SCIENTIFIC LETTER

Implementation of laser warning markings for equipment and instruments in the International Standard ISO 15189:2022 accredited medical laboratory in New Zealand

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Equipment and instruments that incorporate laser products to support diagnostic capacity are widely used in the medical laboratory (1,2). The medical laboratory must implement relevant risk control measures to manage safety-related behaviours and warn of hazards (Subclause 5.6 of ISO 15189:2022). This paper was conceived during our communication with medical laboratories in the Asia-Pacific region relating to laser warning markings. The exact requirements seemed to receive scant attention from laboratory personnel. To make matters worse, it seemed the markings were often invisible during routine operation. In addition, it appeared that the markings were often supplemented with Food and Drug Administration (United States) markings provided by the manufacturers.

The main objective of this paper is to enhance the medical laboratory's awareness of requirements relating to the provision of relevant risk control measures through warning markings for Class 1 to Class 4 laser products (Clause 4.3 of AS/NZS IEC 60825.1:2014). Selected organisations were identified to provide relevant information to support communication of hazard information to laboratory personnel: the Food and Drug Administration (United States), the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO), Standards Australia, and Standards New Zealand.

Definitions

The following definitions should be noted by the medical laboratory:

Good Practice - defined by the ISO as a 'process or method that has been shown to work well, succeeds in achieving its objective(s), is acknowledged and therefore can be recommended as an approach' (Subclause 3.1.2.7 of ISO 22163:2023).

Hazard - defined by the ISO as a 'potential source of harm' (Subclause 3.13 of ISO 15190:2020).

Marking - defined by the ISO and the IEC as 'symbols, pictograms, warning, logos, or inscriptions on the consumer product, label, or packaging to identify its type, which can also include short textual messages' (Subclause 3.12 of ISO/IEC Guide 14:2018).

Contemporary challenges

The risk control measures relating to hazard information communication should include conveying relevant information by displaying relevant warning markings to inform laboratory personnel about laser hazards to minimise undesirable consequences, and such warning markings must be positioned so they are visible to the intended laboratory personnel within a reasonable observation distance (3,4). Implementation of these two abovementioned measures should be in alignment with the medical laboratory good professional practice commitment [Subclause 5.5 a) of ISO 15189:2022].

Laser product warning markings

The medical laboratory is to ensure that appropriate warning markings are displayed according to the laser class (Subclause 9.5.1 of ISO 15190:2020). The markings must be durable, permanently affixed and legible (Clause 7.1 of AS/NZS IEC 60825.1:2014), so that laboratory personnel can recognise a specific source of potential harm, understand the consequences, take appropriate actions and make informed decisions. The appropriate warning markings should be the ones stated in Figure 1 a) (Section 7 of AS/NZS IEC 60825.1:2014); however, the wording of warning labels is recommended, but not mandatory. It is important to note that some Class 1 laser products are classified as exempt laser products, so application of warning markings is not required. The warning markings in Figure 1 b) are from the Food and Drug Administration (United States) that sometimes co-exist with the ones in Figure 1 a) although they do not meet the warning marking requirements in New Zealand.

With the exception of Class 1 and Class 1M, the markings must consist of a laser beam hazard sign (see Sign 448, Table B3 of NZS/AS 1319:1994) with an explanatory label (Section 7 of AS/NZS IEC 60825.1:2014) that includes the name and publication date of the standard to which the laser product was classified or accompanied by a separate explanatory label in close proximity on the product (Clause 7.9 of AS/NZS IEC 60825.1:2014), or an alternative label with an explanatory label.

Figure 1: see supplementary material at https://mix.nzimls.org.nz/journals-recent.html

Placement of warning markings

The medical laboratory is to ensure appropriate warning markings are clearly visible during operation or maintenance (Clause 7.1 of AS/NZS IEC 60825.1:2014); however, providing reasonable visibility only during maintenance of equipment and instruments may reduce the warning effectiveness because it is likely that the warning will be out of view in most circumstances. The medical laboratory should investigate whether such placement could hinder continual awareness communication of the hazard to laboratory personnel during routine operations. The medical laboratory should have the warning markings clearly visible during operations as well as maintenance to ensure the warning to laboratory personnel effectively promotes continual situational awareness. The medical laboratory must, to the extent that is reasonably practicable, make provisions to ensure relevant risk control measures for laser usage are identified unambiguously, implemented effectively, and displayed explicitly for hazard communication to laboratory personnel.

ACKNOWLEDGMENTS

The authors would like to thank: Hideo Sakamoto, PhD, Department Chair and Professor, Department of Medical Technology, Faculty of Health Sciences, Kobe Tokiwa University, Kobe, Japan; Sharita Meharry, BAppSc MMLS (Hons), Senior Lecturer in Biomedicine and Medical Diagnostics, School of Science, Faculty of Health and Environmental Sciences, Auckland University of Technology, Auckland, New Zealand; and Simona Adochiei, BMediaComm LLB LLM, Marketing and Communications Coordinator, Sonic HealthPlus, Brisbane, Australia, for reading the manuscript and suggesting improvements.

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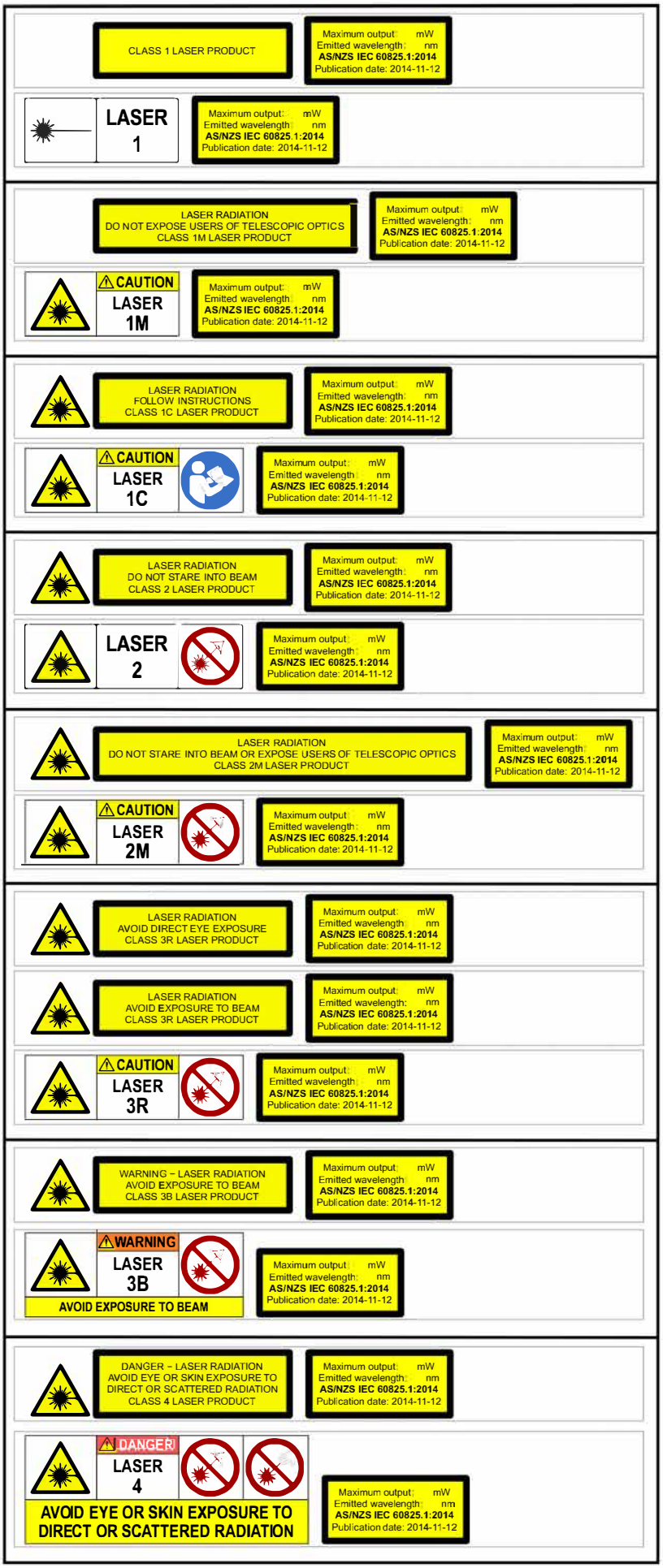
REFERENCES

1. Sveinbjornsson B, Gizurarson S. Waves (microwaves, radiowaves, and light) In: Handbook for laboratory safety. Elsevier, Amsterdam 2022: 39-40.
2. Bruno TJ, Svoronos PD. Laser hazards in the laboratory. In: Rumble JR Jr, Bruno TJ, Doa MJ, eds. CRC handbook of chemistry and physics: a ready reference book of chemical and physical data. 104th edn., CRC Press, Boca Raton 2023; 15-89-15-90.
3. Mayhorn CB, Wogalter MS, Laughery KR. Analysis and design of warnings in the workplace. In: Wilson JR, Sharples S, eds. Evaluation of human work. 4th edn. CRC Press, Boca Raton 2015; 331-358.
4. Wogalter MS, Mayhorn CB, Laughery KR Sr. Warnings and hazard communications. In: Salvendy G, Karwowski W, eds. Handbook of human factors and ergonomics. 5th edn. Wiley, Hoboken 2021; 644-667.



a) Class 1 to Class 4 laser product warning markings according to AS/NZS IEC 60825:2014.

b) Class IIa to Class IV laser product warning markings according to the Food and Drug Administration (United States)

Figure 1. Laser product warning markings

The common warning markings that can be found in medical laboratories are the AS/NZS IEC 60825.1:2014 and the Food and Drug Administration (United States) associated ones. The AS/NZS IEC 60825.1:2014 warning markings should be used in ISO 15189:2022 accredited medical laboratories to support good professional practice in New Zealand.