RST Instruction Manual

This Instruction Manual is related to the development and implementation [1] of an RST focused on a multifunctional method for quantitative evaluation of time-dependent eye hazards from multiwavelength laser pointers. Recently, high-power portable hand-held low-cost laser products, including laser pointers, have become more prevalent due to advances in laser technologies. However, due to misclassification by vendors, these laser products pose serious safety concerns for potential eye and skin tissue damage, including temporary or permanent blindness. Multiple cases of serious eye damage have been recently reported, including full-thickness macular holes caused by exposure to a high-power green (532 nm) laser pointer [2] and a high-power green handheld laser [3]. Because of their high-power levels, complex multiwavelength output, and time-varying radiation characteristics, hazard evaluation of laser pointers has become more challenging and requires innovative test approaches. To address this major research gap and challenge, we have developed and implemented a novel multifunctional test method for quantitative safety evaluation of critical radiant characteristics of these laser products.

A principal RST setup developed for quantitative evaluation of time-dependent eye hazards posed by green laser pointers is illustrated in Fig. 1a [1]. It includes three independent measurement channels for simultaneous time-dependent radiant power assessment of spectrally and spatially separated multiwavelength visible (532 nm) and unintended NIR (808 nm and 1064 nm) laser radiation components. The RST provides time-dependent radiant power data, such as the presented typical plots shown in Fig. 1b. These quantitative data are employed for performing standard eye safety evaluation analysis for assessing the correct laser classification and hazardous exposure conditions defined for all tested laser radiation components.

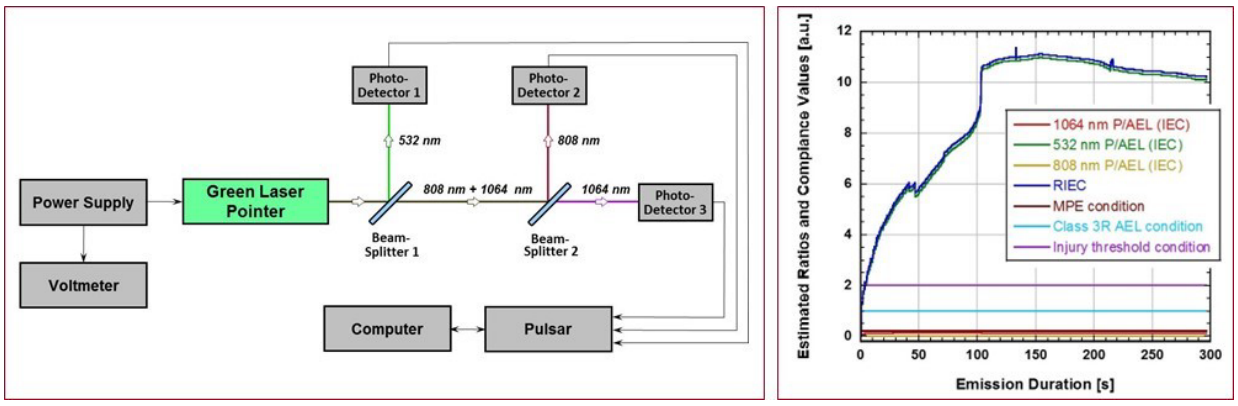

Figure 1: (a) Principal method setup developed for safety evaluation of time-dependent eye hazards posed by green laser pointers. (b) Example laser safety data collected at three detected wavelengths: the fundamental near-infrared (1064 nm), pumping near-infrared (808 nm), and second-harmonic green (532 nm). [1]

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

The RST test procedure for quantitative safety evaluation of time-dependent eye hazards from multiwavelength laser pointers includes the following main steps:

- Employ the test methodology and principal RST schematic presented in Fig. 1 and described in Ref. [1] including specifications of the key RST components to test green laser pointers.
- Measure time-dependent radiant power values using three independent detecting channels designed for simultaneous power assessment of the second-harmonic green (532 nm), pumping NIR 808 nm), and fundamental NIR (1064 nm) wavelengths.
- Perform standard laser classification evaluation using the measured time-dependent radiant power values for all laser radiation components to assess the standard Accessible Emission Limits (AEL) and the resulting correct standard laser classification.
- Perform a standard eye safety evaluation analysis using the measured time-dependent radiant power values to assess the hazardous exposure conditions and safety concerns related to the cases of exciding the standard maximum permissible exposure (MPE) and injury threshold limits.
- The standard eye hazard analysis can be performed according to the test conditions and safety limits specified in a recommended standard IEC 60825-1 [4].

References:

[1] W. Strzelecki, R. James, and I. Ilev, “Quantitative evaluation of a time-dependent eye hazard posed by green laser pointers”, Health Physics Journal, v. 113, pp. 375-381, 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10790719/

[2] S. Androudi, and E. Papageorgiou, “Macular hole from a laser pointer”, The New England Journal of Medicine, v. 378, pp. 2420, 2018. https://pubmed.ncbi.nlm.nih.gov/29924946/

[3] S. Faraj, et al., “Retinal injuries in seven teenage boys from the same handheld laser”, American Journal of Ophthalmology Case Reports, v. 27 pp. 101596, 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9156801/

[4] International Electrotechnical Commission (IEC). International Standard for safety of laser products: part 1: equipment classification and requirements. Geneva; Switzerland: IEC; 60825-1; 2014. https://webstore.iec.ch/publication/3587