



BSI Standards Publication

Safety of laser products

Part 20: Safety requirements for products intentionally exposing face or eyes to laser radiation

National foreword

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The UK participation in its preparation was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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**Safety of laser products -
Part 20: Safety requirements for products intentionally exposing face or eyes to
laser radiation**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**Safety of laser products -
Part 20: Safety requirements for products
intentionally exposing face or eyes to laser radiation**

FOREWORD

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IEC TS 60825-20 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment. It is a Technical Specification.

This Technical Specification is to be used in conjunction with IEC 60825-1:2014.

The text of this Technical Specification is based on the following documents:

Draft	Report on voting
76/766/DTS	76/776/RVDTS

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Specification is English.

A list of all parts in the IEC 60825 series, published under the general title *Safety for laser products*, can be found on the IEC website.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

There is an emerging set of consumer Class 1 laser devices that intentionally directs laser radiation towards a person's eyes, or face, or both to perform a useful function (example: facial or retina or iris recognition, glasses and headsets for augmented reality (AR), virtual reality (VR) and mixed reality (MR), etc.). The nature of these devices is such that in the event of a fault or misuse resulting in excessive emissions, the likelihood of ocular injury can be greater during operation when compared to a device not intended for direct exposure.

This document provides risk-based requirements in the form of a safety-focused failure mode and effects analysis (FMEA) defined in Clause 6 for products that intentionally direct laser radiation towards the user's eyes or face, or both. The purpose of a risk analysis for such laser products is to reduce the risk of potential injury to the eyes or to the face during fault conditions which could occur at any time over the expected useful lifetime of the product.

1 Scope

This document provides radiation safety requirements (normative) and guidelines (informative) for the consideration of faults for Class 1 laser devices with laser radiation directed towards the eyes or face. Requirements for the safety of the nominal emission are not in the scope of this document.

Examples:

- devices with laser light facial or ocular recognition;
- virtual reality headsets or glasses;
- devices with gesture tracking via eye or facial movements;
- driver surveillance cameras;
- full body scanners (including eyes, face, and body).

Products exempted from this document include:

- medical and ophthalmic devices;
- automotive (lidars), lamps;
- laser applications where the laser is used in a professional (non-consumer) setting and is intended for direct or long-time exposure of the eyes or face.

This document provides normative requirements and informative guidelines for:

- radiation safety analysis;
- production-line testing;
- hazard analysis for laser radiation emissions (using a modified safety-focused FMEA approach)

NOTE all subsequent references to FMEA in this document refers to this safety-focused FMEA approach.

- examples of typical failure modes and mitigation techniques

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

ISO/IEC Guide 51:2014, *Safety aspects - Guidelines for their inclusion in standards*

3 Terms, definitions and abbreviated terms

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1 Terms and definitions

3.1.1 FMEA-related terms and definitions

3.1.1.1

action taken

specific action that is implemented to reduce risk to an acceptable level

3.1.1.2

cause of failure

specific reason for the failure, often expressed as a potential design or manufacturing deficiency that results in the failure mode

3.1.1.3

current control

method or action currently planned, or already in place, to reduce or eliminate the risk associated with each potential failure mode and associated cause

Note 1 to entry: The control can be the method to prevent or detect the cause or failure mode during product development.

3.1.1.4

current detection control

method or action by which a failure mode or cause in the product design or manufacturing process is detected, based on current or planned actions

Note 1 to entry: Current detection control is intended to increase the likelihood that the problem will be detected before it reaches the end user.

3.1.1.5

current prevention control

method or actions by which a cause, failure mode, or effect in the product design or manufacturing process is prevented based on current or planned actions

Note 1 to entry: Current prevention controls are intended to reduce the likelihood that the problem will occur and are used as input to the occurrence ranking.

3.1.1.6

failure effect

consequence of the failure on the system or end user, often described from local effect up to end effect

Note 1 to entry: For process FMEAs, analysis should consider the failure effect at manufacturing or assembly level, as well as at system or end user level.

3.1.1.7

failure mechanism

physical, chemical, thermodynamic, electrical or other process that results in failure

Note 1 to entry: For a component it is the actual physical phenomenon behind the failure; for a system it is the process of degradation or chain of events leading to and resulting in a particular failure mode.

3.1.1.8

failure mode

manner in which the item potentially fails to meet or deliver the intended function and associated requirements

3.1.1.9**failure mode and effects analysis****FMEA**

engineering analysis done by a cross-functional team of subject matter experts that thoroughly analyses product designs or manufacturing processes, early in the product development process, with the objective of finding and correcting any potential design or manufacturing deficiency before the product gets into the hands of the customer

3.1.1.10**function**

item's intent usually to a given requirement

Note 1 to entry: For design FMEAs, it is the primary purpose or design intent of the item. For process FMEAs, it is the primary purpose of the manufacturing or assembly operation. A requirement is a measurable characteristic of a function, which can be quantitative or qualitative. A product function may have multiple requirements.

3.1.1.11**harm**

injury or damage to the health of people, or damage to property or the environment

3.1.1.12**hazard**

potential source of harm

3.1.1.13**initiating event**

event and circumstance that can result in a hazardous situation, and potential harm

3.1.1.14**item**

focus of the FMEA project

Note 1 to entry: For a design FMEA, it is the system, subsystem or component under analysis. For a process FMEA, it is one of the specific steps of the manufacturing or assembly process under analysis.

3.1.1.15**new occurrence**

reassessment of occurrence rating after actions have been implemented

3.1.1.16**new risk category**

indication of the level of risk, after actions have been taken

3.1.1.17**new severity**

reassessment of severity rating after actions have been implemented

3.1.1.18**new SxO**

reassessment of SxO after actions have been taken

3.1.1.19**occurrence**

ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analysed

Note 1 to entry: For design FMEAs, it is usually the likelihood of occurrence during the design life of the product; For process FMEAs, it is usually the likelihood of occurrence during the manufacturing process.

3.1.1.20

recommended action

tasks recommended by the FMEA team to improve designs and tests in order to reduce risk to an acceptable level

3.1.1.21

risk category

indication of the level of risk, based on initial severity and occurrence ratings

3.1.1.22

risk prioritization SxO

purpose of risk prioritization is to help understand relative risk within an analysis

Note 1 to entry: One method for risk prioritization is SxO, which is the arithmetic product of severity and occurrence ratings.

3.1.1.23

safety-focused FMEA

modified approach to FMEA focusing entirely on the potential hazard of laser radiation emission

Note 1 to entry: This term is specific to this document. All potential failure modes leading to harmful emissions are listed and analysed, and unacceptable risk is identified and mitigated using FMEA procedure.

3.1.1.24

severity

ranking number associated with the most serious effect for a given failure mode

3.1.1.25

potential for introducing new failure mode

description of any potential new failure mode that is introduced by the actions taken

3.1.1.26

verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

3.1.2 Miscellaneous terms and definitions

3.1.2.1

intended use

use in accordance with information provided with a product or system, or, in the absence of such information, by generally understood patterns of usage

[SOURCE: ISO/IEC Guide 51:2014, 3.6]

3.1.2.2

reasonably foreseeable misuse

use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

[SOURCE: ISO 14971:2019 [1], 3.15]

3.1.2.3

residual risk

risk remaining after risk reduction measures have been implemented

[SOURCE: ISO/IEC Guide 51:2014, 3.8]

3.1.2.4**risk analysis**

systematic use of available information to identify hazards and to estimate risk

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.1.2.5**risk reduction**

action or means to eliminate hazards or reduce risks

[SOURCE: ISO/IEC Guide 51:2014, 3.13, modified – In term entry, the word "measure" has been deleted, the admitted term has been deleted.]

3.1.2.6**useful life**

time interval, from first use until user requirements are no longer met, due to economics of operation and maintenance, or obsolescence

[SOURCE: IEC 60050-192:2015 [2], 192-02-27, modified – Note 1 to entry has been deleted.]

3.1.2.7**excessive emissions**

accessible emissions that exceed the unidentifiable row in Table 1 or the alternative methods

3.2 Abbreviated terms

AEL	accessible emission limit
CW	continuous wave
CIE JTC	Joint Technical Committee (of the CIE - the International Commission on Illumination)
ESD	electrostatic discharge
FMEA	failure modes and effects analysis
FTA	fault tree analysis
IR	infrared
LED	light-emitting diode
MPE	maximum permissible exposure
MTTF	mean time to failure
QMS	quality management system
RG	risk group
SxO	severity times occurrence
Td	Troland

4 Comparison against IEC 60825-1:2014**4.1 Determination of the accessible emission level and product classification**

In addition to IEC 60825-1:2014, 5.1 whereby risk analysis can be used to assist in determining reasonably foreseeable single fault conditions, this document specifies:

Risk analysis per Clause 6 shall be used in determining reasonably foreseeable single and multiple fault conditions.