CISA | CYBERSECURITY AND INFRASTRUCTURE SECURITY AGENCY

NON-RADIOISTOPIC ALTERNATIVE TECHNOLOGIES WHITE PAPER

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Agenda

- ATWG Background and White Paper
- Summary of Findings
  - Blood Irradiation
  - Research Irradiation
  - Radiotherapy
  - Industrial Sterilization
  - Phytosanitary Irradiation
  - Sterile Insect Technique
  - Well Logging
  - Radiography
- Acknowledgments

Alternative Technology Working Group

- Alternative Technologies Working group (ATWG) was established to evaluate non-isotopic alternative technologies by fostering public and private sector engagement, identifying gaps in research and development
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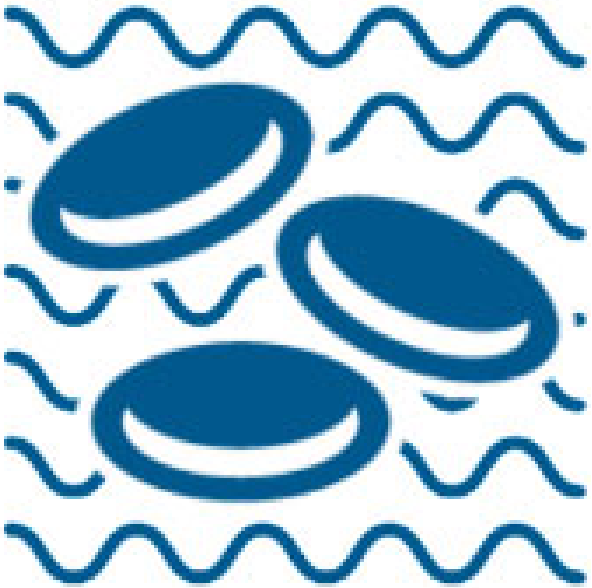
- ATWG is comprised of over 120 members and SMEs from dozens of organizations in the private and public sector
  - Federal agencies
  - SLTT agencies
  - Industry (including manufacturers and users of sealed source containing devices as well as non-isotopic alternative technologies)
  - Academia

Alternative Technologies Working Group

- The findings of the ATWG were documented in a White Paper which:
  - Examined where commercially available, non-isotopic technologies exist or are under development (including technologies that are commercially available internationally but not yet approved in the U.S. market).
  - Where possible, outlined the efficacy, lifecycle costs, and applications of these alternative technologies and potential barriers to adoption.

Chapter One



Blood
Irradiation

Blood Irradiation

- Blood irradiation is the most common method used in the United States to prevent transfusion-associated graft-versus-host disease (TA-GvHD)
- Most blood irradiation is accomplished using self-shielded cesium-137 chloride (CsCl) blood irradiator units.
  - Expose the target to high doses of gamma radiation (25 Gy)
  - Blood irradiators typically contain 1,000 curies (Ci) or more of CsCl at the time of purchase.

Blood Irradiation – Alternative Technologies

- Blood irradiation may also be accomplished with x-ray or UV devices.
  - The FDA has approved x-ray devices from three manufacturers
  - The FDA approved two separate UV systems from one manufacturer for blood pathogen reduction in 2014.

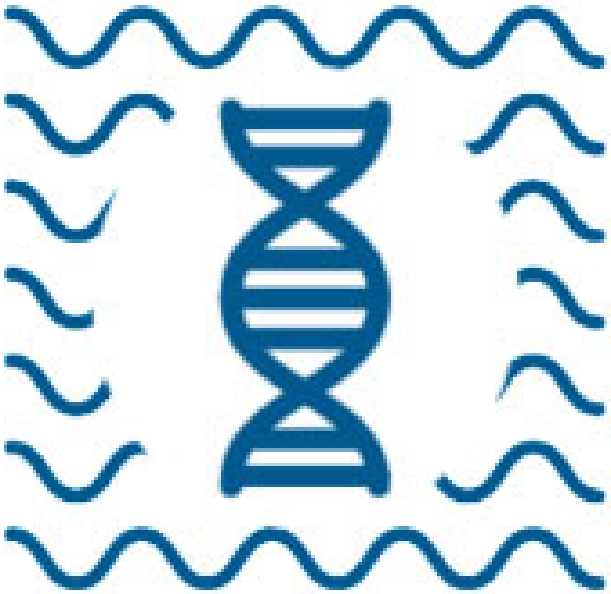
Blood Irradiation – Replacement Considerations

- Technology purchase and replacement decisions largely depend on user confidence in the reliability of currently available x-ray devices and user estimation of the lifecycle costs of the different technologies and the throughput.

Blood Irradiation – CIRP

- In 2014, DOE/NNSA successfully piloted the Cesium Irradiator Replacement Project (CIRP), which facilitates the voluntary replacement of CsCl and cobalt-60 blood and research irradiators with x-ray devices on a cost-share basis. CIRP support also includes the removal and disposal of the CsCl or cobalt-60 device by NNSA. As of June 2019, 158 blood irradiators have been replaced or are in the process of being replaced through CIRP. This is about 33 percent of the 2015 United States blood irradiator inventory.

Chapter Two



Research
Irradiation

Research Irradiation

- Research irradiators are widely used at hospitals, universities, governmental, and commercial laboratory facilities that conduct basic research, medical research, radiobiological science, and materials science research.
- Typically use one or more CsCl or cobalt-60 sources to expose the target to high doses of gamma radiation.
  - CsCl research irradiators range from under 1-20 kCi
  - Cobalt-60 models are higher-activity devices on average, with some exceeding 30 kCi.

Research Irradiation – Alternative Technologies

- X-rays may also be used for research irradiation.
- However unlike radioactive sources, which produce primary gamma rays at just one or a few discrete energies, x-ray devices generate a spectrum of energies below the accelerator maximum energy.

Research Irradiation – Replacement Considerations

- The requirements typically involve four factors within an acceptable margin or error, especially when using live animal targets
  - percentage depth dose (PDD);
  - dose rate;
  - energy delivery;
  - and the size and type of target.

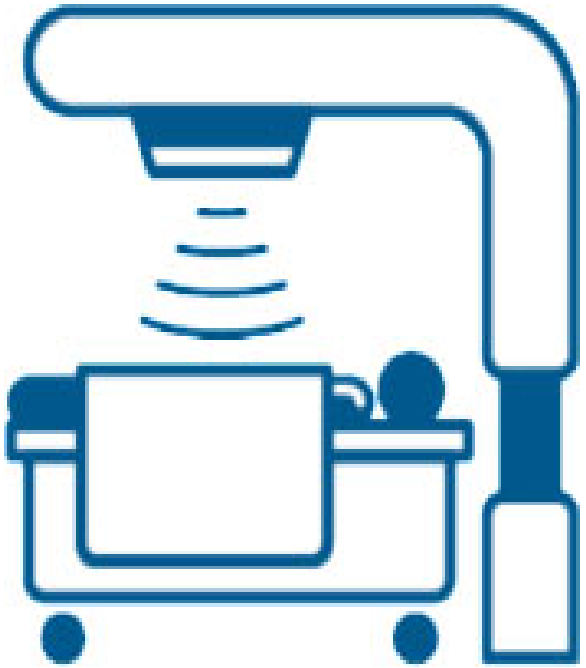
Research Irradiation – Replacement Considerations

- Due to the differential energy distributions of gamma and x-ray sources, the suitability of x-ray irradiators for medical research currently using cesium-137 or cobalt-60 is highly dependent on the specific research goals and requirements.
- These comparison data challenges may discourage or prevent the adoption of alternative technologies in some research applications

Research Irradiation – CIRP

- Since the 2015 inception of the DOE/NNSA CIRP project, about 25 percent of the self-contained research irradiation devices in the United States have been voluntarily replaced, or are in the process of being replaced.

Chapter Three



Radiotherapy

Radiotherapy

- Radiation therapy uses radiation to treat cancer and is an essential tool in curative and palliative cancer care.
- External beam radiotherapy, also called teletherapy, is the application of radiation emitted from a device outside of the patient to treat the disease location.
- Stereotactic Radiosurgery Devices (SRS) are a type of external radiotherapy that precisely target the disease location through three-dimensional localization
  - Cobalt-60 teletherapy and SRS devices use one or more cobalt-60 sources, typically ~5-15 kCi initial inventory

Radiotherapy – Alternative Technologies

- Linacs use high powered electromagnetic fields to accelerate electrons at a heavy metal target to produce high-energy x-rays to deliver the required dose to the patient.
  - Can be used for both teletherapy and SRS
- Proton therapy may also be used for cancer treatments

Radiotherapy – Replacement Considerations

- Cancer treatment decisions made by physicians and their patients are highly complex and must focus on the health and well-being of the patient.
- For standard teletherapy, medical practitioners generally consider linac devices to be superior to cobalt-60 devices for many types of treatment.

Radiotherapy – Replacement Considerations

- Both cobalt-60 and linac radiation sources for SRS, by contrast, retain strong adherents among medical professionals.
- Device selection primarily depends on the range and types of treatment the purchaser expects to provide, the clinical experience and preferences of the practitioners, and the costs associated with the purchase and use of available options.
  - Linacs have higher operational costs due to power, maintenance, and training requirements. They require more extensive and potentially expensive facility shielding than is required for gamma devices. Their training and maintenance costs are also higher due to their complexity.
  - Cobalt-60 devices require an NRC license and implementation of additional security requirements. In addition the devices must be replenished with Co-60 one or more times during the service life of the devices.

Chapter Four

Industrial Sterilization

Industrial Sterilization

- The FDA requires many healthcare products to be sterilized before they are brought to market including a broad spectrum of single-use medical devices and pharmaceuticals.
- Industrial scale gamma irradiation facilities use up to millions of curies of cobalt-60 to sterilize products.

Industrial Sterilization – Alternative Technologies

- Ethylene oxide (EtO) is the modal industrial sterilization techniques. But not all products are compatible with EtO and use ionizing radiation instead.
- The primary ionizing radiation alternatives to gamma sterilization is x-ray or e-beam technology

Industrial Sterilization – Replacement Considerations

- The choice of a sterilization method is an essential component of the product development process and it may depend primarily on regulatory factors.
- FDA approval is significantly faster and less expensive if a device manufacturer can show that a device or product—including assurance of sterility after processing—is "substantially equivalent" to a previously cleared "predicate" device or product.

Industrial Sterilization – Replacement Considerations

- For existing products, a switch in the sterilization technology would require expensive product testing and additional regulatory engagement for revalidation.
- Cost models developed by proponents of gamma processing and alternative technologies rely on significantly different assumptions, making their conclusions difficult to compare.

Chapter Five

Phytosanitary
Irradiation

Phytosanitary Irradiation

- Phytosanitary measures applied to food products are used to prevent the spread of invasive pests that may result from the transport of these products between regions.
- Phytosanitary and pathogen reduction treatment of foods and spices using gamma radiation may take place at the same industrial-scale irradiation facilities that sterilize consumer products and medical.
  - Most of these facilities use a million or more curies of cobalt-60.

Phytosanitary Irradiation – Alternative Technologies

- The primary ionizing radiation alternatives to gamma sterilization is x-ray or e-beam technology

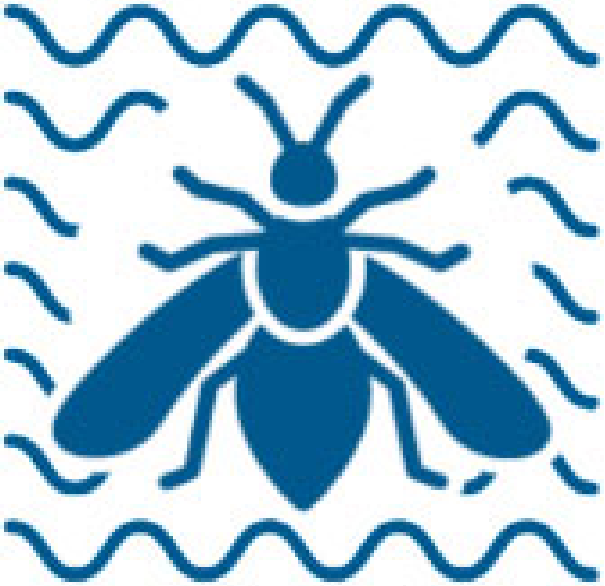
Phytosanitary Irradiation – Replacement Considerations

- The FDA has determined that gamma, x-ray, and e-beam are equally safe and effective for approved food irradiation treatments, including both pathogen reduction and phytosanitary applications.
- When radiation is used as a phytosanitary treatment, a primary challenge is to apply a dose throughout the bulk product that falls between the regulatory minimum (typically 150 Gy to 400 Gy) and the regulatory maximum of 1,000 Gy.
- As a result, a key measure for these applications is the dose uniformity ratio (DUR) achieved during processing.

Phytosanitary Irradiation – Replacement Considerations

- Technical feasibility and processing costs are the primary factors for United States food producers in choosing between e-beam and gamma processing.

Chapter Six



Sterile Insect Technique

Sterile Insect Technique

- The sterile insect technique (SIT) is a type of pest control used to suppress or eradicate a harmful insect pest species.
- SIT involves the use of radiation to reproductively sterilize large volumes of the male insects of the harmful species (or their larvae). The sterilized males are then released into the targeted area in order to mate with the indigenous, non-sterilized female insect population
- Most gamma-based SIT uses self-shielded gamma devices. These devices contain up to 24 kCi of cobalt-60 or 12 kCi of cesium-137, and are capable of 40 Gy/min dose rate.

Sterile Insect Technique – Alternative Technologies

- The primary non-isotopic alternative for SIT is the irradiation insects using relatively low energy x-ray devices (150-225 keV).
- E-beam can also be used for SIT.

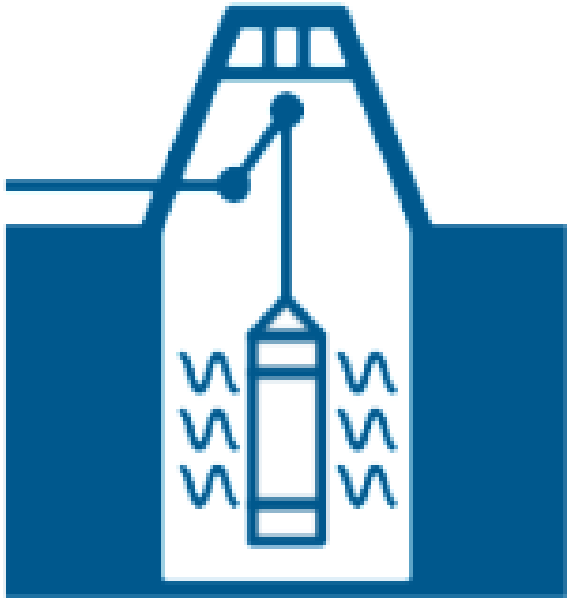
Sterile Insect Technique – Replacement Considerations

- To be effective, the targeted insect volume must be exposed to a dose sufficient for sterilization, but not so high that the ability of the insects to effectively mate after release is negatively affected.
- The irradiator throughput should be sufficiently large to produce enough sterilized insects that each release into the targeted region can noticeably reduce the harmful pest population.
- The irradiation facility should be near the insect dispersion site when feasible; transportation time and conditions can reduce the survivability of the sterilized insects and diminish their ability to effectively mate with indigenous females after release into the wild.

Sterile Insect Technique – Replacement Considerations

- There are still areas for technology improvements, including: balancing the requirements of energy, dose rate, and DUR.
- Currently alternative technology options for SIT applications are limited. There is an insufficient market size for SIT to incentivize commercial developers to produce specialized SIT devices.

Chapter Seven



Well Logging

Well Logging

- Well logging generally refers to the use of a measurement device for the continuous characterization of geological formations along the depth of a well – usually for oil and natural gas.
- Well loggers typically use several different types of tools to collect and interpret data for the geologic parameters: density, porosity, lithology, mineralogy, and fluid saturation

Well Logging

- Radioisotope based-techniques (such as gamma backscatter, neutron backscatter, and neutron capture spectra) are currently used almost exclusively to measure the density, lithology, porosity, and mineralogy of geological formations around a well.
  - Neutron sources, using americium-241 mixed with beryllium (Am-241/Be), are used to determine the lithology and porosity of the formation. These sources are usually just under 16.2 Ci.
  - The density and lithology is usually determined using a device with a 1-3 Ci cesium-137 source

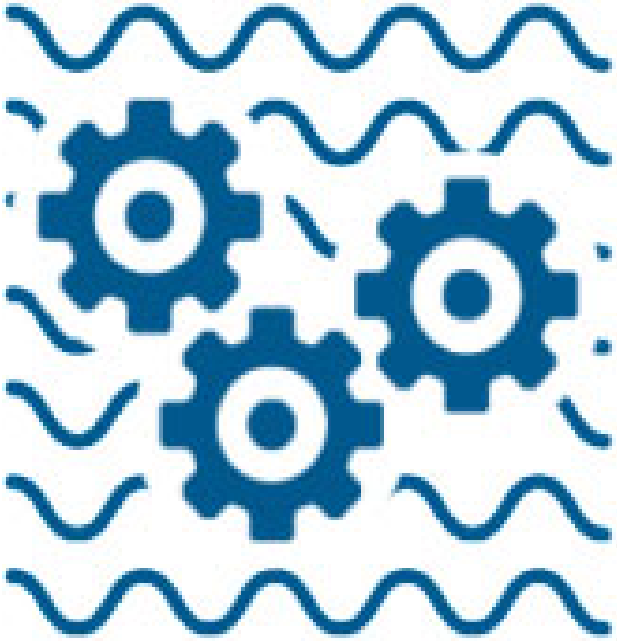
Well Logging – Alternative Technologies

- The most common electronic neutron source is a D-T neutron generator.
- Nuclear magnetic resonance (NMR) is used in well-logging to determine the porosity and fluid types and viscosity.

Well Logging – Replacement Considerations

- The requirements for well-logging devices can vary significantly based on application but are generally: operating environment, logging speed, density accuracy, porosity error, generator lifetime, interpretation requirements, and traceability to legacy data.
- In general, non-radioisotopic technologies for these applications are not currently considered to be fully viable replacements for radioisotope-based logging tools; only electronic nuclear source-based tools have that potential.

Chapter Eight



Radiography

Radiography

- Non-destructive testing (NDT) and analysis is a vital tool for industry. It is often necessary to inspect the safety and quality of both solid metal and welded systems to ensure that everything was built to design and operational specifications.
- The most common isotope used in gamma radiography in the United States is iridium-192 (Ir-192), new iridium-192 sources for these devices are typically about 100 Ci. However, due to its very short half-life—just 73.8 days—iridium-192 sources must be replaced roughly every 6 to 8 months.
- In addition, radiography devices that use between 60 Ci and 300 Ci of cobalt-60 are also common.

Radiography – Alternative Technologies

- There are several types of NDT available, including but not limited to, gamma radiography, x-ray radiography, ultrasonic, eddy current, magnetic particle, and dye penetrant.
- There are other NDT which do not use radioisotopes, but may use electricity, magnetism, visible light, microwaves, millimeter waves, ultrasound waves, or chemicals to probe materials under test. Each of these techniques has their own advantages and disadvantages.

Radiography – Alternative Technologies

- X-ray radiography does not use a radioactive source but does use electrically generated ionizing radiation to find defects beneath the surface of the material.
- X-ray systems generate an image of defects in an object the same way gamma radiography does, but require an active and reliable power source to function- which is particularly important for uses in the field far from established infrastructure
  - However, in factory or laboratory setting X-ray radiography generally provides superior image quality compared with gamma devices.

Radiography – Alternative Technologies

- Ultrasonic testing (UT) is a common and effective industrial tool for finding defects in materials and welds.

Radiography – Replacement Considerations

- Viable replacement technologies need to be able to perform well in extreme environments, and remote field locations without ready access to reliable power.
  - Both the x-ray units and the remote power batteries for these devices are more sensitive to extreme environments.
  - Gamma radiography is also easier to use in inaccessible places—either spatially limited or high above a surface that would preclude the use of more voluminous or heavy equipment.
- Ultrasonic testing is currently used primarily as a complimentary technique with radiography NDT

- https://www.cisa.gov/publication/non-radioisotopic-alternative-technologies-white-paper

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