Mini-review

Warning Markings for Laser Products in the Medical Laboratory

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The purpose of this paper was to provide reasonably feasible guidance for the International Standard ISO 15189:2012 accredited medical laboratory to support the implementation of relevant equipment hazard information provision to laboratory personnel by ensuring the usage of laser warning markings is within acceptable specifications. Guidance documents from selected international organizations were identified: the Institute of Electrical and Electronics Engineers, the International Electrotechnical Commission, and the International Organization for Standardization. This study identified relevant requirements from the selected organiZations (*n* = 3) associated with implementation of laser warning markings 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 provision of relevant equipment hazard information relating to laser hazard warning markings to 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 (ISO) specifies that the laboratory director [or designate(s)] is to 'implement a safe laboratory environment in compliance with good practice and applicable requirements' (ISO 15189:2012, 4.1.1.4 e).[1,2]

How do lasers differ from light emitting diodes?

The term 'laser', an acronym for light amplification by stimulated emission of radiation, defined as 'any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm primarily by the process of controlled stimulated emission' (IEC 60825-1:2014, 3.44).[3] This differs from a 'light emitting diode', defined as 'any semiconductor p-n junction device which can be made to produce electromagnetic radiation by radiative recombination in the semiconductor in the wavelength range from 180 nm to 1 mm' (IEC 60825-1:2014, 3.52).[3]

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

Equipment hazard warnings.

The medical laboratory must provide relevant equipment hazard information to laboratory personnel. Clauses 4 and 5 of ISO 15189:2012 do not provide any practical guidance on how to address the hazard warning issues. However,

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the International Standard ISO 15190:2020 prepared by the ISO specifies that appropriate approved signs must be displayed (ISO 15190:2020, 9.51).[1,4] In addition, the International Standard IEC/IEEE 82079-1:2019 prepared by the International Electrotechnical Commission (IEC) and the Institute of Electrical and Electronics Engineers specifies that relevant safety-related information must be provided in the equipment instructions for use.[2,5] This is 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), supplied by the manufacturer (IEC/IEEE 82079-1:2019, 7.11.2) to support hazard communication (ISO 15189: 2012, 5.3.1.3).[1,6,7]

Laser warning markings

The equipment instructions for use should contain an appropriate level of laser safety information for laboratory personnel. The information can be further supported by the International Standard IEC 60825-1:2014 prepared by the IEC.[3] IEC 60825-1:2014 classifies lasers into eight classes according to the increasing order of ocular hazard (IEC 60825-1:2014, 4.3).[3] Each laser product must carry appropriate labels (IEC 60825-1:2014, 7).[3,] Appropriate warning labels, explanatory labels that contain recommended wordings and alternative labels must be included for each class of laser product (Figure 1 and Table 1).

Class 1. The alternative label is a combination product safety label, defined as 'combination of product safety sign and/or supplementary safety information and/or hazard severity panel on one rectangular label' (ISO 3864-2:2016, 3.2) and (IEC 60825-1:2014, 7.2).[3,8]

Class 1M. The alternative label is a combination product safety label that contains a hazard severity panel, defined as 'area of a combination or multiple product safety label that communicates the category of risk associated with a hazard' (ISO 3864-2:2016, 3.7).[8,] The label must also contain the degree of hazard severity 'CAUTION' defined as a 'signal word used to indicate a potentially hazardous situation which, if not avoided, could result in minor or moderate injury' (ISO 3864-2:2016, 3.1) and (IEC 60825-1:2014, 7.2).[3,8]

Table 1. Warning labels. Warning, explanatory and alternative labels for Class 1 to Class 4 laser products.

Classes	Warning and explanatory labels	Alternative labels
1	CLASS 1 LASER PRODUCT	LASER 1
1M	LASER RADIATION DO NOT EXPOSE USERS OF TELESCOPIC OPTICS CLASS 1M LASER PRODUCT	CAUTION LASER 1M
1C	LASER RADIATION FOLLOW INSTRUCTIONS CLASS 1C LASER PRODUCT	CAUTION LASER 1C
2	LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT	LASER 2
2M	LASER RADIATION DO NOT STARE INTO BEAM OR EXPOSE USERS OF TELESCOPIC OPTICS CLASS 2M LASER PRODUCT	CAUTION LASER 2M
3R	LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT	CAUTION LASER 3R
3B	WARNING – LASER RADIATION AVOID EXPOSURE TO BEAM CLASS 3B LASER PRODUCT	WARNING LASER 3B AVOID EXPOSURE TO BEAM
4	DANGER – LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT	DANGER LASER 4 AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

Figure 1. The medical laboratory must ensure relevant warning labels are displayed at all times. In this case, the plate displays information relating to laser classification and warning in accordance with American National Standard ANSI Z136.1-2014 prepared by the American National Standards Institute and European Standard EN 60825-1:2007 prepared by the European Committee for Electrotechnical Standardization. The medical laboratory must implement the most relevant warning requirements that are in alignment with International Standard ISO 15189:2012 accreditation requirements.

Class 1C. The alternative label is a multiple product safety label, defined as 'product safety label that contains two or more safety signs on the same rectangular label and, if used, the supplementary safety information and/or the hazard severity panel' (ISO 3864-2:2016, 3.8), that contains a hazard severity panel with the degree of hazard severity 'CAUTION' (IEC 60825-1:2014, 7.3).[3,8,]

Class 2. The alternative label is a combination product safety label that contains a hazard severity panel (IEC 60825-1:2014, 7.4).[3]

Class 2M. The alternative label is a combination product safety label that contains a hazard severity panel with the degree of hazard severity 'CAUTION' (IEC 60825-1:2014, 7.4).[3]

Class 3R. The alternative label is a combination product safety label that contains a hazard severity panel with the degree of hazard severity 'CAUTION' (IEC 60825-1:2014, 7.5).[3]

Class 3B. The alternative label is a combination product safety label that contains a hazard severity panel with the degree of hazard severity 'WARNING', defined as a 'signal word used to indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury' (ISO 3864-2:2016, 3.18), with a separate supplementary safety information text panel (IEC 60825-1:2014, 7.6).[3,8]

Class 4. The alternative label is a combination product safety label that contains a hazard severity panel with the degree of hazard severity '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), with a separate supplementary safety information text panel (IEC 60825-1:2014, 7.7).[3,8]

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 ensure the relevant laser hazard information is communicated to laboratory personnel.

References

1. International Organization for Standardization. Medical laboratories — Requirements for quality and competence. 3rd ed. ISO 15189:2012. Geneva (CH): International Organization for Standardization; 2014. 53 p.
2. Van Hulle L, editor. Yearbook of international organizations 2020 - 2021: guide to global civil society networks. 57th ed. Vol. 1, Organization descriptions and cross-references. Brussels (BE): Union of International Associations; 2020. 2992 p.
3. International Electrotechnical Commission. Safety of laser products – Part 1: equipment classification and requirements. 3rd ed. IEC 60825-1:2014. Geneva (CH): International Electrotechnical Commission; 2014. 220 p.
4. International Organization for Standardization. Medical laboratories — Requirements for safety. 2nd ed. ISO 15190: 2020. Geneva (CH): International Organization for Standardization; 2020. 79 p.
5. International Electrotechnical Commission, Institute of Electrical and Electronics Engineers. Preparation of information for use (instructions for use) of products – Part 1: principles and general requirements. 2nd ed. IEC/IEEE 82079-1:2019. Geneva (CH): International Electrotechnical Commission; 2019. 130 p.
6. International Organization for Standardization, International Electrotechnical Commission. Products and related services — Information for consumers. 3rd ed. ISO/IEC Guide 14:2018. Geneva (CH): International Organization for Standardization; 2018. 14 p.
7. Wogalter MS, Laughery KR. Warnings. In: Karwowski W, editor. International encyclopedia of ergonomics and human factors. 2nd ed. Vol. 1. Boca Raton (FL): CRC Press; 2006. p. 1367-73.
8. International Organization for Standardization. Graphical symbols — Safety colours and safety signs — Part 2: design principles for product safety labels. 2nd ed. ISO 3864-2: 2016. Geneva (CH): International Organization for Standardization; 2016. 19 p.