

Development of an International Security Standard for Devices Containing High Levels of Radiological Material

Radioisotopes such as Cs-137 and 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. This 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. A project team was formed as part of the International Electrotechnical Commission (IEC) to develop the standard. 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 of device types and configurations.

This paper will address some of the challenges associated with developing such a standard and ways that these challenges may be resolved.

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