutions, stakeholders include hospital executives and Board of Directors who need to be aware of the unfunded liability due to the lack of affordable terrorism insurance. Other key stakeholders include operational decision makers, environmental health and safety officers, security and liability risk managers, end users, researchers, and blood bank operators. Law enforcement and emergency response officials are also crucial to the consensus process, as they will be significantly affected by changes in mindset from security risk management to risk elimination, as well as operationally involved in the irradiator removals.

IDENTIFY FUNDING AND SUPPORT AT INSTITUTIONAL LEVEL

Identifying funding at the institutional level is also important. Obtaining both political support and financial resources requires active involvement by senior leadership at medical and research institutions, as well as operational decision-makers and risk managers who understand the need to protect public health, safety, and security, and eliminate terrorism risk and potential liability. At the operational level, once a decision was made to move forward, facilities and institutions that participated in these federal programs established protocols to streamline and simplify the purchasing process and work with the federal government to obtain subsidies. It was important to provide information about different manufacturers of x-ray technology, options, and associated costs, as well as annual maintenance and warranty and license change requirements and costs.

COMPARE CRADLE-TO-GRAVE COSTS

Although federal regulations govern the use and storage of both radioactive sources and x-ray irradiators, they are much more extensive and costlier for the former. NRC regulations for the use of high-activity radioactive materials (including cesium-137) require the supervision of RSOs for both the handling of the materials and the installation of costly physical protection around the devices, in addition to other measures related to device operation. Institutions must establish training programs and procedures for all staff who have access to the devices, including fingerprinting and FBI background reviews, and must also develop processes and adjudication procedures within their human resource or legal departments.

Obtaining both political support and financial resources requires active involvement by senior leadership at medical and research institutions, as well as operational decision makers and risk managers who understand the need to protect public health, safety, and security, and eliminate terrorism risk and potential liability.

Users of x-ray irradiators must comply with regulations related to safety and shielding, but there are no onerous physical security requirements for the devices.

A worksheet to determine these cradle-to-grave cost comparisons is available in the Appendix 4.

INCREASE SUBSIDIES AND SUPPORT AT THE FEDERAL LEVEL

In each of the case studies, federal funding was critical to obtaining commitments to transition to x-ray devices. NNSA CIRP provided a financial incentive for purchasing replacement x-ray devices, which defrayed expenditures by hospitals and institutions. In addition to this cost-sharing model, DOE/NNSA has a longstanding program, the Off-Site Source Recovery Project, to assist with permanently removing radiological sources that are no longer needed after a technology switch. Under these programs, participating institutions receive federal assistance for the removal and ultimate disposal of cesium-137 irradiators, saving $100,000 to $200,000 per irradiator. Additionally, CIRP provides a limited financial payment toward a new x-ray device, up to 50 percent of the purchase price. Under the terms of this subsidy program, the federal payment is disbursed once the cesium-137 device has been removed and the x-ray device has been installed. Given the potential costs of a radiological dispersal from a device involving cesium-137—economic losses in the billions of dollars in remediation and relocation—the government investment in replacement and permanent removal of the devices is cost-effective. However, the cost of disposal will likely transfer to the user once the federal government has a commercial disposal site available for Greater-Than-Class C (GTCC) Radioactive Waste.

Unfortunately, these important programs depend on annual appropriations. Congress should commit to sustain or expand NNSA programs to accelerate the pace of technology substitutions and cesium-137 source removal and disposition. Congress also should approve language introduced in the 2019 Nuclear Defense Authorization Act (Subsection 3141) in future authorizations to meet the ambitious goal of phasing out all cesium-137 blood irradiators by 2027. Although such "sense of Congress" language would not constitute a regulatory requirement, it could help increase awareness about these programs and provide incentive for more facilities to voluntarily participate.

ENCOURAGE REGULATORY CHANGES FOR CESIUM-137 USERS TO ACCELERATE AND STANDARDIZE PERMANENT RISK REDUCTION

Although a voluntary, consensus-driven model such as is outlined in the case studies can achieve risk reduction, legal requirements would be more effective. Several regulatory actions should be considered to meet the ambitious goals outlined in Subsection 3141 for both phasing out cesium-137 blood irradiators by 2027 and constraining the introduction of new devices:

- All regulatory agencies—specifically the NRC and FDA—should set deadlines for phasing out cesium-137 blood irradiators to support goals established by Congress. For blood sterilization, there are multiple technologies in the U.S. marketplace that have received regulatory approvals through the FDA. Other countries are undergoing similar reviews. Moreover, replacement technologies are gaining acceptance by industry leaders as effective and equivalent alternatives.
- Regulators should be strongly encouraging the market to create no-risk solutions that meet the research and commercial goals of the end user. Currently, the NRC does not encourage rule-making and has not taken a proactive role in supporting regulatory changes to constrain the use of cesium-137 or to promote the broader use of alternative technologies. To meet the goals set out by Congress, the NRC should fully embrace a regulatory approach that prohibits use of high-activity radioactive material except in specific justifiable cases. For cesium-137 devices associated with research applications, regulators should establish a pre-licensing justification requirement for end users to demonstrate that there is no viable alternative in the marketplace. Regulators should also mandate removal of all high-activity radioactive sources whose use is not adequately justified.
- Regulations should reflect the full life cycle costs of cesium-137 use. Significant governmental resources are dedicated to licensing, security oversight, and disposal management of cesium-137; the costs are not borne by those who receive the benefits of its use. Cradle-to-grave societal costs of cesium-137 devices should be fully reflected in the licensing costs and transferred to the end user.
- National policies must be consistent in supporting elimination (vs. risk minimization) as a public health prevention strategy. Conflicting policies among national agencies often lead to divisive and confusing policies among local regulators and other key stakeholders. Across agreement-state programs, some regulators encourage proactive, preventative policies whereas others follow the minimum federal requirement and play the role of code enforcers. The consistent promotion of public health prevention strategies also would support federal efforts to implement voluntary programs such as CIRP.

About the Authors

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APPENDIX 1

Comparing the Radiological Biological Effectiveness of X-Ray and Cesium-137 Devices

From the University of California System-Wide Radioactive Source Replacement Working Group

	X-ray	Cesium-137
Relative Biological Effectiveness (RBE)	There is a wide variation in RBE values in the literature for x-rays as compared with cesium-137. X-rays are more effective than cesium-137 gamma rays, suggesting that lower doses will be required to achieve the same biological endpoint.	There are fewer variations in the RBE values in literature for cesium-137.
Machine-to-Machine Variation	X-ray irradiators produce different energies and spectra due to variations in x-ray tubes, energy settings, and filtration. While this allows for greater precision in calibration, it also requires more detailed reporting when comparing results from different x-ray machines.	With the single gamma-ray energy, cesium-137 devices yield less variation than x-ray machines.
Effectiveness	X-ray is generally better than cesium-137 for collimation, e.g., for partial body exposures, since it is easy to precisely collimate the x-ray point source with thin sheets of lead. X-ray offers advanced features and imaging that may be needed for some experiments.	Cesium-137 requires thicker collimation and casts a broad penumbra from the extended line source.
Conversion Factors	Each experiment needs to be individually calibrated when converting from cesium-137 irradiators to x-ray irradiators. Conversion factors depend on multiple inputs, including x-ray peak energy, x-ray energy spectrum (filtration), distance of the specimen from the source, field size, and biological system, among others.	Cesium-137 irradiator outputs (energy, dose distributions) are less variable than those of x-rays.

APPENDIX 2

University of California Cesium Irradiator Replacement Program Decision Worksheet

In support of the letter from the President to the Chancellors dated February 16, 2018, each location needs to complete this form as soon as a decision has been made on each irradiator, but no later than ***September 1, 2018.*** Please note there is at least a 3-month lead time on ordering new X-ray irradiators and planning for removals.

Irradiator Information:

Campus	
Location	
Current Point of Contact (POC)	
Campus Radiation Safety Officer	
Use (Medial, Research, Callibrator)	
Irradiator type (Blood, Patient, Speciment, Animal, Cell, Inst. Callibrator)	
Manufacturer and unit ID	
Radionuclide	
Radioactivity	
Enhanced security status (Yes or No)	
Active Use or Inactive	
Qualified for incentives (Yes or No)	
Informal Decision to Date	

Decision: Please select one of the following three choices regarding the decision for this irradiator:

○ **Remove only**	There is no cost for this option. Arrangements for removal will be coordinated with Los Alamos National Laboratory.
○ **Remove & Replace**	The location will be responsible for a portion of costs. UCOP Procurement can provide cost estimates on the planned purchase and assistance with maximizing the incentives by pairing removals.
○ **Retain**	After thoughtful consideration of the activities using this source, and an assessment of the risk and costs imposed, the location is deciding to retain possession of the irradiator. Future disposal costs will be the responsibility of the location.

POC to Implement: Please provide a point of contact for UCOP to work with in implementing this decision:

Name _____ Email _____

VCR/COO signature: _____ Date: _____

APPENDIX 3

Major Life Cycle Cost Considerations for Cesium-137 Irradiators and X-ray Irradiators

By Ioanna Iliopulos, NTI Senior Consultant
November 2018

Hospitals and research centers in the United States and around the world are addressing concerns about radiological security, safety, and liability by replacing irradiators that use radioactive cesium-137 with safe and effective x-ray technology. This paper outlines major life cycle cost considerations for making the switch. Use the worksheet template at the end of this document to help you decide if replacing cesium-137 irradiators with x-ray technology is the right step for you.

WHAT ARE THE PURCHASE COSTS FOR THE CHANGE?

The replacement costs for exchanging a cesium-137 blood irradiator for a new cesium-137 device or an x-ray irradiator are roughly comparable, but the purchase price can vary for each depending on the make, model, and size of the irradiators, and transportations costs. Each also entails delivery costs. However, the costs for transporting cesium-137 are much higher, because of the increased regulatory requirements for transporting the devices mandated by the federal Department of Transportation and the Nuclear Regulatory Commission (NRC). Additional factors include the location of the institution in relation to the vendor and the security required by the municipality and/or state. For example, in a city such as New York, streets must be closed down when such a device is being transported, and police escorts are required. Institutions using cesium-137 blood irradiators also must pay licensing and annual fees, which do not apply to the use of x-ray devices. The licensing price for different devices can vary depending on the specific license request, but the licenses are costly, the expenses are recurring, and there are no economies of scale (i.e., if an institution holds more than one license, its total annual fee assessed is the total of the annual fees applicable to each license held). More information can be found on the NRC website under regulations 10 CFR 171.16 Annual Fees.

The Cesium Irradiator Replacement Project (CIRP), offered by the National Nuclear Security Administration's (NNSA) Office of Radiological Security (ORS), offers a financial incentive for the purchase of new x-ray devices to qualified sites. Institutions can receive up to 50 percent of the purchase price for new x-ray devices.

Another important consideration is the useful remaining life of the radioactive-source-driven device. The expected lifespan of both technologies should also be considered as part of the cost—cesium-137 irradiators are generally operable

for 30 years, while the anticipated life of the proposed alternative replacement is 12-plus—but that is not the only life cycle expense to be taken into account in a cost-benefit analysis. Although they don't last as long, x-ray units require far less security and shielding, and they require no expensive disposal at the end of their life cycle. That makes replacement more cost effective than increasing security around radiological sources, and it completely eliminates the threat, also eliminating liability. The summary below highlights key cost factors.

WHAT ARE THE FACILITY-MODIFICATION COSTS FOR THE CHANGE?

There are facility infrastructure requirements and associated costs for both cesium-137 irradiators and x-ray technology.

Rooms that typically house cesium-137 are in dedicated spaces with strict access controls (e.g., iris reader, card access) and other security surveillance equipment (e.g., cameras, alarms, radiation detection equipment, remote monitoring systems). The extreme weight of shielding devices also necessitates costly facility upgrades.

X-ray technology does not require such costly and burdensome physical security requirements. However, the technology may need accommodations for increased power consumption, cooling water, or additional air conditioning. In some cases, facility modifications may be needed to compensate for the increased weight or noise generated by the new x-ray equipment. However, recent innovations in x-ray technology have led to newer models, such as the Rad Source 3400, that have eliminated the need for water filtration and decreased the number of x-ray tubes, affecting power source and overall room-configuration requirements. Because some hospitals may install x-ray machines in room(s) or facility areas (blood banks) already equipped to handle these issues and the two devices take up similar amounts of space, it is difficult to compare costs for making a switch. Regardless, x-ray technologies generally provide more flexibility in room placement and avoid significant facility-modification costs.

WHAT ARE THE OPERATING COSTS FOR THE CHANGE?

Cesium-137 irradiators must comply with costly NRC regulations. An institution may receive federally funded security upgrades through the NNSA/ORS program, but it will be responsible for operating costs in maintaining the new security infrastructure after the warranty period. The capital costs for the equipment represent a small percentage of the total costs of sustaining the equipment and training its users over the life cycle of an irradiator's use.

Both cesium-137 and x-ray devices also require service contracts for preventative maintenance, calibration, and the replacement of parts as needed. Many manufacturers' service contracts for x-ray machines are appealing to users, because they cover replacement parts and calibration. Cesium-137 irradiator operators also carry service contracts, and they tend be less expensive, because the machines require fewer replacement parts.

Taken together, however, the overall costs of sustaining the necessary security architecture for cesium-137 irradiators, combined with their service contracts, can be just as high as, or higher than, the analogous costs for x-ray devices.

WHAT ARE THE STAFF AND TRAINING COSTS FOR THE CHANGE?

In accordance with NRC regulations, the use of Category 1 and 2 radioactive sources requires the supervision of a radiation safety and security officer (RSO) who is trained in handling the radioactive material, management of the safety and security requirements of the device, and implementation of other federal regulations concerning its operation. Institutions also must establish training programs and procedures for all staff with access to the devices, including the validation of trustworthy and reliability (T&R) requirements involving fingerprinting and FBI background reviews, and establish adjudication procedures for T&R requirements within a human resource or legal department.

X-ray irradiator users also must comply with regulations involving safety and shielding requirements, but these regulations are limited. Moreover, the kinds of security requirements associated with cesium-137 sources don't exist, nor do associated costs of salaries and security training.

WHAT ARE THE REGULATORY COSTS FOR THE CHANGE?

The costs for protecting high-activity radiological sources such as cesium-137 from malicious intent are very high and recurring (e.g., capital investment, maintenance, testing, training). New regulatory security requirements may occur during any of the phases in the life cycle of sources, including (1) in transit to installation, (2) during service life, (3) in transit after service life, and (4) in disposal or long-term storage. Each stage of use has associated regulations and costs, as well as annual license fees. In contrast, the use of x-ray technologies does not come with significant regulatory burdens. X-ray use also reduces licensing activities, regulatory inspections, and sealed-source inventory reporting, as well as a variety of other mandatory security requirements.

WHAT ARE THE TERMINATION COSTS FOR THE CHANGE?

Users have limited options for the disposal of their cesium-137 irradiators: on-site storage, return to the supplier/manufacturer (if available), or transfer of ownership to the federal government through the NNSA's Office Site Source Recovery Program (OSRP). The public costs of termination (OSRP's transport and disassembly costs, purchase and use of specialized containers, and long-term permanent storage costs at a licensed federal facility) are very high and not currently reflected in full life cycle costs of owning and using cesium-137 irradiator.

The NRC is currently reviewing a new rule that, if approved, would require financial assurance for disposition of Category 1 & 2 radioactive sealed sources (RSS). This would mean licensees possessing these sources would have to prove they were financially prepared for the costs of end-of-life dispositioning, dispositioning costs would have to be borne by those who received the economic benefits derived from the use of these sources, timely disposition would be required when radioactive sealed sources became disused or unwanted, and consideration for alternative technologies would be encouraged. Such a regulatory change would significantly affect life cycle costs—shifting significant costs back to commercial users. This would likely influence future purchase and replacement decisions.

WHAT ARE THE LIABILITY/INSURANCE COSTS FOR THE CHANGE?

The financial risk posed by radiological devices is seldom used to justify replacing cesium-137 irradiators, but the intentional misuse of a cesium-137 or any other high-activity radiological source could result in significant economic damages. The liability costs related to sealed-source possession and use should be factored into an institution's decision to continue using a radiological source or to replace it with an available alternative technology. In the United States, for example, very few user facilities have insurance coverage (general liability and excess policies cover) for this contingency; many administrators are not aware that their institutions could potentially be held liable for hundreds of billions of dollars. Insurance coverage, if available, is very costly, leaving most medical or research institutions exposed to first-party and/or third-party liability if a cesium-137 irradiator should be stolen by an actor of malevolent intent. Institutions without insurance to cover such a devastating event could have to pay huge damages and might face bankruptcy. This liability exposure is completely removed if a facility switches to a non-gamma-based technology, such as x-ray.

APPENDIX 4

Irradiator Replacement Cost Estimate Worksheet

	Cesium-137 Irradiator	X-Ray Irradiator
Fixed Costs		
Purchase		
Licensing and Registration		
Facility Modifications		
Regulatory Compliance		
Termination		
Other		
Annual Costs		
Regulatory Compliance (Security Program)		
Operating (Utilities)		
Maintenance (Service Contracts)		
Training for Operators		
Physical Security		
Insurance		
Other?		
Sum of Annual Costs		
Sum of Annual Cost Multiplied by Life Span		
FULL LIFE CYCLE COSTS OF OWNING OPERATING THE DEVICE		

APPENDIX 5

Key Resources

Preventing a Dirty Bomb: Radiological Security for Hospital and Research Centers

NTI's comprehensive collection of online resources for medical and research professionals with cesium-137 irradiators explains risks, steps for replacement, alternative technology, regulation and funding, and experiences from others: **www.nti.org/cesium137**

FEDERAL FUNDING

The Cesium Irradiator Replacement Project (CIRP) of the National Nuclear Security Administration's Office of Radiological Security provides incentives for qualified sites to make the switch, including removal and disposal of cesium-137 irradiators and funding toward the purchase of the new non-radioisotopic devices.

The website for CIRP is available at **https://www.energy.gov/nnsa/office-radiological-security-ors**

The website for the Off-Site Source Recovery Program is available at **https://osrp.lanl.gov/**

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