

Establishing an International Security Standard for Medical Devices containing High-Activity Radioactive Sources

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

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The industry-standard team

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Medical Uses of High-Activity Radioactive Sources

- Radiosurgery (IAEA Category 1)
- Teletherapy (IAEA Category 1)
- Brachytherapy (IAEA Category 2-3)
- Blood Irradiation (IAEA Category 2)
- Sterilization (IAEA Category 1)

Observation:
Security of sources
in medical
applications needs
further attention.

Radioactive sources can be misused

- IAEA has registered more than 3000 cases of illicit trafficking in nuclear and other radioactive materials
- During the past 10 years, 94 incidents involving 126 Category 1-3 radioactive sources occurred.
- About 25% of the cases are associated with unauthorized possession and criminal activity and

High-activity radioactive sources must be protected against theft, loss and intentional or unintentional misuse.

Recall: *Security of radioactive sources is prioritized by the international community*

- Strengthened international legal framework, including:
- *The Convention on the Physical Protection of Nuclear Material and Facilities;* 157(118) Parties
- *The International Convention on the Suppression of Acts of Nuclear Terrorism;* 114 Parties
- *The IAEA Code of Conduct on the Safety and Security of Radioactive Sources;* 137 Unilateral declarations
- The IAEA's *Nuclear Security Series* with recommendations and practical implementation guidance to be implemented by individual States on a voluntary basis.

Overarching objective: Security from cradle to grave, in all circumstances.

Observation: Security of sources in medical applications needs attention.

Security implementation in the medical environment

- Medical facilities are very different from nuclear installations, security:
 - Is often not a high priority; patient treatment is
 - Budgets tend to be small/non-existent
 - Culture/awareness can be low
- Personnel throughput and access varies considerably
 - Patients, relatives, visitors
 - Medical staff
 - Service and maintenance staff
- Patients safety first; immediate response and access at emergency
- Security may be perceived as a hinder

Main challenge: How to design effective security for the medical environment

Developing an Industry Standard brings stakeholder participation and buy-in

- Active participation and contribution of industry and operators, i.e. medical staff
- Consider the full picture: "Built-in" security of medical equipment with facility enhancements
- Normalize security of radioactive sources without negative impact on their uses

International Industrial standards organizations

International Electrotechnical Commission, IEC (86 national member-organizations)

International Organization for Standardization, ISO (162 national standards bodies)

- All stakeholders are represented in the national organizations.
- Standards are developed in Technical Committees with subject matter experts.
- Formal processes, with decisions based on voting, are established for the development of the standards.
- An industry standards must be compatible with international obligations and national regulations. Standards are sometimes referred to in national regulations and licenses.
- Implementation in all Member States.

Initiating a new standard: A New Work Item is normally proposed by a member

NWI content includes:

- Proposed deliverable
- Scope of the proposed deliverable
- Purpose and justification of the proposal
- Outline of the standard
- Draft project plan and development track
- Work group composition, leader and liaisons
- References to existing related standards or relevant documents

Our Vision for an Industry Standard

- **Device-Level Security Enhancements**
 - In-Device Delay (Engineered Delay and Intrusion Detection)
 - Sensor communication
- **Building/Facility Level Security Enhancements**
 - Deter
 - Detect
 - Sensors
 - Alarm Communication
 - Alarm Assessment
 - Delay
 - Hardened doors, windows, walls, vents
 - Access Control
 - Response
 - Communication
 - Security Management

Experience shows that effective security is possible while maintaining high medical productivity, swift access during an emergency, and for device maintenance.

Industry standard vis-a-vis international guidance *a frequently asked question*

- ❖ International standards *comply with and complement* international guidance or agreements
- ❖ *The industry*, e.g. the producers of radioactive sources and medical equipment, *together with the operators*, will participate in and contribute to the development of the standard.
- ❖ Industrial standards contribute a harmonized security approach for the equipment with high-activity radioactive sources, *in the environment in which it is used*.
- ❖ Meeting the industry standard will *validate* a certain level of security.

In Summation

- The effectiveness of security in the medical sector directly depends on proper implementation.
- An international industry standard, compatible with IAEA guidance, would facilitate implementation in the medical sector by direct involvement of industry and operators in its development.
- Recognizing the successes achieved through ORS's In-Device Delay program, a security system with the right balance of physical protection measures would effectively protect the sources from theft, with maintained high medical productivity.
- Globally, an established industry standard would provide a harmonized approach that would facilitate security of radioactive sources used in medical applications.