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Paper

The Gap in Insurance Liability for Blood and Research Gamma Irradiators

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***Abstract*—In 2019, a federal contractor accidently breached a 2,900 Ci ^{137}Cs sealed source while decommissioning it from a University of Washington research building, releasing a single digit curie of its contents. This event contaminated 13 people as well as all seven floors of the research building, which housed the radiation source. Estimates for clean-up costs and lost revenue exceeded $150 million. The magnitude of this cost prompted licensees in possession of such radioactive sources to question whether their insurance coverage is adequate to cover a large-scale incident and if coverage for such exposure even exists. In this article, we identify potential gaps in commercially available insurance policies by evaluating and assessing associated risks, damages, and accountability. While insurance can mitigate the expense associated with remediation, it is unlikely that sufficient limits would exist to fully protect healthcare institutions from direct financial liability in the event that their radioactive sources are implicated in a nuclear, chemical, biological, or radiological (NCBR) (sometimes called CBRN in other literature) mass contamination event. This paper seeks to outline how the risks and liability to healthcare institutions having such gamma irradiators can be reduced significantly by removing them rather than seeking to insure against the cost of remediation in the event of a leak and/or mass contamination. As such, licensees are encouraged to check their policies for the correct coverage and make sure any coverage restriction is removed from their policies. In addition, licensees are also encouraged to explore financial incentives offered by the US government programs to not only dispose of their present gamma irradiator sources at no cost but also to provide financial support to replace them with alternative technologies.**

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INTRODUCTION

HIGH-ACTIVITY SEALED ^{137}Cs and ^{60}Co sources have been in use since the 1950s, most commonly in biomedical institutions and healthcare, as well as in other industrial applications. Cesium-137 irradiators have been in use for many years. Approximately 10% of donated blood, about 3 million units per year, is irradiated in a production mode by blood centers and medical institutions largely to prevent transfusion-associated graft vs. host disease (TA-GvHD) for certain patients (Sullivan et al. 2007). Biomedical and small animal irradiations are mostly used for research purposes at universities and hospitals (Dodd and Vetter 2009). Cesium-137 was selected for irradiation purposes because of its desirable monoenergetic (662 keV, for unshielded photons) gamma energy emission, moderate shielding requirements relative to some other radioisotopes (e.g., ^{60}Co), long half-life, and relative low cost (byproduct of the nuclear irradiators). However, obtaining such sources involves a responsibility to manage them over the course of their life time. Cesium-137 has a half-life of 30 y, and considering that many irradiators used in medical applications use sources on the order of thousands of Ci, even 10 half-lives or 300 y of decaying would not be sufficient to reduce the source to quantities that would not be a risk to the general public (non-SI units are used here to be consistent with NRC NUREG 1556 Vol 9's Table 8-1, which lists the Financial Assurance thresholds in Ci rather than Bq). Cobalt-60, also prevalently in use, has a half-life of 5.27 y but involves similar risk.

Given their long half-lives, widespread contamination with such isotopes would require extensive decontamination, and any remaining contamination would take many years to fully dissipate. Therefore, the risk associated with owning and maintaining such isotopes must be a high priority for licensees. There are two primary ways that such isotopes could cause an event of mass contamination: (1) accidental release and (2) purposeful release.

Accidental release

There have been accidental releases of radioactive isotopes with long half-lives that have proved extremely costly to remediate. Some examples of accidental release are summarized below.

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Example 1: 1987—Goiânia, Brazil. A cesium release accident occurred on 13 September 1987 in the Brazilian state of Goiáns. An old radiotherapy source was accidentally taken from an abandoned hospital site in the city of Goiânia and then subsequently handled by many people. The event resulted in four deaths from overexposure to the material. Also, 112,000 people were screened for radioactive contamination, and 249 were found to have significant levels of radioactive material in or on their bodies. The radiation source involved in the Goiânia accident was a small capsule containing about 93 grams of highly radioactive cesium chloride (^{137}CsCl) encased in a shielding canister made of lead and steel. The International Atomic Energy Agency (IAEA) notes that the source contained 50.9 TBq when it was taken but only about 44 TBq, or 87% of the original activity, of contamination was recovered during the cleanup operation. A key lesson learned from this event was that < 100 g of CsCl powder resulted in more than 40 tons of radioactive waste. Extrapolating from this example, if a similar event were to occur in 2022 in a densely populated area, the result could be economically devastating (IAEA 1988).

Example 2: 2019—Seattle, United States. This incident occurred on 2 May 2019 at the University of Washington Harborview Medical Center during a source recovery operation performed by the subcontractor supporting the National Nuclear Security Administration's (NNSA) Off-site Source Recovery Program. During the recovery operation, a 2,900-Ci sealed source was breached while being removed from the source holder to be placed in a special form capsule for packaging. This breach resulted in contamination within the facility, impacting multiple onsite personnel (HPS 2021a and HPS 2021b). Medical evaluations later cleared all individuals and determined the exposure did not pose a health risk to the individuals or public. A technical analysis estimated that 1 Ci of cesium chloride was released during the accident. The US Department of Energy (US DOE) spent 2 y remediating the contamination and reconstructing portions of the building prior to re-occupation. The total loss from the incident is estimated to be over $150 million (Joint NNSA/TNS 2020). There is no official statement regarding which party/parties covered these costs, but based on personal communications, it seems that the US Department of Energy (DOE) absorbed all the financial losses. This is also likely a complex estimate because the joint report indicates that subcontractors and sub-subcontractors were involved with their own insurance policies for such work.

Purposeful release attempts

Since 11 September 2001, there has been heightened concern around a terrorist attack, which incorporates radioactive material to manufacture a dirty bomb, and there have been several such attempts globally. As defined by the US Nuclear Regulatory Commission (NRC), a "dirty bomb" is a type of "radiological dispersal device" that combines a conventional explosive, such as dynamite, with radioactive material. While none resulted in any radiation being released, it is worth noting that attempts to use such a weapon persist. Some examples of attempted purposeful release follow.

Example 1: 1995, 1998—Chechnya. There have been two known cases of fabricated cesium-containing bombs, neither of which detonated. The first attempt at radiological terror was carried out in November 1995 by a group of Chechen separatists, who buried a ^{137}Cs source wrapped in explosives at the Izmaylovsky Park in Moscow (Krock and Deusser 2003; Ackerman 2016). A Chechen rebel leader alerted the media, but did not activate the bomb. The incident amounted to a publicity stunt. In December 1998, a second attempt was announced by Chechen security services, who discovered a container filled with radioactive materials attached to an explosive mine. The bomb was hidden near a railway line in the suburban area of Argun, 16 km east of the Chechen capital of Grozny. The same Chechen separatist group was suspected of involvement (Krock and Deusser 2003; Ackerman 2016).

Example 2: 2002, 2004—United States. In June 2002, Jose Padilla, a US citizen with links to Al-Qaeda, was arrested in Chicago, IL, for planning to build and detonate a dirty bomb, though no radiological dispersal device was actually found in that case (Cato Institute 2020). In August 2004, Dhiren Barot was arrested for planning to blow up the New York Stock Exchange with a dirty bomb. The intended plan was to collect ^{241}Am from thousands of smoke detectors, develop a dirty bomb, and detonate it in downtown New York City. Fortunately, the terrorist cell was discovered long before they had amassed enough material to create such a device. While the plan was fundamentally defective due to the large quantities of americium needed to make an effective weapon, the group's planning was unusual for being more extensive and detailed than others at the time (Mueller 2020).

Example 3: 2016—Belgium. In 2016, Belgium experienced a series of coordinated terror attacks that killed 32 people and injured 340. It was discovered that several of the attackers had surveilled a nuclear power station prior to the attack. Belgium's Federal Agency for Nuclear Control noted that if the radioactive material had been used in the attacks, there would have been significant remediation costs for contamination cleanup, in addition to an increased number of human casualties caused by the explosions (Chad et al. 2016).

The above cases demonstrate the financial risk to licensees of either an accidental release or a criminal act that uses the licensees' irradiator source. Licensees may face legal action for lack of sufficient prevention and security measures in addition to the cost of loss of life, physical damage, remediation, business interruption, loss of revenue, etc. These costs are hard to estimate, but a baseline consideration is $150 million based on the real cost to remediate the University of Washington release.

DAMAGE COST ANALYSIS AND REMEDIATION

Damage cost analysis and remediation will depend on the degree to which human life, physical structures, and loss of other revenues, etc., are impacted. Relevant factors include:

- Location of release;
- Population density in the vicinity of the source;
- Degree of dispersion of radioactive material;
- Time to discovery;
- Activity of the source (in Curies);
- Response time for first responders;
- Extent of business interruption (first party and third party);
- Ability to dispose of radioactive clean-up material; and
- Any negligence associated with the proper security of the source irradiator.

Many other factors could affect dispersion of the material and impact subsequent contamination.

POTENTIAL FOR INCREASED COST TO REMEDIATE DUE TO DEFICIENT RESPONSE TRAINING

The speed with which a response to a release occurs is an externality over which licensees have no control but can greatly affect the ultimate cost of remediation. In August 2019, the journal *Health Security* published some alarming results from a survey that assessed firefighters' and emergency medical service personnel's knowledge and training on radiation exposures and safety. This study found that first responders' knowledge of radiation exposure and prevention is insufficient. In particular, more than 64% of the 433 first responders who participated in the survey said they had zero hours of training in responding to a dirty bomb (Rebmann et al. 2019). An earlier survey conducted by Reilly et al. (2007) found that a mere 30% of Emergency Medical Service (EMS) professionals had been trained in radiological terrorism. The same team also found that only 10% of EMS personnel in a survey received training from public health officials—even though all EMS personnel are regulated by public health departments, which determine training requirements and issue compliance directives (Markenson et al. 2005). In a 2006 radiological terrorism simulation study with EMS personnel, many participants did not correctly identify when patient decontamination was needed, and three quarters entered the hot zone without wearing appropriate personal protective equipment (Kobayashi et al. 2006). Lack of training and experience will amplify the inherent risk and hazards associated with an accidental or purposeful radiological release.

IRRADIATOR SECURITY

Licensees of radioactive irradiators shall comply with the NRC regulations in 10 CFR part 37, which mandates extra security for high activity radioactive sources. In addition, the NNSA offers Federal support for licensees who volunteer to enhance (Harvey 2014) the security of their facilities beyond the level required by the regulations. Although these measures provide an additional measure of protection, risk for misuse by criminals or terrorists remains a concern.

Accidental release

An accidental release can occur during an earthquake or other natural disaster, against which the licensee cannot predict or fully safeguard. The University of Washington complied with all required security protocols, and an accident still happened.

Purposeful release

The DOE's Office of Radiological Security and the `NRC have worked diligently for decades to ensure that security around such irradiators involves protection by multiple layers of security, both stand-alone and overlapping, from outside agents. However, no security system is foolproof, so the risk of a purposeful release cannot be fully eliminated. A source could be seized by other parties to purposefully contaminate a public area and expose members of the public to harmful quantities of radiation.

An example case where, despite multiple strong security measures, a source was left vulnerable took place in May 2015 in a property owned by Avax Technologies (US NRC 2019b). The biotech company owned a 600-Ci ^{137}Cs research irradiator so they could use it on their rented Philadelphia property, but after they ceased operation in 2014, they left their source behind. The property management only notified the Department of Environmental Protection (DEP) in May 2015, at which point the landlord had already disabled the irradiator's required security measures to inventory the area. These included a key card entry system, locks on the entrance doors, and 24-h surveillance of the clean room where the source itself was located. After the DEP investigated on-site, these security measures were restored and local authorities were notified. Avax still wanted to retain the source, so the DEP required them to include a surety bond and provide assurances that security would be maintained by Avax at all times. Had the DEP not taken action, there would have been an unsecure ^{137}Cs source only blocks away from a Papal visit scheduled to take place in September 2015. In June 2016, Avax could no longer maintain security due to the company's lack of payment to the landlord and suppliers, so the DEP decided to dispose of the source. The bond allowed the DEP to cover most of the costs, approximately $144,000, besides the actual disposal which was $68,000 (US NRC 2019b). In the context of source management, this type of disposal refers to the isolation of a radioactive source in a licensed low-level radioactive waste facility and is not the same as disposition. Disposition refers to the transfer of radioactive sources to a different location and/or licensee for subsequent reuse, recycling, or disposal. This event is an example of how security could be circumvented in unexpected ways that may endanger members of the public with unsecure radioactive sources.

COST AND RISK SHARING

The owner of the source irradiator would bear the cost of damages and remediation in the event of a release. Some of the risks associated with the potential cost could be transferred to another party by purchasing an insurance policy. Insurance policies will only cover terrorism if the owner decides to purchase such coverage. It is important to note that with respect to insurance, coverage would be subject to the policy limits and exclusions, which could still leave the owner liable for a large portion of the cost. In the event of radioactive material release - whether accidental, a result of negligence, or perhaps even due to criminal activity - the party responsible (the licensee) for the damages will have to consider how to mitigate such costs from becoming direct expenses.

INSURANCE—BACKGROUND

Insurance policies are risk transfer mechanisms that are often used to hedge against the risk of financial loss. Commercial insurance programs have adapted over time as a response to factors such as:

- New exposures encountered by clients that were not contemplated under existing programs;
- Coverage restrictions added to standard policies which now cause a gap in coverage to the Insured; and
- Loss history analysis, which has caused carriers to be reactive and add coverage restrictions or full coverage exclusions to their insurance program.

Prior to the World Trade Center attacks on 11 September 2001, insurance policies inadequately addressed terrorist attacks in the context of their coverage, and in many cases, such events were by default covered by commercial property insurance companies. Beyond the obviously devastating loss of life, the 9/11 attack had a significant financial impact. According to the Institute for the Analysis of Global Security, there were over $100 billion in losses related to property damage, loss of production of goods and services, and the lost potential of those killed. Total insured losses from 9/11 reached approximately $40 billion (IAGS 2003). The payment for the human costs of the disaster came from the 9/11 compensation fund at a rate of $400,000 per injury and $2 million per death, with a total of $7 billion paid to 5,300 people (Feinberg 2022). This magnitude of insurance payouts resulted in 45 states allowing insurance companies to exclude acts of terrorism from property and casualty policies—all within 1 y of the attack (III 2021).

In response to the terror attack of 9/11, the Terrorism Risk Insurance Act (TRIA) was enacted, and it created the Terrorism Risk Insurance Program (TRIP). This made coverage available to insureds of commercial insurance policies for losses arising out of a terrorist act. However, this coverage does not overtly include damages and losses from terrorist activities using radiologic or other NCBR weapons. In fact, commercial high-value-property policyholders reported that they could not obtain NCBR coverage because of insurers' worries surrounding risk and the potential for significant losses. Today, this uncertainty continues to hinder the ability to accurately set a price for commercial insurance premiums that do provide coverage for radiologic terrorist acts (Klitzman and Freudenberg 2003).

In a May 2020 report, the Advisory Committee on Risk-Sharing Mechanisms (ACRSM) issued recommendations and outlined concerns with the current state of the TRIP (USDT 2020). The expert panel questioned the ability of the Federal Insurance Office to effectively administer the program when insurers continue to not fully understand how to price terrorist acts. This uncertainty leads to poor communication and a reduced understanding of the benefits of risk mitigation (USDT 2020). An earlier report in 2019 by AON, before TRIA was reauthorized until 2027 (CRS 2019), had similar concerns but also recommended that the program is necessary (AON 2019).

In most cases, standard facility insurance policies do not include coverage for acts of terrorism, and it is unclear if NCBR attacks are adequately addressed by TRIA. The US nuclear power plant industry is protected from any such liability and is government-backed via the Price-Anderson Act (ANS 2005), but medical use licensees are not explicitly offered the same option of pooled no-fault insurance. The purpose of the Act is to "ensure the availability of a large pool of funds (currently about $10 billion) to provide prompt and orderly compensation of members of the public who incur damages from a nuclear or radiological incident no matter who might be liable" (ANS 2005). While the definition of these "nuclear or radiological incidents" seems to be vague enough that courts have had varied interpretations, the Price-Anderson Act: 2021 Report to Congress (NUREG/CR-7293) refers to a nuclear facility-specific interpretation. The NUREG defines that, "Under broad interpretations of the definition of 'nuclear incident,' the scope of Price-Anderson coverage for nuclear facility sites subject to Price-Anderson requirements may include accidents or malicious attacks occurring in the course of transportation of nuclear fuel or material to a covered site; the storage of nuclear fuel at a covered site; the operation of a covered facility, including discharges of radioactive emissions or effluents; the storage of nuclear wastes at a reactor site; and the transportation of radioactive material from a covered site to a storage or disposal site."

REGULATORY FINANCIAL ASSURANCE FOR POSSESSING RADIOACTIVE MATERIAL

Some western countries like Canada implemented a financial guarantee for licensees to ensure there will be sufficient resources to safely dispose of radiological material under normal license-termination circumstances (CNSC 2020). In the United States, some radioactive sources, sealed or unsealed, of certain activities have an additional restriction put on them by the NRC. The NRC requires licensees possessing such sources, referred to as Category 1 or Category 2, to maintain sufficient financial resources to cover the decommissioning costs, known as financial assurance (FA). Decommissioning in this case refers to decontaminating a facility in which radioactive materials are handled, including dismantling and re-purposing the area for non-radioactive uses. Financial Assurance (FA) acts as a type of earmarked fund for any costs or damages caused from removing and disposing radioactive material. The precise conditions and requirements for financial assurance of radioactive materials are documented by the US Nuclear Reglatory Commission (US NRC) in NUREG 1556 V9 Rev 3 Table 8-1, 10 CFR 30.35, Appendix B of 10 CFR 30 and 10 CFR 40.36. The threshold activity where FA is required is different for every isotope, and if a licensee has multiple sealed source isotopes, then the activities of all of them must be taken into consideration (US NRC 2016). The calculation of the FA threshold for sealed sources is provided in NUREG 1556 Table 8-1. Therefore, based on this table, a licensee that only possesses ^{137}Cs must have 100,000 Ci to need FA. This activity is equivalent to having about 30-40 cesium irradiators (biomedical research or blood irradiator type). Most of the institutions in the US come nowhere near reaching this threshold, so they may not have a fund set aside for any decommissioning costs let alone any type of accidental/purposeful release event. The amount of funding set aside for decommissioning will not be sufficient to cover mass decontamination of areas outside of the facility, total losses revenues, and the value of lives that would be incurred by a radiological accident or intentional event, as seen with the costs of University of Washington's remediation efforts.

The National Academies of Sciences (2021) recommended that the US NRC should not only expand its current requirements for FA but also develop and implement a national strategy for end-of-life management of currently owned sources. The current US NRC regulation 10 CFR 30.35, due to activity thresholds, does not require FA for decommissioning for every Category 1 and 2 byproduct material. However, another NRC study, "Radioactive Byproduct Material Financial Scoping Study" (US NRC 2016) suggests that the current NRC regulations should be expanded to include all Category 1 and 2 byproduct material that is being tracked by the National Source Tracking System (NSTS). The NRC has acknowledged all of these issues and begun a rulemaking process (US NRC 2021), the name for the procedure used to create new regulations, to implement new requirements to better secure these sources. These changes include an expansion to the FA requirements to include Category 1 and 2 source disposition, which is intended to act as a safety net ensuring that licensees are prepared for the costs of responsibly dealing with such radioactive material (US NRC 2016).

It is important to note that a ^{137}Cs irradiator source without US government support will cost about \$200,000 to be disposed (NAS 2021; Kamen et al. 2019), where the total damage from a cesium source used as a dirty bomb (RDD) may exceed \$1 billion. Several cost estimates were conducted by the NRC in 2008 regarding disposal costs for various types of gamma irradiators that, if accounted for inflation, is very close to \$200,000 (US NRC 2008, 2009b).

Additionally, Western countries have already started requiring justification to have ^{137}Cs sources if an Alternative Technology is available.

RISK MITIGATION THROUGH INSURANCE

How can insurance be used to mitigate the financial exposure of an insured associated with a release from a high-activity radioactive source? Insurance policies that should be considered in order to mitigate risk of financial loss to an insured are:

- Property and Business Income: coverage for direct damage to property in the event of a release;
- Site Pollution Liability Policy and associated Business Interruption Coverage;
- Worker's Compensation Coverage: for employees injured in the event of a release;
- Commercial General Liability Coverage: for third parties injured in the event of a release; and
- Special Crime Insurance (i.e., kidnap ransom and extortion insurance): for ransom or other extortion demands under threat of a release of radioactive material.

With respect to a purposeful release in conjunction with a terrorist attack, commercial insurers must offer coverage for "certified acts of terrorism" but are free to either cover or exclude "noncertified acts of terrorism." Terrorism coverage is offered for additional premium and scheduled as an endorsement to commercial policies. The intent of the coverage is specific to the commercial policy it is endorsed onto (examples include property liability, general liability, pollution liability). The coverage extension could provide coverage for damaged or destroyed property, interruption of an insured's normal business operations, clean-up associated with a pollution condition, and even third party liability claims against an insured's business associated with a terrorist attack.

For the terrorism coverage to be triggered under TRIA for commercial policies, a terrorist attack has to be declared a "certified act" by the Secretary of the Treasury in concurrence with the Secretary of State and the Attorney General of the United States.

A certified and non-certified Act of Terrorism is defined in the Terrorism Risk Insurance Act of 2002 and is summarized as follows (Congress 2002):

- Certified act of terrorism[4]: To qualify as a certified act of terrorism, the incident must: (1) be a violent act or an act that is dangerous to human life, property, or infrastructure; (2) cause damage within the United States or other area of US sovereignty (e.g., an US embassy, airplane, ship); and (3) be committed as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the US government by coercion. The Insurance Act also assigns limitations where certification is invalid if the act in question is committed during the course of a war declared by Congress or if the act produces property-casualty (P&C) insurance losses in excess of $5 million. When all of these conditions are met, the final decision to initiate certification is up to the Secretary of the Treasury, personally, as the program's administrator and source of financial compensation. Their decision is also not subject to judicial review. It is notable that there is no explicit delineation or definitions for "accidents" and "purposeful" incidents in the Act. Insurers paying claims in response to certified acts of terrorism qualify for federal reimbursement.
- Non-certified act of terrorism[5]: A terrorist act that does not meet the criteria for a certified act of terrorism and does not trigger the federal reimbursement provisions of TRIA.

To date, 9/11 is the only certified act of terrorism in US history, so it is clear that TRIP has been very conservative with certifying acts of terror, and the Secretary of Treasury may not choose to activate the program even in the case of a purposeful release of radioactive material. If the program is activated though, the federal payments would go directly to insurers (Webel 2019). This difficult situation makes having insurance that covers terrorism the only way for an organization to receive any Federal support in the case of such a release. A recommendation would be to ensure that all of an entity's commercial insurance policies provide coverage for both certified and non-certified acts of terrorism.

Ensuring coverage for both certified and non-certified acts of terrorism is an important step to covering loss attributable to misuse of a high-level radioactive source, but it is not the only area of focus when reviewing coverage afforded in commercial insurance policies. It is important to review the coverage restrictions in each of the above-recommended policies as well. Insurance carriers learn from past losses and have added coverage restrictions or full coverage exclusions for exposures they never intended to pick up under their policy or for which they feel they cannot underwrite to the exposure. The current TRIA statute does not specifically include or exclude NCBR events. Thus, the TRIA program in general would cover insured losses from a certified terrorist action due to NCBR as it would for an attack by conventional means. However, many commercial policies have a restriction built into the policy form for NCBR events regardless of whether accidental or due to terrorism. This means that despite the TRIA requirement to offer terrorism coverage (and the 70% to 80% reported take-up rate of this coverage), most purchasers of terrorism insurance may not be covered for damage from a terrorist attack using chemical gas, a radiological "dirty" bomb, or any of dozens of other similar scenarios that could result in extremely large losses (CRS 2019). Under TRIA, if some NCBR exclusions are permitted by a state, an insurer in that state does not have to make available the excluded coverage. Therefore, it is important to review all insurance programs and make sure any exclusions applicable to NCBR are removed.

In summary, facilities must (1) ensure that the correct coverage is endorsed onto the policy and (2) ensure that any coverage restrictions built into the policy form that could negate the added coverage have been removed.

RECOMMENDATION—REPLACE IRRADIATORS WITH ALTERNATIVE TECHNOLOGY

Irradiator risks

In 2008, the US National Academy of Sciences (NAS) published a landmark report, "Radiation Source Use and Replacement," which examined the feasibility of replacing high-risk radioactive sources with less risky (and most likely non-radioisotopic) alternatives in order to forestall an act of radiological terrorism. The report expressed particular concern about the threat posed by the continued use of one radioactive source—cesium chloride—whose unique characteristics make it especially susceptible to being used by terrorists. The report recommended that government policies be enacted that would lead to the substitution of less hazardous technologies (Pomper et al. 2014). In 2010, an interagency Task Force on Radiation Protection and Security submitted its quadrennial report to the President and Congress. The report emphasized the security measures that have been implemented to protect existing, risk-significant, radiological sources. It concluded that for cesium chloride "immediate phase-out would not be feasible because the sources are extensively used in a wide range of applications in medicine, industry, and research (Jaczko 2010). However, it concluded

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[4] https://www.irmi.com/term/insurance-definitions/certified-act-of-terrorism

[5] https://www.irmi.com/term/insurance-definitions/noncertified-act-of-terrorism

that a gradual stepwise phase-out could be feasible as alternatives become technologically viable and if disposal pathways are identified. It also noted that, "While alternatives exist for some applications, the viability, relative risk reduction achievable, and state of development of these alternatives varies greatly." The Academies report on 2021 (NAS 2021) had 15 findings including: "The US government has taken action to strengthen the security and accountability of radioactive sources with the focus is on category 1, 2 sources." The Academies recommend that the IAEA, NRC, and other organizations should make changes to their security and source tracking guidance and regulations based on their probabilistic health, economic, and social impacts. They also advise that the NRC not only should expand its current requirements for FA but also "develop and implement a national strategy for end-of-life management of currently owned and orphan Category 1 and Category 2 radioactive sources…" In the medical applications, the financial incentives from the US government have been a major contribution to the transition from cesium sources to x-ray technologies, and additional progress could be made in research irradiators by funding more equivalency studies.

Another factor to consider when evaluating the risks and liability of healthcare institutions with gamma irradiators is the impact on the mental health of workers who may experience a radiation incident. Previous studies of radiation disasters such as Chernobyl and Three Mile Island show that the largest public health problems resulting from these events are mental health, including significant increases in depression, anxiety, post-traumatic stress disorder, poor self-rated health, and medically unexplained symptoms (Bromet 2014). This issue can be addressed monetarily by increasing the availability of mental health surveillance programs to those affected (NAS 2011). In addition to mental health, these events can cause workers to have distrust of and/or hostility toward the institution where the incident occurred (Bromet 2014). This can lead to damage to the institution's reputation; however, there have not been many academic investigations done into the costs of this type of damage.

Domestic efforts to combat irradiator risk

The events of 11 September 2001 brought to light the need to achieve greater national security by offering government funding for the increased protection of high-activity radioactive sources and for reducing the number of high-activity radioactive sources that could serve as targets for misuse. The NNSA implemented the Cesium Irradiator Replacement Project (CIRP) to provide financial backing for not only the removal of the irradiators and the disposal of the radioactive cesium source but also for the adoption of x-ray irradiators.

In 2015, former Georgia Senator Sam Nunn, who was the co-chairman of the Nuclear Threat Initiative (NTI), wrote "Isotopes that can make life-saving blood transfusions and cancer treatments possible...could be used to build a bomb that would spread radioactive material...and should provide impetus for governments, the medical community and industry globally to immediately secure all such materials or replace them with alternative technologies" (Nunn and Bieniawski 2015).

A few years later, the John S. McCain Fiscal Year 2019 National Defense Authorization Act set a goal for the NNSA to eliminate the use of approximately 400 radioactive cesium blood-irradiation devices by 2027 (Congress 2018). This Act allowed the US government to pay up to 50% of the per device cost of replacing the cesium blood irradiator devices covered by CIRP and also pay for 100% of the cost of removing and disposing cesium sources.

According to the NNSA, approximately 315 cesium research irradiators and 400 cesium blood irradiators in use in the US fall within the scope of CIRP (Garrison et al. 2018). Following a slow start, when about 20 replacements occurred in the span of 2 y, CIRP activity has increased exponentially. As a result of partnering with institutions, another 90 irradiator removals occurred in 2018 and 2019. The NNSA's Office of Radiological Security (ORS) has now dispositioned more than 283 cesium irradiators as of 11 November 2022, though a single device may contain multiple radiation sources. The authors' personal communications with the NNSA suggest that they are on track to replace 330 cesium irradiators with non-radioactive alternatives by late 2023. Since 2001, the NNSA, through the Off-Site Source Recovery Program (OSRP), removed more than 3,500 Category 1 and 2 sources from US industrial, educational, healthcare, and government facilities (Garrison et al. 2018; Ingalls 2019). The demand for the voluntary removal is ever increasing. The US government is in the process of preparing an assessment of the CIRP program to be submitted to the appropriate congressional committee by September 2023.

There have already been several successful larger-scale source removals carried out by facilities working with the OSRP. The experiences of the University of California (MacKenzie et al. 2020) and Mount Sinai Hospital (Kamen et al. 2019) are well documented and involve multiple irradiators per facility. These institutions have reduced their irradiator risk, with Mount Sinai completely removing all of their irradiators (Kamen et al. 2019). In the University of California's case, they decided that five of their irradiators would be retained because staff was uncertain whether x-ray irradiators would be a suitable substitute for their research applications (MacKenzie et al. 2020). More information about how to determine if an x-ray irradiator could replace ^{137}Cs can be found in the "Risks and Limitations" section of this paper.

Assuming that an institution's radioactive source is dispositioned, what would be the risk of a dispersal event occurring during transit from a licensee's facility to a US DOE disposal facility? This is a scenario that the OSRP considered (Griffin 2010). Their evaluations show that out of 28 million radioactive material shipments done in the United States from 1997 through 2006, there were only 147 cases of reportable domestic transport incidents. These incidents are mostly minor cases like “fender benders.” OSRP also considers the Class 7 cargo packages to be suitably durable, as required by Department of Transportation regulations, as to not release radioactive material even in the case of a serious accident. The OSRP identified many ways for a previously secure source, which may be held by a licensee rather than disposed, to fall through the cracks of regulations and end up at risk of causing an accident (Griffin 2010). It should be noted that sources held outside of the United States were also included in these considerations, such as the sources that led to the dispersal events discussed in the “Accidental Release” section of this paper.

Domestic disposal pathways

Radioactive waste disposal has been a large concern in US nuclear policy and is tied to the disposal of gamma irradiators. The primary problem relating to sealed sources has been the unavailability of waste facilities licensed by the US NRC that are able to dispose of such sources. The main two sites that accepted disused commercial sources were EnergySolutions in Barnwell, SC, and US Ecology in Richland, WA (another EnergySolutions site exists but only accepts small amounts of activity), which also only accepted materials from certain states that were part of corresponding compact agreements (NAS 2021). The majority of states did not have an option for commercial waste disposal until the US DOE worked with the state of Texas to allow Waste Control Specialists in Andrews, TX, which accepts radioactive waste from all non-compact states (NAS 2021). This opened up a way for all states to have some option for disposal, but those not in a compact will have to hope that the Texas facility has enough space for waste from 34 states. Specifically, the facilities mentioned above accept waste classified as Class A, B, or C. These classes are defined in the US NRC’s 10 CFR 61.55, so this means that all ^{60}Co irradiators and ^{137}Cs irradiators less than 4,600 Ci per cubic meter would be acceptable for disposal. It should be noted that these classifications were updated in 2015 by the US NRC, increasing the radioactivity limits for classes A through C, in response to issues states were having with disposing waste after the Texas facility opened (US NRC 2018). However, another issue remains in that there is still no pathway to disposal for waste considered greater than Class C, which would include ^{137}Cs in quantities exceeding 4,600 Ci per cubic meter. The US NRC’s rulemaking process has started to address this issue, though there is no final proposal yet (NAS 2021). Users that dispose of their sources, either through a US DOE program or independently, will likely be sending them to one of the waste facilities listed above as commercial waste, and each of them is licensed for a finite volume and activity. The Texas facility publicly lists their capacity on their website (https://www.wcstexas.com/about/our-facilities/facilities/) where their Texas Compact Waste Facility for commercial waste offers 9,000,000 cubic feet and 3,890,000 curies of space. They also indicate that parties not in their Texas compact (the states of Texas and Vermont) are only allowed to occupy 30% of that space. It seems that based on this curie capacity, for now, there should be enough space for all remaining ^{137}Cs blood irradiators in the US.

Global efforts to combat irradiator risk

Concerns over the threat of dirty bombs extends beyond the borders of the United States. Efforts were made globally to replace cesium-source blood irradiators even prior to the 9/11 attacks. Japan started replacing cesium blood irradiators 20 y ago, and according to the 2017 Nuclear Threat Initiative report, 80% of them have been replaced by x-ray irradiators (Bieniawski 2017). France started a campaign in 2006 to remove all 30 cesium irradiators located at blood transfusion centers. In 2016, the country’s goal was achieved by allowing existing irradiators to be licensed for only 10 y, not reissuing permits for expired licensed units, and not accommodating new requests (Bieniawski 2017). They had 30 irradiators, and they have completely replaced them with x-ray irradiators. A year earlier, Norway successfully replaced all 13 of its cesium blood irradiators with x-ray technology (Nalabandian et al. 2016, Bieniawski 2017; HPS 2021a). Today, the governments of Norway, France, and Belgium require institutions to provide a clear justification for the purchase of a replacement cesium-source irradiator if an alternative technology is available (Pomper et al. 2014). The Swiss government has a goal to replace all its cesium blood irradiators by 2025 (HPS 2021a).

RISKS AND LIMITATIONS

Users interested in dispositioning their gamma irradiators may also be interested in understanding the risks involved before the source is removed from their property. The recent Harborview Medical Center dispersal accident has reminded us that despite prior successes, there is never zero risk involved when handling such materials. Unfortunately, the authors are not aware of any insurance policy or company that would insure facilities like hospitals for disposing radioactive sources per se. There are insurance policies for impairment of the environment, which may apply. An article from before the Harborview accident suggests that there used to be 15 insurers that offered this type of insurance (Gonzalez 2004), but that could have changed in more recent years. At the time of writing, Zurich North America and American International Group Inc. include “pollution” as part of their insurance programs listed on their website. Both indicate that their coverage limits go up to $25 million, which is still much less than the costs incurred by the University of Washington Medical Center. However, it is difficult to say whether these insurers are willing to cover disposal scenarios, and the insured party must confirm that such coverage exists when negotiating their policy. The authors were unable to find any further information about changes to these policies in response to Harborview. Transportation of radioactive material and waste is well regulated by state governments and federal organizations, giving insurers some confidence to believe an accident will not happen, but a disposal operation is not regulated in the same way. These insurance policies are more applicable to waste facilities and waste transporters because they are required in at least some states, as noted in their Waste Transporter Permit Applications (i.e., New York State's 6 NYCRR Parts 364/381 Waste Transporter Permit Application and California Environmental Protection Agency's Hazardous Waste Transporter Registration Application DTSC Form 187). The authors' previous experiences with CIRP indicate that the liability for source disposal depends on the details of the contract signed between the institution and the corresponding US DOE agencies. The US DOE contractors would likely have their own insurance policies as waste transporters, but comparing insurance policies and determining liability based on when and where a radiological accident may happen is not within the scope of this paper.

The use of gamma radiation sources is not limited to medical facilities. Although those other applications are not within the scope of this paper, it is helpful to have an overview of how they compare to one another. The case of industrial applications involves many isotopes with a range of activities. Non-destructive testing (NDT) and radiography are commonly done using curie or lower amounts of gamma sources, but the associated risk comes from the fact that these operations tend to be done in remote areas to which the sources must be transported (NAS 2021; Moore and Pomper 2015). These areas are likely to be less secure than a static and enclosed area with security personnel. Replacing these isotopes with specialized portable battery-based x-ray tubes is possible (NAS 2021) in some cases, but the financial investment required to do so is a significant factor for the companies conducting these operations. Disposal of the isotopes these companies use can be as simple as decaying in storage for a few years, but their ^{137}Cs, ^{60}Co, and neutron sources could pose a more complicated disposal problem without assistance due to their long half-lives and high specific activity. While the former may qualify for CIRP assistance, it is possible for users to find assistance with other sources through the Source Collection and Threat Reduction (SCATR) program or RadSecure 100, a relatively new project, depending on the half-life of the source. The latter is involved in disposing a wider range of sources than CIRP and also provides assistance with security in case a non-radioactive alternative is not practical. Users of gamma irradiators that cannot be replaced with an alternative should consider increasing their security with programs like RadSecure 100 or independently, along with possible insurance policies. Mount Sinai Hospital documented their experience with increasing security of their ^{137}Cs irradiators in cooperation with local law enforcement and the NNSA, which can be a useful reference (Kamen et al. 2019). It should be noted that portable sources like the ones used for industrial radiography may or may not be practical to secure by similar methods due to their transportation and use in remote areas.

While research irradiators can be referred to as a separate category of sources, they are not treated differently in terms of disposal because of their role. Research irradiators can include a wide range of isotopes and activities, overlapping those previously referred to as medical or industrial sources. The main scope of this paper includes the risks and actions that medical facilities can take with regard to sources they possess, but this may overlap with other organizations depending on the isotope and specific activity, along with other characteristics of their sources. The US NRC has developed guidance on how they categorize waste, which would include sealed sources, in 10 CFR 61.55. Although it is not up to date with more recent US DOE programs and US NRC regulations, the Sealed Source Disposal and National Security—Problem Statement and Solution Set (US NRC 2009a) is useful for understanding how such sources tend to be grouped for disposal. The issue of replacing a research irradiator is a separate and ongoing discussion that varies case-by-case in terms of equivalent radiation effects.

Irradiators are used for a wide range of activities and each application they are used in may value certain metrics over others. The goal of an irradiation application is the best indicator for whether or not an x-ray irradiator can replace an isotope-based one. With respect to blood irradiation applications, the US Food and Drug Administration (US FDA) is responsible for determining whether a product is suitable to provide a dose that will prevent graft vs host disease. Certain x-ray irradiators have been licensed for this specific purpose after studies showed that the differences in irradiators were not clinically significant (Dodd and Vetter 2009). The purpose of a research irradiator may be more specialized for an experiment, in which case the relative biological effectiveness (RBE), energy spectrum, throughput, and dose homogeneity are some of the many factors that can change the actual biological effects of a dose. For example, a working group from the University of California noted x-ray machines emitting less than 320 keV photons are more biologically effective and are more likely to interact with thinner targets, such as cells, than ^{137}Cs 662-keV photons (MacKenzie et al. 2020). However, higher energy x-ray machines would be necessary to better mimic the dose distribution from a ^{137}Cs source to small animals like rats. Other factors to consider are the beam hardness and source geometry relative to the target of x-ray irradiators, which have a significant effect on the output dose and RBE (MacKenzie et al. 2020). Dodd and Vetter's analysis of various x-ray irradiator models also finds that their characteristics require a different approach to output a dose similar to ^{137}Cs, like irradiating from multiple directions (Dodd and Vetter 2009). Researchers must identify precisely what part of a beam of radiation is important to their work to decide whether or not an x-ray irradiator can do the job. Depth-dose may be a more important value than RBE for some work, in which case it is very likely that x-rays are a viable replacement based on previous dosimetry work (Murphy and Kamen 2019). Comparing gamma and x-ray irradiators based on their depth-dose is helpful to determine the best configuration necessary of an x-ray irradiator to produce a researcher's desired results.

Once a user decides to migrate from a gamma irradiator to an x-ray irradiator, there are several pros and cons to consider. In the case of blood irradiation, the US FDA requirements for the isotope source includes quality control and calibration that requires expensive equipment and skilled labor to perform. These operations and procedures for the x-ray alternative would be cleared by the US FDA in the licensing process with the manufacturer, and dosimetry work can be included in a service contract with the user, though this is an extra package with an extra fee. Various quality control features would also be implemented into the irradiator device itself. Although research applications are not regulated in this way, some calibration would still be necessary at least periodically to give researchers some assurance that they are delivering the dose they expect. The maintenance for a gamma irradiator is very different from that of an x-ray irradiator in that the former has a relatively simpler design where the mechanical and electrical safety mechanisms are the main concern for a user. The x-ray device is complicated by the use of an x-ray tube, electrical power supply, cooling system, and other electronic interfaces. These factors require more complex maintenance and a correspondingly expensive contract. Outages due to maintenance are a large concern for medical facilities that would irradiate blood regularly but may be a lower priority for researchers that irradiate once in a while. The security costs, on the other hand, for a ^{137}Cs or ^{60}Co source are significantly higher because they can involve getting staff cleared with FBI finger printing and background checks. Possession of an x-ray irradiator does not require such strict controls, and these measures are not part of inspections by regulatory agencies. There is no annual reconciliation with the National Source Tracking System like with isotopes.

The cost of facilities that house these irradiators may be a factor depending on the model of irradiator. Many of the isotope irradiators that are used for biological experiments or irradiation are self-shielded, in which case the room they are housed in does not need more shielding engineered into the design. In this case, they would be the same as their x-ray alternatives, which are also self-shielded, not considering stand-alone x-ray tubes.

Some models of gamma irradiators like ^{137}Cs and ^{60}Co can be incorporated into a room's design for improved shielding of very strong sources with extra thick walls and/or water tanks. These scenarios would require some more in-depth price estimation to decide whether the costs of shielding outweigh the costs of supplying power to a similar x-ray irradiator. The throughput, or the number of simultaneous targets a device can dose, is a concern for some users like blood irradiation facilities, but researchers may not value that as highly depending on how many colleagues need to share it. There are some models of gamma irradiators with larger volume capacities than x-ray irradiators and some with less capacity, though accessories and attachments can affect this.

It should be noted though that x-ray irradiators have been made specifically for dosing up to five or six individual blood bags at once (Dodd and Vetter 2009), while isotope-based irradiators can instead have large single containers for targets. X-ray devices that are in the licensing process can be equipped with larger capacity in the future as well. The issue of dose rate with both of these devices is somewhat complicated by the fact that many models exist that cater to different needs. The dose rate for an x-ray irradiator, no matter its age, is always consistent, while the issue unique to gamma irradiators is the need for decay correction as the source decays, which decreases its output. Self-shielded gamma and x-ray irradiators have limits on how far away one can move a target to change the dose rate. There are many of the former that are not self-shielded, which have more room for variation with the trade-off of more shielding in the facility walls. Shielding used to change the energy of the output beam is available for both devices but may have a different hardening effect on x-ray tubes that output a wider energy spectrum. Overall, each user should consider what their facility is capable of handling in terms of infrastructure, budget, and risk when deciding which irradiator will work for them.

HARBORVIEW INCIDENT OVERVIEW OF LESSONS LEARNED

The Joint Investigation Report (JIT) conducted by the NNSA and Triad has critically evaluated the factors that led to the ^{137}Cs source release incident. The analysis concluded that although the immediate cause of the release was the cutting operation on the ^{137}Cs holder, many of the contributing factors were related to lack of oversight and regulation over the actions of the workers contracted to retrieve the source. This came about from the organizational structure used for conducting source disposition. The US DOE uses a contractor, Triad, to manage the field work in disposition and they hold a bid to choose a subcontractor that conducts the field work (Joint NNSA/TNS 2020). The US DOE and US NRC authorities overlap during such field operations involving an NRC-licensed source which led to confusion about who was responsible for what. This led to a lack of checks on the contractor and subcontractor regarding work plans, safety policies, and stakeholder responsibilities (Joint NNSA/TNS 2020). When the field workers had decided to cut open the ^{137}Cs source in an unrestricted area, they did not understand the risks of their actions because the subcontractor's decision-making did not have appropriate oversight.

The direct actions of the subcontractor's employees were factors out of the control of the University of Washington, but any user considering using OSRP in the future does have some agency to ensure an event like this does not happen to them. During discussions about the work to be done for source removal between the user, their relevant state regulatory body, and the contractor, it may be worthwhile to discuss the subcontractor's license. The US NRC license granted to the subcontractor, International Isotopes Inc. (INIS), for source disposition indicated what operations they are allowed to carry out in the course of their work. The JIT report found that INIS was actually not authorized to remove the ^{137}Cs material from its holder (Joint NNSA/TNS 2020). Even though a user should not expect to be directly involved with such licensing issues, notifying the state regulatory agency and being proactive about the user's concerns will prevent parties from getting complacent about their responsibilities to maintain safety. In Harborview's case, The State of Washington Department of Health's health physics staff were present to observe the source recovery but were not involved in INIS's pre-job briefing (Joint NNSA/TNS 2020). This was one of the cases in this incident where confidence in other agencies led to complacency. Another case was during walk-downs of the work activities, when Harborview's Facility Manager asked about the procedures, Job Hazard Analysis, and other information. The procedure provided did not include cutting into the source holder, and a full Job Hazard Analysis was never provided. Various personnel were overconfident in INIS's technical experience and ability (Joint NNSA/TNS 2020) without doing their own due diligence, which might have averted the incident. As with many other licensing activities, maintaining a cooperative and open relationship with your regulators where both can share their concerns and address them is a great tool for ensuring compliance and safety.

Although the Harborview event is certainly a stain on the CIRP's track record, the JIT report's evaluation offers great insight into why it happened. Until the changes recommended by the document are implemented, it should be an excellent tool that interested participants should use to understand the regulatory complexity of source recovery and what they can do to avoid a repeat incident.

RECOMMENDATION—INSURANCE INCENTIVES

Commercial insurers who offer NCBR coverage could follow a similar approach to the auto insurance market, which has developed models for how to incentivize safe driving practices, with institutions who have ^{137}Cs sources. They can offer a premium discount to institutions that join the US government CIRP program to replace irradiators with an x-ray irradiator (in conjunction with the US DOE) to improve compliance. In addition, institutions without any gamma irradiators should ask for a discount during the negotiations by explaining they have reduced their relative risk.

CONCLUSION

Gamma irradiators have had many useful applications over the years; however, malicious interest in the use of such material as a dirty bomb has persisted and thus has focused much attention on how to safely and responsibly transition such equipment out of use and move toward radioactive source-free alternative technologies. The most compelling reason to transition is the potential cost of an accidental or purposeful release resulting in widespread contamination. If the accident at the University of Washington cost $150 million to remediate for a small leakage, it is not unreasonable to use that as a baseline for other accidental or purposeful mass contamination releases. We would expect remediation costs today to vary widely because they depend on too many factors and can exceed $1 billion.

Three considerations make owning irradiators particularly risky:

1. The potentially astronomical cost of a radioactive mass decontamination (accidental or purposeful);
2. The high target value of gamma irradiators to terrorists; and
3. The limited ability to shift risk to insurers or the federal government. It is unlikely that the insurance options and programs available today will sufficiently protect institutions from significant financial loss in the event of a release, and any such insurance program would come with an astronomical cost.

Therefore, licensees of irradiators should make use of financial incentives to minimize and reduce the number of such irradiators in their organizations. Notwithstanding this recommendation, owners/licensees who choose to continue to own a gamma irradiator(s) should:

1. Ensure that correct coverage is endorsed onto their insurance policies; and

2. Ensure that there are no restrictions built into the policy coverage. These restrictions could excuse insurers from covering irradiator mass contamination events.

The good news is that there are alternative technologies available and that many major institutions, such as The Mount Sinai Hospital in New York, have successfully removed all their gamma irradiators and migrated to alternative technologies (Kamen 2019). The NNSA has disposed of more than 240 radioactive cesium irradiators and has provided enticing financial resources to make the transition possible. More institutions should take advantage of the readily available federal funding for alternative technology and cesium irradiator replacement.

Licensees are encouraged to investigate their liabilities and insurance coverages and explore financial incentives offered by the US government offices of DOE-NNSA-ORS under the OSRP and CIRP programs to not only dispose of their present gamma irradiator sources at no cost but also provide financial support to replace them with alternative technologies. To find out about government funds for the removal or replacement of cesium irradiators, contact the NNSA Office of Radiological Security (https://www.energy.gov/nnsa/office-radiological-security-ors) about the CIRP program.

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