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PROGRESS UPDATE ON THE DEVELOPMENT OF AN INTERNATIONAL STANDARD TO PROTECT MEDICAL EQUIPMENT THAT USES RADIOACTIVE SOURCES

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Abstract

With overwhelming support by participating national committees, the International Electrotechnical Commission (IEC) approved, in May 2020, a new project to develop and publish an international standard on the security of medical equipment containing high-activity radioactive sources. The title of the new standard is: *Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources*. The paper presents the standard and its development. Requirements included in the standard are directed to the manufacturer of medical equipment with radioactive source(s) *and* to the organization (e.g. the hospital) that will operate the equipment. By applying the standard, the *security risk* associated with the medical equipment will be reduced, i.e., the risk that contained radioactive sources can be stolen by an intruder will be lowered. The standard underlines the need for a security culture, in which all staff is aware of the possibility of a security event and the necessity to guard against it.

1. INTRODUCTION OF THE NEW IEC STANDARD

Aware of the need and the urgency for a standard that aims at protecting medical electrical equipment with high-activity radioactive sources from unauthorized access by terrorists or criminals, the International Electrotechnical Commission (IEC) embarked on a project to develop an international standard on security for medical equipment using high-activity radioactive sources. The proposal for a new standard was submitted in February 2020 for acceptance voting to the 22 IEC Committees responsible for the development of international standards for medical electrical equipment. A very positive voting-result was received in April 2020, when all 20 voting Committees approved the proposal.

1.1. The development of the standard

Once the new-standard-proposal was approved, an Expert Group with fourteen qualified experts nominated by 10 National Committees was established. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, require competence in security. An overall time-plan for the development of the standard includes the circulation of draft standards for comments, the first by the end of 2020, and a final draft for acceptance voting in June 2022, with the intention of publishing the standard mid-2023. The completion of the time-plan will be adjusted for delays caused by the COVID-19 pandemic.

The first draft standard was circulated as planned, with comments received in April 2021. The National Committees supported the direction of development and recognized the complexity of the standard. Medical equipment containing high-activity radioactive sources are used in an environment which must be arranged to support the overall security of the device and its use. The standard therefore contains requirements directed both to the manufacturer of medical equipment and to the operator of the equipment, normally a hospital.

1.2. The content of the standard

The Scope defines the overall purpose of the standard and the kind of equipment that is included. The direction of development is to obtain a standard that is applicable for all medical equipment that uses high-activity radioactive sources. The standard addresses security when the equipment a) is being installed, b) is used in the intended manner and c) when it is stored over a longer time by the operator. The standard does not address the period when the radioactive source is disused or ready for disposal.

Radioactive sources used as medical implants, are not included in the scope of the standard.

Brachytherapy, the precise placement of short-range radiation-sources inside the human body directly at the site for radiation treatment, normally is achieved by the use of medical equipment referred to as an "Afterloader for brachytherapy". The Afterloader injects the sources into the target organ and extracts them after treatment. Sources inside the Afterloader are physically protected by the equipment, but when used in therapy, other security measures take over.

One type of medical equipment using high-activity radioactive sources is the "blood irradiator" in which a Cs-137-source is used to irradiate blood which has been donated e.g. for use in surgery. Unless the blood is treated, the transfusion carries a risk of graft-versus-host disease, GvHD, which is a serious side-effect. Transfusion-associated GvHD is almost entirely preventable by controlled irradiation of blood products to inactivate the white blood cells. Irradiation of blood products may be done using a Cs-137-irradiator or an X-ray machine.

The table below provides an overview of the medical equipment that uses radioactive sources and will be updated to account for equipment relevant for the standard in its final form.

Radioactive Source Category[1]	Activity/Ratio	Medical equipment, examples	Radioactive isotope
1	A/D ≥1000	Teletherapy equipment. Multi- source stereotactic radiotherapy equipment. Blood irradiation and sterilization equipment.	Co-60, Cs-137
2	1000 > A/D ≥ 10	Brachytherapy equipment, afterload.	Co-60, Cs-137, Ir-192, I-125
3	10 > A/D ≥ 1	Brachytherapy equipment, afterload.	Co-60, Cs-137, Ir-192, I-125 Other sources

Table 1: Overview of ME-equipment, the isotopes and related source categories

Categories of radioactive sources

The IEC standard refers to the categorization of radioactive sources that is developed by the IAEA. The *categories*[1] of radioactive sources defined by the IAEA are based on their specific and actual activity as well as other characteristics of security importance. Isotopes have been grouped into five categories based on the sources' A/D-value. The A value is the actual activity of the radioactive material in the source, and the D value is the radionuclide specific activity of a source which, if not under control, could cause severe deterministic effects in a range of scenarios that include both external exposure from an unshielded source and internal exposure following dispersal of the source material.

[1] IAEA Safety Standards Series No. RS-G-1.9 STI/PUB/1227 | 92-0-103905-0

ME equipment subject to this standard contain sealed radioactive sources within IAEA categories 1-3.

Vulnerability assessments

Recognizing the possibility of security events, and that radioactive sources in equipment intended for medical treatment, may be a security target, serves as background for a vulnerability analysis that should be performed on the medical equipment and of the location/hospital in which the equipment is going to be used. The purpose of the vulnerability assessment is to generate the information needed to best allocate the protective measures of the equipment and the additional security arrangements required at the location of equipment.

The vulnerability assessment performed by the manufacturer shall evaluate how the equipment can be opened and the contained sources extracted. A foundation for the assessment is the assumptions made regarding the tools that the perpetrators carry. The capacities of the tools shall be in pair with the efforts that are anticipated to forcefully open the equipment. The vulnerability assessment, together with the category of the sources contained in the ME equipment, will serve as input to the manufacturer during the design and construction of medical equipment to ensure that it *resists* a defined intrusion attempt.

The vulnerability assessment performed by the operator, normally the hospital, shall result in knowledge of the different ways an intruder can get access to the equipment, either in the treatment room or in a temporary storage place. The assessment will provide input to the security arrangements that are needed to guard access to the equipment, either by locks, electronic devices or guards.

The results of the vulnerability assessments performed by the manufacturer and by the operator are highly sensitive, and the confidentiality of the information must be maintained. The standard contains requirements in this regard.

Allocation of responsibilities. Security of ME equipment with high-activity radioactive sources is a combination of measures at the equipment itself, i.e., its design and construction and of arrangements made in the location where the equipment is used or stored. The requirements of the standard that relate to the design and construction of ME equipment are the responsibility of the manufacturer and requirements regarding the use and storage of the equipment with its radioactive sources are directed to the user organization, normally the hospital. The manufacturer and the user organization share responsibility to achieve reduced security risk in the use of ME equipment. Any change in the threat level, perhaps as a result of other events, will have to be dealt with by the user organization in communication with the regulator and other national authorities.

Requirements on the manufacturer.

The equipment manufacturer will be responsible for compliance with the requirements of the standard for the equipment. The IEC standard provides specific requirements for the design and construction of the equipment to make the equipment *resistant* to attempts to open the equipment and steal the contained radioactive source(s).

Medical equipment with radioactive sources shall meet the graded requirements of increased resistance; equipment with category-1 sources shall be more resistant than equipment with category-2 sources which shall be more resistant than equipment with category-3 sources.

The *resistance grades* will be defined with the same methodology that defines the resistance of safes, strong rooms or ATM machines, in a graded approach depending on the category of the radioactive source(s) contained. The methodology to define resistance grade takes into account the capacity of the tools available to open a device, e.g. a safe. With higher resistance grades, more advanced tools are forecasted to be used to open the device. If the device cannot be opened with the tools, as defined by the test methodology, the equipment has met the requirements for that particular resistance grade.

Requirements on the operator

The location in which the medical equipment is used is also the interface between the equipment and the open areas of the hospital. The security arrangements made in this location, the interface to the open areas, complement the resistance of the equipment, and include access control, detection of intrusion, alarm, planned response in case of a security event and staff training. Compliance with these requirements will be the responsibility of the operator, normally a hospital.

The arrangements in the location will include connection(s) to the medical equipment, including means to receive signals of attempts to forcefully open the equipment. This is a normal safety precaution, which is equally valid for a security incident.

Planned response in case there is a security alarm, is of key importance. As a minimum, the planning includes communication about the event to an external organization, normally the police.

The arrangements made by the operator, the hospital, shall be documented and available when needed. The staff needs to be briefed and, some of them, trained to know the routines for daily work in a secure environment and the procedures that apply in case of a security event.

The result

As a result, medical equipment constructed according to the requirements of the standard will be hardened and resist attempts to open and steal the sources. With security arrangements at the location of use, considerable advancements in the security of radioactive sources used for medical purposes will be achieved.

1.3. Testing compliance with the requirements of the standard

Compliance with an international IEC standard is tested according to an agreed test-protocol which is also referred to in the standard. Tests are performed as a " tool attack", characterized and quantized by the tools used, the amount of time the tools are used, and the characteristics of the tools used. A tool is characterized by a basic *tool-value* which represents difficulties in obtaining, transporting, in using and operating the relevant tool at the site in question, and the necessary knowledge and experience for its efficient use. Another characteristic of a tool is its *tool coefficient*, representing factors such as noise, smoke, fumes or other effects, which increase the likelihood that a attack is detected.

Accredited test-houses conduct tests according to specified protocols. Thereby, the medical equipment will be subject to a *Type Test*. Provided the tests show compliance with the requirements, the test-house is authorized to provide a certificate of compliance to the manufacturer. Equipment manufactured according to the same specifications may claim compliance with the standard.

Compliance of requirements that are the responsibility of the operator, normally the hospital, will be established through *verification of compliance*. Such verification can be made by a credible party, e.g. at a site visit, or an inspection, in which the associated documentation is examined.

A certificate of compliance with the standard indicates a) a reduced risk of theft of the contained radioactive source(s) and b) excellence in security management related to the medical equipment that uses high-activity radioactive sources.

2. IEC STANDARD REQUIREMENTS VERSUS IAEA SECURITY GUIDANCE

The IAEA security guidance published in the Nuclear Security Series and in the Code of Conduct on the Safety and Security of Radioactive Sources, identify *principles and performance goals,* e.g. for the physical protection of the radioactive source, for access to the source(s), or for the planning that is required in case of a security event. These guiding principles are implemented by IAEA member States, in a way that each State and regulatory authority decides. The IAEA guidelines do not prescribe *how* to reach the goals, which will be regulated by each national authority. This is fully recognized in the new standard.

The standard in progress; *Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources* is the first IEC-developed security standard with the objective of security

risk reduction. The standard is directed to the audiences that are directly involved with medical equipment using radioactive sources; the manufacturer for the design and construction of equipment and the operator for arrangements at the site of use. The standard does not replace or overtake national requirements, the standard will rather facilitate implementation of national requirements.

The new IEC standard recognizes the principles and goals established by the IAEA. Together, the IAEA guidance and the IEC standard provide a major contribution to security of radioactive sources in medical uses.