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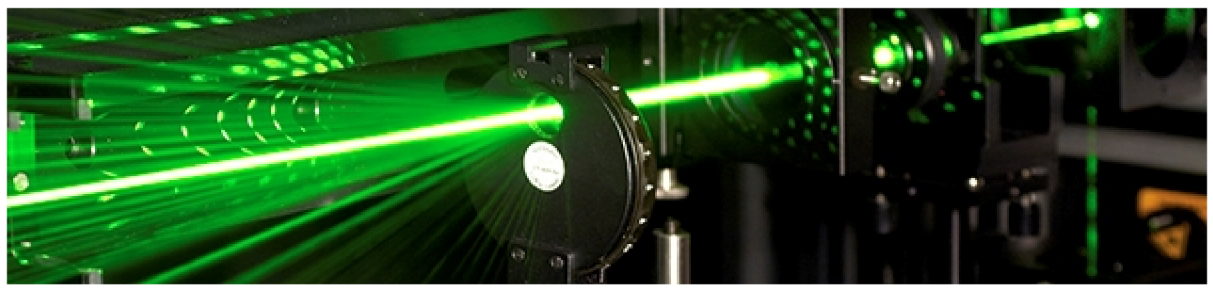

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ISO 15004-2 (Ophthalmic instruments): 2nd edition Dec. 2024

In December 2024, ISO 15004-2:2014 ‘Ophthalmic instruments [ ] Light hazard protection’ was published as the second edition. For some Group 1 limits, as well as for the ‘recommended maximum exposure’ (RME) values for Group 2, there are notable changes, especially for the limits intended to protect against thermally induced injury.

For Group 2, some of these were set so high that ocular injury cannot be ruled out. This was the main reason why the Austrian National Committee voted negatively on the final draft (as did Japan). The standard takes these high RME into account in that if a Group 1 limit value is exceeded, a risk analysis must be carried out:

“For each operating mode where Group 1 limits are exceeded, the manufacturer shall document a justification and address the associated risks in the risk management file.”

There are many useful changes, for example, ‘dose-limited instruments’ are now included, similarly as in ANSI Z80.36.

Our testing laboratory is available for testing according to ISO 15004-2:2024. With our comprehensive collection and know-how of damage thresholds, we can also provide support for the risk analysis that is required for Group 2 instruments.

If you are interested in examples where Group 2 RME may potentially be above retinal damage thresholds, please email karl.schulmeister@seibersdorf-laboratories.at.

Canada: Laser Product Safety Regulation Update

In September 2024, the update of the Canadian Laser Product Safety Regulation was issued. Our contact at the Canadian authorities has informed us that the requirements align closely with IEC 60825-1:2014. With some exceptions, it is mandatory that laser products comply with IEC 60825-1.

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Harmonisation of EN 50689 (Consumer Laser Products) under the General Product Safety Directive

In September 2024, the standard EN 50689:2021 ‘Safety of laser products - Particular requirements for consumer laser products’ was harmonised under the General Product Safety Directive (GPSD) 2002/95/EC, with its reference published in the Official Journal of the EU. Karl Schulmeister has updated his White Paper on EN 50689 accordingly.

At our test house, tests according to IEC 60825-1 includes testing according to EN 50689 and the European Amendment A11 to EN 60825-1 at no extra charge.

>> Link to our white papers

>> Link to the OJ-EU

Seibersdorf Labor GmbH
Laser, LED and Lamp Safety
Test House and Consulting

2444 Seibersdorf
Austria

T: +43 50550-2533
W: https://laser-led-lamp-safety.seibersdorf-laboratories.at
E: laser-led-lamp-safety@seibersdorf-laboratories.at