

Single-Use Sharps Containers for Medical Waste Disposal in the Medical Laboratory

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The purpose of the current paper is to provide reasonably practicable guidance for the International Standard ISO 15189:2012 accredited medical laboratory to support the implementation of disposal facilities for medical waste by ensuring the usage of single-use sharps containers is within acceptable specifications. Guidance documents from selected international organizations: The International Electrotechnical Commission, the International Organization for Standardization, and the World Health Organization, were identified. This review identified relevant requirements from selected organizations ($n = 3$) associated with the support of implementation of storage and disposal facilities for dangerous materials in the medical laboratory. The information could be used to develop conformity checklists for internal auditing, if required. The present paper has provided a practical contribution to established knowledge of International Standard ISO 15189:2012 accreditation compliance management in the disposal of potentially hazardous sharps using single-use sharps containers by laboratory personnel.

Key words: Accreditation, management audit, quality improvement, quality management.

Contemporary situation

International Standard ISO 15189:2012 prepared by the International Organization for Standardization specifies that the medical laboratory is to have storage and disposal facilities for dangerous materials appropriate to the hazards of the materials (ISO 15189:2012, 5.2.3).^{1,2} To support the implementation of such facilities in the medical laboratory, potential hazardous sharps management should be maintained in compliance with good practice and applicable requirements (ISO 15189:2012, 4.1.1.4 e).¹

How should the medical laboratory ensure suitable type of single-use sharps containers are selected to support ISO 15189:2012 accreditation?

Medical waste disposal measures

The medical laboratory should use an acceptable waste receptacle for the disposal of potentially hazardous sharps, defined as 'objects capable of cutting or penetrating skin' (ISO 23907-1, 3.15).³ A commonly used item for the disposal of such medical waste, defined as 'any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biological materials, including but not limited to isolation wastes, infectious agents, human blood and blood products, pathological wastes, sharps, body parts, contaminated bedding, surgical wastes and potentially contaminated laboratory wastes and dialysis wastes' (ISO 16304:2018, 3.5), in the medical laboratory is the use of a specified puncture-resistant container, such as a single-use sharps conta-

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iner, defined as a ‘container designated by the manufacturer to be filled only once’ (ISO 23907-1:2019, 3.17), to support the waste management implementation.^{3,4}

Relevant good practice guidance

Clauses 4 and 5 of ISO 15189:2012 do not provide any specified conformance requirements in relation to single-use sharps container physical specifications, it is good practice for the medical laboratory to establish relevant medical waste disposal practices that are in alignment with the following guidance documents from selected international organizations, such as the International Electrotechnical Commission, the International Organization for Standardization, and the World Health Organization.^{1,2}

International Standard ISO 15190:2020 prepared by the International Organization for Standardization specifies that all sharp objects must be discarded directly in specified puncture-resistant containers (ISO 15190:2020, 17.3 c) and the containers must be positioned within arm’s reaching distance, below eye level and not be filled to more than two-thirds of the capacity (ISO 15190:2020, 14.8 d).⁵




Figure 1. The medical laboratory must ensure only single-use sharps containers that meet relevant marking and performance requirements are used for the disposal of potentially hazardous sharps.

International Standard ISO 23907-1:2019 prepared by the International Organization for Standardization specifies performance specifications (ISO 23907-1:2019, 4) and marking specifications (ISO 23907-1:2019, 6) for single-use sharps containers.³ The medical

laboratory should ensure the single-use sharps containers are safe for laboratory personnel to use for medical waste disposal by non-technically inspecting the following selected specifications. First, the display of the fill line, defined as ‘mark, indicator or feature on the container that represents the fill volume’ (ISO 23907-1:2019, 3.3).³ Second, the display of the word ‘DANGER’, defined as ‘signal word used to indicate an imminently hazardous situation which, if not avoided, will result in death or serious injury’ (ISO 3864-2:2016, 3.3), or the equivalent wording in the language of the country where the container is used.⁶ Third, the display of the fill volume, defined as ‘usable volume determined by the manufacturer and indicated by the fill line on the container’ (ISO 23907-1:2019, 3.4).³ Fourth, the display of the lot number. Finally, the display of a warning notice ‘not filling above fill line and not forcing sharps into container’.³

Guide ISO/IEC Guide 37:2012 prepared by the International Organization for Standardization and the International Electrotechnical Commission specifies the information presentation format relating to instructions for use, defined as ‘information provided by the supplier of a product to the user, containing all the necessary provisions to convey the actions to be performed for the safe and efficient use of the product’ (ISO/IEC Guide 14:2018, 3.9) for reagents and consumables by containing information required by users to be able to minimize harm to people, property and the environment.^{7,8} In particular, the medical laboratory should take note to storage requirements in normal use that may influence the effectiveness of usage of single-use sharps containers (ISO/IEC Guide 37:2012, 4.11).⁷

Table 1. The biological risks symbol. The symbol ISO 7000-0659 (2004-01) by the International Organization for Standardization is the graphical symbol for biological risks.

Symbol	Description
	Reference: ISO 7000-0659
	Referent: Biological risks
	Registration date: 2004-01-15

The World Health Organization has a segregation scheme for sharps disposal for

puncture-proof containers.⁹ The medical laboratory should ensure the single-use sharps containers are safe for laboratory personnel to use for medical waste disposal by non-technically inspecting the following selected specifications.⁹ First, the container is yellow. Second, the display of the word 'SHARPS'. Finally, the display of the symbol ISO 7000-0659 (2004-01)¹⁰ (Table 1).

It should be noted that applicable international, national or regional requirements may also be enforceable (ISO 15189:2012, 1).¹ The medical laboratory must do what is reasonably practicable to implement relevant safety features to the normal usage of single-use sharps containers to ensure the safety of laboratory personnel during the disposal of potentially hazardous sharps (Figure 1).

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