

Personal Protective Measures for Laboratory Personnel in the Medical Laboratory

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The aim of this paper was to provide reasonably practicable guidance for the International Standard ISO 15189:2012 accredited medical laboratory to support the implementation of personal protective measures for laboratory personnel. Guidance documents from selected international organizations were identified: The Institute of Electrical and Electronics Engineers, the International Commission on Occupational Health, the International Electrotechnical Commission, and the International Organization for Standardization. This study identified relevant recommendations and requirements from the selected organizations ($n = 4$) associated with implementation of relevant personal protective measures 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 existing knowledge of International Standard ISO 15189:2012 accreditation compliance management in personal protective measure provision to laboratory personnel in the medical laboratory.

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

Contemporary situation

International Standard ISO 15189:2012 prepared by the International Organization for Standardization (a Type B international organization according to the Union of International Associations) specifies that the laboratory director (or designate/s) is to 'implement a safe laboratory environment in compliance with good practice and applicable requirements' [Subclause 4.1.1.4 e) of ISO 15189:2012].^{1,2}

How should the medical laboratory deliver safety messages to laboratory personnel relating to mandatory action to support International Standard ISO 15189:2012 accreditation?

The medical laboratory may wish to provide safety information to laboratory personnel by using safety signage in the areas of responsibility. A safety sign, defined as a 'sign giving a general safety message, obtained by a combination of a color and geometric shape and which, by the addition of a graphical symbol, gives a particular safety message' (Item 3.3 of ISO 7010:2019), may signify information of a mandatory action relating to the application of personal protective measures.³ While Clause 4 (Management requirements) of ISO 15189:2012 and Clause 5 (Technical requirements) of ISO 15189:2012 do not provide any practical guidance on how to address the use of safety signs to indicate specific action relating to personal protective equipment, defined as a 'variety of barriers including clothing and respi-

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rators used alone or in combination to protect mucous membranes, airways, skin, and clothing from contacts with infectious or hazardous agents' (Item 3.1.36 of ISO 15190:2020), in the medical laboratory.^{1,4}

International Organization for Standardization.

International Standard ISO 7010:2019 prepared by the International Organization for Standardization specifies information to address the provision of safety signage in the medical laboratory.³ ISO 7010:2019 classifies safety signs into five categories: Category E [signs indicating an evacuation route, the location of safety equipment or a safety facility, or a safety action (safe condition signs)], Category F (fire equipment signs), Category M (mandatory action signs), Category P (prohibition signs) and Category W (warning signs) [Subclause 4.3 (Categorization of safety signs) of ISO 7010:2019].³ Category M signs (mandatory action signs) are the ones providing personal protective measures information (Table 1). The relevant symbols ($n = 7$) are described below:

Face and body protection.

The symbol (ISO 7010-M004) (2011-05) implies the wearing of a face shield, defined as a 'protector that is worn directly or indirectly on the head and covers the eyes and all, or a substantial part, of the face' (Item 3.5.1.6 of ISO 4007:2018), and the symbol (ISO 7010-M013) (2011-05) implies the wearing of goggles, defined as a 'protector that fully encloses the orbital area and fits firmly on the face' (Item 3.5.1.7 of ISO 4007:2018), in the medical laboratory.^{3,5}

Footwear.

The symbol (ISO 7010-M008) (2011-05) implies the wearing of safety footwear, defined as 'footwear incorporating protective features to protect the wearer from injuries that could arise through accidents' (Item 3.1 of ISO 20345:2011), in the medical laboratory.^{3,6}

Gloves.

The symbol (ISO7010-M009) (2011-05) implies the wearing of gloves, including protective

gloves against cold, protective gloves against dangerous chemical risks, defined as 'protective gloves which form a protective barrier to dangerous chemicals' (Item 3.3 of ISO 374-1:2016), protective gloves against ionizing radiation and radioactive contamination, protective gloves against micro-organisms, defined as 'protective gloves which form a protective barrier to microbiological agents' (Item 3.1 of ISO 374-5:2016), in the medical laboratory.^{3,7,8}

Table 1. Safety signs (Category M).³ Mandatory action signs.

Symbols	Information
	Functional reference number: M004 Referent: Wear eye protection
	Functional reference number: M008 Referent: Wear safety footwear
	Functional reference number: M009 Referent: Wear protective gloves
	Functional reference number: M010 Referent: Wear protective clothing
	Functional reference number: M013 Referent: Wear a face shield
	Functional reference number: M016 Referent: Wear a mask
	Functional reference number: M017 Referent: Wear respiratory protection

Protective clothing.

The symbol (ISO 7010-M010) (2011-05) implies the wearing of protective clothing, defined as 'clothing including protectors which cover or replace personal clothing, and which is designed to provide protection against one or more hazards' (Item 3.5 of ISO 13688:2013), in the medical laboratory.^{3,9}

Respiratory protection.

The symbol (ISO 7010-M016) (2011-05) implies the wearing of a medical face mask, defined as an 'item of protective clothing designed to protect portions of the wearer's face, including at least the mucous membrane areas of the

wearer's nose and mouth, from contact with blood and other body fluids during medical procedures' (Item 3.6 of ISO 22609:2004), in the medical laboratory.^{3,10} The symbol (ISO 7010-M017) (2011-05) implies the wearing of respiratory protective device,^{3, 11,12} defined as 'personal protective equipment designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres' (Item 3.203 of ISO 16972:2020), in the medical laboratory.¹³

Concurrently, International Standard ISO 15190:2020 prepared by the International Organization for Standardization specifies the relevant actions relating to personal protective measures that the medical laboratory should take to address the compliance requirements [Subclauses 15.2 (Protective clothing in the laboratory), 15.4 (Face and body protection), 15.5 (Gloves), 15.6 (Footwear), and 15.7 (Respiratory protection) of ISO 15190:2020].⁴ This is supported by International Standard ISO 11014:2009¹ prepared by the International Organization for Standardization.⁴ ISO 11014:2009 classifies a safety data sheet under 16 document headings [Clause 5 (Contents and general layout of an SDS) of ISO 11014:2009] where Section 8 provides recommendations relating to appropriate personal protection equipment when handling chemical related risks [Annex A.9 (Section 8 – Exposure controls and personal protection) of ISO 11014:2009].¹⁴

Institute of Electrical and Electronics Engineers and International Electrotechnical Commission.

This is further supported by the instructions for use information provision requirements in International Standard IEC/IEEE 82079-1:2019 prepared by the International Electrotechnical

Commission (a Type C international organization according to the Union of International Associations) and the Institute of Electrical and Electronics Engineers (a Type F international organization according to the Union of International Associations) that specifies the location of instructions for use where relevant safety-related information is to be displayed to the users.^{2,15} Relevant safety-related information is to be provided to users if the task requires the use of personal protective equipment [Subclause 7.11.2 (Location of safety-related information) of IEC/IEEE 82079-1:2019] and recommendations in Guide ISO/IEC Guide 37:2012 prepared by the International Organization for Standardization and the International Electrotechnical Commission that specifies the provision of special protective measures that are required to protect bystanders and users (Subclause 4.7 of ISO/IEC Guide 37:2012).^{15,16}

International Commission on Occupational Health.

The International Commission on Occupational Health (a Type B international organization according to the Union of International Associations) has relevant information relating to the selection and use of personal protective equipment for respiratory protection, eye protection, head protection, foot protection, and hand protection.^{2,17}

It should be noted that applicable international, national or regional requirements may also be enforceable [Clause 1 (Scope) of ISO 15189:2012].¹ The medical laboratory must do what is reasonably practicable to ensure relevant information relating to personal protective measures in the medical laboratory is properly identified to support accreditation compliance management.

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