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AN UPDATE ON THE DEVELOPMENT OF AN INTERNATIONAL SECURITY STANDARD FOR DEVICES CONTAINING HIGH LEVELS OF RADIOLOGICAL MATERIAL

Michal Kuca
Sandia National Laboratories
Albuquerque, United States
Email: mkuca@sandia.gov

Per Kjäll
Elekta Instrument AB
Stockholm, Sweden
Email: per.kjall@elekta.com

Anita Nilsson
AN&Associates
Uppsala, Sweden
Email: anitanilsson.swe@gmail.com

Abstract

Radioisotopes such as cesium-137 (Cs-137) and cobalt-60 (Co-60) are used in various medical, industrial, and research applications. This radiological material can be a theft or sabotage target and needs to be protected. The paper will provide an update on the progress of developing an international security standard for devices used in clinical medical settings that contain high-activity radioactive sources. This topic was originally presented at the IAEA International Conference on Security of Radioactive Material in December 2018. Although the mission of this effort has stayed the same several changes to the scope have materialized and significant progress has been made since that December 2018 conference. This paper provides an updated to that presentation and reflects these recent developments. This standard will contribute to reducing the threat of radiological theft and sabotage, and, at the same time, take into full consideration the effect on end-user safety and patient workflow. The contribution of operators, device manufacturers, radioactive source producers, and medical staff in the development of the standard will ensure effective security implementation while minimizing unintended effects of the security measures. The paper will show how an international IEC standard, existing safety standards, and IAEA security guidance can be complementary. While IAEA guidelines primarily focus on the State, competent authorities, and regulatory agencies, the new standard will address device manufacturers and facility operators such as medical clinics, hospitals, universities, and research facilities.

The standard intends to provide practical implementation of sound security measures that can be incorporated into the medical device without affecting the safety and operation of the device, and with minimal impact on device maintenance. This standard also intends to take into account specific medical device and environmental requirements and be flexible enough to provide appropriate levels of protection for a variety device types and configurations. The paper will address some of the challenges associated with developing such a standard and ways that these challenges may be resolved.

1. THE RISK OF MALICIOUS USE OF RADIOACTIVE SOURCES

Nefarious use of high-activity radioactive sources may result in the deliberate dispersal of radioactivity intended to cause death, severe health effects, destruction, or grave disturbances to society. When combined with conventional explosives, radioactive materials can become a radiological dispersal device (referred to as an RDD or “dirty bomb”). Dispersal may also occur without conventional explosives, through air or water, with severe effects over a long period of time. Over and above the health effects, the radiological contamination may make infrastructure inaccessible, buildings inhabitable, and cause serious environmental damage. Decontamination and clean-up efforts are likely to be very costly. Malicious dispersal of radioactivity remains as the main threat factor. Radioactive sources, therefore, must be protected against acts of theft or sabotage [1].

The international community has identified the risk of terrorists’ or criminal organizations’ acquisition of high-activity radioactive sources as a major threat to civil society and strengthened the international legal framework to enable effective security as risk reduction strategy.

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The IAEA continues to receive information from States that nuclear material or radioactive sources are seized or reported lost in illicit trafficking [2]. Since the inception of the IAEA's Incident and Trafficking Database (ITDB), more than 3000 cases have been reported, slightly more than 150 cases annually. During the past ten years, a total of 94 incidents involving 126 high-activity radioactive sources (Category I, II, and III [3]). Approximately 40% of these cases were associated with theft. In the hands of terrorists, high-activity radioactive sources may be intentionally used to cause deaths, severe health-effects and contamination of property and the environment, with very significant restitution costs.

The data collected points to a continued need to strengthen security of high-activity radioactive sources and that there is no room for complacency in their protection. At the same time, the measures applied should be designed in a way to allow continued uses, in a safe and secure manner, in applications where the sources are essential for medical or industrial purposes.

2. NORMATIVE REFERENCES AND IMPLEMENTATION

2.1 The International Legal Framework for Nuclear Security

In recognition of increasing, violent terrorism, the international community has strengthened the international legal framework for radiological security and given priority to enhancing the security of high-activity radioactive sources. The strengthening effort has taken place over a period of about 15 years, with increased awareness of the necessity for a changed approach to management of radioactive sources wherever they are used. Outside of nuclear facilities, sealed radioactive sources are frequently used in medical and industrial applications, such as radiation therapy, oil rigging, or welding.

International agreements of relevance for the security of radioactive sources include:

— The *Convention on the Physical Protection of Nuclear Material and Facilities* (CPPNMNF), which was amended in 2005 and entered into force in 2016; and

— The *International Convention on the Suppression of Acts of Nuclear Terrorism* (ICSANT), which was agreed on in 2005 and entered into force in 2007.

These two international conventions provide a solid legal foundation for both nuclear and radiological security and should be implemented in an integrated manner. The IAEA carries out responsibilities as a depositary of the CPPNMNF and is referred in ICSANT as the competent international organization for information exchange and guidance on how to handle radioactive materials.

The IAEA is the international organization with a mandate to initiate and develop safety standards and security guidance. Important advances in the establishment of security guidance are the establishment of:

- The *IAEA Code of Conduct on the Safety and Security of Radioactive Sources*, provides non-binding directions on how to manage high-activity radioactive sources. The Code, agreed in an open-ended process with IAEA member States, is not legally binding and is implemented upon unilateral declarations made by individual States;
- The IAEA's *Nuclear Security Series* delivers recommendations and practical implementation guidance that are developed in open-ended technical processes in which experts from IAEA Member States participate. The implementation of published guidance is made on a voluntary basis by the individual State.

In the development of the safety standards and security guidance, the IAEA interacts with representatives of governments and national regulatory bodies. It is up to the State to implement the agreed safety standards and security guidance. The IAEA offers *services* in the implementation of standards or guidance, help with human resource development, evaluation of technical systems and other, limited, technical assistance to strengthen national systems and capacities.

2.2 National regulations and industrial standards

A national legislative system normally reflects obligations undertaken in international agreements and considers IAEA nuclear safety standards and security guidance. National regulatory systems may also refer to international or national industry standards, recognizing the role industry standards may have in the national context. Industrial standards are normally implemented on a voluntary basis by the target industry or organization, as part of their performance basis. The reference is perceived to contribute to the industrial quality of the product or service offered. Standards established by the international standards organizations [4] typically have a high level of support, being developed in processes where all stakeholders participate.

Representatives of operators, manufacturers, and professional organizations do not normally participate in the development of IAEA standards and guidance, albeit have responsibility for implementation. In addition, the civilian, non-nuclear use of high-activity radioactive sources takes place in an environment that is very different from that in a nuclear facility. The security infrastructure is very different in a nuclear facility compared with a hospital, for example. While the former is "closed" always with access control for both persons and goods, a hospital is an open place with a flow of persons and goods. This difference is relevant for security implementation and requires different approaches for the security to be effective. In addition, the awareness in the medical community of the need for security that may limit access to critical medical equipment may be lower, which carries a risk of leading to less effective security.

Industry standards are developed in a broader context, in which representatives of operators, manufacturers, and other stakeholders may participate. An industry standard will thereby be supported by the users, a "buy in" of the staff categories that have implementation responsibility and may lead to increased compliance with rules and policies, thereby also increased implementation effectiveness.

So far, security has not been a subject of industry standards. The evolution of security for high-activity radioactive sources has taken place over a very short time, and security implementation in the medical sector, in many cases, has not received the same priority as high medical productivity.

An international industry standard on radiological security is likely to accelerate implementation of effective security in the civil medical sector due to the participation and contributions of operators, manufacturers, and professionals in the development process. The standard will thus contribute to harmonize, in the global perspective, the approach for security of medical equipment using high-activity radioactive sources. The standard will do this by facilitating harmonization of equipment design to achieve equipment hardening against theft, in combination with measures for access control, detection of intrusion and incident response planning that would not negatively impact the medical uses of the equipment.

An industry standard on security of high-activity radioactive sources share the same goals and objectives as IAEA security guidance, although with separate starting points. While the IAEA guidance is general and directed at the national level, it does not approach the specific circumstances that prevail for the operator in the medical sector, which is the main purpose of the proposed industry standard. Therefore, the two approaches will be mutually supportive by addressing the same topic from two different perspectives: the national versus the operating and equipment manufacturing perspective.

3. RADIOACTIVE SOURCES USED IN THE MEDICAL CIVIL SECTOR

Hospitals and medical research organizations use radioactive sources as tools to achieve their goals and objectives. Modern cancer treatment, diagnosis, radio-surgery, and brachytherapy rely on radiation from radioactive sources or alternative technologies. High-activity radioactive sources are commonplace in teletherapy, brachytherapy, and advanced stereotactic radiosurgery equipment. In addition, high-activity radioactive sources are frequently used in sterilization equipment and blood irradiation. These sources generally belong to IAEA Categories 1-3 (referred to as dangerous sources) based on the potential of the source to cause detrimental health effects.

3.1 Medical procedures using high-activity radioactive sources

Radiation therapy, radiosurgery, diagnostics, and research are key medical procedures/activities that often use, and sometime depend on, the use of high-activity radioactive sources. Although alternative technologies without the use of a radioactive source are available to replace radioactive sources (such as linear accelerators or

x-ray machines), high-activity radioactive sources will remain essential in several medical applications over a foreseeable future.

Medical uses include:

- ***Teletherapy devices*** provide doses of high-energy ionizing radiation to treat deep-seated tumors in the body. These devices either rotate around a patient or use multiple sources of radiation, focused on the tumor. The technique focuses beams intersecting the tumor, which delivers high doses of radiation to the tumor and much lower doses to surrounding tissues. Typically, a high-activity Co-60 source is used in teletherapy devices. Teletherapy is a cornerstone of cancer treatment, both in the early stages of a tumor's development and for palliative purposes in later stages of treatment. Linear accelerators are increasingly replacing teletherapy devices in high-income countries.
- ***Brachytherapy*** is used for internal (within the body) radiation therapy. In brachytherapy, small-size, but high-activity radioactive sources are applied next to the tumor to deliver local radiation, e.g., in the uterus, cervix, or prostate. By placing the radioactive source near or within the tumor, a high dose is achieved locally in the tumor, while the surrounding tissue is spared. Various isotopes are used in brachytherapy, including Cs-137, Co-60, Ir-192, I-125, and Pa-103.
- ***Radiosurgery/Gamma Knives*** are advanced applications that perform surgery using radiation beams. The Gamma Knife, a high-technology assembly of a large number of Co-60 sources arranged three-dimensionally, e.g., in the form of a helmet for intra-cranial radiosurgery, is used to obtain a high radioactive dose in a very well-defined volume that is difficult or impossible to reach with normal surgery. Examples include intra-cranial tumors, aneurysms, and neurological anomalies.
- ***Blood Irradiation*** is routinely performed in self-shielded gamma irradiators to prevent transfusion-associated graft versus host disease (TA-GvHD), a rare but usually fatal complication that may occur in blood transfusion. The devices used for blood irradiation usually contain Cs-137 sources, in the form of cesium chloride salt. X-ray devices are also effective for blood irradiation. Although blood irradiation can be accepted as a medical use of radioactive sources it has since been removed from the initial scope of this effort as this application is outside of the scope of the International Electrotechnical Commissions' (IEC) Subcommittee 62C. More information is provided in section 4 of this paper.

The use of radioactive sources in the civil sector meet high standards for radiation safety. The awareness of the risk that radioactive sources may be intentionally misused is sometimes not fully shared among the various stakeholders, which could negatively impact on security implementation. Unfortunately, effective implementation of the international legal system remains inconsistent.

3.2 Security challenges in the medical sector

Specific challenges exist when applying security measures in the medical sector. Challenges include:

- ***Understanding the need for radiological security.*** For decades, the use of radioactive sources was regulated with requirements on radiation safety. Security was not seen as relevant, as it was falsely believed that its radioactive properties granted the substance "self-protection." This view, which has been completely abandoned by the international community, still prevails to some degree in the civil sector, creating inertia in the implementation of effective radiological security.
- ***Flow of operation.*** A hospital's primary objective is to deliver effective treatment to as many patients as possible, which involves the presence of different categories of staff and visitors. Security procedures that may or could interfere with the medical objectives will be problematic.
- ***Safety of patients.*** Patients undergoing diagnostics, radiation treatment, or radiation surgery are vulnerable. Their safety, the highest priority for the hospital, must not be compromised. Emergency requirements include prompt access by rescue staff, whether for medical, radiation safety, or security purposes. Failure to address patient safety and emergency operations will risk the effectiveness of security arrangements, possibly by bypassing the measures.

4. INDUSTRY STANDARDS TO COMPLEMENT INTERNATIONAL OBLIGATIONS AND IAEA GUIDANCE

The development of an international industry standard on radiological security will harmonize approaches and security performance specifications, thereby facilitating radiological security implementation globally. An industrial standard for radiological security would identify and specify equipment design features to protect the radioactive source from unauthorized access, without degrading the performance of the device. In addition, the standard would identify additional security measures, such as access control, communication, and response preparedness, to achieve an integrated system in which the equipment design contributes a risk reduction. Together, equipment hardening and procedures for access control, detection, and incident response suitable for implementation in the medical environment will provide effective security.

The development of an industry standard would facilitate and accelerate effective radiological security in the medical civil sector, *inter alia,* by providing an opportunity to hospital owners, operators, radioactive source or equipment producers, and relevant professional organizations to share their experiences.

4.1 Scope and content of an international industry standard on security of medical equipment using high-activity radioactive sources

The standard will apply to requirements of security of medical equipment that uses high-activity radioactive sources, in radiotherapy, radiosurgery, or sterilization equipment. Examples are Category I, II, or III radioactive sources containing isotopes of Co-60 and Cs-137. The standard will address equipment security-by-design features and complementary operational procedures. The security approach will align with classic security measures, such as:

- ***Delay*** of unauthorized access to the radioactive sources. This will include technical arrangements to harden the equipment against theft or sabotage of the radioactive sources and to control access to the equipment and its sources;
- ***Detection, assessment, and response*** to attempts of unauthorized access. This will include communication through automatic systems and personnel responsibilities. Attention will be given to the specific operational requirements in the medical field, such as patient safety, maintenance, and the efficiency of the medical processes;
- ***Integrity*** will be addressed by considering the clinical workflow when security solutions are implemented, including service and maintenance.

The standard will contribute to a clarification and harmonization of the implementation of obligations included in international conventions and Codes of Conduct established to address security of vulnerable radioactive sources or other radioactive materials. The standard will align with recognized national requirements and their guiding principles, such as the international guidance issued by the IAEA.

The standard will first introduce the reasons for developing a standard on radiological security, define its scope, and give normative references and general requirements. In the substantive articles of the standard, the security principles will be described as well as the specific considerations regarding security requirements for medical equipment. The measures applied to harden the device against possible theft of the radioactive source(s) will be developed, as well as the complementary arrangements for communication and alarm. It is foreseen that the standard will be performance based and give objectives and goals for the measures to be applied. The standard would further establish a standard approach to making the security arrangements compatible with requirements for service and maintenance for medical equipment and with patient and staff safety. Validation testing would be included as the basis for certification to meet the standard, including the require tools and equipment to conduct the tests.

4.2 Development of industry standards

Three international organizations that develop and publish standards that are most applicable to this proposed standard are: the International Standards Organization (ISO), the International Electrotechnical

Commission (IEC), and the International Telecommunication Union (ITU). These organizations cooperate to ensure that all international standards fit together seamlessly and complement each other.

The international standards organizations interact closely with their national member organizations. An organization/network is formed with the members and with technical committees and sub-committees. The member organization interacts with all stakeholders for participation in the work that takes place in technical committees and subcommittees with suitable profiles of expertise. Competent authorities are important stakeholders. The development of an industry standard for radiological security will include the national regulator, operators or end-users (hospitals or research institutions), device manufacturers, radioactive source producers, and representatives from law enforcement and emergency response organizations.

In 2019, a draft new work item proposal (NWIP) intended for submission to the IEC was developed. After various meetings and discussions with industry and as a means of limiting the initial scope of this effort, it was decided that the IEC was the most likely logical standards organization to address to taken on the development of this standard. The IEC is an independent, international organization with a membership of 83 national committees plus several affiliate countries. IEC develops international standards for all electrical, electronic, and related technologies. Several standards have been published for medical equipment, e.g., linear accelerators and radio-surgical devices. It is certainly possible and probable that other standards organizations, such as the ISO, may be involved at later time when the scope of the project is expanded.

The NWIP provides a brief description of the proposed standard's scope, purpose, and issues to be addressed, beneficiaries, and justification. References to other related documents, e.g., international agreements or IAEA security guidance, and anticipated cooperation with other standards organizations, will ensure coherence and the absence overlaps. The NWIP was submitted to the Swedish National Committee to the IEC, Svensk Elstandard Kistagången (SEK), for consideration to the IEC. The SEK made some minor edits and submitted the NWIP to the IEC Subcommittee 62C (SC 62C). SC 62C is a technical committee responsible for drafting, updating, and reviewing international standards related to equipment for radiotherapy, nuclear medicine and radiation dosimetry. They are the most likely subcommittee within the IEC organization to take on this effort. Upon review of the draft NWIP SC 62C made the decision to limit the scope of this standard only to medical electrical equipment. The term "medical electrical equipment" generally includes equipment that is used on a patient, as such, self-shielded blood and research irradiators have been removed from the scope of this initial proposal. There is a possibility that a security standard for self-shielded irradiators could be developed and referenced by this standard. There is also a possibility that such a standard could be developed in collaboration with the ISO.

The next step in the process is for the IEC to send the NWIP to the IEC national committees for voting. The voting period typically takes 90 days and, if the necessary votes are garnered, development of the new standard can begin. If approved, a working group within SC 62C consisting of various experts will be created to begin the standards development process. The IEC has very robust, well written guidelines and tools to ensure that standards are written in an internationally recognized manner.

5. CONCLUSION

An international industry standard on the security of medical equipment using high-activity radioactive sources would complement existing international legal framework for nuclear and radiological security and facilitate implementation. The standard will accelerate radiological security in the medical sector, by soliciting the diverse experiences and views of operators, manufacturers, and professionals in a global perspective.

The availability of an industry standard that integrates device security design measures with other location-based security measures will benefit *both* manufacturers *and* users by facilitating the production of new, hardened equipment that reduces the security risk associated with the radioactive sources contained, thereby enabling the selection of procedures and arrangements required to detect intrusion attempts and respond to them in a way that will not negatively impact the medical procedures for which the equipment is intended. Commencing development of an international industry standard will be a constructive action to strengthen security of high-

activity radioactive sourced in medical applications, in line with intentions and objectives defined within the international community.

6. ACKNOWLEDGEMENTS

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7. REFERENCES

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