

## **REGULATORY IMPACT ANALYSIS (RIA)**

### **SAFETY, HEALTH AND WELFARE AT WORK (GENERAL APPLICATION) (AMENDMENT) REGULATIONS 2009**

#### **CONTROL OF ARTIFICIAL OPTICAL RADIATION AT WORK**

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## Foreword

The Health and Safety Authority has prepared this Regulatory Impact Analysis (RIA) on the potential impact of the draft Safety, Health and Welfare at Work (General Application)(Amendment) Regulations 2009 (re. Control of Artificial Optical Radiation at Work) which amend the Safety, Health and Welfare at Work (General Application) Regulations 2007 (S.I. No. 299 of 2007). The proposed Regulations are designed to transpose into Irish law Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (Artificial Optical Radiation). The deadline for transposition of this Directive into Irish law is 27 April 2010.

The purpose of this RIA is to support the development of effective and proportionate national Regulations by providing a thorough examination of the nature and extent of the potential impacts on a range of stakeholders.

## 1.0 BACKGROUND INFORMATION

The Artificial Optical Radiation Directive is the fourth and final of a package of physical agents Directives covering Noise, Vibration, Electromagnetic Fields and Artificial Optical Radiation. The Noise and Vibration Directives have already been transposed into Irish law in Part 5 of the Safety, Health and Welfare at Work (General Application) Regulations 2007. The deadline for transposition of the Electromagnetic Fields Directive has been postponed by the Commission until 2012.

The Artificial Optical Radiation Directive was proposed during the Irish Presidency of the European Union and was developed by the European Council Social Questions Working Group during 2004 and 2005.

The final Directive is confined to artificial sources of optical radiation. The original proposal had included natural radiation (sunlight), but was amended during negotiations. The costs of implementing the Directive are, therefore, significantly reduced on the original proposal.

Artificial optical radiation includes all man-made sources including lasers, ultraviolet radiation sources and some furnaces, but it excludes the sun. Artificial optical radiation is used in processes across a range of sectors. Medical applications include bloodless surgery, laser healing, surgical treatment, kidney stone treatment, eye treatment and dentistry. In industry, it is used for cutting, welding, material heat treatment and marking parts. In research environments it is applied to processes such as spectroscopy, laser ablation, laser annealing, laser scattering, laser interferometry. The development of products such as laser printers, CDs, barcode scanners, laser pointers and holograms and laser lighting displays and laser skin procedures such as acne treatment, cellulite reduction, and hair removal all involve artificial optical radiation.

The areas of the body most at risk from excessive optical radiation exposures are the skin and eyes. The effects on the eye include damage to the cornea and lens. Effects on the skin include redness, burning, blistering and an increased risk of skin cancer.

Based on the available evidence, the Health and Safety Authority takes the view that there is relatively low risk of injury through exposure to artificial optical radiation. The Authority's database of reported injuries does not include any reports of injuries due to optical radiation. Approximately 8,000 injuries

are reported annually to the Authority by employers but none of these (since 2000) include any reference to the terms 'radiation' or 'laser'.

Currently there is no Irish legislation specific to artificial optical radiation. The general duties to assess and control risks contained in the Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (General Application) Regulations 2007 apply. The proposed Regulations add to these existing requirements in that they define more precisely what is expected. For example, it requires assessment of exposures as a means of assessing risk, and compliance with standard exposure limit values (ELVs).

The production and application of artificial optical radiation is already tightly controlled. The International Electrotechnical Commission (IEC) has set an international standard for laser safety – IEC 60825. The standard contains several elements including a manufacturer's checklist, guidance for laser displays and medical laser equipment and a classification and labelling system for lasers or laser devices being used or sold into any European country. Each country has its own version of this standard with minor differences mainly due to translation. The Irish version of the standard is IS EN 60825.

## **2.0 OBJECTIVES OF THE DIRECTIVE/PROPOSED REGULATIONS**

The primary objective of the Directive is to lay down minimum requirements for the protection of workers from risks to their health and safety arising from artificial optical radiation during work. To this end, the Directive requires employers to assess risks arising from optical radiation exposures, eliminate or reduce these risks, provide appropriate training and health surveillance, and suitable treatment for staff who do suffer damaging exposures. It is the responsibility of the Member States to enforce the legislation and devise a proportionate and dissuasive penalty structure.

A secondary objective of the Directive is to achieve greater harmonisation of control regimes across Member States. A set of minimum exposure limit values produced by the International Commission for Non-ionising Radiation Protection (ICNIRP) is included as an Annex to the Directive. Since these exposure limits are the minimum required, Member States have the option to include more stringent provisions, e.g. fixing lower limit values than those in the Directive.

The objective of the proposed national Regulations is to directly transpose all the minimum requirements of the Directive, including the minimum exposure limit values set out in Schedule 11 to the Regulations.

The Authority intends to produce guidance prior to the introduction of the Regulations in April 2010 which will outline the measures that employers should take to achieve compliance.

## **3.0 OPTIONS CONSIDERED IN THIS ANALYSIS**

The transposition of the Directive into national legislation is mandatory. To take any action other than making Regulations would leave Ireland in breach of European law and would ultimately result in the Commission taking legal proceedings against Ireland.

There is the option to incorporate more stringent provisions in the Regulations. It is the Authority's view that ICNIRP values represent sufficient protection in an area that is already highly regulated and controlled.

The following analysis will consider the potential benefits and costs of the introduction of the Regulations for a range of stakeholders based on minimum requirements.

#### **4.0 INFORMATION SOURCES**

Data on the extent of optical radiation usage in Ireland is limited. However, in the interests of proportionality and in light of the relatively low risk associated with artificial optical radiation, the Authority deemed it appropriate to base the analysis on the available data sources. As such, the costs are intended to be indicative and should be interpreted with caution.

Several of the key estimates are derived from the Health and Safety Executive (UK) RIA. Judgements on the figures have also been made by technical experts in the Health and Safety Authority. The analysis also incorporates data from the Central Statistics Office and from industry professionals.

The public consultation phase will afford an opportunity for testing the assumptions in the Authority's analysis. The calculations and conclusions of this RIA may be updated to take account of any relevant and reliable data provided by stakeholders.

#### **5.0 BENEFITS**

##### **5.1 Health and safety benefits**

Compliance with the provisions of the proposed Regulations should lead to a reduction of the number of injuries suffered as a result of damaging exposures to artificial optical radiation. While compliance with requirements in existing legislation should already have this effect, the proposed Regulations and the associated guidance document should bring clarity and increased compliance by setting out more specifically what is required of employers.

##### **5.2 Trading benefits**

Adhering to the set of common guidelines for exposure limit values should facilitate trade between Ireland and other member states.

##### **5.3 National competitiveness benefits**

The implementation of a standardised system for the protection of workers from harmful artificial radiation exposures may encourage businesses from a range of sectors in other countries to establish plants in Ireland, compared to other jurisdictions that do not comply with the same standards.

#### **6.0 COMPLIANCE COSTS FOR BUSINESS**

The Authority does not expect that the Regulations will impose significant costs on employers who are already assessing and controlling health and safety risks. These employers will need to familiarise with the Regulations and conduct a specific risk assessment, but no further action would be required for

employers whose employees are at low risk from artificial optical radiation. For employers with workers who are at high risk of excessive exposures, the costs of developing an appropriate action plan may be more significant. Health surveillance will need to be provided for workers exposed above the limit value. However, given the existing high levels of control around the use of laser and broadband optical radiation, the Authority expects that employers whose work processes involve high exposures are likely to already have many of the appropriate assessment and control measures in place.

A more detailed breakdown of the likely cost elements is presented below. The following points should be noted -

- a) Costs are calculated only for Year 1 of the proposed Regulations. Costs relating to familiarisation with the Regulations are one-off costs, but other elements such as risk assessment and training would be repeated at regular intervals.
- b) The figures represent the costs if 100% of affected employers were to comply fully with the Regulations. In reality, the level of compliance is likely to be much lower (HSE UK anticipates a compliance level of 10%).
- c) The estimates of the proportion of industries and workers that may potentially be impacted by the Regulations are based on the midpoint of ranges produced by the HSE UK. The Authority is not in a position to provide meaningful ranges for the Irish context due to the lack of data. Technical experts in the Authority believe that UK estimates are likely to be over-estimates in the Irish context. This suggests that the figures in this analysis represent the maximum costs of compliance with the Regulations.

## **6.1 Familiarisation with the regulations**

In the absence of data on the number of Irish employers using artificial optical radiation, the Authority has used the HSE estimate that 16% of workers are in industries which utilise artificial optical radiation. Taking an average of 15 workers per employer<sup>1</sup>, there are approximately 21,800 employers who at least need to familiarise with the Regulations. Allowing an average of 30 minutes for familiarisation, and based on the CSO hourly labour cost of €39.19 for 'managers, professionals and associated professionals', the one-off costs for familiarisation are in the region of €427,000.

## **6.2 Risk assessment**

Using the UK figure for the number of workers that experience some level of exposure to artificial optical radiation (12%), it is estimated that 250,000 Irish workers are exposed to artificial optical radiation in the course of their work, of which approximately 10% are assumed to be at risk of high exposures. It is assumed that one risk assessment per 15 workers (or average workplace) is necessary. A manager could conduct a risk assessment in 45 minutes in a low-risk environment or take up to four hours in a high-risk environment. The estimated cost of risk assessments across all affected workplaces is approximately 707,000.

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<sup>1</sup> HSE estimate a range of 7-20 workers per employer, HSE RIA

### 6.3 Training

The provisions of the Regulations are unlikely to create any additional training requirement in workplaces with low risk of artificial optical radiation exposure. The Authority estimates that approximately one half day training session may be required in high-risk environments. Information from training providers suggests that 10 employees per training session is a reasonable estimate and that such a training session would cost in the region of €500. On this basis, training costs for high risk environments could cost €1.25 million in the first year.

### 6.4 Control measures

Control measures specified in the Regulations include action plans, implementation and health surveillance provision. Given the high levels of control already existing in most high-risk exposure environments, only a minority of risk assessments are expected to identify a need for additional control measures.

Of the risk assessments in high-risk environments, it is assumed that 12.5%<sup>2</sup> would require action plans to be prepared – i.e. 210 action plans in the Irish context. Action plans are likely to require 2 hours of manager time at €39.19 per hour and 90 minutes of consultant time at an average €150 per hour. The total cost for the preparation of the action plans is expected to be in the region of €75,000 in the first year of the Regulations.

Of the 25,000 workers at high risk of exposure to artificial optical radiation, it is suggested that approximately 27.5% of these will require health surveillance services<sup>3</sup>. Experts from the Authority's medical panel suggest that a charge of €100 per worker would apply for health surveillance provision. Depending on the number of serious exposure incidents, an estimated maximum cost for health surveillance is approximately €692,000. The HSE UK RIA does not include any additional costs for health surveillance as these costs are accommodated under the UK's national health structure.

Action plans may require upgrades of equipment to reduce exposure risks - HSE UK estimate that this may be the case in 50% of the action plans for high risk environments. Average costs for equipment are estimated at €500, resulting in costs of €65,000. Again, the Authority believes that this is likely to be the maximum required, given that the manufacture and maintenance of equipment using lasers and broadband is already highly regulated.

### 6.5 Compliance cost for a typical business

***A business operating in a low-exposure environment will be required as a minimum to familiarise with the Regulations and to carry out a dedicated risk assessment. The figures indicate that the average cost of this process for a business with 15 employees will be less than €50.00 in the first year.***

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<sup>2</sup> HSE estimate a range of between 5 and 20% of risk assessments will require action plans

<sup>3</sup> This proportion is based on an average from HSE UK RIAs for the noise and vibration directives which indicate that 30% of workers exposed to high level risk from noise and 25% of workers exposed to high level risk from vibration are provided with health surveillance services.

***For the small proportion of businesses operating in high-exposure environments and which may need to implement all the elements of the Regulations including training, action plan, health surveillance and equipment upgrades, the costs are estimated to be less than €2,200 (based on a business with 15 employees) in the first year of the Regulations.***

The total costs for year 1 of the Regulations are presented in Table 1:

<b>Costs of proposed Artificial Optical Radiation Regulations</b>	<b>€</b>
Familiarisation	427,182
Risk assessment	707,262
Training	1,258,972
Action plan	75,346
Health surveillance	692,400
Equipment	65,000
<b>Total</b>	<b>3,226,161.83</b>

## **7.0 ENFORCEMENT COSTS FOR HEALTH AND SAFETY AUTHORITY**

The proposed Regulations will be administered and enforced by the Health and Safety Authority. Given the relatively low risk of injury caused by artificial optical radiation, the Authority does not expect enforcement of these Regulations to require significant additional resources. Some re-allocation of resources will be necessary in relation to inspector training, inspection targets and the production of guidance documents, but it is anticipated that these changes can be accommodated within existing budgets.

## **8.0 ENVIRONMENTAL IMPACT**

The Authority does not foresee that the proposed Regulations will have any environmental impacts.

## **9.0 ADMINISTRATIVE BURDEN**

The proposed Regulations will not require employers to keep any additional records beyond the maintenance of risk assessments; there is no requirement to report any data to the Authority or any other agency.

## **10.0 CONSULTATION**

The proposed Regulations and the associated RIA will be made available for public consultation on the Authority's website for a one month period in May 2009, in accordance with the Authority's standard public consultation policy. Selected stakeholders may be contacted directly by the Authority and invited to make submissions.

The submissions from the public consultation will be collated by the Authority and relevant additions or amendments will be considered. Any changes to the proposed Regulations will be reflected in this RIA.



The revised documents will be submitted to the Legislation and Guidance Sub-Committee of the Board and the Board of the Authority for consideration and approval. The proposals as approved will be submitted to the Minister for Labour Affairs at the Department of Enterprise, Trade and Employment for his consideration with a view to formal legal settlement by the Office of the Parliamentary Counsel to the Government.

## **11.0 REVIEW**

The Commission has committed to reporting on the practical implementation of the Directive, based on five-yearly reports from the Member States. The Authority will maintain records of the implementation process and enforcement actions so that a progress report may be submitted to the Commission in 2015.

## **REFERENCES**

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