



Laser, LED & Lamp Safety / Newsletter 2024/01

CDRH/FDA withdraws Laser Notice 50

The US authority CDRH/FDA will withdraw Laser Notice 50 at the end of 2024. LN50 expresses the acceptance of the CDRH of a laser product meeting the requirements of IEC 60825-1 Edition 2.0 from 2007, as well as of laser medical devices with regard to IEC 60601-2-22 Edition 3.0 from 2007.

From the beginning of 2025, only Laser Notice 56, which refers to IEC 60825-1:2014 (i.e. Edition 3.0) or IEC 60601-2-22 Edition 3.1 from 2012, will be applicable for the US market. Laser products placed on the market in the USA from January 1, 2025 must comply with the requirements given in Laser Notice 56, i.e. the new editions of the corresponding IEC standards, whereby exceptions are also listed in LN56, e.g. with regard to subclause 4.4.

This concerns not only, potentially, the classification, but also the labeling and information to the user, as well as formal documents that are necessary for compliance with the corresponding US federal regulations (CFR).

[>> Link to FDA information](#)

Differences regarding the accessible emission limits of Ed. 3.0 and Ed. 2.0 are discussed in one of our whitepapers.

[>> Link to whitepaper](#)

Dr. Neumann new Managing Director of Seibersdorf Labor GmbH

Dr. Markus Neumann has been appointed as the new Managing Director of Seibersdorf Labor GmbH. Markus Neumann holds a Doctor of Medicine degree from Goethe-University Frankfurt and has previously held senior management positions in international sales and business development functions, in healthcare, pharmaceutical and ICT companies.

Most recently Dr. Neumann worked as Managing Director for Bioscientia Labs / Sonic Healthcare Group, in charge of their international business, as well as Board Advisor for various life science companies.

Five new Proceeding Papers

Since the open access online publication of the papers of the ILSC 2023 (International Laser Safety Conference) is still pending, we are making our five papers available as preprints.

In our download category **Laser Safety**

- New European laser product safety standards: Amendment for EN 60825-1 and EN 50689

[>> Link to download \(Laser Safety\)](#)

In our download category **Bioeffects, Exposure Limits and Risk**

- Review of experimental and computer model retinal injury thresholds in the wavelength regime of 1300 nm to 1400 nm
- Computer model results on the wavelength dependence for retinal thermal injury in the visible regime
- Comparison of computer model thresholds with laser safety MPEs for the skin
- Examples of multiple pulse computer model predictions for laser induced retinal injury thresholds

[>> Link to download \(Bioeffects, Exposure Limits, Risk\)](#)

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