
Laser pointers held up to the light

A risk assessment

(aanbiedingsbrief)

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Executive summary

For several years, small hand-held lasers have been available to the general public, incorporated into items such as pens, key rings, pocket-knives and credit cards. These small diode lasers emit red light with a power varying between one and five milliwatts. Such devices were originally intended as pointers, for use by people making presentations or giving lessons. However, being cheap and compact, they are often now used as novelties, with the result that one comes across them on the street, in discotheques and in classrooms. Lasers of this kind are often labelled as class 3A, in accordance with the American ANSI classification system, when for the European market they should in fact be labelled class 3B, implying that they are capable of causing eye injuries.

More powerful lasers can cause retinal lesions. Exposure limits have accordingly been formulated, the first being put forward in the early seventies. The nominal ocular hazard distance (NOHD) can be calculated from the output power, the aperture and the divergence of the beam. A person who is further from the source than the NOHD is not exposed in excess of the maximum permissible exposure (MPE) levels. For most laser pointers, the NOHD is between five and fifteen metres.

MPE levels are based on ED_{50} data obtained from experiments with laboratory animals. (An ED_{50} level is the exposure level at which 50 per cent of the subjects in a test sustain a lesion.) An analysis of the relationship between, on the one hand, ED_{50} levels and other such data and, on the other, MPE levels shows that eye injuries are very unlikely at levels of exposure around the MPE levels.

Several European countries, including the Netherlands, have decided that class 3A and 3B lasers are suitable only for professional use by adequately trained individuals. In these countries, the sale of class 3A and 3B laser pointers and the incorporation of class 2 lasers in toys are prohibited. In most cases, these measures have been introduced following incidents which apparently involved eye injuries. However, not a single case of permanent eye injury attributable to a laser pointer could be found in the international peer-reviewed literature. Nor were any cases of permanent eye injury reported in a survey of Dutch ophthalmologists.

Nevertheless, exposure to low-power lasers can cause flash-blindness and induce strong aversion responses. The seriousness of such problems depends on the output power of the laser, the ambient light level and the duration of exposure. Unexpected exposure can be dangerous, especially if the person in question is engaged in an activity which requires his or her full concentration, such as driving.

The ban on the sale of higher-power laser pointers in the Netherlands helps to prevent misuse and laser-related problems. It also ensures that more powerful laser pointers capable of causing permanent eye injury cannot be brought onto the market in the future.

Introduction

Since late 1997, the European and American media have regularly reported incidents in which laser pointers have apparently caused eye injuries.

Laser pointers are relatively cheap. Their incorporation in toys, pens, key rings and the like means that they are at the disposal of a wide range of people, most of whom have no expertise in the handling of lasers. Not all users are aware of the risks associated with lasers, and the devices are liable to be used for purposes other than those for which they were intended.

As well as being cheap, modern laser pointers are very compact and capable of creating a powerful beam of light from a modest energy source. As admirable as the manufacturers' ingenuity may be, it has a down side. Because of their relatively high power (often several milliwatts (mW), sometimes as high as eleven milliwatts), the pointers can produce energy densities sufficient to cause eye injury.

Laser classification systems have accordingly been in place for some years, with a view to ensuring that users are aware of the risks associated with the devices and how injury can be avoided. In both the United States and Europe (EU), manufacturers are obliged to label their products with a laser safety symbol, a classification mark and (if appropriate for the class of laser concerned) a warning. Although the US and EU regulations are similar in principle, they differ slightly in their technical detail. Partly as a result of this, incorrectly classified lasers sometimes find their way onto the European market.

This report outlines the problems caused by laser pointers and explains why uncertainty exists regarding the associated risks. The differences between the European

and American classification systems are set out and the potential these differences have for the misclassification of laser products is explored. Both classification systems are based on the biological effects that lasers are capable of producing.

The report goes on to put forward exposure limits, reflecting the levels of exposure below which no permanent eye or skin injuries should occur. The method for calculating safe distances, beyond which exposure would not exceed the proposed limits, is outlined.

A separate section of the report is devoted to factors which influence the level of risk and the likelihood of permanent injury. The report concludes with a survey of the regulations and guidelines applied in various European and non-European countries or formulated by international advisory committees following cases apparently involving laser-induced injury.

The means by which this report has been formulated is described in Annex A.

Physical properties of laser pointers

2.1 Dimensions and wavelengths

Since the early eighties, lasers have been used as pointers by people making presentations and giving lessons. Originally, these pointers generally contained gas-filled helium-neon lasers. Such first-generation laser pointers produced a bright reddish-orange beam (wavelength 632.8 nanometres (nm)) and were usually about the size of a large torch. Being relatively inefficient by today's standards, they required mains power or several powerful batteries.

Towards the late eighties, much smaller diode lasers emitting light with a wavelength of 670 nm came onto the market. With their higher-wavelength beam, the early diode lasers produced a less conspicuous dark red point of light. However, more efficient diode lasers followed, emitting shorter-wavelength light. Today, between 640 and 670 nm is normal for this kind of device. Because diode lasers are comparatively cheap, second-generation laser pointers are a lot less expensive than pointers containing helium-neon light sources. What is more, since the lasers require only penlight or even button batteries, pointers can be made the size of a pen, key ring or credit card.

It is now also possible to obtain laser pointers which produce a clear green beam (532 nm). Such devices remain expensive, however: between seven hundred and a thousand Dutch guilders each. As well as emitting much shorter wavelength light, such up-market pointers can be a lot more powerful than cheaper products. The combination of greater power and green light, to which the human eye is more sensitive, increases the risk of flash-blindness or permanent injury.

2.2 Output power ratings and classification

The most powerful first-generation laser pointers had an output power of one milliwatt (mW). Second-generation pointers, with their more efficient diode lasers, are often several times as powerful, despite using only batteries.

Both in the United States and in Europe (EU), manufacturers are obliged to label their products with a laser safety symbol, a classification mark and (if appropriate for the class of laser concerned) a warning (see Figure 1)*.



Figure 1 Specimen warning label on a laser.

The International Electrotechnical Commission (IEC) has drawn up an international standard (IEC-60825-1) covering the classification, technical quality and use of lasers and incorporating maximum permissible exposure (MPE) levels (IEC93). This standard has since been reproduced as a European standard (EN-60825-1), which is in turn published as a Dutch standard: NEN-EN-60825-1(NEN94). The IEC standard was amended in 1998 (IEC98) to include details of how a laser's class should be determined. In the US, the American National Standard for Safe Use of Lasers Z136.1-1993 applies (ANSI93).

Both standards use a classification system based on a laser's capacity to cause certain forms of eye or skin injury**. The classes for lasers emitting visible light (radiation with a wavelength of between 400 and 760 nm) have been defined assuming a human pupil diameter not exceeding 7 mm and a normal blink reflex, involving closure of the eyes or turning of the head, which limits exposure to 0.25 seconds.

Class 1 covers intrinsically safe lasers. They lack the power to cause eye or skin injuries, even in the event of sustained intrabeam exposure. The use of such lasers is not

* The texts of the warnings are set out in Annex B.

** The actual classification definitions are given in Annex C.

subject to any restrictions and no protective measures or equipment are considered necessary.

Class 2 covers lasers which emit visible radiation with a wavelength of between 400 and 700 nm, which cannot cause retinal lesions in a person with a normal blink reflex. The American standard recognizes a subclass (subclass 2a), covering visible-light lasers intended for purposes that do not involve any risk of intrabeam exposure or of the class 1 limits being exceeded in the event of exposure for up to 1000 seconds.

Class 3 is subdivided as follows:

- *Class 3A* covers lasers* which it is just about safe to look into with the naked eye. Where lasers emitting visible light are concerned, this means devices against which the blink reflex offers sufficient protection to prevent eye injury. However, looking into the beam through optical aids, such as binoculars, microscopes or telescopes can result in retinal lesion.
- *Class 3B* covers lasers producing beams of sufficient intensity that direct exposure is always dangerous to the naked eye. Exposure to diffuse reflected radiation from Class 3B lasers is nevertheless normally safe.

Class 4 includes all lasers whose power is such that even diffuse reflection can be dangerous. Lasers in this class are capable of causing skin and eye injuries. They also represent a potential fire hazard, insofar as they are capable of igniting combustible materials. Class 4 lasers should always be used with great care.

Although the American standard is in principle very similar to that applied in Europe, certain significant differences exist between the two standards in terms of their technical detail. The most important difference in relation to laser pointers (640 to 670 nm) is the distinction between classes 3A and 3B. Under the ANSI standard, devices with an output power of up to 5 mW fall in class 3A, while products rated between 5 and 500 mW are class 3B. The IEC standard employs the same distinction, but additionally stipulates that the power density of a class 3A laser may not exceed 25 watts per square metre (W/m^2). In other words, classification of a laser depends not only on its output power, but also on its power density. The standard stipulates that the density must be measured at the

* In accordance with article 4.7.4.2. of the ANSI standard, further distinction is made within class 3A between lasers which are capable of causing exposure in excess of the MPE (Maximum Permissible Exposure) level within 0.25 seconds and those which are not. Lasers which can cause such exposure should carry the following warning: 'Do not stare into beam or view directly with optical instruments'. Those which cannot should carry the following warning: 'Avoid direct eye exposure'.

minimum distance from the light source at which exposure can occur, or 10 cm from the source, whichever is the greater.

The purpose of this additional requirement is to ensure that, in the event of exposure to radiation from a class 3A laser, the power of the light reaching the retina cannot exceed one mW, even if the pupil is fully dilated (i.e. open to a diameter of 7 to 8 mm). Hence, unexpected exposure to light from a laser in this class is no more hazardous than exposure to class 2 laser emissions, since the blink reflex will limit the duration of exposure to 0.25 seconds.

For a laser with an output power of between 1 and 5 mW to meet the IEC's additional criterion, its beam must diverge considerably. At 10 cm from the source (the minimum distance at which the power density may be measured), a 1-mW laser beam has to be at least 8 mm in diameter and a 5-mW beam would need to measure 16 mm across. Such a beam would be unsuitable for pointing; given an aperture diameter of 2 mm, the beam's divergence would need to be between 60 and 140 milliradians (see 1.3). As a result, almost all laser pointers of more than 1 mW are treated as class 3B under the European system, as opposed to class 3A (Egg98, Cot98).

Unlabelled or incorrectly labelled lasers (e.g. class 3A or 3B lasers bearing class 2 labels) are quite common on the European market.

2.3 Divergence and aperture diameter

For a laser to be useful as a pointer, the point of light it projects needs to be quite small, even at some distance from the source. Hence, divergence of the beam has to be minimized. In most laser pointers, divergence is between 0.5 and 2 milliradians, which corresponds to an angle of between 0.03 and 0.12 degrees.

The diameter of the beam as it leaves the pointer (the aperture diameter, see Figure 2) usually varies between 1 and 3 mm. At a distance of 10 metres, therefore, the diameter of a laser pointer beam is normally between 6 mm (given an aperture diameter of 1 mm and a divergence of 0.5 milliradians) and 23 mm (given an aperture diameter of 3 mm and a divergence of 2 milliradians).

Since laser pointer beams are not focused, the theoretical maximum energy density — output power divided by cross-sectional beam area — depends on the aperture diameter.

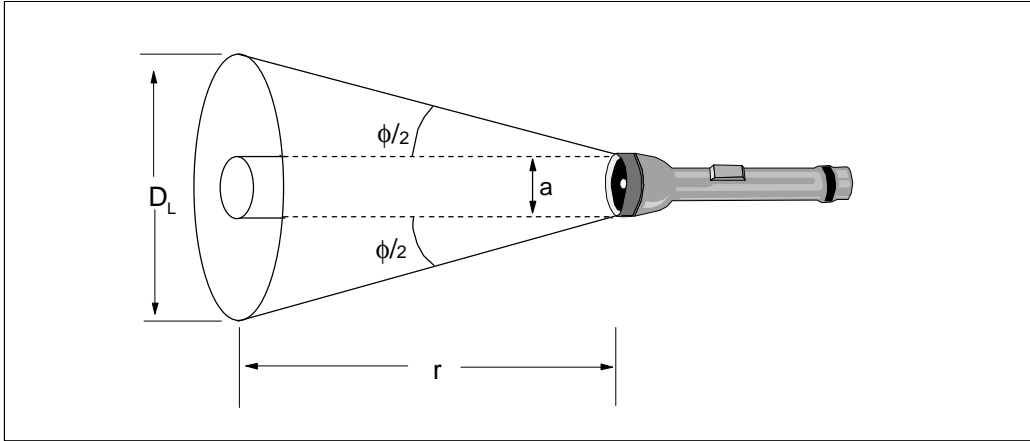


Figure 2 Beam divergence $\phi = (\text{beam diameter } D_L - \text{aperture diameter } a) / \text{distance } r$.

Biological effects

3.1 The perception of light

Very little optical radiation with a wavelength of 400 to 780 nm is absorbed by the eye's cornea, lens or vitreous humour; almost all therefore reaches the retina (Sli80).

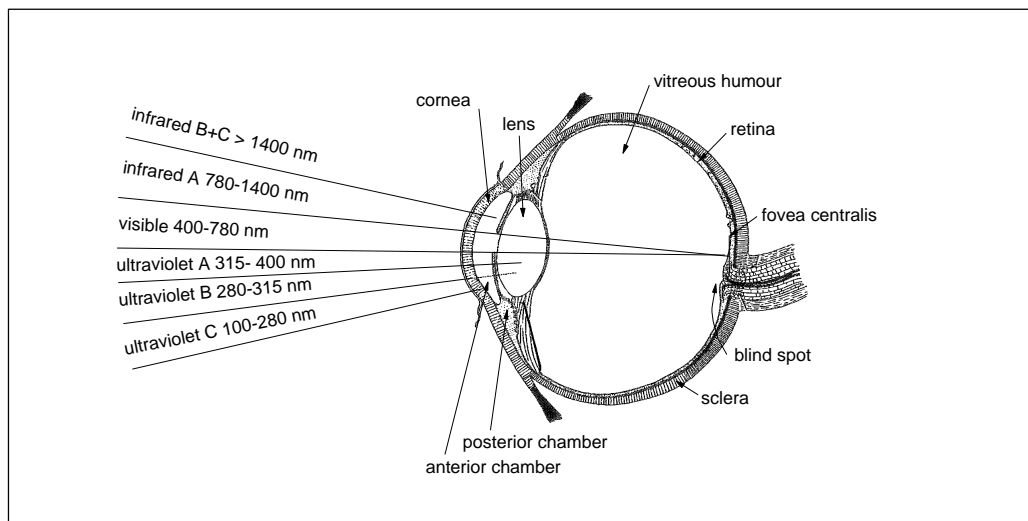


Figure 3 Simplified diagram of the eye.

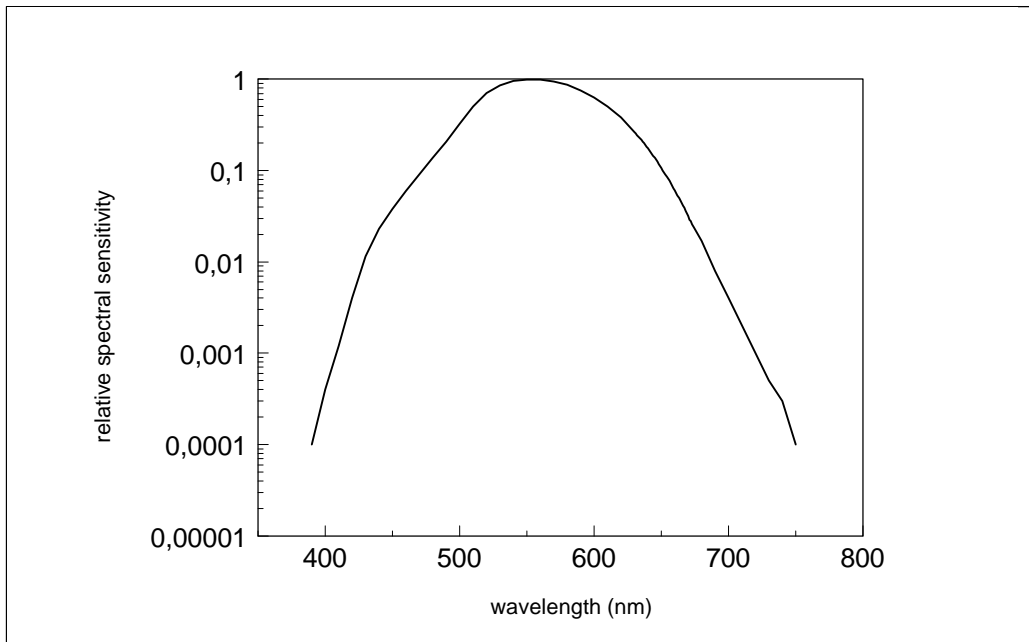


Figure 4 Relative spectral sensitivity of the human eye to optical radiation as a function of wavelength.

Irradiation of the photoreceptors (light-sensitive cells in the retina) generates electrical signals, which are ultimately used by the brain to construct an image. The eye's photoreceptors are not equally sensitive to all wavelengths. The optimum is about 560 nm; at higher wavelengths, sensitivity decreases rapidly, so that sensitivity to 700-nm light is about a hundred times less than to 560-nm light (see Figure 4). Between 633 nm (the wavelength of the light from helium-neon lasers) and 670 nm (the corresponding figure for certain diode lasers), the sensitivity of the human eye falls by a factor of eight.

Most of the energy entering the eye is converted into heat in the pigmented epithelium and the choroid of the retina. If the temperature of the tissue rises beyond a certain point, thermal damage occurs. If exposure lasts for more than 10 seconds, photochemical retinal lesion can result, even at relatively low light intensities. However, injuries of this kind are produced only by blue light (i.e. radiation with a wavelength of less than 440 nm) and are therefore not relevant in relation to laser pointers.

Very little radiation is absorbed by the eye's lens, which can consequently be damaged only if the energy density is higher than 1 to 2 kW/m² (GR93). Such densities cannot be created by laser pointers.

Laser pointers are not capable of causing skin injuries. Although dependent partly on the wavelength of the light and the complexion of the person concerned, the threshold

for skin injury is about 20 kW/m^2 in the range of wavelengths associated with laser pointers.

3.2 Point image or field image?

The temperature rise in the retina depends on the size of the projected image and the duration of irradiation. If the image is small, the heat can be dissipated more quickly than if the image is large, since the ratio between the irradiated area and the heat-dissipating area is greater.

Research into retinal lesions has shown that, where very small images are concerned, it is the amount of energy absorbed in the retina (expressed in joules, J) which determines the severity of the damage. Where large images are concerned, however, it is the irradiation dose (expressed in J/m^2) that matters. In practice, the critical border line is an image diameter of approximately $70 \mu\text{m}$. An image formed on the retina which is less than $70 \mu\text{m}$ across is known as a point image, while a larger image is referred to as a field image. The optical properties of the eye are such that the smallest image that can be formed on the retina is between 10 and $20 \mu\text{m}$. An object which is at an angle of 1 milliradian relative to the eye produces an image of $17 \mu\text{m}$ on the retina (Sli80). The beam from a laser pointer will usually produce a point image on the retina. Only if the light is viewed from very close up will the image on the retina exceed $70 \mu\text{m}$.

In practice, if the source is at an angle of less than about 10 milliradians relative to the eye, the image on the retina may be assumed to be a point image. In the case of a laser pointer with an aperture diameter of 2 mm , this corresponds to a distance of at least 10 cm .

3.3 Thermal damage to the retina

If enough energy is converted into heat (see 2.1), the temperature of the tissue can rise sufficiently to cause damage. Given time, the body is capable of repairing such damage, provided it is not too serious; slightly damaged photoreceptors and pigmented epithelium will recover in about a week (Min95). However, if the temperature rises too far, permanent damage to the pigmented epithelium and the retina can result. Damage to the central area of the retina, especially the *fovea centralis**, is certain to impair visual acuity. Damage to a peripheral part of the retina, on the other hand, may not affect the individual's sight. The repair of serious damage involving more than one type of tissue can easily take several weeks, if not months (Min95).

* The *fovea centralis* is the small part of the retina which forms the centre of the field of vision and which is used for fixation. Damage to this spot can impair visual acuity.

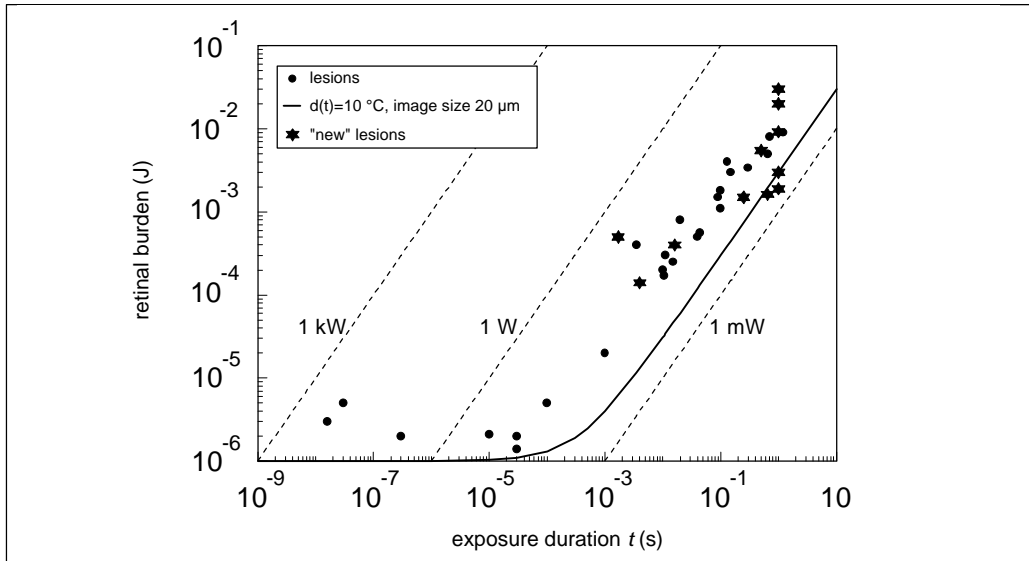


Figure 5 Retinal burden as a function of exposure duration leading to just-observable damage to the retina (ED_{50}). Solid line: the isotherm calculated for the solid dots for a temperature rise of $10\text{ }^{\circ}\text{C}$, for a point image with a diameter of $20\text{ }\mu\text{m}$. The figures marked with an asterisk were not included in determination of the health-based recommended exposure limit. Diagonal dashed lines: irradiation powers of 1 kW , 1 W and 1 mW , respectively. (Source: GR78)

A thermal retinal lesion is visible with the aid of an ophthalmoscope; it appears as a localized discoloration of the fundus of the eye. The degree of discoloration depends on the seriousness of the damage, or the temperature rise induced.

Figure 5 illustrates the relationship between the duration of exposure and irradiation energy in numerous cases of externally just-observable retinal lesions caused by point images* (GR78). The figures marked with an asterisk relate to recent cases, which were not taken into account when the current health-based recommended exposure limits were calculated (GR78, GR93, Sli80). Nevertheless, all cases involve exposure in excess of the recommended 1-mW limit. The solid line represents the calculated isotherm for a temperature rise of $10\text{ }^{\circ}\text{C}$, for a point image with a diameter of $20\text{ }\mu\text{m}$. The diagonal lines represent irradiative powers of 1 kW , 1 W and 1 mW , respectively.

As detection techniques have improved, so it has become possible to discern signs of damage at lower irradiation doses. For example, the threshold for detecting damage by histological means (using tissue preparations) is about three times lower than the threshold for external detection (on the basis of abnormalities in form or colour, observed using a slit lamp) (Bir83). Damage which is just externally observable is not necessarily serious enough to reduce visual acuity discernibly or to be irreparable over time by the body's own mechanisms.

* Where field images are concerned, the energy density on the retina proves to be the damage-determining variable. Since all laser pointers produce point images only, no further consideration is given to this issue in this report.

The solid line in Figure 5 represents the calculated isotherm for a temperature rise of 10 °C, for a point image with a diameter of 20 µm. It has been plotted using the following empirical formula:

$$Q_{\text{threshold, retina, point image}} = 10^{-6} + 3 \times 10^{-3} t \text{ (in J)} \quad (1)$$

Given an irradiation duration, t , of more than 0.01 seconds, the threshold will be roughly equal to 3 mW dissipated across the retina. As Figure 5 shows, if exposure to a given source does not cause damage within a few milliseconds, more prolonged exposure will not actually lead to thermal damage. Hence, the blink reflex (by which exposure is limited to 0.25 seconds) is not critical in determining the level of damage in a given situation.

When calculating its health-based recommended exposure limits, the Health Council took the isotherm as a descriptor of minimal thermal damage attributable to point images (GR78, GR93). The limits worked out in this way correspond closely with those suggested in the IEC and ANSI standards (see 1.2.1).

The IEC and ANSI standards are not the only guidelines on the use of lasers; the ICNIRP* and the ACGIH** have also addressed the subject and suggested MPE levels (ICN96, ACG93). The various standards and guidelines are generally quite similar. The various authors have all derived their limits from ED₅₀ data, mostly relating to retinal lesions in rhesus monkeys and rabbits (Bir83, Bre71, Sli80). Given exposure lasting for 0.1 to 2 seconds, the ED₅₀ figures range from about 5 to 10 mW.

There remains a risk — albeit a lower one — of damage at levels of exposure below the ED₅₀ levels. Indeed, damage has been detected by optical and electron microscopy even at 25 to 50 per cent of the ED₅₀. However, in no case has damage been found following levels of exposure corresponding to one tenth of the ED₅₀ (ICN96).

Several researchers have determined the risk of damage at higher and lower levels of exposure. From the reported data, it is apparent that the distribution patterns either side of the ED₅₀ are normal (Sli80, Bir83). Data relating to various combinations of wavelength, exposure duration and laboratory animal are presented in Figure 6. The gradient of the line is determined by the steepness of the S-curve. Using a plot of this kind, it is possible to determine what the risk of just-observable damage is at a given dose. Nevertheless, it should be stressed that accurately plotting the gradient of the line depends to a considerable extent on having reliable extreme values. In other words, the position of the ED₂₀ and ED₈₀ points are more important than the position of the ED₅₀

* International Commission on Non-Ionizing Radiation Protection. Until 1992 the International Non-Ionizing Radiation Committee of the International Radiological Protection Association, INIRC/IRPA.

** American Conference of Governmental Hygienists.

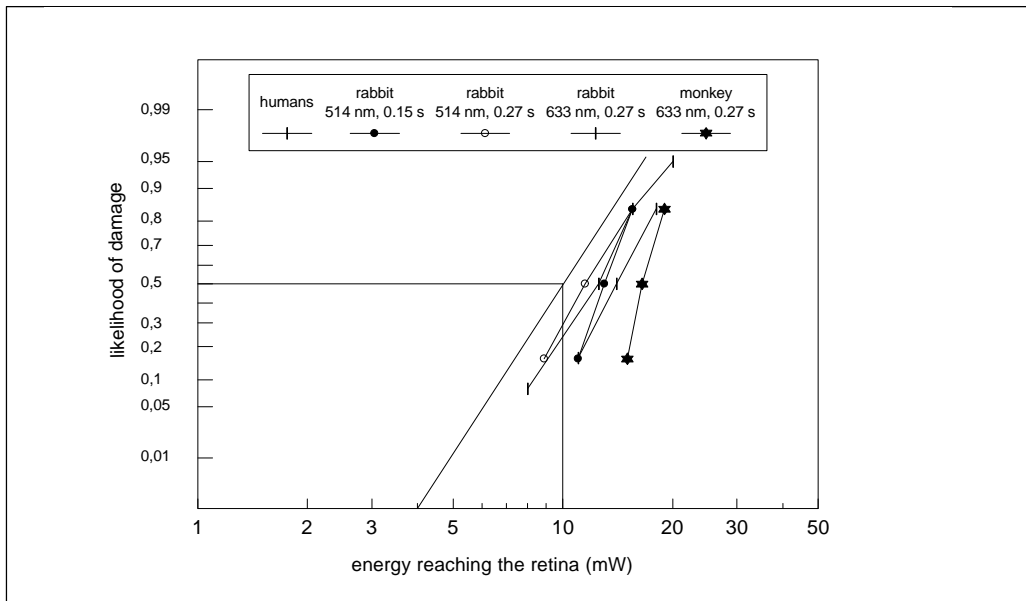


Figure 6 Likelihood of externally detectable damage to the retina, as a function of irradiation power in mW. (Source: Bir83, Sli80) The sloping line through the 10 mW point represents the hypothetical risk of damage in relation to the energy reaching the retina.

point. However, the extreme points cannot be determined with the same degree of confidence as the ED₅₀ point (Bir83, ICN96, Sli80). Since the data was derived from animal experiments, and the animals in question proved to be roughly three times as sensitive as humans, the threshold values can reasonably be employed as recommended limits for human exposure. On the basis of these considerations, it is often assumed that the ED₅₀ for just-observable retinal lesions is 10 mW.

3.4 Temporary effects and annoyance

A laser beam can cause annoyance — sometimes serious annoyance — even at energy densities too low to induce thermal damage. The first temporary effect is flash-blindness. If a light source is particularly bright, the light-sensitive cells exposed to it are temporarily ‘switched off’, leaving an after-image or spot before the eyes, which can remain for several minutes (Sli80, Mar97b).

People unexpectedly exposed to radiation from laser pointers report after-images (often green), flash-blindness, pain in or behind the eyes, heat in the eyes, irritation of the eyes, headache and red eyes (Mar97a, Mar97b, Nor98). The eyes do not contain pain receptors, so any pain can only result from rubbing (Nor98).

The degree of irritation or annoyance depends on the level of ambient light. If there is little ambient light, the pupils will be dilated and quite a lot of light from the laser will

reach the retina. Also, when the ambient conditions are dim, the contrast between the brightness of the laser and the level of light to which the eye is already adjusted is likely to be sufficient to induce an aversion response. Consequently, a beam with an energy density of 25 W/m^2 can be perceived as very bright or even blinding under daylight conditions. In the dark, a light of that intensity would certainly be sufficient to cause annoyance. Indeed, in the dark, as little as about 1 mW/m^2 can be perceived as blinding and is liable to cause persistent after-images (Mar97a).

Health-based recommended exposure limit and safe distances

4.1 Determining the health-based recommended exposure limit or maximum permissible exposure level

Because laser pointers emit an almost parallel beam of light (the divergence varies from 0.5 to 2 milliradians, see 1.3) with an aperture diameter of only a few mm, exposure produces a point image on the retina (see 2.2). In its 1993 report, the Health Council used the formula presented in subsection 2.3 as the basis for its recommended exposure limit (GR93). For practical reasons, the energy on the retina was converted into energy density H on the cornea:

$$H_{\text{threshold, cornea, point image}} = \frac{Q_{\text{threshold, point image}}}{A_{\text{pupil}} \times F_{\lambda}} \quad [\text{in J/m}^2] \quad (2)$$

$Q_{\text{threshold, point image}}$	threshold level for point images on the retina (in J)
F_{λ}	transmission through the eye media; for radiation with a wavelength of between 640 and 670 nm, this is 0.91 (GR93)
A_{pupil}	area of the pupil in m^2

The limit was calculated assuming a fully dilated pupil, which the Health Council took to have a diameter of 8 mm and therefore an area of about 50 mm^2 . Hence, the formula used was as follows:

$$H_{\text{threshold, cornea, point image}} = 2.2 \times 10^4 \times Q_{\text{threshold, point image}} \quad [\text{in J/m}^2] \quad (3)$$

It is worth noting that ANSI, IEC and ICNIRP assume the maximum pupil diameter to be 7 mm, giving an area of 38 mm².

In its report Optical Radiation (GR93), the Health Council states that, because the threshold levels were calculated from animal experiments involving species which were roughly three times as sensitive to light as humans, the threshold curves obtained could reasonably be taken as recommended exposure limits for humans. Hence, the report recommends the following limit for point images:

$$H_{rec, \text{cornea, point image}} = \frac{0.006 + 20t}{F_\lambda} \quad [\text{in J/m}^2] \quad (4)$$

where:

$H_{rec, \text{cornea, point image}}$	is the recommended exposure limit in J/m ²
t	is the duration of exposure in seconds
F_λ	is the transmission through the eye media.

Thus, the Health Council implicitly built a safety factor into the recommended exposure limit. This factor varies between 3 and 4, depending on the duration of exposure and the pupil diameter, corresponding to a retinal burden of 1 mW where the duration of exposure exceeds 0.01 seconds.

4.2 Minimum safe distance

Using the limit specified above as a starting point, it is possible to calculate how close one must be to a given source before one may be considered to be at risk. Known as the NOHD* (nominal ocular hazard distance), this distance is as follows:

$$\text{NODH} = \frac{1}{\phi} \left[\sqrt{\frac{4 P_0}{\pi E_{MPE}}} - a \right] \quad [\text{in m}] \quad (6)$$

E_{MPE}	maximum permissible exposure level or health-based recommended exposure limit, in W/m ²
P_0	power, in watts
a	aperture diameter, in metres
ϕ	divergence, in radians

Where the exposure limit is expressed in J/m² — as is the case with the Health Council's health-based recommended exposure limit — the formula is as follows:

* For a detailed explanation of the derivation of this formula, refer to Annex C.

$$\text{NODH} = \frac{1}{\phi} \left[\sqrt{\frac{4 P_0 t}{\pi H_{MPE}}} - a \right] \quad [\text{in m}] \quad (7)$$

Insertion of formula (4) in (7) gives:

$$\text{NODH} = \frac{1}{\phi} \left[\sqrt{\frac{4 P_0 t F_\lambda}{\pi (0.006 + 20t)}} - a \right] \quad [\text{in m}] \quad (8)$$

Where $t > 0.01$, 0.006 is negligible in relation to $20t$. Furthermore, at wavelengths of 640 to 670 nm, $F_\lambda = 0.91$. Hence:

$$\text{NODH} = \frac{1}{\phi} \left[0.24 \sqrt{P_0} - a \right] \quad [\text{in m}] \quad (9)$$

Figure 7 shows how far one must be from a laser pointer to ensure that one does not exceed the exposure limit, given various divergences and output powers, assuming an aperture diameter of 2 mm and a wavelength of between 640 and 670 nm. It will be seen that, if the divergence is 1 milliradian (typical for laser pointers) and the pupil is fully dilated, the minimum safe distance varies between 5.5 and 15 metres.

Since, where laser pointers are concerned, the aperture diameter is very small (usually just a few mm) it makes little difference to the minimum safe distance. The degree of beam divergence, on the other hand, is very influential. It is also worth noting that the minimum safe distance for a pointer with an output power of less than 1 mW is zero, since the power of the beam is below the limit even at the source.

ANSI, ICNIRP and IEC include exposure limits (expressed as maximum permissible exposure (or MPE) levels) for all wavelength-exposure duration combinations. They recommend determining the risks associated with light-emitting lasers on the basis of exposure for 0.25 seconds and a fully dilated pupil (ANSI93, ICN96, IEC98).

Using formula (2) on the basis indicated above, it proves that the pupil diameter has a major influence on the threshold level, but that the duration of exposure ceases to be significant above 0.01 seconds. Under such circumstances, the limit corresponds to a constant power, which is not time-dependent.

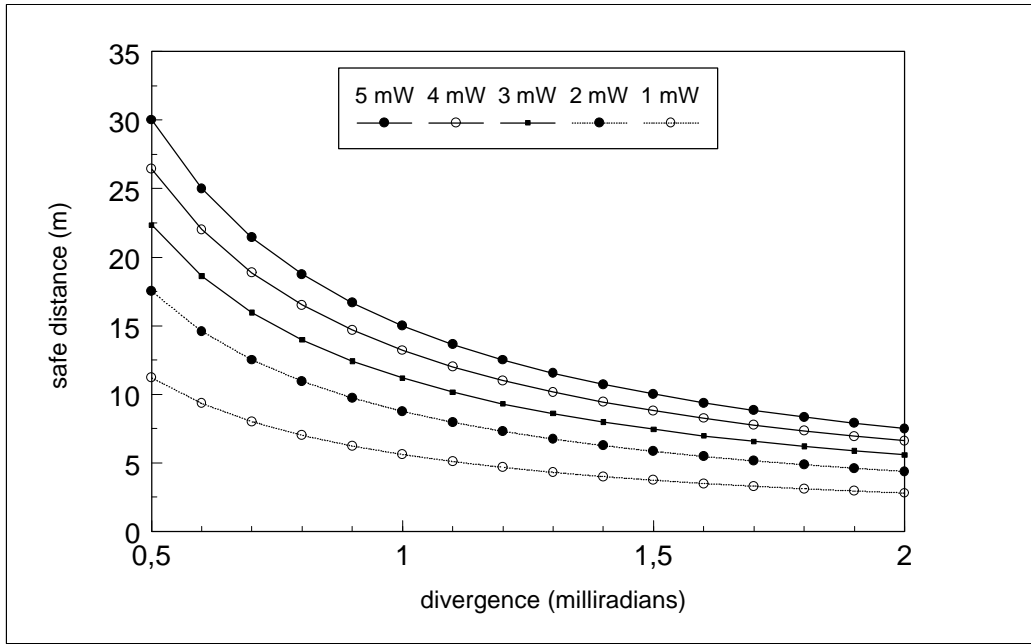


Figure 7 Minimum safe distance from a laser pointer ($640 \text{ nm} < \lambda < 670 \text{ nm}$, $a = 2 \text{ mm}$) as a function of divergence for various output power ratings.

Risk of eye injury associated with laser pointers

The risk associated with using a given laser system is determined by three factors:

- the physical specifications of the laser
- the circumstances under which the laser is used
- the individuals using and exposed to the laser.

Laser systems are classified purely on the basis of the first factor (see 1.2). The second and third factors differ not only from one laser to another, but also from one occasion to another and cannot therefore be standardized. Nevertheless, these factors are relevant in the context of risk assessment.

5.1 Physical specifications of the laser

As indicated in 1.2, most laser pointers fall within European classes 2 and 3B. Class 2 lasers are by definition rated at less than 1 mW and cannot therefore cause exposure in excess of the limit. Class 3B lasers, by contrast, can be sufficiently powerful for the MPE level to be exceeded.

5.2 Circumstances of use

Laser pointers were originally intended as optical aids for people making presentations or giving lessons. Such applications will generally involve indoor use in a fairly dim environment, with the audience sitting opposite the person using the pointer. In most

cases, the audience will be one to several metres from the user. Because of the lack of light, the pupils of people in the audience will be dilated, increasing the risk. The environment in a cinema or discotheque will be quite similar: low lighting, resulting in dilation of the pupils. Alcohol and other depressants or stimulants can also bring about or increase dilation of the pupils.

However, laser pointers are also often used in, for example, well-lit classrooms. Under such circumstances, the people present will have fairly small pupils. Although this will limit the amount of energy reaching the retina, people in a classroom are more likely to be close to the source, thereby offsetting any benefit.

Outdoor use of laser pointers is a lot more likely to result in uncontrolled exposure. Because the range of the beam from a laser pointer can extend to several dozen metres, people at considerable distance from the source are liable to display an aversion response if exposed. Under such circumstances, however, the energy density is unlikely to be sufficient to result in exposure exceeding the MPE level.

5.3 Individuals using and exposed to the laser

Laser pointers sold as novelties often come into the possession of people who understand neither the significance of the device's classification nor the risks associated with exposure. The possibility of inappropriate use cannot therefore be excluded; indeed, such use may be regarded as probable where children or young people are involved.

The intensity and colour of laser pointer beams are such that exposure will almost always produce an aversion response, flash-blindness and after-images. Depending on the intensity of the beam and the position of the image on the retina, after-images or flash-blindness can cause annoyance or danger. The level of any danger depends partly on the circumstances: a road user who suffers unexpected exposure is in greater danger than someone exposed while sitting outside a street café or strolling in the park. Considerable danger could result from the exposure of people engaged in professional activities, such as bus drivers.

5.4 Potential exposure versus actual exposure

The potential level of exposure can easily be determined as a function of distance on the basis of the laser's physical properties. The relationship between retinal burden and distance in various situations is shown in Figure 8. By way of comparison, the threshold for inducing just-observable retinal lesions (3 mW, given exposure lasting between 0.01 and 10 seconds; see Figure 5) is also shown.

The plateau in retinal burden is dictated by the maximum amount of energy that can enter the eye (i.e. the whole beam entering the eye). If the exposed individual is more

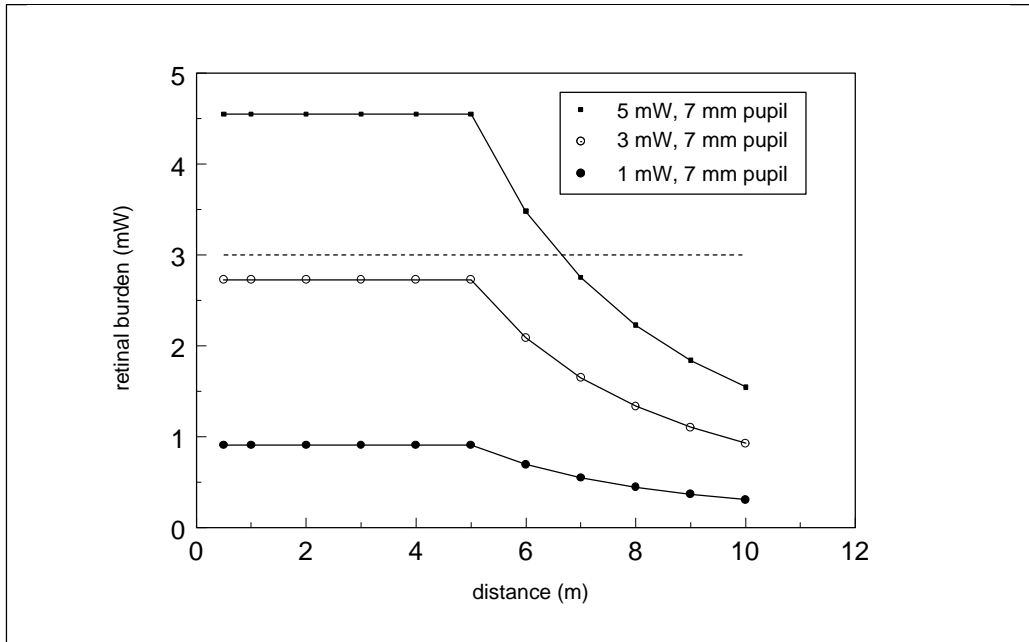


Figure 8 Retinal burden caused by laser pointers emitting a beam with an aperture diameter of 2 mm and a divergence of 1 mrad. The dotted line represents the threshold (3 mW) for just-observable retinal lesions (GR93).

than a certain distance from the source, the width of the beam will be greater than the pupil diameter. Under such circumstances, the pupil will act as a diaphragm, preventing the whole beam from entering the eye. In the examples cited (assuming a pupil diameter of 7 mm), the critical distance is about 5 m from the source. If the pupil diameter were only 3 mm, the distance would be just 1 metre from the source.

Most laser pointers have an output power of less than 5 mW, but 11 mW is not unknown (Bar98).

The retinal burden curves in Figure 8 relate to potential exposure. In various practical situations, however, the level of exposure actually suffered is liable to be less than the potential level. If conditions are bright, for example, the pupil will not be fully dilated, so the amount of energy reaching the retina may not be as great as allowed for in the calculations. Individual factors can also play a part; thus, if an exposed person is on medication, or under the influence of alcohol or drugs, this may influence his or her pupil diameter.

NB: It has often been suggested that it would be extremely difficult to shine a laser beam into someone's eye for 0.25 seconds, certainly from any distance. This point is irrelevant, however, since, if exposure lasts for anything between about 0.01 seconds and 10 seconds, the amount of energy that has to reach the retina to induce a

just-observable retinal lesion is in direct proportion to the duration of exposure. It is not therefore the duration of exposure that determines whether injury is suffered, but the retinal burden.

5.5 Likelihood of injury

The threshold level was discussed in subsection 2.3, where it was pointed out that this level is derived from ED₅₀ data. It was also indicated that the Health Council's MPE level for humans is based on an ED₅₀ of 3 mW for just-observable retinal lesions. A level of exposure corresponding to the health-based recommended exposure limit (derived from the MPE level), which works out at a retinal burden of no more than 1 mW for exposure lasting between 0.01 and 10 seconds, is therefore extremely unlikely to cause injury.

Using Figures 8 and 9, it is possible to estimate the likelihood of retinal lesion at a given level of exposure. Because injury-risk data is less reliable at the extremities of the range, the accuracy of an estimation decreases where unusually high or low power ratings are concerned (the grey band in Figure 9).

Exposure in daylight, when the pupil diameter is normally much smaller, is a lot less likely to lead to injury. It should also be remembered that, in most cases, the injuries suffered will be very minor and only detectable using special equipment. Certainly, exposure affecting areas of the retina outside the *fovea centralis* — while liable to cause genuine temporary problems — is highly unlikely to result in any injury of which the person in question will be aware.

A survey of Dutch ophthalmologists carried out by Van Norren *et al.* failed to discover a single case of permanent injury in the Netherlands. Nor could any reference to permanent injury attributable to laser pointers be found in the international peer-reviewed literature (Nor98).

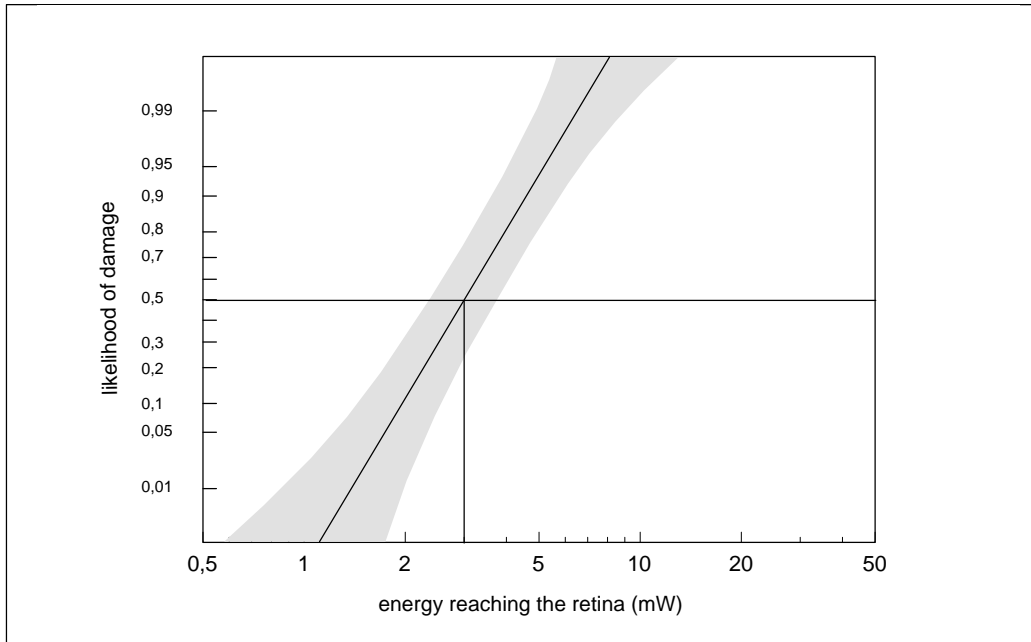


Figure 9 The likelihood of retinal lesion as a function of energy reaching the retina. The sloping line is calculated from the line running through the 10-mW point in Figure 6. This has been shifted to the left so that the intersection representing a risk of 0.5 is at 3 mW, the threshold for thermal retinal lesions indicated in subsection 2.4. The grey band shows the distribution estimated on the basis of the experimental data presented in Figure 6.

International reports and guidelines

In the latter part of 1997, the United States Food and Drug Administration (FDA) issued a warning about the misuse of laser pointers (FDA97). The FDA indicated that such devices were suitable only for use by adults; although the visual impairment associated with short-term exposure was only temporary, it was nevertheless dangerous, certainly if the exposed individual was at the time of exposure engaged in a vision-critical activity, such as driving.

The World Health Organization has also published a fact sheet highlighting the health risks associated with laser pointers (WHO98). In this publication, the WHO drew attention to the fact that lasers are often incorrectly labelled (class 3A lasers frequently being marked as class 2). The organization also suggested that class 3 lasers were not suitable for general use and that only class 1 lasers should be incorporated in children's toys. Finally, the WHO advised against the sale of class 2 lasers to children. In response to similar advice from Britain's National Radiological Protection Board (NRPB), the UK's Department of Trade and Industry banned the sale of potentially dangerous laser pointers (classes 3 and 4) (OHa98).

In many European countries, measures have since been taken to restrict the use of laser pointers. Several countries, including the Netherlands, have prohibited the sale of laser pointers in class 3A or higher (Abb97, VWS98). The incorporation of class 2 lasers in toys, key rings, pens and so on is now illegal as well in the Netherlands. Furthermore, the government has concluded on basis of research by the Health Care Inspectorate that class 3a and class 2 laser pointers are dangerous even in normal use

(Beu98, VWS98). Both prohibitions are based on Section 18c of the Commodities Act, which prohibits

... the sale of goods (other than goods intended for consumption), which by their nature may be deemed intended or suited for private domestic use, insofar as it is known or may reasonably be anticipated that, when used in a way which may be expected, given their intended purpose, they will constitute a threat to human health or safety.

Britain's NRPB and the German Bundesamt für Strahlenschutz have also ruled that only class 1 and class 2 lasers are suitable for use as pointers. Class 3B lasers may only be used for certain purposes, and then exclusively by specially trained individuals. Both organizations have recommended that only class 1 and class 2 lasers should be allowed on general sale, and that even these lasers should be accompanied by comprehensive information (Abb97, BfS98, NRPB98, OHa98, SSK98).

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- A Formulation of this report
 - B Warnings required under IEC-60825-1
 - C IEC-60825-1 classification
 - D Calculation of the NOHD

Annexes

Formulation of this report

This report was drawn up at the request of the President of the Health Council of the Netherlands by GJ Eggink of the Rijksinstituut voor Volksgezondheid en Milieu (National Institute of Public Health and the Environment), who was seconded to the Health Council secretariat for three months for the purpose.

The following experts were consulted:

- JWN Tuyn, physicist, Zwinderen
- Dr D van Norren, physicist, Professor of Ophthalmology at the University of Utrecht and Director of the Aeromedical Institute, Soesterberg
- Dr RM Verdaasdonk, laser physicist, Utrecht University Hospital

A draft copy of the report was submitted to the Health Council's Standing Committee on Radiological Protection for review.

Warnings required under IEC-60825-1

Class 1 lasers:

CLASS 1 LASER PRODUCT

Class 2 lasers:

LASER RADIATION

DO NOT STARE INTO BEAM

CLASS 2 LASER PRODUCT

Class 3A:

LASER RADIATION

DO NOT STARE INTO BEAM OR VIEW

DIRECTLY WITH OPTICAL INSTRUMENTS

CLASS 3A LASER PRODUCT

Class 3B:

LASER RADIATION

AVOID EXPOSURE TO BEAM

CLASS 3B LASER PRODUCT

Class 4:

LASER RADIATION

AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION

CLASS 4 LASER PRODUCT

IEC-60825-1 classification

Class 1:

Lasers which are safe under reasonably foreseeable conditions of operation.

Class 2:

Lasers emitting visible radiation in the wavelength region from 400 nm to 700 nm. Eye protection is normally afforded by aversion responses including the blink reflex.

Class 3A:

Lasers which are safe for viewing with the unaided eye. For lasers emitting in the wavelength range from 400 nm to 700 nm protection is afforded by aversion responses including the blink reflex. For other wavelengths the hazard to the unaided eye is no greater than for Class 1. Direct intrabeam viewing of Class 3A lasers with optical aids (e.g. binoculars, telescopes, microscopes) may be hazardous.

Class 3B:

Direct intrabeam viewing of these lasers is always hazardous. Viewing diffuse reflections is normally safe.

Class 4:

Lasers which are also capable of producing hazardous diffuse reflections. They may cause skin injuries and could also constitute a fire hazard. Their use requires extreme caution.

Calculation of the NOHD

The NOHD is the distance beyond which, under ideal circumstances, the irradiation strength and power density are lower than the maximum permissible exposure level or the health-based recommended exposure limit. It is calculated as follows:

The diameter of the image formed by a laser spot is (see Figure 2):

$$D_L = r \sin(\phi/2) + r \sin(\phi/2) + a$$

Where the angle is acute, $\sin \phi \cong \tan \phi \cong \phi$. Hence:

$$\begin{aligned} D_L &= (r \phi/2) + (r \phi/2) + a \\ &= a + r \phi \end{aligned}$$

The area A_L of a beam with a circular cross-section may then be obtained from the following equation:

$$\begin{aligned} A_L &= (\pi/4)(D_L^2) \\ &= (\pi/4)(a + r \phi)^2 \end{aligned}$$

Given an output power of P_0 , the irradiation strength E at distance r from the laser can be calculated thus:

$$E = P_0 / A_L \quad [\text{in W/m}^2]$$

Substitution then yields the following:

$$E = \frac{4 P_0}{\pi (a + r \phi)^2} \quad [\text{in W/m}^2]$$

If E is replaced by E_{MPE} , the maximum permissible radiation strength, r equals the NOHD, and the formula can be rewritten as follows:

$$\text{NODH} = \frac{\sqrt{4 P_0 / \pi E_{MPE}} - a}{\phi} = \frac{1}{\phi} \left[\sqrt{\frac{4 P_0}{\pi E_{MPE}}} - a \right] \quad [\text{in m}]$$

If the MPE level is expressed as the energy density H in J/m^2 , it follows that:

$$\text{NODH} = \frac{1}{\phi} \left[\sqrt{\frac{4 P_0 t}{\pi H_{MPE}}} - a \right] \quad [\text{in m}]$$