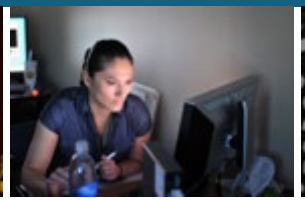
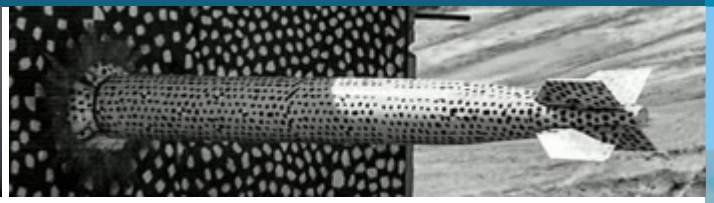
Security by Design

World Institute for Nuclear Security
Round Table on the Role of Standards for Strengthening the Security of Radioactive Sources used in Medical Applications

PRESENTED BY
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Outline

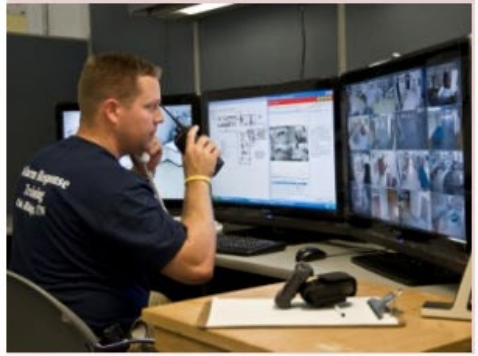
- ORS Overview
- Security by Facility Design
- In-Device Delay (IDD)
- Security by Device Design
- Accomplishments and Challenges

Office of Radiological Security

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

PROTECT

PROTECT radioactive sources used for vital medical, research, and commercial purposes



REMOVE

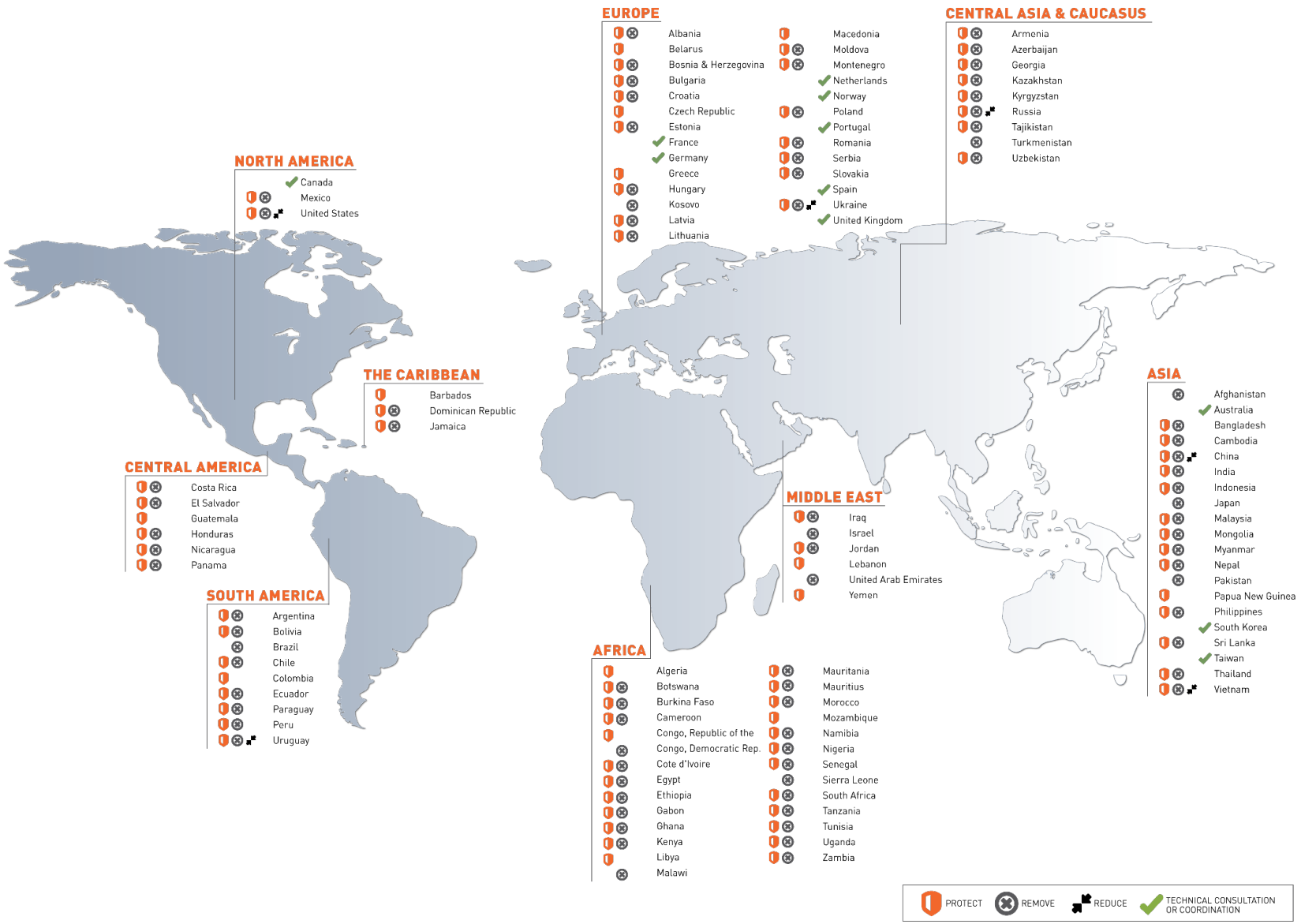
REMOVE and dispose of disused radioactive sources

REDUCE

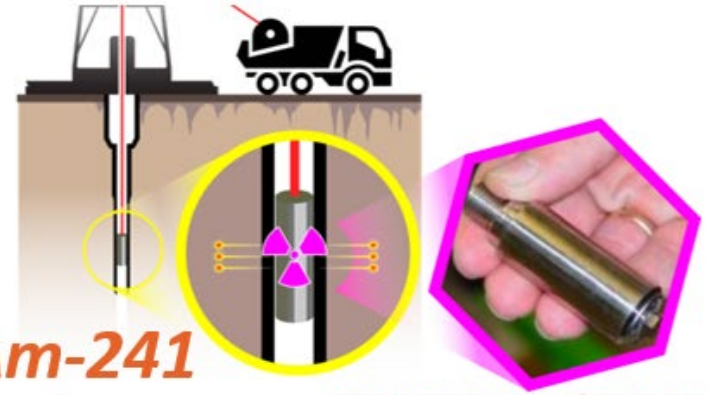
REDUCE the global reliance on radioactive sources by promoting the adoption and development of non-radioisotopic alternative technologies

ORS
Office of Radiological Security
Protect · Remove · Reduce

ORS Partners



ORS focuses on high activity sources commonly used in industrial and medical applications



Am-241

Normal Device Activity
8-20 Ci

Oil well logging (industrial imaging)

Ir-192

Normal Device Activity
10-100 Ci

Radiography (industrial imaging)

Cs-137

Normal Device Activity
1,000 – 50,000 Ci

- Self-shielded irradiators (research and sterilization),
- brachytherapy (cancer treatment),
- calibrators (dosimeter and detector calibration)

Protect: Security Enhancements

DETECT
Prompt Detection and Reliable Notification

Next Generation Integrated Remote Monitoring System (Sentry RMS): *Fully networked, hardened, and encrypted security monitor*

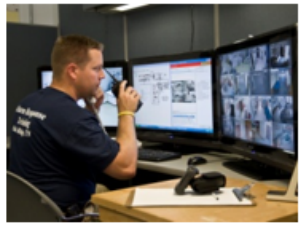
Multi-Factor Access Control: *Requires combination of card, pin, or biometric scan for entry*

DELAY
Extended Adversary Task Time

Hardened Doors

Facility Hardening

RESPOND
Timely, Aware, Equipped and Trained Response



Centralized Monitoring Stations

Personal Radiation Detectors (PRDs) (Domestic only)

TRAIN
Security and Response Training

Alarm Response Training . Response Planning PRD Training, Tabletop Exercises

Security Planning, Performance Testing, Regulatory Development

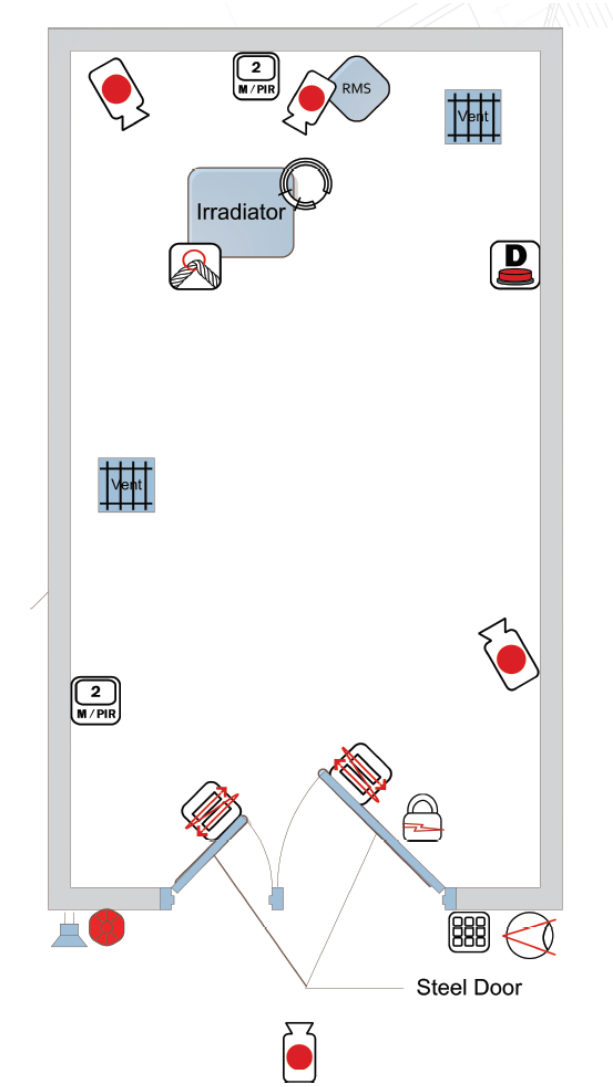
ORS Containment Strategy

Security by Facility Design

- ORS provides assistance to sites with new facilities
- Collaboration with site, security integrator, and other stakeholders to design facilities with security "built-in"
- Recommendations utilize PPS principles
- Conceptual Designs by Device Type (teletherapy, blood irradiator, etc.)
- General Facility/Room Characteristics
  - Example: Building located farther from population centers
  - Example: Target room inside building, below grade, no windows

Security by Facility Design

- Detection and Assessment
  - Access Control
  - Intrusion Detection System
  - Video Assessment
  - Sensors specifications and installation locations
- Delay
  - Wall, door, window, vent, etc.
  - Device Hardening (In-Device Delay)
- Response
  - Location and design of Alarm Station
  - Response Training
- Security Management



In-Device Delay

The In-Device Delay (IDD) program supports ORS's Protect mission.

- Partners with manufacturers to incorporate engineered security enhancements into device or facility designs that will make illicit removal of sources difficult.
  - Manufacturer participation in IDD is voluntary
- Incorporate detection components as well as delay where possible to increase time for local law enforcement to respond.
- Existing devices/facilities retrofitted with enhancements; new devices/facilities incorporate enhancements into manufacturing process.

IDD provides substantial delay time against an adversary that attempts to remove the source from the device, thus buying time for off-site responders to arrive at the site to contain the adversary.

What is IDD?

Passive barrier

- Attached directly to the shielding
- Underneath covers
- Over likely point(s) of source removal

Barriers typically comprises of

- Multiple steel plates
- Concealed tamper resistant hardware
- Penetration resistant materials
- Cost <10% of device cost

Regulatory approvals

- United States Nuclear Regulatory Commission – Amended Sealed Source Device Registration Certificate for IDD upgrades
- Canadian Nuclear Safety Commission – Amended Certificate for Radiation Device for IDD upgrades

IDD certified to not affect device operation, maintenance, or safety

- Device manufacturer performs the installation

Physical Protection System Design Principles

- Detection occurs before delay – Delay before detection does not count.
- Balanced design – A physical protection system should equally protect all possible paths to the asset.
- Designed to meet threat – A designated threat is used to design the physical protection system elements.
- Assessment – Detection should incorporate some means of assessing an alarm to determine validity.

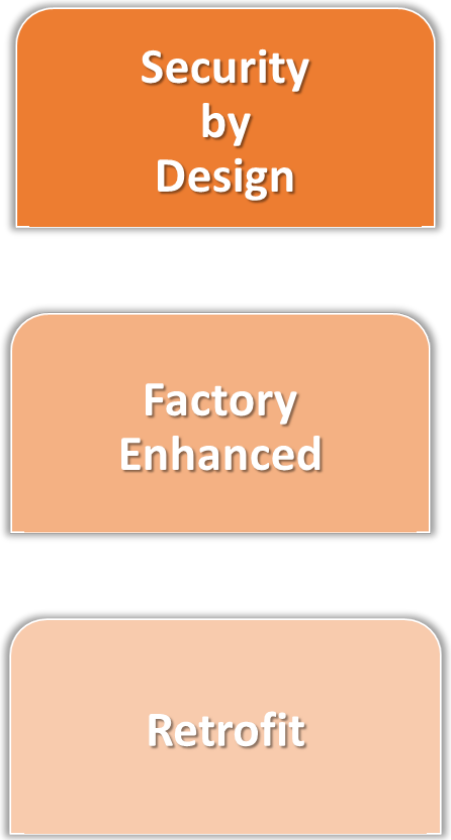
IDD Process Overview

- Vulnerability Analysis
  - Adversary pathway analysis
  - Baseline attack testing
- Collaborate with partner to design a solution
  - Requirements Specification
  - Conceptual Design utilizing PPS design principles
  - Prototype Design
  - Design validation attack testing
  - Refine Design (if needed)
  - Pilot Installation(s)
  - Implementation

Security is often most effectively designed into a device or facility from the beginning rather than added afterwards.

Security by Design Benefits

- SbD significantly reduces cost vs. retrofit
  - Minimize integration effort into facility
  - Reduce travel, labor, and installation costs
- Less impact on end user
- Minimize potential insider knowledge
- Increase likelihood of end user acceptance



IDD Accomplishments

Development

- Over 10 successful industry partnerships since 2007
- Best Theratronics Ltd. (Canada)
- Gamma-Service Medical GmbH (Germany)
- Elekta AB (Sweden)

Implementation

- Over 580 IDD kits installed in the United States
- Some International IDD kit installations

Current and Upcoming Efforts

- International Industry Standardization
- Industrial Irradiators

Challenges

- The threat
- Device vulnerability
- Financially viable for manufacturers
- Manufacturer engineering resources
- Information sharing
- Regulatory requirements
- Security Standard

Conclusion

- Many successful radiological security efforts have been completed.
- A strong international framework for radiological security exists (via IAEA, UN).
- WINS and ORS Best Practices guides provide a wealth of valuable information.

However…

- A need exists to build on top of the existing success.
- A need exists to harmonize an approach to radiological security for medical devices with all stakeholders.
- A international industry standard is one way to address this need.

Thank you!

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