

Report to Congressional Committees

October 2021

ALTERNATIVES TO RADIOACTIVE MATERIALS A National Strategy to Support Alternative Technologies May Reduce Risks of a Dirty Bomb

Accessible Version

GAO Highlight

Highlights of GAO-22-104113, a report to congressional committees

October 202

ALTERNATIVES TO RADIOACTIVE MATERIALS

A National Strategy to Support Alternative Technologies May Reduce Risks of a Dirty Bomb

Why GAO Did This Study

Radioactive material, which is dangerous if mishandled, is found in many medical and industrial applications. In the hands of terrorists, it could be used to construct a radiological dispersal device, or dirty bomb, that uses conventional explosives to disperse the material. Replacing technologies that use dangerous radioactive materials with safer alternatives may help protect people and reduce potential socioeconomic costs from remediation and evacuation of affected residents.

Senate Report 116-102 included a provision for GAO to review alternative technologies to applications that use radioactive materials. This report examines (1) the potential for adopting alternative technologies in the United States for the six most commonly used medical and industrial applications; (2) factors affecting adoption of alternative technologies; and (3) federal activities relating to alternative technologies in the United States. GAO reviewed relevant documents to identify potential alternative technologies, conducted interviews with users of applications that employ radioactive material to identify factors affecting adoption of alternatives, and interviewed federal officials to discuss current federal activities relating to alternative technologies.

What GAO Recommends

Congress should consider directing an entity to develop a national strategy to support alternative technologies. The federal agencies involved in research and adoption of alternative technologies neither agreed nor disagreed with our matters for congressional consideration.

View GAO-22-104113. For more information, contact Allison Bawden at (202) 512-3841 or bawdena@gao.gov.

What GAO Found

GAO examined six common medical and industrial applications that use high-risk radioactive materials—identified through agency and expert reports—and found that three applications already have technically viable alternative technologies in many circumstances and for which there is market acceptance. For example, x-ray provides a technically viable alternative to replace cesium-137 blood irradiators, one of the common applications. Another of the applications has a technically viable alternative, though only in certain limited circumstances, and the two remaining applications do not yet have viable alternatives. For example, alternatives to replace americium-241 used in oil and gas well logging equipment, another common application, are still under development.

Irradiator with Radioactive Material (left) and Alternative Technology (right)





Sources: Brookhaven National Lab and Rad Source Technologies Inc. | GAO-22-104113

Users of applications that employ high-risk radioactive materials identified six factors they take into account when determining whether to adopt alternative technologies: technical viability of alternatives, device cost, costs to convert (such as facility renovations), disposal of radioactive materials, regulatory requirements, and liability and other potential costs associated with possessing high-risk radioactive materials. An accident at the University of Washington in May 2019 shows that liability and other potential costs would likely range from millions to billions of dollars if radioactive materials were accidentally released or used in a dirty bomb. These largely uninsured socioeconomic costs are an implicit fiscal exposure for the federal government, which could be expected to provide financial assistance.

Several federal agencies and interagency entities support research and promote adoption of alternative technologies. For example, the National Nuclear Security Administration (NNSA) has removed 355 irradiators since 2004 and subsidized the replacement of some with x-ray technology. Congress also established the goal for the NNSA to eliminate the use of cesium-137 blood irradiators in the United States by 2027. At the same time, the Nuclear Regulatory Commission licenses radioactive materials for irradiators, consistent with its mission. Currently, no strategy exists to guide federal efforts to find alternatives and reduce risk. A strategy to support alternative technologies would ensure a cohesive federal approach and potentially reduce the implicit fiscal exposure associated with addressing socioeconomic damage from a dirty bomb.

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Abbreviations

Abbreviations		
AEC	Atomic Energy Commission	
CIRP	Cesium Irradiator Replacement Project	
DOE	Department of Energy	
DHS	Department of Homeland Security	
FDA	Food and Drug Administration	
NCBR	nuclear, biological, chemical, or radiological	
NIH	National Institutes of Health	
NNSA	National Nuclear Security Administration	
NRC	U.S. Nuclear Regulatory Commission	
OSRP	Off-Site Source Recovery Program	
OSTP	Office of Science and Technology Policy	
Task Force	Interagency Task Force on Radiation Source Protection	
	and Security	
TRIP	Terrorism Risk Insurance Program	
UW	University of Washington	
WINS	World Institute for Nuclear Security	

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441 G St. N.W. Washington, DC 20548

October 21, 2021

The Honorable Dianne Feinstein
Chair
The Honorable John Kennedy
Ranking Member
Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate

The Honorable Marcy Kaptur
Chair
The Honorable Mike Simpson
Ranking Member
Subcommittee on Energy, Water Development and Related Agencies
Committee on Appropriations
House of Representatives

Although radioactive materials will likely be needed in medical and industrial applications for many years to come, replacing some applications with safer alternatives would provide permanent security risk reduction and decrease the potential for socioeconomic costs that could result from improper use.¹ Radioactive materials—such as americium-241, cesium-137, cobalt-60, and iridium-192—are commonly used throughout the U.S. in technological devices for medical, industrial, and research purposes such as treating cancer, sterilizing food and medical instruments, and detecting flaws in metal welds. However, these materials, if used improperly, can be harmful and dangerous; in the hands of terrorists, even a small amount of radioactive material could be used to

¹Socioeconomic costs are non-health related, such as costs to individuals with homes and businesses in areas affected by radioactive materials who are not able to return for an extended period because of actual or feared contamination.

construct a radiological dispersal device, also known as a dirty bomb, which disperses radioactive material with conventional explosives.²

Recent security threats have raised concern that terrorists could target radioactive material for theft and use in a domestic attack. From 2010 through 2019, the U.S. Nuclear Regulatory Commission (NRC) reported 2,133 nuclear materials events, which include instances of lost or stolen radioactive materials, radiation overexposures, leaking sources of radioactive material, and other events.3 One of these incidents occurred in April 2019 when a technician was arrested after stealing three iridium-192 radiography devices from his workplace in Arizona. The material in the devices was regulated under NRC's 10 C.F.R. Part 37 security regulations, which govern the physical protection of certain quantities of radioactive material.4 According to a court filing, the technician intended to release the radioactive material at a nearby mall, but before he could. he was arrested after a 2-hour standoff. Furthermore, National Nuclear Security Administration (NNSA) officials told us that current assessments of the threat environment show an increasing interest in using radioactive material for making a dirty bomb. 5 The January 6, 2021, attack on the U.S. Capitol has also led to a renewed focus among federal security agencies on domestic terrorism.

We have repeatedly reported on the deficiencies in and opportunities to improve agencies' policies and procedures relating to the security and vulnerability of radioactive materials. NRC and the Department of

²The NRC identifies 16 radionuclides of concern that pose the greatest risk of being used by terrorists to make a radiological dispersal device, also known as a dirty bomb. The list includes americium-241, cesium-137, cobalt-60, and iridium-192 (the most prevalent radionuclides of concern). The remaining 12 radionuclides of concern include americium-241/beryllium, californium-252, curium-244, gadolinium-153, plutonium-238, plutonium-239/beryllium, promethium-147, radium-226, selenium-75, strontium-90, thulium-170, and ytterbium-169.

³NRC's Nuclear Material Events Database contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees.

⁴NRC's 10 C.F.R. Part 37 regulations (commonly known as Part 37) address topics such as physical security, access control, monitoring and detection, and employee trustworthiness and reliability.

⁵NRC officials stated that their operating assumption for NRC's regulatory frameworks has been, and continues to be, that terrorist groups may be interested in acquiring radioactive material for malicious purposes. Furthermore, NRC officials stated that they have the authority to issue additional binding security requirements quickly, if warranted, to licensees via Order.

Homeland Security (DHS) have taken a number of actions to address some recommendations we made. For example, DHS implemented recommendations that improved licensing verification for shipments of imported radioactive material.⁶ However, as we reported in April 2021, NRC has not yet implemented a number of key recommendations to address identified vulnerabilities we have identified.⁷ Some of these vulnerabilities include

- In August 2003, we described weaknesses in NRC and state security controls for radioactive material.⁸
- In March 2006, we demonstrated through an investigation that it was
 possible to transport unlicensed radioactive material through ports of
 entry into the U.S. using a fake license.⁹
- In the course of a 2007 investigation, we established a fake business through which we obtained a real NRC license, which we then used to secure commitments to purchase a dangerous quantity of radioactive material.¹⁰
- In September 2012, we found security weaknesses at U.S. medical facilities.¹¹

⁶See *GAO*, *Priority Open Recommendations: Department of Homeland Security*, GAO-21-377PR (Washington, D.C.: to be issued shortly).

⁷See GAO, *Priority Open Recommendations: Nuclear Regulatory Commission*, GAO-21-453PR (Washington, D.C.: April 28, 2021).

⁸GAO, *Nuclear Security, Federal and State Action Needed to Improve Security of Sealed Radioactive Sources*, GAO-03-804 (Washington, D.C.: Aug. 6, 2003). For the current status of the recommendations from this report and all the GAO reports listed below, click on the report links. Alternatively, go to www.gao.gov, and search for the report number.

⁹GAO, Border Security: Investigators Successfully Transported Radioactive Sources Across Our Nation's Borders at Selected Locations, GAO-06-545R (Washington, D.C.: Mar. 28, 2006).

¹⁰GAO, Nuclear Security: Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective, GAO-07-1038T (Washington, D.C.: July 12, 2007).

¹¹GAO, Nuclear Security: Additional Actions Needed to Improve Security of Radiological Sources at U.S. Medical Facilities, GAO-12-925 (Washington, D.C.: Sept. 28, 2012).

- In a June 2014 report, we identified security challenges at industrial facilities.¹²
- In the course of a 2016 investigation, we established three fake businesses and, again, successfully obtained a real license for one of these businesses that we used to obtain commitments to purchase a dangerous quantity of radioactive material.¹³
- In February 2017, we described weaknesses in how radioactive material is secured when transported within the U.S.¹⁴
- In January 2018, we found gaps in DHS's procedures to ensure that only properly licensed radioactive material is imported into the U.S.¹⁵
- In 2019, we concluded that NRC's consideration of the risk of radioactive materials does not consider socioeconomic effects (e.g., evacuations, clean-up costs, effects to food and water supplies, and business interruption or relocation) and fatalities that could result from evacuations following a dirty bomb—factors that experts agreed were the most relevant criteria for evaluating the risks of radioactive materials.¹⁶

Further, in June 2021, the National Academies of Sciences, Engineering, and Medicine (National Academies) released a report supporting our findings on considering socioeconomic effects when establishing radioactive materials security regulations.¹⁷ The report found that small radiation releases may have serious and long-term socioeconomic consequences, and it recommended that NRC consider reframing its

¹²GAO, Nuclear Nonproliferation: Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources, GAO-14-293 (Washington, D.C.: June 6, 2014).

¹³GAO, Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain, GAO-16-330 (Washington, D.C.: July 1, 2016).

¹⁴GAO, Radioactive Sources: Opportunities Exist for Federal Agencies to Strengthen Transportation Security, GAO-17-58 (Washington, D.C.: Feb. 7, 2017).

¹⁵GAO, Nuclear Security: CBP Needs to Take Action to Ensure Imported Radiological Material Is Properly Licensed, GAO-18-214 (Washington, D.C.: Jan. 10, 2018).

¹⁶GAO, Combating Nuclear Terrorism: NRC Needs to Take Additional Actions to Ensure the Security of High-Risk Radioactive Material, GAO-19-468 (Washington, D.C.: April 4, 2019).

¹⁷National Academies of Sciences, Engineering, and Medicine, *Radioactive Sources: Applications and Alternative Technologies (2021)* (Washington, D.C.: June 2021).

source categorization schemes to account for health, economic, and social effects.

Senate Report 116-102 includes a provision for us to review the use of alternative technologies that would function in place of those that rely on radioactive materials. This report examines (1) the potential for adopting non-radioisotopic alternative technologies in the United States from among the commonly used medical and industrial applications; (2) factors affecting adoption of non-radioisotopic alternative technologies; and (3) federal activities relating to non-radioisotopic alternative technologies in the United States.

To examine the potential for adopting non-radioisotopic alternative technologies in the medical and industrial sectors, we used a two-step process. First, we identified six applications that use either americium-241, cesium-137, cobalt-60, or iridium-192,19 based on three criteria: (1) the socioeconomic and health risks presented by the release of the radioactive material, (2) the prevalence of the application in the U.S. economy, and (3) the vulnerability of the material to theft. Second, for each of these applications, we collected information on the technical viability of each potential alternative technology based on a variety of factors, including technical maturity, performance, physical nature of the device, and power requirements. Specifically, we reviewed relevant reports addressing alternative technologies, including published reports from the National Academy of Sciences, the World Institute for Nuclear Security (WINS), and DHS. We also conducted 21 interviews with knowledgeable stakeholders and current and former users of devices with radioactive material in the medical and industrial sectors to obtain their views on technical viability of each alternative, including the technical maturity, performance, physical nature, and power requirements. We supplemented these interviews by attending five public meetings put on by the National Academies to evaluate the current state of alternative technologies and reviewed materials presented during those meetings.

¹⁸S. Rep. No. 116-102 at 126-27 (2019) (accompanying Energy and Water Development and Related Appropriations Act, 2020, 116th Cong. (2019)).

¹⁹NNSA has identified four high-risk isotopes as being the most prevalent in commercial use: americium-241, cesium-137, cobalt-60, and iridium-192. Isotopes are varieties of a given chemical element with the same number of protons but different numbers of neutrons. For example, the helium-3 isotope, which is used in research and to detect neutrons in radiation detection equipment, has one less neutron than the helium-4 isotope, which is the helium isotope commonly used in party balloons.

We presented the information we gathered about technical viability in our first section of this report.

To understand the factors affecting adoption of non-radioisotopic alternative technologies, we conducted semi-structured interviews addressing factors with 21 knowledgeable stakeholders and users of radioactive material in the medical and industrial sectors. We also attended five public meetings put on by the National Academies that included discussions of factors. After conducting the interviews, we undertook a content analysis to list these factors and assign determinations to indicate whether each factor inclined each user toward or against adopting alternatives. In addition, we spoke to university officials and reviewed studies related to the 2019 accidental release of cesium-137 at the University of Washington (UW), which demonstrated the socioeconomic costs that can result from the release of radioactive materials. Finally, we reviewed previous GAO reports, federal terrorism insurance regulations, and spoke to officials in the insurance industry to describe the risk to the federal government associated with a dirty bomb attack.

To evaluate the current status of federal activities relating to alternative non-radioisotopic technologies, we interviewed officials at agencies, including NRC, NNSA, DHS, Office of Science and Technology Policy (OSTP), and the Food and Drug Administration (FDA), to discuss what actions they are taking in regards to alternative technologies. We also reviewed legislation, regulations, and guidance directing federal alternative technology activities and interagency efforts. Finally, we reviewed prior GAO reports addressing coordination between agencies and the implementation of national strategies.

We conducted this performance audit from March 2020 to October 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Americium-241, cobalt-60, cesium-137, and iridium-192 are the most prevalent high-risk radioactive materials in the U.S. economy, and they

are frequently found in dangerous quantities.²⁰ We refer to these radioactive materials as "high-risk" because of their potential to harm people and result in socioeconomic costs if released into the environment, whether by accident or through a dirty bomb.²¹ These high-risk radioactive materials are used throughout the U.S. in a variety of medical and industrial applications.²² Table 1 and the corresponding bullets summarize some of the most prominent uses of these materials in the U.S. economy.

Application	Purpose	Types and typical quantities of radioactive materials used
Blood irradiation	Irradiate blood products to prepare them for transfusion.	cesium-137 (category 1 or 2)
Medical research irradiation	Irradiate cell cultures or animal specimens for research purposes.	cesium-137 (category 1 or 2); cobalt-60 (category 1)
Industrial sterilization	Sterilize medical and food products for public use.	cobalt-60 (category 1)
Stereotactic radiosurgery	Treat brain cancer and cranial nerve disorders with targeted beams of radiation.	cobalt-60 (category 1)
Well logging	Detect and measure the properties of underground geological formations to detect fossil fuel deposits.	americium-241 (category 3); cesium-137 (category 3 or 4)

²⁰In September 2003, the U.S. and other nations endorsed International Atomic Energy Agency's Code of Conduct, which established basic principles and guidance for the safe and secure use of radioactive materials that are dangerous when unshielded and uncontrolled. It ranked quantities of individual radioactive materials into one of five categories on the basis of their potential to harm human health. A category 1 quantity, the most dangerous, is defined as an amount 1,000 times or more than the amount necessary to cause permanent human injury if handled for more than a few minutes. A category 2 quantity is still considered dangerous to human health and is defined as an amount at least 10 times but less than 1,000 times the amount necessary to cause permanent human injury if handled for a short time (minutes to hours). A category 3 quantity is defined as at least the minimum amount, but less than 10 times the amount, sufficient to cause permanent injury if handled for some hours. Category 4 and 5 quantities of radioactive materials are unlikely to cause permanent injury.

²¹In 2016, NRC interpreted "high-risk" to mean the largest quantities of radioactive material (categories 1 and 2). In our 2019 report, we used the views of security experts to define high-risk, and these experts generally agreed that high-risk includes both larger quantities and some smaller quantities of radioactive materials, including some category 3 quantities. See Nuclear Regulatory Commission, *Report to Congress under Public Law 113-235: Effectiveness of Part 37 of Title 10 of the Code of Federal Regulations* (Washington, D.C.: Dec. 14, 2016); and GAO-19-468.

²²While other applications for these radioactive materials exist, we identified these six as high-risk applications based on our methodology, see appendix I for details.

Industrial radiography

Detect and measure imperfections in industrial pipes and welds.

iridium-192 (category 1 or 2)

Source: GAO analysis of information from the Department of Homeland Security and the National Research Council of the National Academies. | GAO-22-104113

Note: The table does not include all applications of radioactive materials. In addition, according to NNSA officials, well logging users commonly store multiple americium-241 sources that, in aggregate, achieve category 2 quantities.

Blood irradiation. A widely used process whereby donor blood is exposed to radiation, which inactivates a type of white blood cell that may fatally complicate transfusion for some recipients. The most common method of using radiation to treat blood is to place blood bags into a shielded chamber inside of an irradiator containing cesium-137.²³

Medical research irradiation. Research irradiators are used in medical research to expose cell cultures or animal specimens to gamma radiation from cesium-137 or cobalt-60. Research irradiators are used to study DNA damage, immune response, cancer development, and other areas.

Industrial sterilization. Cobalt-60 panoramic irradiators use gamma radiation to sterilize large quantities of medical devices and food products before being sold to consumers. According to the International Irradiation Association, gamma-based sterilization using cobalt-60 represents about 40.5% of the sterilization market, with non-radioisotopic methods making up the remainder.²⁴ Gamma-based industrial sterilization is typically conducted in warehouses, and involves conveying pallets of product through a shielded room to be exposed to radiation from large quantities of cobalt-60.

Stereotactic radiosurgery. A large, helmet-like device focuses beams of gamma radiation from several cobalt-60 sources to treat brain and cranial illnesses. Gamma Knife[®] devices use cobalt-60 to treat tumors and nerve disorders.²⁵

²³A small number of blood irradiators also use cobalt-60.

²⁴According to the International Irradiation Association, cobalt-60 gamma irradiation and ethylene oxide gas together account for 90 percent of the industrial sterilization market, with the remainder comprised of methods using alternative technologies such as electron beam and x-ray. Though ethylene oxide gas is a popular sterilization method, it has different properties and capabilities than cobalt-60, and it is used to sterilize products not suitable for irradiation with cobalt-60 or alternative technologies. However, according to a report from the National Academies, there are regulatory pressures to reduce emissions from ethylene oxide, which may drive products to be sterilized by other modalities, when possible.

²⁵Gamma Knife® is a registered trademark of the Elekta Group.

Well logging. As an aid to searching for oil, gas, and water, or conducting environmental or other forms of underground monitoring, well logging devices using americium-241 and cesium-137 are used to examine geologic features around a borehole or well. Well logging devices are lowered downhole and emit radiation and take readings on the characteristics of an underground formation, such as its chemical and mineral contents.

Industrial radiography. Hand-held iridium-192 radiography "cameras" are used for the non-destructive inspection of welds, pipes, and other materials. Industrial radiography typically exposes the object to gamma radiation that, once deposited onto a detector, produces a fine-detail image of any imperfections in the object.

Several agencies and interagency entities play a role in alternative technologies. For example,

- NRC is responsible for licensing and regulating the safety, security, and disposal of radioactive materials for industrial, medical, and research uses in the U.S.²⁶ Though it does not take a direct role with regard to alternative technologies, NRC officials acknowledged that its requirements influence the cost of using radioactive materials versus pursuing an alternative. For example, NRC's Part 37 security regulations require users of category 1 and 2 quantities of radioactive materials to establish security perimeters, continuously monitor and control all access to the materials, and notify local law enforcement agencies in the event of a breach in security.
- NNSA's Office of Radiological Security (ORS) works with domestic and foreign governments, law enforcement, and private businesses to provide security upgrades and dispose of radioactive material. It also runs the Cesium Irradiator Replacement Project (CIRP), which provides incentives to domestic users of blood and research irradiators to replace their cesium-137 irradiators with x-ray devices. In addition, the agency runs the Off-Site Source Recovery Program (OSRP), which subsidizes the cost of removing and disposing of unwanted blood and research irradiators and their high-risk radioactive material. According to NNSA officials, the purpose of the

²⁶NRC may also enter into agreements with states (called agreement states), so they assume, and NRC discontinues, regulatory authority over specified radioactive materials. To date, NRC has discontinued for 39 agreement states its authority to license and inspect the possession and use of specified radioactive materials.

- program is not to subsidize industry costs but to address risks to national security and the health and safety of the public.
- The Department of Energy's (DOE) Office of Science manages the Accelerator Stewardship Program, which funds basic research into compact accelerator technologies to potentially replace technologies that use high-risk radioactive materials.
- FDA reviews sterilization methods—including methods that use highrisk radioactive materials—as part of its process to regulate devices that sterilize medical products. According to FDA officials, the purpose of FDA's review process is to help ensure that the applicant's chosen sterilization method does not impede the effectiveness or safety of the new device.
- OSTP chartered a working group (chaired by NNSA, NRC, and the National Institutes of Health) that published a guide in 2016,²⁷ which outlined best practices federal agencies could use to transition from high-risk radioactive materials to alternative technologies.²⁸
- NRC and DOE, among other agencies, serve on the Interagency Task Force on Radiation Source Protection and Security (Task Force), which is chaired by NRC. The Task Force was established by the Energy Policy Act of 2005 to, among other things, provide recommendations to Congress on the establishment of appropriate regulations and incentives for the replacement of devices using radioactive materials with non-radioisotopic alternative technologies.²⁹ According to NRC officials, the Task Force is also a forum for agencies to share information.

Some Alternatives to Technologies

²⁷Office of Science and Technology Policy, *Transitioning From High-Activity Radioactive Sources To Non-Radioisotopic (Alternative) Technologies: A Best Practices Guide for Federal Agencies* (Washington, D.C.: December 2016). In 2015, an OSTP working group was chartered and began an assessment of federal agency involvement with high-risk radioactive materials. It also developed best practices on how agencies can incorporate the transition to alternative technologies into their strategic plans. This guide is the result of that assessment, and it was published by OSTP.

²⁸OSTP is housed within the White House's National Science and Technology Council, which provides the principal means by which the Executive Branch coordinates science and technology policy across the diverse entities that make up the federal research and development enterprise.

²⁹Pub. L. No. 109–58, § 651(d)(1), 119 Stat. 594, 804 (codified at 42 U.S.C. § 2210h(f)).

That Use High-Risk Radioactive Materials Have Potential for Adoption

We examined the potential for adopting non-radioisotopic alternative technologies (alternative technologies) for six medical and industrial applications currently using high-risk radioactive materials, and we found that the alternative technologies had a range of technical viabilities. Of the six applications we examined, some already had alternative technologies that were technically viable replacements, while some required additional development (see table 2).

Table 2: Evaluation of Six Applications That Use High-Risk Radioactive Materials and Their Potential Alternative Technologies

Radioactive material application	Prospective alternative technology	Considerations affecting technical viability	Current state of technical viability
Blood irradiation (cesium-137)	X-ray irradiator	X-ray irradiators are approved by the Food and Drug Administration and commercially available with equivalent cost and performance.	Our discussions with users and evaluation of technical reports suggest that x-ray irradiators provide a technically viable alternative to replace cesium-137 irradiators for blood irradiation.
Research irradiation (cesium- 137, cobalt-60)	X-ray irradiator	X-ray irradiators are commercially available with equivalent performance in many research applications.	Our discussions with users and evaluation of technical reports suggest that x-ray irradiators provide a technically viable alternative to cesium or cobalt-based irradiators for research irradiation, depending on the circumstances of the research project.
Industrial sterilization (cobalt-60)	Electron beam and x-ray sterilization	Electron beam and x-ray sterilization devices are commercially available, with expanding market adoption.	The existence of widespread and expanding adoption of x-ray and electron beam sterilization and growing research on their equivalency suggest they offer technically viable alternatives. Equivalent sterilization performance can be demonstrated on specific products.
Stereotactic radiosurgery (cobalt-60)	Linear accelerators (linacs)	Linacs have sufficient performance for some treatments, and the market has increasingly adopted linacs.	Some doctors rely on cobalt-60 devices as a key treatment option. Our discussions with users and evaluation of technical reports suggest that linac technology (1) has achieved expanded adoption and trust among users; and (2) can provide a technically viable alternative to cobalt-60 stereotactic radiosurgery for an increasing number of treatments where the current precision of linacs is sufficient.
Industrial radiography (iridium-192)	X-ray radiography and ultrasound testing	X-ray and ultrasound are used in some instances but have limitations that hamper their ability to replace radioactive materials in most applications (e.g., need for external power supply).	Some alternative technologies exist for industrial radiography, but our discussions with users and evaluation of technical reports suggest that these alternatives have not yet shown sufficient technical viability to supplant the use of devices using high-risk radioactive materials.

Well logging (americium-241 and cesium-137)

Nuclear magnetic resonance, acoustic sources, and neutron generators Alternatives, including nuclear magnetic resonance, acoustic sources, and neutron generators, do not yet achieve the same performance as devices using radioactive material. They may face other limitations such as longer measurement times.

Development of alternatives for well logging continues, but our discussions with users and evaluation of technical reports suggest that current technologies have not yet reached the technical viability necessary to replace well logging devices using high-risk radioactive materials.

Source: GAO analysis of technical documents and interviews with users. | GAO-22-104113

Blood irradiators. X-ray irradiators use electrically driven x-ray tubes to apply a high dose of x-rays to the target material. The x-ray radiation works like the gamma radiation used in cesium-137 irradiators to disable the cells that cause graft-versus-host disease, as long as a high enough dose can be delivered. Commercially available x-ray irradiators are FDA approved for blood irradiation and have been adopted already by users to whom we spoke at blood banks and hospitals, including users who replaced or plan to replace their entire fleet of cesium-137 irradiators. For blood irradiation, multiple users expressed a general consensus that x-ray irradiators could perform equivalently to the typical cesium-137 irradiators. Furthermore, users told us that x-ray irradiators have the added benefit that they can treat blood faster. Therefore, our discussions with users and evaluation of technical reports suggest that x-ray provides a technically viable alternative to replace cesium-137 irradiators for blood irradiation.³⁰

Research irradiators. Some users at universities and hospitals told us they were initially reluctant to switch to x-ray irradiators for conducting research. While x-ray irradiators can produce an equivalent dose of radiation, the x-rays are produced through a different physical mechanism, meaning they have a different energy spectrum compared with the gamma rays from a cesium-137 or cobalt-60 irradiator. This difference in energy spectrum led to concerns among researchers about applying an even dose throughout test subjects—such as mice—variability in x-ray production between irradiators, and demonstrating equivalency between experiments done with cesium-137 and x-ray irradiators. While the circumstances of each individual research project

³⁰See also National Academies of Sciences, Engineering, and Medicine, *Radioactive Sources*; U.S. Department of Homeland Security, Cybersecurity and Infrastructure Agency, *Non-Radioisotopic Alternative Technologies White Paper* (Washington, D.C.: September 2019); and World Institute for Nuclear Security, *Considerations for the Adoption of Alternative Technologies to Replace High Activity Radioactive Sources* (Vienna, Austria: September 2018).

may vary and some studies may not be able to switch to x-rays,³¹ studies and surveys we reviewed showed that x-ray irradiators performed well enough to replace cesium-137 irradiators in many research applications.³² Furthermore, officials at multiple universities to whom we spoke were able to transition from cesium-137 to x-ray irradiators with minimal effect on their research. One official from a medical research facility noted that switching to x-ray had never compromised their researchers' ability to win grants. Thus, our discussions with users and evaluation of technical reports suggest that x-ray provides a technically viable alternative to cesium or cobalt-based irradiators for research irradiation, depending on the circumstances of the research project.

Industrial sterilization. Both electron beam and x-ray technology offer alternatives to cobalt-60 industrial sterilizers for treating many medical devices and food products. Both electron beam and x-ray devices use particle accelerator technology to either directly irradiate products with the electron beam from the accelerator or convert that beam into x-rays for irradiation (see figure 1).33 According to the International Irradiation Association,34 50 percent of the global sterilization market uses a non-radiation based technique using ethylene oxide.35 Of the remaining market share, cobalt-60 sterilizers represent about 40.5 percent of the sterilization market. Electron beam devices are currently used commercially in 4.5 percent of sterilizations, and the remaining 5 percent includes x-rays and other techniques. Representatives from multiple sterilization companies with whom we spoke stated they had facilities using electron beam or x-ray technologies, and they indicated they had

³¹According to NIH officials, basic research is one area where x-rays may not always provide the technical capabilities needed.

³²See Mount Sinai, *Mount Sinai Experience In Migrating From Radioactive Irradiators to X-ray Irradiators for Blood and Medical Research Applications* (New York: September 2018); and University of California, Office of the President, *University of California Systemwide Radioactive Source Replacement Workgroup Recommendations* (April 2018).

 $^{^{33}}$ Some manufacturers combine these modalities into a single machine that can switch between electron beam and x-ray generation.

³⁴Gamma Industry Processing Alliance and International Irradiation Association, *A comparison of gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products* (Aug. 31, 2017).

³⁵Ethylene oxide is a gas that sterilizes products by killing microorganisms residing on the device.

plans to expand their use of alternative technologies as part of their plans to meet growing demand.

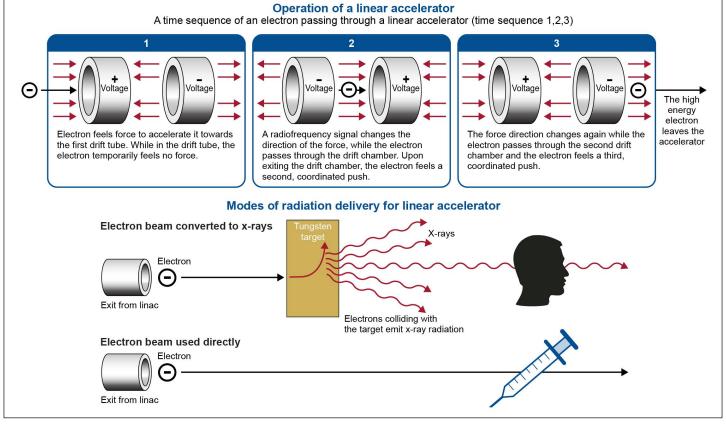
Users to whom we spoke have mixed views about the future of cobalt-60 sterilizers. For example, one representative from a sterilization company remarked that electron beam sterilization is "where the market is going." Another representative from a different company, however, cautioned that alternative technologies still remain unproven and may not prove suitable for some applications, such as large pallets of medical products. Multiple representatives at industrial sterilizers stated that they expected FDA requirements would be a disincentive to switching to alternative technologies. However, FDA considers cobalt-60, electron beam, and xray to all be well-known and established methods for sterilization, and FDA officials with whom we spoke noted that FDA is agnostic as to the method of sterilization, so long as it is safe and effective. Ongoing research efforts, led by NNSA, are also showing equivalent sterilization performance with electron beam and x-ray without negative consequences. Thus, the existence of widespread and expanding adoption of x-ray and electron beam sterilization and growing research on their equivalency suggest they offer technically viable alternatives; equivalent sterilization performance can be demonstrated on specific products.

Figure 1: Linear Accelerators Are Potential Alternative Technologies in Industrial and Medical Sectors

A linear accelerator, or linac, is a device for accelerating charged particles. While a linac can accelerate a variety of charged particles (such as electrons, protons, or heavy ions), the linacs discussed as alternative technologies to applications of high-risk radioactive materials accelerate electrons.

The linac accelerates the electrons using radiofrequency waves, which create forces that change with time. As the electrons travel through the linac, they pass a series of accelerating segments where the electron feels a force that pushes it forward, interspersed with drift tubes where it temporarily feels no force (see depiction below). The drift tubes shield the electron, while the radiofrequency signal quickly changes the direction of the accelerating force. In doing so, the electron experiences a coordinated sequence of pushes, as it reaches higher speeds. This technique allows the linac to push electrons to much higher energies than, for example, an x-ray tube, which relies on a single, high-voltage to accelerate the electrons.

Once the electrons have been accelerated, they can either be used directly as an electron beam or converted to x-rays. Conversion to x-ray involves colliding the electrons with a heavy material like tungsten. When the electrons interact with this material, they produce an effect called bremsstrahlung radiation, which emits x-rays across a wide energy spectrum (see depiction below).



Source: GAO analysis of technical literature. | GAO-22-104113

Stereotactic radiosurgery. While some users we interviewed acknowledged the superiority of cobalt-60 stereotactic radiosurgery devices to treat specific illnesses, they noted that continued improvement in linac technology has made it possible to treat an increasing number of patients without technologies using high-risk radioactive materials. The

most common type of radioisotopic device for stereotactic radiosurgery is the Gamma Knife® device, which uses approximately 190 tubes of cobalt-60 to perform an extremely precise irradiation of a person's head. Linacs, on the other hand, use accelerated beams of charged particles to produce x-ray beams that can be shaped to perform targeted irradiation. Some linacs are optimized for stereotactic radiosurgery treatments, while others cannot perform stereotactic radiosurgery or require modifications to perform the treatments. Multiple users told us that the key differentiator between a Gamma Knife® device and the linac is precision. According to a report by the National Academies, a Gamma Knife® device can deliver a dose with an accuracy of around 0.3 millimeters, while current linacs can only achieve an accuracy of around 1 millimeter, which could result in more harm to healthy tissue. This difference means that Gamma Knife® devices remain the preferable treatment method, according to users, for conditions in the brain that require extremely high precision. For example, one user told us that Gamma Knife® devices are still the preferred treatment method for trigeminal neuralgia, a condition where the brain's trigeminal nerve sends chronic, extreme pain to a person's face. Figure 2 shows a picture of a Gamma Knife® device.

Figure 2: Gamma Knife® Device That Uses Cobalt-60 to Conduct Stereotactic Radiosurgery

Source: Radiosurgical Center of Memphis. | GAO-22-104113

Note: The image shows where the patient is secured and directed into the hemispherical configuration of cobalt-60 sources.

As linac technology continues to improve, the use of linacs to treat more conditions is expanding and a number of studies have found equivalent performance with Gamma Knife® devices for some treatments. A 2018 report from WINS summarized this trend by stating that researchers over the last 10 years have found that "linac-based radiation for brain tumors achieves dosimetry, safety, and efficacy comparable to that achieved by Gamma Knife® treatment." The report also noted an increase in linacs among medical users, and it postulated that the trend towards increased use of linacs for stereotactic radiosurgery is likely to continue.

Users to whom we spoke have a variety of opinions on the future use of linac and Gamma Knife® device treatments. One radiation oncologist, for example, told us that linacs were essentially equivalent to a Gamma Knife® device for treating brain tumors, and the linac comes with increased flexibility that makes administering different treatments easier. This oncologist also said their facility's use of its Gamma Knife® device has declined as linac use expands, and they are considering whether to discontinue use of the Gamma Knife® device when the cobalt-60 requires replacement in 4 years. Radiation oncologists at another facility, however, said they found Gamma Knife® devices to be by far the best treatment for the brain. While they noted that the number of such devices in the U.S. could be reduced, they said that doctors would need to continue to have access to the devices on a regional basis because they remain the best treatment option for certain conditions. Therefore, while applications for Gamma Knife® devices remain, and some doctors rely on this as a key treatment option, our discussions with users and evaluation of technical reports suggest that linac technology has achieved expanded adoption and trust among users. It can provide a technically viable alternative to cobalt-60 stereotactic radiosurgery for an increasing number of treatments where the current precision of linacs is sufficient.

Industrial radiography. Ultrasound and x-ray technologies can be substituted for some applications of industrial radiography, but they face technical challenges for greater adoption. X-ray radiography devices use an x-ray tube to produce an image, similar to a medical or dental x-ray. Ultrasound machines produce an image using reflected sound waves, as opposed to the high-energy light particles used in iridium-192 and x-ray

³⁶World Institute for Nuclear Security, *Considerations for the Adoption of Alternative Technologies*.

devices. An industrial radiography user told us that they have found some limited applications of x-ray radiography for their aerospace customers.³⁷ However, a recent report from the National Academies on alternative technologies noted that x-ray systems require external 220V power supplies and water cooling, which make them difficult to operate in the restricted spaces, harsh environments, or remote locations where industrial radiographers typically work. An industrial radiography user also told us that they employ ultrasound as an alternative to iridium-192 devices. However, they said that ultrasounds are limited because they cannot scan insulated pipes and require a more skilled technician to be operated correctly. A WINS report more broadly summarized the state of alternatives for industrial radiography, stating that devices using radioisotopes are easy to use, and "new non-isotopic alternatives do not offer a major improvement in terms of cost or quality, so movement towards alternatives has been relatively slow." Thus, some alternative technologies exist for industrial radiography, but our discussions with users and evaluation of technical reports suggest that these alternatives have not yet shown sufficient technical viability to supplant the use of devices using high-risk radioactive materials. Figure 3 shows how an industrial radiography device using iridium-192 is deployed in the field.



Figure 3: Industrial Radiography Device Using Iridium-192

Source: GAO. | GAO-22-104113

³⁷In controlled settings, x-ray devices can actually produce a better image than iridium-192, which makes them attractive to industries like the aerospace industry where the environment is highly controlled.

Note: The iridium-192 source is stored in the shielded yellow container on the ground. It passes through the yellow tube until it is positioned next to the pipe to generate a radiographic image.

Well logging. Several alternative technologies for well logging have been pursued—including nuclear magnetic resonance, acoustic sources, and neutron generators—but none have achieved technical viability to replace current well logging devices using americium-241 and cesium-137. Reports surveying the commercial availability of alternative technologies by DHS and WINS both identified that alternative technologies for well logging are not as accurate as technologies using radioactive materials. In addition, these technologies might require special data processing and analysis, operate at slower speeds and, thereby, lengthen the measurement time. They may face other limitations, such as increased technical complexity, which are not easily overcome. A representative from a well logging trade group told us that he was aware of various federal and private research efforts to develop alternative technologies for well logging, but he reiterated that their accuracy may not be sufficient for the industry. Therefore, while development of alternatives for well logging continues, our discussions with users and evaluation of technical reports suggest that current technologies have not yet reached the technical viability necessary to replace well logging devices using high-risk radioactive materials.

Radioactive Material Users Identified Six Factors Affecting Adoption of Alternatives, and Limited Insurance to Mitigate One Factor Creates a Potential Fiscal Exposure for the Federal Government

Users we interviewed from the primary industries using radioactive materials identified six factors that they take into account when considering adoption of alternative technologies. The significance of these factors in incentivizing or dis-incentivizing adoption of alternative technologies varied based on the user of radioactive material. In particular, one of these factors—concern regarding liability and other potential costs associated with possessing radioactive material—was identified as a significant factor by some users with respect to adopting

alternatives.³⁸ However, the limited availability of insurance to address this liability—and its substantial cost when available—leave the federal government with a potential fiscal exposure in the event that radioactive materials were mishandled or released through a dirty bomb.

Users Identified Six Factors Affecting Adoption of Alternative Technologies, and the Importance of the Factors Varied Depending on the User

Users of radioactive materials identified six factors they take into account when determining whether to adopt alternative technologies. These factors include: (1) technical viability of alternative technologies, (2) comparative costs of devices, (3) capital costs of converting, (4) disposal of radioactive material, (5) regulatory requirements, and (6) liability and other potential costs associated with possessing high-risk radioactive materials. The six factors are described in table 3.

Table 3: Six Factors Users of Radioactive Material Identified as Affecting Their Decision to Adopt Alternative Technologies

Factor	Description
Technical viability of alternative technologies	The alternative technology's technical maturity, including elements such as performance, physical nature of the device, and power requirements, among other things.
Comparative cost of devices	The cost of switching to an alternative technology, including the comparative price of the new device, training, and maintenance costs.
Capital costs of converting	The economic costs surrounding making a switch to alternative technologies, including sunken capital costs and facility renovations.
Disposal of radioactive material	The cost to permanently remove radioactive material from the user's facility or site when the material is no longer usable or needed.
Regulatory requirements	The cost of implementing regulatory requirements for possessing radioactive materials, including the costs for licensing and physical security.
Liability and other potential costs associated with possessing high-risk radioactive materials	The potential costs that could result from the theft and use of a licensee's radioactive material in a dirty bomb.

Source: GAO analysis of interviews with users of radioactive material in the medical and industrial sectors, April 2020–March 2021. | GAO-22-104113

The extent to which each of these factors was viewed as either an incentive for or disincentive to adopting alternative technologies varied by user. For example, users of blood and research irradiators found most of the factors to be incentives for adopting alternative technologies, whereas

³⁸The term "liability" is used to express a general concern by users about the costs that might result from the theft and use of their radioactive material in a dirty bomb. It is not necessarily meant to express any judgment regarding who might bear legal responsibility for such an incident or the costs.

users of stereotactic radiosurgery, industrial sterilizers, well loggers, and industrial radiographers considered some factors to be disincentives to adopting.

Blood irradiators. Users of blood irradiators identified NRC's regulatory requirements, disposal of cesium-137, and potential liability associated with accidental release or theft of their radioactive materials as the primary factors affecting their adoption of alternative technologies. As stated above, the comparative performance of x-ray irradiators in treating blood has enabled users to switch from cesium-137 without technical viability concerns.

Users told us that they consider the cost of compliance with NRC's Part 37 security regulations to be an incentive for switching to alternative technologies. For example, one user pointed to background checks. including fingerprinting, and educational verification as costly to their institution, particularly when needed for foreign-born employees. Blood bank operators told us that disposal of cesium-137 when it is no longer usable is expensive. These users often store the material on-site, as disposal options can be prohibitively expensive. Options include contracting with an irradiator manufacturer to retrieve the radioactive material, paying to ship the material to NNSA for disposal, or having NNSA pick up the material via its OSRP.³⁹ One official at a blood bank told us that disposing of an x-ray device costs about \$2,500, while disposing of a cesium-137 irradiator may cost up to \$200,000. When possible, users said that they have used OSRP. The program is free to the user, but it costs the federal government, thus subsidizing private users' costs to dispose of the material.40

Users also expressed concern regarding the potential liability and other potential costs of possessing high-risk radioactive materials. For example, one user at a major urban hospital told us that they feared being the target of legal action in a scenario where, despite the hospital following

³⁹Since 2004, industry has paid to ship 43 cesium-137 irradiators to NNSA, which disposed of, or plans to dispose of, these irradiators at a federal facility.

⁴⁰The OSRP is a U.S. government activity sponsored by NNSA's Office of Global Material Security and managed at Los Alamos National Laboratory through its Nuclear Engineering & Nonproliferation Division. OSRP's mission is to remove excess, unwanted, or disused radioactive material that poses a potential risk to national security, health, and safety. Since 1997, OSRP has recovered more than 43,300 sources of radioactive material from more than 1,560 sites (including all 50 states, Washington, D.C., Puerto Rico, and 27 foreign countries). These recoveries have resulted in more than 1.35 million curies of radioactive material being removed and secured.

NRC's security protocols and passing NRC inspections, the hospital's cesium-137 was somehow stolen and released in a dirty bomb. After conducting comparison studies that found x-ray devices to be largely equivalent to cesium-137 blood irradiators, hospital officials decided to mitigate the risk by removing all of its cesium-137 irradiators from operation and replacing them with x-ray devices.

Research irradiators. As with users of blood irradiators, the comparative performance of x-ray irradiators for medical research has led to switching from devices using cesium-137 to x-rays. Users of research irradiators, which are typically used for research on mice and cells, also identified NRC's Part 37 security regulations, disposal of cesium-137, and liability as the primary factors affecting their decision to switch to alternative technologies.

Conducting background checks on researchers, which is required to comply with NRC's Part 37 security regulations, is particularly difficult for the research industry when applied to foreign researchers. For example, officials at a large research institution told us that the primary benefit of switching to an x-ray irradiator was that they no longer had to conduct background checks on international post-doctoral medical students. They said that about half of their post-doctoral students are foreign, including students from China, India, Japan, Europe, and the Middle East. While the requirement to conduct background checks applies to all those with unescorted access to category 1 and 2 quantities of radioactive materials, conducting background checks on individuals from other countries is very burdensome for their institution, and they anticipated that it could become more difficult in the future.

Officials at another medical research institution told us that the research center is less financially robust than the adjoining medical facility, and it was facing financial challenges that would have made it difficult to pay 100 percent of the costs to dispose of their existing irradiators. According to officials at NNSA, when radioactive material becomes unusable, the old cesium-137 irradiators may end up sitting in the facility's basement.⁴¹ Having disused cesium-137 at a facility presents a security concern, as the material can be forgotten and become vulnerable to theft and use in a

⁴¹Disused radioactive materials are still required to meet NRC security regulations.

dirty bomb.⁴² This is consistent with findings from our 2012 report reviewing the security of radioactive material at medical facilities.⁴³ In that report, we found old disused cesium-137 irradiators stored on-site to avoid the cost of disposing of them.

As with users of blood irradiators, users of medical research irradiators cited concerns about liability in the event their devices were stolen. Although research irradiators are used for different purposes than blood irradiators, users of research irradiators cited the same potential liability risks to their institutions. In addition to the major urban hospital cited above, representatives from three other university hospital systems with whom we spoke said their institutions have undertaken efforts in recent years to replace as many of their research irradiators with x-rays as possible.

Stereotactic radiosurgery. Users of stereotactic radiosurgery identified the comparative costs of devices and regulatory requirements as factors influencing their adoption of alternatives, but unlike users of blood and research irradiators, users of stereotactic radiosurgery did not see disposal of radioactive materials as an incentive to switch. As stated above, the main difference between Gamma Knife® devices and linacs is accuracy. However, linac technology is improving and becoming increasingly capable of replacing many of the functions currently performed by a Gamma Knife® device, and treatment option flexibility with linacs makes them preferable in certain circumstances.

In addition, a user told us that the cost of linacs relative to Gamma Knife® devices has improved over time. For example, a medical professional said that Gamma Knife® devices require replenishment with fresh cobalt-60 every 4 to 5 years at a cost from \$800,000 to \$1 million. In contrast, linacs do not require replenishment. Furthermore, possessing linacs removes the requirement that the facility comply with NRC's Part 37 security regulations, which were seen as burdensome by one of the users to whom we spoke.

However, doctors at another medical facility told us that the benefits of Gamma Knife® devices for treating cranial issues outweighs the costs associated with the security controls. In their opinion, the ability of

⁴²Cesium-137 remains a high-risk material for use in a dirty bomb for approximately 300 years.

⁴³GAO-12-925.

Gamma Knife® devices to minimize damage to the brain during some surgeries makes them the medical device of choice regardless of the other factors. In addition, disposal of cobalt-60 does not present a problem for the institution, and the downtime for the device is typically less than with linacs.

Industrial sterilization. For industrial sterilizers, the comparative cost of devices using x-rays and e-beam technologies and concerns about the supply of cobalt-60 are prompting companies to consider alternative technologies. However, users are not concerned with the costs surrounding regulatory requirements or the disposal of cobalt-60. As stated above, some industrial sterilizers have already adopted alternative technologies for sterilizing agricultural and medical products, and they expect to increase the use of alternative technologies in the future.

In particular, some industry professionals identified the current lack of cobalt-60 as a concern and a potential incentive for switching to alternatives. For example, one user told us that they are expecting "headwinds" with cobalt-60 supply in the future, and they believe that cobalt-60 costs will go up as capacity tightens. This industrial sterilizer told us that they do not believe they can procure sufficient cobalt-60 supplies in the future to expand their market with only gamma radiation, and they are, therefore, looking to alternative technologies for future growth.⁴⁴ However, industrial sterilizers are not looking to abandon their existing cobalt-60 facilities, only augment them with alternative technologies.

In contrast, users in the industrial sterilization industry told us that they are not concerned with the cost of NRC's security regulations, and see them as a cost of doing business. They said that removal of these costs by switching to alternative technologies would not be a deciding factor. Furthermore, disposal of cobalt-60 is not a problem, as sterilizers typically sign 3- to 5-year agreements with cobalt-60 suppliers whereby users agree to purchase fresh sources in exchange for returning their used sources.

Industrial radiography. While one industrial radiographer to whom we spoke said that not having to implement NRC's Part 37 security

⁴⁴In contrast, a supplier of cobalt-60 told us that these concerns are overblown. They said that they are increasing cobalt-60 supply by making capital investments to expand existing reactor output of cobalt-60, improving logistics to gain access to new sources of cobalt-60, and promoting new reactor technology such as light water reactors.

regulations was an incentive for switching to alternative technologies, industrial radiographers view most of the factors as disincentives for switching. As stated above, ultrasound and x-ray technologies are used as alternatives for industrial radiography in some limited circumstances, but overall, alternatives face technical challenges that make greater adoption difficult. Users also told us that the comparative cost of alternative technologies and the cost of converting are too expensive for an industry with thin profit margins. For example, one industrial radiographer said that the main disadvantage of x-ray devices is that the tubes are expensive, and, if dropped, they can cost the company \$60,000 to replace. In contrast, an iridium-192 device costs between \$20,000 and \$30,000 to purchase. Furthermore, he said that switching to devices using x-rays and ultrasound require a higher level of expertise for the technician, which translates into higher training costs. He added that clients are unwilling to pay higher costs for alternative technologies when basic methods work at lower costs. Finally, users said that they do not face any disposal challenges, as iridium-192 is easily disposed of through service contracts with suppliers.

Well logging. Well loggers noted that the cost of conversion and comparative price of devices make it difficult to switch to alternative technologies, but they also identified NRC's Part 37 security regulations and liability as factors that would incentivize switching. As we stated above, while there are alternative technologies for well logging, current alternative technologies are not considered technically viable alternatives.

An official who oversees regulatory affairs at a large well logger told us that devices that use americium-241 are more durable, more accurate, and have a longer working life. Another official also said that the reduced accuracy of alternative technologies may not be acceptable to well logging clients. Furthermore, one user told us that 60 percent to 70 percent of well logging in the U.S. is undertaken by "Mom & Pop" companies using off-the-shelf technology. He said that these companies have limited technological and financial capabilities, and they would struggle to switch to a new technology. Another official appeared to agree with this statement. They told us that the well logging industry has invested tens of millions of dollars in current americium-241 technology, and it has no money to invest in replacement technologies.

On the other hand, users identified security measures as a significant ongoing cost and raised concerns about the liability of possessing radioactive materials. For example, one well logger told us that he spends \$10,000 per year to maintain radioactive materials, which is a substantial

annual expense for his company. However, he said that these security investments may not prevent the catastrophic damage one terrorist event could cause his company and the already struggling well logging industry as a whole.

Limited Insurance to Address Radioactive Material Liability Leaves the Federal Government with Potential Fiscal Exposure

As discussed above, users at hospitals and well logging companies expressed concern regarding liability and other potential costs associated with accidental release or theft of their radioactive materials as a consideration for switching to alternative technologies. These users said that, despite these concerns, there is limited insurance available to cover radiological releases or attacks from dirty bombs, which are a type of event known in the insurance industry as a nuclear, biological, chemical, or radiological (NBCR) event. When available, users told us that such coverage is prohibitively expensive.⁴⁵ For example, officials from a major urban hospital said that the hospital has assumed the responsibility for any costs associated with the release of its radioactive material because its general insurance policies exclude NBCR coverage; the few policies available on the market that include such coverage are too expensive.

Representatives from an insurance company that provides coverage for users of radioactive material confirmed the prohibitive cost of such insurance. They stated that at least 90 percent of companies they cover do not purchase general liability coverage for terrorist events at all, NBCR or otherwise. Furthermore, an official from a major urban hospital told us that it was unclear if the hospital would be the target of legal action in the event of someone accessing its cesium-137 and using it in a dirty bomb.

⁴⁵We have previously reported on the extent of NBCR coverage as part of our ongoing reporting on Treasury's Terrorism Risk Insurance Program, under which the government and insurers share losses in the event of certain acts of terrorism. In 2008, we found that commercial property/casualty insurers and reinsurers generally seek to exclude coverage for NBCR risks or place significant restrictions on such coverage because of uncertainties about the risk and the potential for catastrophic losses. Treasury officials and stakeholders we interviewed for a follow-on report in 2020 agreed that primary and reinsurance coverage for NBCR events is limited, resulting in many businesses having limited or no coverage. See GAO, Terrorism Insurance: Status of Coverage Availability for Attacks Involving Nuclear, Biological, Chemical, or Radiological Weapons, GAO-09-39 (Washington, D.C.: Dec. 12, 2008); and Terrorism Risk Insurance: Program Changes Have Reduced Federal Fiscal Exposure, GAO-20-348 (Washington, D.C.: Apr. 20, 2020).

The official also pointed out that NRC does not require facilities with radioactive materials to purchase NBCR coverage. This official looked into costs for NBCR coverage and found that \$1 billion in coverage would cost about \$1.5 - \$5 million annually, which the hospital could not afford. Finally, representatives from a well logging company stated that small companies like theirs typically do not buy insurance with specific riders covering their radioactive materials.

We have previously reported that the catastrophic and uninsured or underinsured losses resulting from an NBCR event, such as a dirty bomb, represent an implicit fiscal exposure for the federal government.⁴⁶ An implicit fiscal exposure is spending the federal government might be expected to incur even if it is not required to by law. Though modeling these types of losses is difficult, expert estimates and some recent events demonstrate that socioeconomic damage from a dirty bomb could range in the tens of millions to billions of dollars. For example, the National Association of Insurance Commissioners (NAIC) estimated that a dirty bomb in New York City could generate about \$158 billion in socioeconomic costs.⁴⁷ As we reported in 2020, such catastrophic losses could create a strong public expectation of federal financial assistance.

In 2019, we reported that Sandia National Laboratories (Sandia) estimated that a dirty bomb using a category 1 quantity of radioactive material could result in \$30 billion in socioeconomic costs, and a dirty bomb using a category 3 quantity of material could result in \$24 billion in such costs. While Sandia's models did not estimate the extent of insurance coverage, the limited availability of NBCR coverage in general suggests that uninsured losses would be significant in these scenarios as well. A May 2019 incident at the University of Washington (UW) illustrates the costs that could result from such scenarios (see figure 4). In that incident, a small amount of radioactive material was accidentally released during the removal of a research irradiator, resulting in approximately \$150 million in cleanup, remediation, reconstruction, and other costs,

⁴⁶GAO-20-348.

⁴⁷National Association of Insurance Commissioners, *NAIC Center for Insurance Policy and Research Terrorism Risk Insurance Act Policy Workshop* (presentation from the NAIC 2019 Summer National Meeting, August 4, 2019). NAIC is a standard-setting and regulatory support organization governed by the chief insurance regulators in each state, Washington, D.C., and the U.S. territories. NAIC based its estimates of insured losses on data collected from its members and the Department of the Treasury.

⁴⁸GAO-19-468.

according to current NNSA estimates. UW representatives stated that this estimate does not reflect the lost opportunities for researchers to execute their current grants, apply for new ones, treat patients, or to complete work necessary to meet tenure. Though not a dirty bomb, and not an uninsured incident, the accident illustrates the costs that can result from the release of even a small quantity of material,⁴⁹ even in the absence of the mass evacuations and fatalities that informed the Sandia studies reviewed in our 2019 report.⁵⁰

⁴⁹DOE estimates that 1.25 curies of cesium-137 was released. A curie is a unit of measurement of radioactivity. NRC's Part 37 security regulations establish enhanced security requirements for category 1 and 2 quantities of radioactive materials. The quantity of cesium-137 released at UW was a category 4 quantity of material. Therefore, if licensed on its own, it would not have been a large enough quantity to require enhanced security measures under Part 37.

⁵⁰According to NNSA, the UW incident is covered under indemnification provisions of the Atomic Energy Act, known as the Price-Anderson Act Amendments. These provisions indemnify DOE and NNSA contractors and subcontractors against public liability in the event of a nuclear incident for third-party damage claims related to bodily injury, sickness, disease or death, loss of or damage to property, or loss of use of property arising out of a nuclear incident.

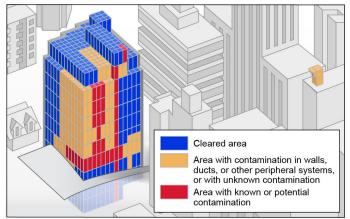
Figure 4: Cesium Release at the University of Washington, Seattle (May 2019)

A recent accident demonstrates the damage that the release of a small amount of radioactive material can cause.

In May 2019, a subcontractor for the National Nuclear Security Administration (NNSA) inadvertently breached a sealed cesium-137 source at the Research and Training building at the University of Washington (UW) Harborview Medical Center near downtown Seattle. The subcontractor was removing the irradiator under the direction of NNSA's Off Site Source Recovery Program, which UW had engaged previously in 2018 to remove three of its blood and research irradiators. The breach occurred when the subcontractor inadvertently cut into the sealed container holding cesium-137. The cut released radiation into the building's loading dock. Subsequent assessments found that radioactivity made its way throughout much of the building via the ventilation systems and elevator shaft, also reaching an adjacent building's roof, and UW closed off the entire building.

According to Department of Energy estimates, a maximum of 1.25 curies of radioactive material was released in the breach (curies are a measurement of radioactivity). Nuclear Regulatory Commission (NRC) regulations apply enhanced security requirements to certain quantities of radioactive materials, but the amount of material released in this accident, had it been licensed on its own, would not have been enough to subject it to NRC's enhanced security requirements or require tracking in NRC's licensing databases. Despite the small amount of material, representatives from UW we interviewed said that the socioeconomic consequences on UW faculty and students have been severe. Over 200 researchers and laboratory staff had to be relocated. Several researchers could not find replacement laboratories to host their research, and when grant funding was halted for research programs that could not be continued as a result of the disruption, many of these researchers sought employment elsewhere. Over 80 research programs valued in the tens of millions of dollars were affected, with only half of this productivity recovered to date, according to UW representatives. The loss of the ability to provide education to medical residents in the adjacent Harborview Hospital has also impacted UW's ability to retain and attract new residents. As of July 2021, NNSA estimates the total cost of the incident—including cleanup, remediation, reconstruction, and other costs—to be approximately \$150 million. UW representatives stated that this estimate does not reflect the lost opportunities for UW researchers to execute their current grants, apply for new ones, treat patients, or to complete work necessary to meet tenure.

According to UW officials, remediation has been completed, and the Washington State Department of Health released the building for unrestricted use on April 29, 2021. Construction activities to rebuild areas affected by the remediation work will continue into the summer, with full re-occupancy expected in late summer or early fall 2021.



Graphical depiction of areas of known or suspected contamination (as of September 2019) in the UW Research and Training Building and an adjacent building following the accidental release of radioactive cesium-137



Image of experts in protective gear preparing to sweep the UW Research and Training Building following an accidental release of radioactive cesium-137.

Sources: Department of Energy, NNSA, and GAO interviews with officials from the UW School of Medicine and the Washington State Department of Health (text); Department of Energy (photo); and GAO graphic based on information and illustrations from NNSA and Los Alamos National Laboratory (graphic). | GAO-22-104113

Government Activities Supporting Alternative Technologies Have Contributed to Progress but Lack Coordination

The development and adoption of alternative technologies to replace devices that rely on radioactive materials can help address the implicit fiscal exposure associated with the continued use of these materials, and several federal agencies and interagency entities have undertaken activities to support alternative technologies that have resulted in some progress in their development and adoption over the past 15 years. However, there is no national strategy to coordinate and implement these efforts, leading to a lack of coordination between agencies, and in some cases, resulting in agencies working at cross-purposes. This lack of coordination is ultimately impeding the federal government's ability to reduce the implicit fiscal exposure associated with the continued use of high-risk radioactive materials.

Government Activities Supporting Alternative Technologies Have Contributed to Progress

Several agencies and interagency entities are undertaking activities to support development and adoption of alternative technologies, and these efforts have made some progress over the past 15 years. For example,

Since its establishment by the Energy Policy Act of 2005, the Task
Force has issued reports every 4 years, including the evaluation of
potential efforts to develop and support the adoption of viable
alternative technologies to replace radioactive materials in the U.S.⁵¹
For example, in its 2014 report, the Task Force stated that regardless
of cost and viability differences, all Task Force member agencies

⁵¹The Task Force is required to submit a report to Congress and the President every 4 years that contains recommendations on topics. These topics include alternative technologies that may perform some or all of the functions performed by devices or processes that employ radiation sources, the establishment of appropriate regulations, and incentives for the replacement of such devices and processes in order to reduce the number of radiation sources in the U.S. 42 U.S.C. § 2210h(f).

- support efforts to further reduce security risks by developing alternative technologies as replacements, especially for cesium-137.52
- NNSA has removed a total of 355 irradiators since 2004 through OSRP and CIRP, at a cost of approximately \$100,000 per removal, according to NNSA.⁵³ CIRP typically offers to pay half the cost of new x-ray devices for users wishing to replace their irradiators with an alternative technology.⁵⁴
- DOE's Office of Science has awarded \$19.3 million from 2016 to 2020 through its Accelerator Stewardship Program for basic research into compact accelerator technologies to potentially replace technologies using radioactive materials in industries like well logging and industrial radiography. According to DOE officials, the Office of Science coordinates with NNSA to determine DOE's funding priorities for alternative technology research and development.
- OSTP published a guide in 2016 outlining best practices federal agencies could use to transition from radioactive materials to alternative technologies. The report recommended, among other things, that federal agencies currently using technologies that employ radioactive materials should evaluate whether to incorporate into their internal policies and procedures justification of the benefits of those devices relative to alternative technologies. The guide also recommended that agencies incentivize transitions to alternative technologies in the private sector by, for example, supporting disposal of radioactive material, providing financial incentives for device replacements, and investing in research and development to expand the commercial availability of alternative technologies.

⁵²U.S. Nuclear Regulatory Commission, Report to the U.S. President and Congress under Public Law 109-58 (The Energy Policy Act of 2005): The 2014 Radiation Source Protection and Security Task Force Report (Washington, D.C.: Aug. 14, 2014).

⁵³Of the total of 355 irradiators removed by NNSA, 348 were cesium-137 based and seven were cobalt-60 based. According to NNSA, CIRP remains focused on cesium137-based irradiations but will on occasion remove a cobalt-60-based irradiator when it facilitates risk elimination.

⁵⁴CIRP may provide financial assistance to purchase an x-ray device to replace each irradiator or to purchase a single x-ray device to replace several irradiators, depending on the needs of the user. Because there is not always an exact one-to-one ratio of x-rays to irradiators, CIRP communicates its progress in terms of irradiators removed to avoid confusion.

 FDA, which regulates devices that sterilize medical products, has consulted with OSTP, the Task Force, and NNSA regarding the use of x-rays to replace cesium-based blood irradiation methods.

Government Activities Supporting Alternative Technologies Lack Coordination, Leaving Some Agencies Working at Cross Purposes

Though the federal government has undertaken various efforts to advance alternative technologies, there is currently no federal strategy to coordinate and implement these efforts in a manner that effectively addresses the risk presented by the continued use of high-risk radioactive materials. There is no cohesive federal strategy because the federal government has yet to resolve two opposing objectives: permanent risk reduction where possible, on the one hand, and the continued licensing of high-risk radioactive materials without an evaluation of available alternatives, on the other. As a result, agencies' efforts are uncoordinated and, in some cases, working at cross-purposes. We have previously reported that complex interagency undertakings—like advancing the development and adoption of alternative technologies across different industries—can benefit from a national strategy with certain desirable characteristics, including clear goals with meaningful performance measures and well-defined roles for agencies implementing the strategy that address organizational differences.⁵⁵ Such complex interagency undertakings also benefit from leadership with sufficient responsibility and authority to ensure efforts are well coordinated. 56 At present, federal

⁵⁵In our prior reporting, we identified six desirable characteristics of national strategies: (1) purpose, scope, and methodology; (2) problem definition and risk assessment; (3) goals, subordinate objectives, activities, and performance measures; (4) resources, investments, and risk management; (5) organizational roles, responsibilities, and coordination; and (6) integration and implementation. For the purposes of this report, we discuss issues of leadership and authority, as well as organizational challenges separately, though in our prior reporting these elements are subcomponents of the single characteristic "organizational roles, responsibilities, and coordination." See GAO, Combatting Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism, GAO-04-408T (Washington, D.C.: Feb. 3, 2004). See also, GAO, Uranium Management: Actions to Mitigate Risks to Domestic Supply Chain Could Be Better Planned and Coordinated, GAO-21-28 (Washington, D.C.: Dec. 10, 2020); and Nuclear Nonproliferation: Action Needed to Address NNSA's Program Management and Coordination Challenges, GAO-12-71 (Washington, D.C.: Dec. 14, 2011).

⁵⁶GAO-12-71; and GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010).

efforts to address alternative technologies lack these characteristics. See appendix II for a complete list of the desirable characteristics of national strategies.

No clear goals and meaningful performance measures. With the exception of cesium-137 blood irradiators—for which the fiscal year 2019 National Defense Authorization Act established the goal for NNSA to eliminate their use in the U.S. by 2027—the government has not articulated clear goals for the advancement of alternative technologies to replace high-risk radioactive materials where possible, and it has not provided a way to measure performance to help provide a clear picture of progress.⁵⁷ What goals do exist are general in nature, lack measurable targets or performance measures, and are voluntary, meaning no agency or entity is accountable to meet them. For example, the Task Force recommended in 2014 that the U.S. government, as appropriate, investigate options such as voluntary, prioritized, and incentivized programs for the replacement of Category 1 and 2 quantities of radioactive materials with effective alternatives, and it recommended that agencies lead by example in the transition to alternatives.⁵⁸ To date, the Task Force has broken down implementation of these and other recommendations into only general subtasks, which lack prioritization and performance measures to track progress.59 In addition, OSTP's 2016 Best Practices Guide provides only voluntary recommendations, and it does not suggest specific interim goals or timelines for agencies to implement the recommendations.

No clear roles to address organizational differences. No entity has addressed how organizational differences among relevant agencies could hinder the government's ability to align its collective efforts to support alternative technologies. As a result, some agencies are working at crosspurposes. For example, despite NNSA's mandated effort to eliminate the use of cesium-137 blood irradiators in the U.S., NRC also has a mandate

⁵⁷John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115–232, § 3141, 132 Stat. 1636, 2303 (2018).

⁵⁸Radiation Source Protection and Security Task Force, *The 2014 Radiation Source Protection and Security Task force Report* (Washington, D.C.: Aug. 14, 2014).

⁵⁹See, for example, U.S. Nuclear Regulatory Commission, *U.S. Nuclear Regulatory Commission Implementation Plan for the Radiation Source Protection and Security Task Force Report* (Feb. 22, 2021). This and previous Task Force reports and associated implementation plans are available at https://www.nrc.gov/security/byproduct/task-force.html.

to license cesium-137 and other high-risk radioactive material. NRC officials told us that introducing consideration of non-radioisotopic alternatives into NRC's licensing process would be inconsistent with this mandate. NNSA officials acknowledged that these functions conflict.⁶⁰

Similarly, the FDA does not require applicants seeking approval of new medical devices to justify their need to sterilize the devices with cobalt-60 versus a viable alternative technology. ⁶¹ FDA officials stated that their agency is agnostic with regard to a sterilization method; however, a recent FDA program to encourage the use of alternatives to ethylene oxide—a toxic chemical that is the most widely used form of commercial sterilization—demonstrates that FDA can promote certain methods. ⁶² FDA officials also stated that nothing would prohibit them statutorily from considering a similar effort to encourage alternatives to cobalt-60 in industrial sterilization, though FDA has no plans to do so currently.

Lack of alignment may also exist within the same agency. For example, NNSA's OSRP indirectly subsidizes the continued use of high-risk materials by paying the cost of disposal, whereas CIRP subsidizes the replacement of such materials with alternatives. NNSA officials told us that OSRP and CIRP typically work in tandem, but despite its mandated goal to eliminate blood irradiators by 2027, NNSA does not currently require OSRP to ensure that irradiators of which it disposes are replaced with alternative technologies when needed.

As stated above, NRC currently plays an indirect role in the advancement of alternative technologies by setting safety, security, and disposal requirements. These requirements affect users' costs for possessing

⁶⁰NRC stated that NRC's and NNSA's functions could be viewed as consistent with each agency's respective missions and authorities.

⁶¹FDA considers radiation from radioactive material, as well as from alternative technologies such as x-rays or electron beams, to be "established" methods, meaning they all have a long history of safe and effective use based on international voluntary consensus standards recognized by FDA.

⁶²In 2019, FDA launched two Innovation Challenges: (1) encourage the development of alternatives to ethylene oxide for medical device sterilization, and (2) develop strategies to reduce ethylene oxide emissions. According to FDA officials, the genesis of the Innovation Challenges was the forced closure of certain large sterilization facilities using ethylene oxide after EPA placed the chemical on its dangerous carcinogens list. Officials stated that FDA realized it would have a substantial role to play in the reduction in ethylene oxide's prevalence going forward due to the agency's role reviewing sterilization methods.

radioactive materials versus alternatives, according to NRC officials.63 However, the Task Force has discussed ways for NRC to play a more direct role, such as by requiring applicants for radioactive material licenses to examine alternative technologies. 64 For example, countries such as Norway and the United Kingdom currently require applicants for new radioactive materials to justify their need for such materials, which helps ensure that such materials are not being used for purposes for which a viable, less dangerous alternative exists. According to NRC officials, the agency has not taken a more direct role in the advancement of alternative technologies because they believe that doing so would not be consistent with the agency's statutory authority. Officials from NRC's Office of General Counsel noted that the Energy Reorganization Act of 1974 split the functions of the original Atomic Energy Commission (AEC) between NRC and the agency that was to become DOE. Officials noted that the promotional functions of the AEC were given to DOE, whereas the NRC was established as an independent safety regulator.65 These officials told us that this means it would be beyond NRC's statutory purview to require license applicants to choose between technologies that use radioactive materials, to ask applicants to justify their use of technologies using radioactive materials, or to ask applicants to consider

⁶³Our above analysis of the factors affecting user decisions confirms that NRC requirements play a role in business decisions about alternative technology. As discussed previously, NRC has not implemented several recommendations we have made to enhance its security framework. These recommendations, if implemented, would likely further affect user decisions. See GAO-21-453PR.

⁶⁴See U.S. Nuclear Regulatory Commission, *U.S. Nuclear Regulatory Commission Implementation Plan for the Radiation Source Protection and Security Task Force Report* (Washington, D.C.: Dec. 27, 2012). Though the Task Force did not recommend NRC require justifications at the time, it stated this approach may be more appropriate in the future when alternative technologies become viable. NRC officials said that this approach would need to be evaluated from a legal and policy standpoint.

⁶⁵The AEC was established in 1946 to research, produce, and control nuclear materials; and apply nuclear technology. Atomic Energy Act of 1946, Pub. L. No. 79-585, 60 Stat. 755. In 1974, the AEC was abolished and its functions split between the NRC and the Energy Research and Development Administration, later the DOE. Energy Reorganization Act of 1974, Pub. L. No. 93-438, 88 Stat. 1233; Department of Energy Organization Act, Pub. L. No. 95-91, 91 Stat. 565 (1977). The NRC was established as an independent entity and given the licensing and related regulatory functions of the AEC. The other functions of the AEC were transferred to Energy Research and Development Administration. Legislative history suggests that "a basic purpose of [the 1974 split was] to separate the regulatory functions of the Atomic Energy Commission from its developmental and promotional functions." S. Rep. No. 93-980 at 19 (1973).

alternative technologies.⁶⁶ Officials said that incorporating the consideration of alternative technologies into NRC's licensing process would require clear, new direction and authority from Congress.

No overall leader and authority. We have reported that complex interagency undertakings that require the cooperation of agencies exercising different statutory authorities can benefit from a national strategy that clarifies implementing organizations' relationships, including who will lead the implementation.⁶⁷ We have also reported that such undertakings benefit from leadership with sufficient responsibility and authority to ensure that efforts are well coordinated.⁶⁸ Although many agencies currently work on alternative technologies to radioactive materials, no agency or entity has responsibility or authority to manage the government's collective efforts.

Officials at NRC, NNSA, and OSTP agreed with this assessment. NNSA officials told us that the OSTP-led interagency effort to develop the White House's 2016 Best Practices Guide injected a sense of top-level investment that temporarily reinvigorated interagency coordination around alternative technologies. However, White House officials in the previous and current administrations told us that OSTP has taken no further action to date to verify if agencies are implementing these practices.

Additionally, the Task Force is charged with producing recommendations on alternative technologies to replace radioactive materials but not with implementing those recommendations. Agencies may choose to implement recommendations that are within their current authority, but no member, including NRC as chair of the Task Force, can direct others to implement such recommendations. The program-level offices that typically participate in the Task Force take direction from their own agency leadership or Congress, not the Task Force, according to a senior official who served on the Task Force. Furthermore, though NRC chairs the Task Force, NRC officials said, as noted above, that the promotion of alternative technologies is beyond their statutory purview.

⁶⁶In commenting on a draft of this report, NRC officials clarified that they believe such actions would be beyond NRC's statutory purview "absent a safety or security basis," but did not explain why they do not consider these actions to present safety or security issues.

⁶⁷GAO-04-408T.

⁶⁸GAO-12-71.

Previous studies and legislation provide helpful examples of strategies the government could use to better support alternative technologies. For example, in 2008, the National Academies issued a report outlining policy options to replace technologies using radioactive material with alternatives, such as by tying licensing fees to radioactive materials' risk level or subsidizing the cost of testing and certification for users willing to replace their devices with alternative technologies. 69 The National Academies updated this report in 2021, finding that, while there has been progress in adopting alternative technologies to radioactive sources, adoption has progressed at different rates for different applications, and for some applications, no suitable replacement technology has been developed.⁷⁰ The White House's 2016 best practices guide, though voluntary and lacking long-term goals, provides specific actions federal agencies can take to incorporate the transition to alternative technologies into their strategic plans, such as by requiring programs to justify using technologies employing radioactive materials over an alternative.

Section 3141 of the fiscal year 2019 NDAA includes elements that align with the desirable characteristics of a national strategy, including (1) a goal for NNSA to remove cesium-137 blood irradiators from the U.S. by 2027;⁷¹ (2) the requirement that NNSA develop a plan to achieve the goal to remove irradiators; (3) accountability mechanisms in the form of two required reports to Congress; and (4) direction that NNSA consult with NRC and FDA in the development of a strategy outlining legislation, regulation, or other measures to constrain the introduction of new cesium-137 blood irradiators into the U.S. market.⁷²

Conclusions

Radioactive materials will continue to play an important role in medicine, industry, and research for the foreseeable future. Nonetheless, the federal government can do more to encourage greater use of alternatives in order to reduce the quantity of high-risk radioactive material in use

⁶⁹National Research Council of the National Academies, *Radiation Source Use and Replacement: Abbreviated Version* (Washington, D.C.: 2008).

⁷⁰National Academies of Sciences, Engineering, and Medicine, *Radioactive Sources*.

⁷¹As noted above, however, this goal is at cross-purposes with NRC's continuing mandate to license such technology.

⁷²John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115–232, § 3141, 132 Stat. 1636, 2303 (2018).

around the country for different applications. The lack of a national strategy for permanent risk reduction through development and adoption of alternative technologies has left the federal government vulnerable to the implicit fiscal exposure associated with the theft or accidental release of high-risk radioactive materials. The cesium-137 release at UW, the recent theft of radioactive materials in Arizona, and our recent report outlining potential socioeconomic costs from a dirty bomb demonstrate the risk presented by the continued use of even small quantities of highrisk radioactive materials, especially when viable technology alternatives already exist.⁷³ Without a national strategy guiding the federal government's alternative technology efforts, agencies will continue to operate without meaningful goals, clear roles, or leadership and authorities that can ensure accountability and an alignment of functions. The current lack of coordination—and in some cases, contradiction of effort—is resulting in tax payer dollars being devoted to, on the one hand, reducing the risk associated with high-risk radioactive materials. On the other hand, it supports the continued licensing of such materials without, at a minimum, requiring the consideration of alternatives. This lack of coordination ultimately leaves the federal government vulnerable to the implicit fiscal exposure associated with addressing large-scale socioeconomic damage that could be caused by the mishandling of radioactive materials or their release through a dirty bomb.

Matters for Congressional Consideration

We are making the following three matters for congressional consideration:

If Congress agrees that replacing technologies that use high-risk radioactive materials with alternative technologies is a priority to achieve permanent risk reduction, then it should consider establishing this goal in statute, and then take the steps necessary to establish—including directing an appropriate interagency entity to develop—a national strategy to achieve this goal. The strategy should include all the desirable characteristics of national strategies that we have previously identified, including specific goals and performance measures, clear roles, and proposals to provide relevant authorities to execute these roles, as necessary. (Matter for Consideration 1)

⁷³GAO-19-468.

If Congress believes that actions included in a national strategy for replacing technologies that use high-risk radioactive materials with alternative technologies should be implemented, then Congress should consider directing the relevant agencies to implement the strategy in accordance with the goals and timelines identified in the strategy. To facilitate agencies' implementation, Congress should provide authority to agencies to implement any aspects of the strategy not currently within their authorities. (Matter for Consideration 2)

If Congress agrees that replacing technologies that use high-risk radioactive materials with alternative technologies is a priority to achieve permanent risk reduction, then it should consider directing and authorizing, as necessary, NRC to incorporate the consideration of alternative technologies into its licensing process. Options could include: (1) direct NRC to implement a justification process, or (2) direct NRC to require applicants for new radioactive materials to consult with other agencies (such as NNSA or FDA) about alternatives before NRC will consider an application. (Matter for Consideration 3)

Agency Comments and Our Evaluation

We provided a draft of this report to the Chairman of NRC; the Secretaries of DOE, DHS, and Treasury; the Administrators of NNSA and FDA; the Director of NIH; and the Principal Assistant Director for National Security and International Affairs in the White House Office of Science and Technology Policy.

In its written comments, NRC officials neither agreed nor disagreed with our matters for congressional consideration. They did state that they consider security and appropriate control of nuclear and radioactive materials to be a top priority for the agency. Specifically, NRC officials said that the agency, in coordination with the agreement states, has developed a robust program of security measures for nuclear and radioactive material that is focused on providing protection commensurate with the risk associated with the material.

Five agencies (DHS, DOE, NIH, NNSA, and NRC) provided technical comments, which we incorporated as appropriate. Further, we received emails from officials of FDA, OSTP, and Treasury. In all of those emails, the officials stated that the entities had no comments on the draft report.

We are sending copies of this report to the appropriate congressional committees; to the Chairman of NRC; the Secretaries of DOE, DHS, and Treasury; the Administrators of NNSA and FDA; the Director of NIH; the Principal Assistant Director for National Security and International Affairs in the White House Office of Science and Technology Policy; and other interested parties. In addition, this report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or bawdena@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made significant contributions to this report are listed in appendix IV.

Allison Bawden

Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

Senate Report 116-102 includes a provision for us to review the use of alternative technologies that would function in place of those that rely on radioactive materials. This report examines (1) the potential for adopting non-radioisotopic alternative technologies in medical and industrial applications; (2) factors affecting adoption of non-radioisotopic alternative technologies; and (3) the federal government's efforts to coordinate federal activities relating to non-radioisotopic alternative technologies in the United States.

To examine the potential for adopting non-radioisotopic alternative technologies in the medical and industrial sectors, we used a two-step process. First, we identified six applications that use either americium-241, cesium-137, cobalt-60, or iridium-192,¹ based on three criteria: (1) the socioeconomic and health hazards presented by the potential release of the radioactive material, (2) the prevalence of the application in the U.S. economy, and (3) the vulnerability of the material to theft. Second, for each of these applications, we collected information on the technical viability of each potential alternative technology based on a variety of factors, including technical maturity, performance, physical nature of the device, and power requirements. Specifically, we reviewed relevant reports addressing alternative technologies, including published reports from the National Academies of Sciences, Engineering, and Medicine (National Academies); the World Institute for Nuclear Security; and the Department of Homeland Security (DHS).²

We also conducted 21 interviews with knowledgeable stakeholders and current and former users of devices with radioactive material in the medical and industrial sectors to obtain their views on technical viability of each alternative, including the technical maturity, performance, physical

¹The National Nuclear Security Administration (NNSA) has identified four high-risk isotopes as being the most prevalent in commercial use: americium-241, cesium-137, cobalt-60, and iridium-192.

²See National Research Council of the National Academies, *Radiation Source Use and Replacement*; World Institute for Nuclear Security, *Considerations for the Adoption of Alternative Technologies*; U.S. Department of Homeland Security, Cybersecurity and Infrastructure Agency, *Non-Radioisotopic Alternative Technologies White Paper*; and National Academies of Sciences, Engineering, and Medicine, *Radioactive Sources*.

nature, and power requirements. Our interviewees included medical professionals involved with blood irradiation and medical research who use cesium-137 irradiators, officials from the industrial sterilization industry overseeing cobalt-60 panoramic irradiators, industrial radiographers using iridium-192 to detect cracks in pipelines, and well loggers using americium-247 to evaluate oil and gas wells. The interviews were conducted by videoconference and by telephone, and the interviewees did not represent a statistically significant number of users of radioactive materials. Therefore, our results are non-generalizable. We identified organizations that have switched to alternative technologies, have not switched, and have made the switch but had reservations about doing so. We supplemented these interviews by attending five public meetings put on by the National Academies of Sciences, Engineering, and Medicine (National Academies) to evaluate the current state of alternative technologies and reviewed materials presented during those meetings.

The interviewees and relevant reports were identified with guidance from relevant agencies involved in alternative technologies to help ensure the testimony we obtained was as balanced as possible. We were invited to the public meetings by the National Academies, which was also working on a report evaluating alternative technologies. Our interviews with experts and users of radioactive material were semi-structured to ensure we asked similar questions and covered the information in a consistent manner. We presented the information we gathered about technical viability in our first section of this report.

To understand the factors affecting adoption of non-radioisotopic alternative technologies, we conducted semi-structured interviews addressing factors with 21 knowledgeable stakeholders and users of radioactive material in the medical and industrial sectors. We also attended five public meetings put on by the National Academies that included discussions of factors. During our interviews, we discussed the factors they take into consideration when evaluating whether to switch to alternatives. We also undertook a content analysis to list these factors and assign determinations to indicate whether each factor represented an incentive to switching to alternative technologies or a disincentive. For example, a user of cesium-137 blood irradiators told us that the U.S. Nuclear Regulatory Commission's (NRC) Part 37 security regulations create a hardship to running their blood operation. We understood this to mean that replacing their irradiators with an alternative technology would be an advantage, as they would no longer have to comply with the security regulations. In contrast, a user of iridium-192 industrial

radiography devices said that x-rays cannot compete economically with radioisotopes, which we understood to mean that x-rays were not yet a technically viable alternative. After one analyst completed the assignation of determinations, a second analyst reviewed the results and either agreed or disagreed with the findings. The two analysts met, reconciled their views, and came to agreement on final determinations. The first step of the analysis found 17 factors, which were grouped into six high-level factors based on thematic linkages and confirmed by the two analysts. We concluded the analysis by counting up whether each factor inclinded each user toward or against adopting alternatives.

We also spoke to university officials and reviewed studies related to the 2019 accidental release of cesium-137 at the University of Washington, which demonstrated the socioeconomic costs that can result from the release of radioactive materials. These interviews included university officials and doctors, National Nuclear Security Administration (NNSA) officials involved with the removal of the cesium-137 irradiator, and officials from the Washington State Department of Health. The studies we reviewed included the Joint Investigation Report and summary documentation from NNSA.

Finally, we reviewed previous GAO reports, reviewed federal terrorism insurance regulations, and spoke to officials in the insurance industry to describe the risk to the federal government associated with a dirty bomb attack. Specifically, we reviewed GAO reports addressing the Terrorism Risk Insurance Program (TRIP) and spoke to the analysts about their findings. We also spoke to officials at Treasury about how TRIP functions and whether it addresses nuclear, biological, chemical, or radiological (NBCR) events. Finally, we spoke to officials and experts in the insurance industry to understand the socioeconomic costs of a dirty bomb attack and the preparedness of the private insurance industry to respond to an NBCR attack.

To evaluate the current status of federal activities relating to alternative non-radioisotopic technologies, we interviewed officials at agencies, including NRC, NNSA, DHS, the Office of Science and Technology Policy, and the Food and Drug Administration to discuss what actions they are taking in regards to alternative technologies. We also reviewed legislation, regulations, and guidance affecting federal alternative technology activities and interagency efforts. Finally, we reviewed prior GAO reports addressing coordination between agencies and the implementation of national strategies.

Appendix I: Objectives, Scope, and Methodology

We conducted this performance audit from March 2020 to October 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Summary of Desirable Characteristics of National Strategies

Appendix II: Summary of Desirable Characteristics of National Strategies

Desirable characteristic	Description
Purpose, scope, and methodology	Addresses why the strategy was produced, the scope of its coverage, and the process by which it was developed.
Problem definition and risk assessment	Addresses the particular national problems and threats the strategy is directed towards.
Goals, subordinate objectives, activities, and performance measures	Addresses what the strategy is trying to achieve, steps to achieve those results, as well as the priorities, milestones, and performance measures to gauge results.
Resources, investments, and risk management	Addresses what the strategy will cost, the sources and types of resources and investments needed, and where resources and investments should be targeted based on balancing risk reductions with costs.
Organizational roles, responsibilities, and coordination	Addresses who will be implementing the strategy, what their roles will be compared to others, and mechanisms for them to coordinate their efforts.
Integration and implementation	Addresses how a national strategy relates to other strategies' goals, objectives, and activities; and to subordinate levels of government and their plans to implement the strategy.

Source: GAO, Combatting Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism (Washington, D.C.: Feb. 3, 2004). I GAO-22-104113



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 29, 2021

Ms. Allison Bawden, Director Natural Resources and Environment U.S. Government Accountability Office 441 G Street, NW Washington, DC 20548

Dear Ms. Bawden

Thank you for the opportunity to review and comment on the United States Government Accountability Office (GAO) draft GAO-22-104113 report, "Alternatives to Radioactive Materials: A National Strategy to Support Alternative Technologies May Reduce Risks of a Dirth Bomb," which the U.S. Nuclear Regulatory Commission (NRC) received on August 25, 2021. The NRC has general comments, which are provided below, and more specific comments on the report, which are provided in the enclosure.

As noted in the draft GAO report, the NRC was established by Congress to regulate the civilian use of radioactive materials in the United States, with a non-promotional safety and security mandate. The NRC was granted broad authority for the regulation of radioactive material to provide reasonable assurance of adequate protection of the public health and safety and common defense and security in the use of such materials.

The security and appropriate control of nuclear and radioactive materials is a top priority for the NRC. Together, the NRC and the Agreement States have established a strong regulatory framework that ensures the safety, security, and control of radioactive materials and discrete sources. This framework includes Title 10 of the Code of Federal Regulations (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," to ensure the appropriate access to, secure storage of, and effective detection, assessment, and response to any unauthorized access to risk-significant radioactive materials. The framework also includes robust oversight and enforcement programs. There are an estimated 2 million radioactive sources and devices in the United States, including approximately 80,000 risk-significant Category 1 or Category 2 sources. Since the 2013 implementation of 10 CFR Part 37, there have not been any incidents that have resulted in unrecovered Category 1 and 2 radioactive sources.

The NRC's mission and regulatory framework are complemented by those of several other Federal and State agencies. Each of these agencies, including the Department of Homeland Security, the Department of Energy and the Food and Drug Administration, plays an integral role in the domestic architecture for radioactive material safety and security while also ensuring risks are adequately mitigated so that the United States reaps the societal benefits of many technologies.

The NRC staff participates in multiple fora, both formal and informal, that contribute to the advancement of safety and security nationwide, and many of them include discussions of various non-isotopic technologies. Informal activities have included participation in public

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meetings of the National Academies of Sciences, Engineering, and Medicine, Nuclear and Radiation Studies Board, cooperation in interagency working groups to streamline international grantmaking for linear accelerators for cancer treatment in underserved countries, and periodic information sharing with other Federal partners on new or existing programs. Most recently, the NRC staff and the National Nuclear Security Administration worked collaboratively to develop Key messages regarding information available on domestic programs for the replacement of cesium irradiators.

Formally, through the Radiation Source Protection and Security Task Force (Task Force), 14 federal agencies, and others, coordinate on a routine basis to ensure that the United States is appropriately positioned to protect the country from potential terrorist threats, such as the use of radioactive material in a radiological dispersal device or a radiation exposure device. Alternative technologies is a specific area of consideration by the Task Force as a whole, with specific programs noted by agencies with statutory authority to support them. In October 2018, the Task Force submitted a report to the President and Congress (Agencywide Documents Access and Management System Accession No. ML18276A155), in which the 14 Task Force member agencies concluded that there are no significant gaps in the area of radioactive source protection and security that are not already being addressed by ongoing efforts of the appropriate agencies. The Task Force is currently working to draft the next report, which will be submitted to the President and Congress in 2022.

Consistent with these roles and responsibilities, the NRC staff, in coordination with its Agreement State partners, has developed a robust program of security measures for nuclear and radioactive materials that is focused on providing protection commensurate with the risk associated with the material. The United States was the first country in the world to require such enhanced security requirements for radioactive materials, and both Federal and State regulators actively oversee licensee implementation of these requirements to ensure that such materials remain secure throughout the lifecycle—from manufacture through disposal, and including long-term storage if disposal is not an option. As such, the security of Category 1 and 2 radioactive materials at domestic facilities has greatly improved since the terrorist attacks of September 11, 2001. In addition, the NRC will continue its efforts to improve the security of radioactive material and discrete sources, in coordination with Federal, State, and international partners. In partnership with appropriate elements of the United States Government, the NRC will also continue to evaluate the current domestic threat environment, to ensure its security rules and regulations are risk-informed, appropriate, and effective.

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While the NRC does not take a position on the matters for congressional consideration included in the draft report, the agency is providing comments for GAO's consideration as GAO finalizes the report. Thank you for the opportunity to review the draft report. Should you have any questions concerning these comments, please contact John Jolicoeur at (301) 415-1642.

Sincerely,

Mayart Th Joane Signed by Doane, Margaret on 09/29/21

Margaret M. Doane Executive Director for Operations

Enclosure: NRC comments on draft report GAO-22-104113

cc: Mr. Edwin Woodward, GAO Mr. Jeffrey Baron, GAO

Agency Comment Letter

Text of Appendix III: Comments from the Nuclear Regulatory Commission

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September 29, 2021

Ms. Allison Bawden, Director Natural Resources and Environment U.S. Government Accountability Office 441 G Street, NW Washington, DC 20548

Dear Ms. Bawden:

Thank you for the opportunity to review and comment on the United States Government Accountability Office (GAO) draft GAO-22-104113 report, "Alternatives to Radioactive Materials: A National Strategy to Support Alternative Technologies May Reduce Risks of a Dirty Bomb," which the U.S. Nuclear Regulatory Commission (NRC) received on August 25, 2021. The NRC has general comments, which are provided below, and more specific comments on the report, which are provided in the enclosure.

As noted in the draft GAO report, the NRC was established by Congress to regulate the civilian use of radioactive materials in the United States, with a non-promotional safety and security mandate. The NRC was granted broad authority for the regulation of radioactive material to provide reasonable assurance of adequate protection of the public health and safety and common defense and security in the use of such materials.

The security and appropriate control of nuclear and radioactive materials is a top priority for the NRC. Together, the NRC and the Agreement States have established a strong regulatory framework that ensures the safety, security, and control of radioactive materials and discrete sources. This framework includes Title 10 of the Code of Federal Regulations (10 CFR)

Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," to ensure the appropriate access to, secure storage of, and effective detection, assessment, and response to any unauthorized access to risk-significant

radioactive materials. The framework also includes robust oversight and enforcement programs. There are an estimated 2 million radioactive sources and devices in the United States, including approximately 80,000 risk-significant Category 1 or Category 2 sources. Since the 2013 implementation of 10 CFR Part 37, there have not been any incidents that have resulted in unrecovered Category 1 and 2 radioactive sources.

The NRC's mission and regulatory framework are complemented by those of several other Federal and State agencies. Each of these agencies, including the Department of Homeland Security, the Department of Energy and the Food and Drug Administration, plays an integral role in the domestic architecture for radioactive material safety and security while also ensuring risks are adequately mitigated so that the United States reaps the societal benefits of many technologies.

The NRC staff participates in multiple fora, both formal and informal, that contribute to the advancement of safety and security nationwide, and many of them include discussions of various non-isotopic technologies. Informal activities have included participation in public

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meetings of the National Academies of Sciences, Engineering, and Medicine, Nuclear and Radiation Studies Board, cooperation in interagency working groups to streamline international grant making for linear accelerators for cancer treatment in underserved countries, and periodic information sharing with other Federal partners on new or existing programs. Most recently, the NRC staff and the National Nuclear Security Administration worked collaboratively to develop Key messages regarding information available on domestic programs for the replacement of cesium irradiators.

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Sincerely,

Margaret M. Doane Executive Director for Operations

Enclosure:

NRC comments on draft report GAO-22-104113

cc: Mr. Edwin Woodward, GAO

Mr. Jeffrey Baron, GAO

Appendix IV: GAO Contact and Staff Acknowledgments

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GAO Contact

Allison Bawden at (202) 512-3841 or bawdena@gao.gov

Staff Acknowledgments

In addition to the contact named above, Ned Woodward (Assistant Director), Jeffrey Barron (Analyst in Charge), David Wishard, William Bauder, Stephen Brown, Antoinette Capaccio, Pamela Davidson, Corinna Nicolaou, and Dan Royer made contributions to this report.

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