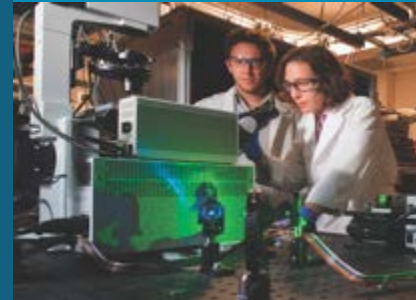


Proposed Industry Standard

Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources



PRESENTED BY

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National Academy
of Sciences Meeting

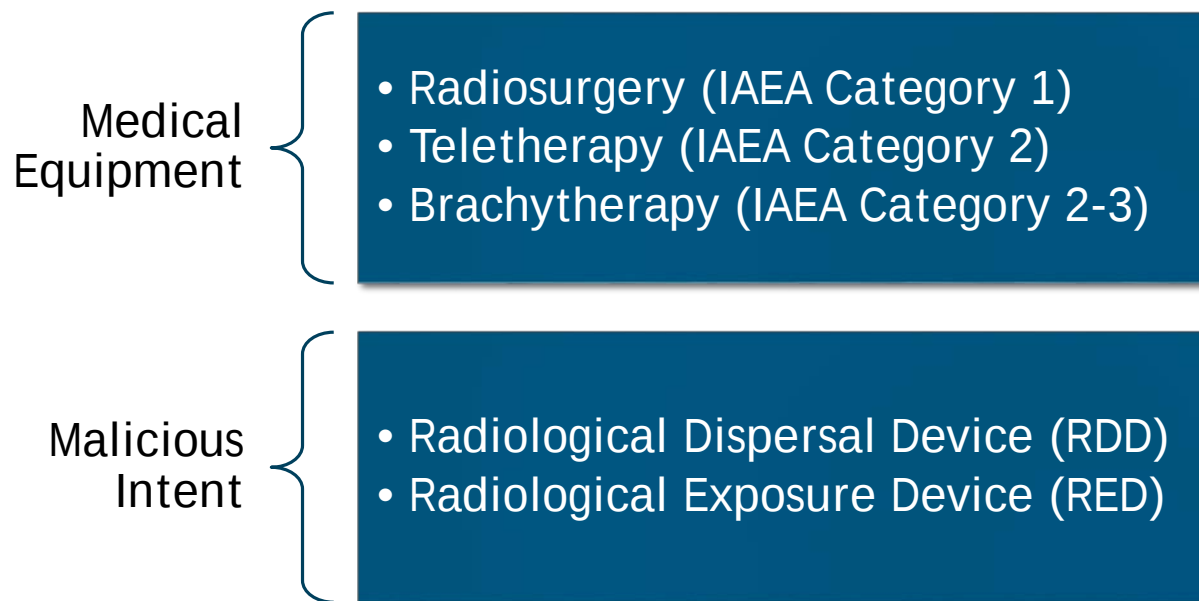
Albuquerque, NM
April 30, 2020

SAND2020-3023 PE

New Work Item Proposal



A harmonized approach to: Protect medical equipment that contain high-activity radioactive sources against malicious intent



Safety is often times not a substitute for security



DOE Office of Radiological Security In-Device Delay (IDD)

- Collaborate with manufacturers of gamma irradiators and medical equipment
- Voluntary participation
- Dozens of designs
- Several manufacturers deploy devices with enhancements already integrated

Deployed IDD “retro fit” kits

- Over 95% of all eligible devices hardened in the U.S.
- Representing ~650 installations as of January 2020
- ~10 installations have been completed internationally

IDD Partners:

- Best Theratronics, Ltd. (Canada)
- JL Shepherd & Associates (U.S.)
- Xcision Medical Systems (U.S.)
- Elekta AB (Sweden)
- Beijing SanQiangHeLi Radiation Engineering Co Ltd (China)
- Hopewell Designs Inc. (U.S.)
- Gamma-Service Medical GmbH (Germany)
- Nordion Inc.(Canada)
- Others...

Security of Radioactive Sources: International Commitments and Agreements



- The Convention on the Physical Protection of Nuclear Material and Facilities; IAEA; 160 Parties
- The International Convention on the Suppression of Acts of Nuclear Terrorism; United Nations; 116 Parties
- The IAEA Code of Conduct on the Safety and Security of Radioactive Sources; 137 Unilateral declarations
- IAEA Nuclear Security Series:
 - NSS-11: Security of Radioactive Sources (Implementing Guide)
 - NSS-14: Nuclear Security Recommendations on Radioactive Material and Associated Facilities
 - NSS-20: Objective and Essential Elements of a State's Nuclear Security Regime

These agreements and documents are generally intended for governments and regulatory bodies

The Challenge



An industry standard that addresses unique challenges in the medical environment

- Medical Facilities:
 - Are often “soft targets”
 - Security is not a high priority, patient treatment is
 - Security budgets tend to be small/non-existent
 - Security culture/awareness can be low
- Standards will consider potential impact on medical electrical equipment:
 - Clinical workflow
 - Patient safety
 - Equipment safety
 - Equipment serviceability

The Proposed Standard



Device-Level Security Enhancements

- Access Delay
- Intrusion Detection
- Sensor communication

Utilizing common physical protection principals

- Defense in Depth
- Balanced protection
- Complimentary technologies



<https://sentinelblog.com.au/high-security-removable-fastener/>



<https://i-fiberoptics.com/pofiber.php?cat=POF&subcat=Transmissive>

E X A M P L E S

Access Delay:

- Tamper resistant fasteners
- Multiple hardened plates

Intrusion Detection:

- Tamper switches
- Fiber optic sensors



Table 1 - Minimum requirements for classification of safes (excluding ATM safes) into resistance grades

Resistance grade	Tool attack test (Clause 7)		Anchoring strength ^a (Clause 8)	Locks		Additional requirements for EX designation (optional) (Clause 9)	Additional requirements for CD designation (optional) (Clause 11)
	Resistance value for		Required force	Quantity	Class according to EN 1300	Post-detonation resistance value ^d	Resistance value ^d
	partial access	complete access					
	RU	RU	kN	RU	RU		
0	30	30	50	1	A	b	c
I	30	50	50	1	A	b	c
II	50	80	50	1	A	4	c
III	80	120	50	1	B	6	c
IV	120	180	100	2	B	9	1000
V	180	270	100	2	B	14	1000
VI	270	400	100	2	C	20	1000
VII	400	600	100	2	C	30	1000
VIII	550	825	100	2	C	41	1000
IX	700	1050	100	2	C	53	1000
X	900	1350	100	2	C	68	1000

a Applicable only to free-standing safes with mass less than 1000 kg.

b EX designation is not permitted for resistance grades 0 and I.

c CD designation is not permitted for resistance grades 0 to III.

d Resistance value for partial access.

- European Standard
- Safes, strongrooms, and strongroom doors
- Assigns Resistance Value



The Proposed Outline

Forward

I. Introduction

II. Scope

III. General Requirements

IV. International Legal Framework for Security of Radioactive Sources

V. Medical Electrical Equipment and the Use of High-Activity Sealed Radioactive Sources

VI. Source Categorization

VII. Security Principles

VIII. Security Considerations and Requirements for Medical Electrical Equipment

IX. Security Compatible with Service and Maintenance for Medical Electrical Equipment

X. Security Compatible with Patient and Staff Safety

XI. Validation Testing

References

Terms and Definitions

Accompanying documents

Annexes

Thank You

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