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Concepts of Probabilistic Risk Analysis and Applicability for "Day-to-Day" Laser Safety Evaluations

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ABSTRACT

In recent years, more and more emphasis was placed on considering probabilistic risk analysis (PRA) to be performed by the user as basis for deciding on appropriate user control measures.

The concept of PRA in terms of probability for exposure to a certain level of exposure for a certain exposure duration, probability that that exposure level leads to an injury of the eye or the skin and finally the severity of the injury is reviewed. The authors discourage attempts to adopt this concept for day-to-day laser safety evaluations in respect to quantifying the probability that an injury occurs as a function of how much the exposure level is above the MPE and to characterize the corresponding severity of an injury. For anything but very sophisticated treatments of high profile issues, any ocular exposure above the MPE should be considered as severe enough to prompt control measures, unless the probability for the exposure to occur as such is negligible. It is argued that rather than suggesting the user to perform involved quantitative risk analysis, the concepts of PRA lend themselves as tools for standards committees and their development of guidelines for controls measures.

Some level of risk analysis should still be performed by the user in order to adopt the 'default' control measures (as defined by standards committees) to the specifics of the laser applications under consideration. However, this user performed risk analysis can be greatly simplified and in most cases quantitative approaches are not only unnecessarily involved but might also be inappropriate.

1. INTRODUCTION

It is a general principle in the field of health and safety that for all relevant hazards, safety measures (also referred to as control measures) need to be defined and adhered to in order to counteract the hazard and thereby establish a satisfying level of safety (i.e. to reduce the hazard to an acceptable level). In order to define appropriate control measures that on the one hand effectively reduce the hazard but on the other do not cause unnecessary burdens on the user, the hazards need to be well characterized and practical issues of use need to be taken into account. The techniques of risk analyses are a valuable tool to characterize the hazards and risks. When some level of quantification is involved in the analysis regarding the level of risk, especially when it comes to characterize the likelihood that the hazard manifests itself and harm is caused, then the term 'probabilistic risk analysis' is used, abbreviated to PRA. PRA is an established technique for failure analysis in high profile safety relevant engineering tasks but there is also a tendency to suggest it as basis for the selection of control measures by the laser user. While it is certainly prudent to perform some level of hazard analysis for any laser application, we would like to argue in this paper that the techniques of PRA are in most cases not appropriate for these 'day-to-day' laser safety evaluations. General aspects of the role of PRA in the development of laser safety standards and issues of risk communication are discussed in another paper at this conference[1], here we try to suggest a practicable and balanced approach when it comes to defining control measures for the user by committees and to hazard evaluation to be performed by the user.

The following discussion concentrates on hazards to the eye and the skin from exposure to laser radiation. While non-beam hazards such as mechanical or chemical hazards associated to some laser applications can often be more serious than laser eye and skin hazards, these non-beam hazards and their control is not specific to the field of laser safety.

2. DISCUSSION

2.1 Committee vs. user-defined control measures

In terms of definition of control measures for the use of lasers, two institutional levels can be distinguished: the definition of generalized safety precautions by safety committees and subsequent publication in laws, standards, or guidelines, and control measures defined by the user, based on a hazard analysis performed for a specific laser installation and application. The committee approach could be seen as 'top down' and the user specific analysis as 'bottom up'. The two approaches are not necessarily in competition, it is rather that the control measures defined in the committee guidelines can be seen as 'default' user requirements, while an analysis of the specific hazards of a given application can or should be performed to 'optimize' these default control measures.

Control measures that are developed by standards committees have the basic advantage that they are based on a consensus of experts in the field and that document development often includes a multiple draft stages with comments and input from interested parties and in the case of international documents of national committees. However, user controls defined in such documents can only be very general and they can not, by their nature,

account for specifics of special applications. While there are a number of established laser applications (such as medical procedures in surgery, ophthalmology and dermatology or the use of visible lasers as alignment or pointing tool) that are generally performed with the same types of lasers and where hazards are well known and user control measures can be defined that are generally appropriate, in other fields where lasers are used, such as often in industry, consumer products and research, laser types and applications often vary widely, and it is not possible for committees to anticipate practical issues of use and associated hazards and to define control measures that are appropriate for every kind of laser application. This is also an issue of size and complexity of the documents (ideally, hundreds or even thousands of applications would need to be analyzed, described and treated specifically) and of anticipating future developments, as the development durations of international documents can be several years.

2.2 Guidelines vs. laws

The technique of hazard analysis to identify appropriate user control measures is naturally not limited or unique to laser safety, rather, it is a generally applied concept in work place safety. For instance, it is a legal requirement in Europe that a documented hazard evaluation is performed for each work place. The hazards to the eye and the skin from laser radiation are only one type of hazard that should be also seen in perspective to the more general health and safety policy. The extent to which there are prescribed control measures that need to be adhered to or how much responsibility and freedom the user has to define appropriate user controls depends on national legal requirements and on the category of hazards. For instance, in many countries, the control measures for use of ionizing radiation or the maximum concentration of hazardous substances are defined in laws, while control measures for the use of lasers are usually defined in guidance documents that do not have the status of laws. An exception in Europe is Germany, where the national workers insurance board "Berufsgenossenschaften" issues prescriptive rules that define user controls based on the international laser classification scheme. When the control measures are legally required, then it is certainly more critical that they are both appropriate and do not place an unnecessary burden on the user than user controls that are published in international guidelines which have only advisory character. However, the authors of such guidelines still have a high responsibility in respect of appropriate user controls and in taking practical issues into account as these international guidelines are often adopted as 'state of the art' in countries where there are no specific legal requirements and are then often also used in court for the case that a serious accident happens.

2.3 Zero Risk vs. PRA to be performed by the user

The law maker and safety committees have the burden of defining controls that should ideally assure safety on the one hand and on the other the challenge that almost every laser application is different and that would ideally require individualized control measures. Two reactions to this dilemma can be observed: on the one extreme, there is a tendency to be on the 'safe side', or even towards 'zero risk', where the choice of control measures is driven by the most hazardous of applications and by the most hazardous exposure conditions even if highly unlikely (such as prolonged exposure to the direct beam without moving of the body for hours or observing a laser installation with binoculars from a distance of 2 meters). On the other extreme, the burden of decision making is moved to the user: the control measures are not defined by the committee, but the committees suggest that the user performs a (quantitative) risk analysis and, based on the results of this analysis, to define the appropriate user control measures.

Faced with the problems inherent in safety policy of complex and widely varying technological systems, it is only natural that committees or individual committee members tend towards one or the other extreme, and elements indicative for both approaches can be found in recent documents developed by working groups within TC 76: a draft standard for free air communication (to become part 12 of IEC 60825) contained elements that tended towards the 'zero risk' approach and a draft for general user guidelines (to become part 14 of IEC 60825) is an example where the 'user PRA' approach was in some points carried to an extreme. It should be pointed out however, that both documents were early drafts and were revised in the following step of the document development.

It is obvious that both approaches have serious drawbacks and above all, result in severe difficulties when they are to be followed on the practical level. Zero-risk, committee defined control measures will be overcritical for all but some extreme cases, i.e. for most practical cases they place an unnecessary burden on the installer or user of the laser system and therefore often the requirements are not followed as they are identified by the user to be unnecessary or impractical, which is particularly problematic if the control measures have a binding legal status. In the other extreme, when the user has the responsibility or is suggested to identify and judge the acceptability of all involved risks, based on a quantitative PRA, this is also not practical as the level of expertise and the resources required for such an analysis are extensive, and in some cases, such as when it comes to judge the severity of potential injuries as a function of how much the exposure is above the MPE, the required information is not available at all.

3. ARGUMENT FOR A BALANCED AND PRACTICAL APPROACH

We would like to argue that the most practical approach from the viewpoint of the laser user would be an adoption of PRA principles by the committees to leave only simple hazard evaluations to be performed by the user. As PRA can be quite involved, it might well be that the committees themselves might not have sufficient resources, however, all the more problematic would it be to expect the user to perform such an analysis on a general basis. When control measures are based on PRA, it would of course be prudent to clarify any limitations of the control measures and to state in which (unlikely) cases the default user control measures as defined for realistic and practical modes of use might not be sufficient. For these special cases, additional user controls could be also specified, but they should not be presented as default control measures to be generally adopted. It is still prudent and sometimes required for the user to perform a minimum level of risk analysis, however, in practice, such a risk analysis can be highly simplified and will not be dealing with probabilities of harmful events or with quantifying levels of severity. Following the principles of risk analysis even the most simplified hazard analysis intrinsically involves some judgment on likelihood of manifestation of the hazard: in the process of reflecting on what kind of hazards are presented by a given applications, those kind of hazards that have negligible probability of occurring are generally dismissed as not being a hazard. The question for such a simplified risk analysis is not: 'what is the probability for occurrence' but 'is the hazard relevant or not'. When the hazard is identified to be relevant, something needs to be done about it.

Such a (simplified) hazard analysis that is performed by the user is important for many laser applications since the hazards of specific applications can vary so widely. It is necessary for the user to reflect on the hazards and understand the hazards so that control measures once they are defined are also followed and 'lived'. Another aspect is that even when committees do work hard to make the user requirements as practicable as possible, it is still not possible to account for all the different types of applications. One or the other of the generalized control measures defined or recommended by the committee might not be applicable or necessary for a given application. It might also be that in special cases the mode of use and hazards are beyond the limitations of the guidance document and control measures additional to the generalized control measures need to be considered.

4. APPLIED PRA

4.1 Notion of 'risk'

The depth and complexity of risk analysis can vary widely from a simple identification of the hazards to a quantitative analysis that takes account of the uncertainties associated to the relevant parameters by Monte Carlo simulation.

The general understanding and definition of the term 'risk' involves both a sense of severity of the harm that might occur as well as a sense of likelihood that the harm occurs, i.e. the likelihood that the hazard manifests itself and the harmful event occurs.

Some attempts have been made to introduce a simplified quantitative character for the two risk parameters likelihood and severity. For instance by choosing from five levels of likelihood (for example: highly unlikely or virtually impossible, improbable, probable, highly probable and certainty) and characterizing the severity of the harmful event or injury as one of four (for example: negligible, minor, serious, and very severe (lethal)) and then the two parameters can be assigned numbers (starting from 0 or starting from 1). Subsequently they can be added or more often multiplied in order to quantify the level of risk (so that a highly probable event that causes minor injuries ($4 \times 2 = 8$) would have a risk level comparable (or actually according to the scheme equivalent) to an improbable event that causes severe injuries if it occurs ($2 \times 4 = 8$). While such a scheme, often using a matrix representation, was more common 5 to 10 years ago and was also suggested to be adopted in the field of laser safety, it is nowadays not used very often. It has some obvious limitations of first having to define (and make generally understood) the levels of the scheme and then using the scheme by assigning levels to some hazard.

4.2 MPEs vs. likelihood and severity of injury

For application in the field of laser safety, it is very difficult or rather impossible to account for the severity of ocular or skin injuries for a given level of exposure above the injury threshold values. Rather, it is the purpose of the MPEs to be adopted as the threshold between safe exposure levels and exposures that need to be considered as potentially hazardous. In this sense, all levels of exposure above the MPE should be treated as severe enough to call for control measures. While it is generally correct that for a given wavelength, exposure duration and spot size, the injury will be more serious for exposure levels well above the threshold (also referred to as 'suprathreshold') than exposures which are just sufficient to lead to an injury (referred to as 'at threshold'), it is not possible to generally scale the level of severity as a function of by what factor the MPE is exceeded – both because the scaling factor between the threshold and MPE is not defined and known and because the severity depends on a great number of factors, such as on the location of the retinal lesion, the diameter of the injury, etc.

It is not only that the severity of a suprathreshold injury can not be characterized, it is also the probability that an injury actually develops for exposure levels above the MPE can only be estimated with great effort and resources and then only with considerable uncertainty[2]. The authors were involved in the development of a probabilistic ocular damage model for exposure with large telescopes that also models uncertainties of model parameters and that is discussed in another paper presented at the conference[3]. For general laser user issues, such a model is not appropriate and the MPE should be treated as threshold for acceptable exposure levels both in terms of likelihood that a given exposure leads to an injury and in terms of severity of the injury.

4.3 Probability of exposure

Based on the usage of the MPE as border between safe and potentially hazardous exposure levels, a risk analysis regarding the probability that hazardous exposure, i.e. exposure above the MPE values occurs at all can in some cases be helpful to decide on appropriate user control measures. For a given laser exposure level, this is not only a question of does exposure occur or not but also of how long exposure occurs since the MPE depends on the exposure duration. A given exposure level might be safe (i.e. below the MPE) for short exposure durations of less than a second but might be above the MPE for prolonged staring - but how likely is it that such an exposure conditions occurs? Similarly, whether the MPE is exceeded or not might depend on the potential use of optical instruments such as magnifying glasses for divergent beams or binoculars and telescopes for large diameter collimated beams. Exposure to the naked eye might be safe but exposure with one of the two categories of optical instruments might be hazardous – however, how likely is it that such an exposure with optical instruments occurs? These questions could and should well be considered by standards committees in the framework of PRA as it is argued also in another paper presented at this conference[1].

Examples where there is still some need for further discussion and work within the committees are to consider the likelihood (or un-likelihood) of exposure with binoculars in an area where Class 1M or Class 2M laser products that fail condition 1 are used. This issue is an example where at the moment, some draft user guidelines seem to lag behind the definition of these new classes and currently simply and generally suggest to 'ensure' that binoculars are not used within the extended NOHD of such products or that the use of binoculars is 'prevented'. The (probabilistic) risk analysis is currently left for the user to perform, although it can be shown with relatively simple calculations that the risk for an exposure (that is above the MPE) is quite low and could be regarded as negligible for all but extreme cases where the laser is pointed intentionally into localized areas with high 'concentration' of binoculars and if there might be a reason to observe the laser with binoculars. Consequently, the typical use of collimated-beam Class 1M or Class 2M lasers require some level of understanding of the hazard on the side of the user, but usually not any sign-posting or controlling of the use of binoculars in the area where the laser is pointing.

4.4 Class 3R

A case where standards committees have considered probabilities that an actual lesion develops for exposure levels that are some limited factor above the MPE is the definition of Class 3R. Since the MPE is exceeded, some level of risk analysis is required both on the side of the committees that define user controls and on the side of the user: when used professionally as alignment or pointing tool, i.e. in a mode of usage that does not make intentional ocular exposure likely, some level of training of the user is usually considered as appropriate and sufficient user control measures. User control issues for the use of the new Class 3R is one example where there might even be some uncertainty in some committees that were not involved in the definition of Class 3R: as a natural reaction to the uncertainty in terms of the risk associated to these types of lasers, a tendency towards overcautious user requirements can be observed, especially for non-visible Class 3R lasers (as there is extensive practical experience and good safety records with visible Class 3R lasers but only limited discussion so far regarding non-visible Class 3R lasers). In the view of the authors, non-visible Class 3R lasers are quite safe for all but extreme exposure conditions, and even the class definition itself could have been extended for instance to include wavelengths below 302.5 nm. Since the time base for classification of UV lasers is 30 000 s, Class 3R laser exposure which can be up to a factor of 5 above the MPE for the eye and the skin does not exceed the MPE for exposure durations of at least 1 hour and 40 min for wavelengths less than 315 nm. This simple consideration of the dependence of the MPE on exposure duration and a simple non-quantitative 'risk analysis' of the likelihood of exposure to the direct beam and a non-moving body for 1 h and 40 min should result in accepting such lasers as quite safe even without having to argue with the safety factor (which is less than 5 for wavelengths at around 270 nm which was the reason to limit Class 3R to wavelengths above 302.5 nm). For wavelengths in the IR, following the time base of 100 s and a risk analysis of practical exposure durations to the direct beam (for wavelengths above 1400 nm these exposure can also be felt as heat long before they lead to an injury) including the consideration of the safety factor can lead to the result that for all but intentional prolonged staring into the beam (which is really only possible for wavelengths close to the visible as other wavelengths can not be seen) these can be considered quite safe. Such prolonged staring can be counteracted by a minimum

level of the training of the (professional) user, making other user control measures such as laser controlled areas usually not necessary.

4.5 Tolerable or acceptable levels of hazard

The final step in a quantitative probabilistic risk analysis is often the most difficult one: after the effort of coming up with a probability figure that should ideally also include the uncertainty of the analysis, it has to be judged whether the calculated risk number is acceptable or not. Such a decision is more of a political nature and unfortunately but understandably there is limited guidance regarding such a 'risk threshold' number. This is especially problematic when a committee suggests the user to perform a (quantitative) risk analysis and to judge if a given risk is acceptable or not and does not give a guidance of what level of risk would be considered acceptable.

The simplistic non-quantitative approach to risk analysis also has the advantage of not requiring such acceptable risk numbers, as it basically follows the general principle of reducing the hazard as much as reasonably practicable.

5. CONCLUSIONS

It is suggested that PRA is used by standards committees to define appropriate 'default' user control measures that are not based on simplified zero-risk approaches rather than suggesting the user to perform involved quantitative PRA. While some level of hazard analysis is certainly prudent to perform for any laser application, we argue that the techniques of PRA are in most cases not necessary or appropriate for these 'day-to-day' laser safety evaluations.

6. LITERATURE

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