SEPTEMBER 2015
DG EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States

REPORT BY DIRECTIVE: DIRECTIVE 2006/25/EC ON THE MINIMUM HEALTH AND SAFETY REQUIREMENTS REGARDING THE EXPOSURE OF WORKERS TO THE RISKS ARISING FROM PHYSICAL AGENTS (ARTIFICIAL OPTICAL RADIATION)

IOM WORKING FOR A HEALTHIER FUTURE
milieu Law & Policy Consulting
COWI

ADDRESS COWI A/S
Parallelvej 2
2800 Kongens Lyngby
Denmark

TEL +45 56 40 00 00
FAX +45 56 40 99 99
WWW cowi.com

SEPTEMBER 2015
DG EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States

REPORT BY DIRECTIVE: DIRECTIVE 2006/25/EC ON THE MINIMUM HEALTH AND SAFETY REQUIREMENTS REGARDING THE EXPOSURE OF WORKERS TO THE RISKS ARISING FROM PHYSICAL AGENTS (ARTIFICIAL OPTICAL RADIATION)

PROJECT NO. A031983
DOCUMENT NO. 1
VERSION 1.0
DATE OF ISSUE September 2015
PREPARED Core team
CHECKED IOM team
APPROVED RG

CONTENTS

APPENDICES

List of abbreviations

Acronym	Definition
ACSH (WP)	Advisory Committee on Safety and Health at Work (Working party)
AOR	Artificial optical radiation
CPM	Common processes and mechanisms
DVS	German Welding Society
DWEA	Danish Working Environment Authority
ELV	Exposure Limit Value
EQC	Evaluation question Coherence
EQE	Evaluation question on Effectiveness
EQR	Evaluation question on Relevance
ESAW	European Statistics on Accidents at Work
ESENER	European Survey on New and Emerging Risks
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
EWCS	European Working Conditions Survey
EWF	European Federation for Welding, Joining and Cutting
HSA	Health and Safety Authority
HSE	Health and Safety Executive
ILO	International Labour Organisation
IR	Infrared
KR	Key requirement
LFS	Labour Force Survey
MPE	Maximum Permissible Exposure
MQ	Mapping question
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne (Statistical Classification of Economic Activities in the European Community)
NIR	National Implementation Report
OSH	Occupational Safety and Health
PPE	Personal Protective Equipment
RIA	Regulatory Impact Analysis
SBS	Structural Business Statistics
SLIC	Senior Labour Inspectors Committee

Acronym	Definition
SME	Small and medium enterprises
TFEU	Treaty on the Functioning of the European Union
TS	Tender Specifications
UV	Ultraviolet

Executive summary

Introduction and background

The AOR Directive places obligations on the employer, in the case of workers exposed to artificial sources of optical radiation, to assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect.

Objectives

The principle impact of the AOR Directive is intended to be a reduction in the incidence of injuries associated with artificial optical radiation (AOR). The hazards are wavelength dependent (for example lasers of a certain frequency range will burn the retina, whilst others will be absorbed by the cornea and lens and cause burn injuries or possibly cataracts).

It aims to do so by laying down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to AOR during their work.

Methodology

Findings are based on an analysis of the OSH legislation in each of the MSs (embodied in Country Summary Reports (CSRs) prepared by national experts for the project), official statistics at national and EU level, National Implementation Reports (NIRs) (submitted to the Commission by the MSs by end of 2013) as well as on scientific articles, existing studies and interviews with both national and EU stakeholders.

Implementation

All MSs have implemented the AOR Directive, mostly within one piece of legislation with fewer implementing it in several pieces. There have been no infringement proceedings initiated for non-communication of transposing measures for any of the MSs and no observed discrepancies (case of incorrect transposition) were identified between the Directive and national legislation. Although only very limited information is available it appears that the implementation of the directive into a single piece of legislation has facilitated its application in a coherent manner. Limited information suggests that the requirements are applied coherently, with the risk assessment and removal/reduction requirements functioning in the expected manner. Other requirements such as training, consultation and surveillance are often implemented within existing general OSH national structures and arrangements for such measures.

Compliance

Data on levels of compliance with the requirements of the AOR Directive within MSs are extremely sparse as most national authorities do not monitor levels of compliance in a directive-specific way.

For those three MSs where data were available, the level of compliance with the CPMs can be regarded as moderate with two (Slovakia and Romania) reporting compliance levels of 45% across all of the articles (estimated by the national expert). A third, Estonia, reported 71% compliance with the requirement for risk assessments, but provided no further information regarding any of the other articles. Of course, these figures should not be regarded as indicative of the situation in the remainder of the EU-27.

As with most of the other Directives, a number of MSs reported and commented upon the difficulties encountered by employers, especially in SMEs. In this case however, the difficulties were less restricted to SMEs and appeared to be more widespread. In essence, the issue of AOR appears to be regarded as a complex and complicated area of occupational health and safety, with considerable concerns regarding the understanding of the technicalities of the subject amongst employers and regarding competence in its measurement and assessment.

Accompanying actions

Despite recognition of this complexity, MS level supporting actions are relatively sparse compared to some other Directives. However, there is an EU Non-binding guide to good practice for implementing the earlier version of the AOR Directive (Directive 2006/25/EC), to provide some assistance.

Relevance

Evaluation of commonly encountered sources of AOR, and the sectors in which AOR is likely to be found, indicated that occupational risks relevant to the AOR Directive are potentially experienced by some workers in all MS. On this basis the Directive is regarded as relevant in all MS.

Estimates of the proportion of the EU workforce potentially at risk from AOR exposure and to whom the Directive is therefore relevant are difficult because no specific statistics can be identified. Estimates using two different approaches suggest a range of 1.54-3.31% of the EU workforce.

According to the ESAW database for 2007, the most recent year for which suitable data were available, there were just 70 injuries entailing four or more days off work, across the EU-15 for ‘effects of temperature extremes, light and radiation’, and no fatalities. For ‘effects of radiation (non-thermal)’ there were again no fatalities and a total of 1,481 injuries, again across the EU-15. It is not possible to separate ionising and non-ionising radiation from these figures. Incidence figures are not available.

Clearly these statistics are not entirely satisfactory as measures of AOR-related injuries. However, even if all of these injuries were attributable to agents covered by the AOR (which seems unlikely) they clearly suggest a very low level of relevant injuries. The EWCS 2005 included a question in the category on employment health which asked respondents if their work gave them problems with their vision. The survey text does not define ‘problems’ but, in the context of the survey, it can be assumed to relate to health problems of some description.

Clearly, visual problems can arise for many reasons, other than exposure to AOR. To provide some insight therefore, the responses to the EWCS were further analysed to identify those from a selected subgroup (possibly exposed to AOR) who indicated that they were exposed to 'Radiation etc.' and who also indicated that their work gave them problems with their vision. A total of 21.82% of the radiation-exposed group (0.72% of the total dataset) indicated that they worked in the qualifying occupational group; that they were exposed at all to 'Radiation, etc.'; and that their work gave them visual problems. It is unlikely that X-rays or radioactive radiation would give rise to visual problems. In addition, given existing protection for workers exposed to ionising radiation such as the basic safety standards laid down by Directive 96/29/Euratom (due to be repealed by Directive 2013/59/Euratom), exposure 'all of the time' seems particularly unlikely. On this basis this would seem to be an appropriate subgroup for analysis. The restriction of the analysis to this subgroup means that, although theoretically including those exposed to X-rays and radioactive radiation, it would seem likely that the majority of respondents in this figure would be exposed to visible radiation.

It cannot be assumed that all respondents were exposed to sources encompassed by the provisions of the AOR Directive. Nor can it be assumed that this exposure was responsible for their visual problems. However, these figures provide the best available overall insight into the possible scale of the problem to be used in gauging the relevance of the AOR Directive.

Subjective opinions on relevance

An EU stakeholder interviewed regarding the AOR Directive suggested that the provisions stipulated were disproportionate to the risks from AOR, which were perceived to be of low risk and low frequency but very high in terms of cost. This would seem to be supported by the accident material, including that from a specific study in one MS, which identified no relevant injuries across a ten-year period.

A number of national stakeholders expressed a variety of sometimes conflicting views. These included:

- the AOR Directive was insufficient in that it did not cover outdoor work and the associated increased risk of skin cancer (a view shared by a multinational expert group on skin cancer).
- awareness-raising via guidelines would have been preferable to implementation of regulations.
- the AOR Directive had great relevance, in particular for the health sector, where the problem was prevalent in their MS.
- the AOR Directive brought no additional benefit to their MS, an opinion which was echoed by a subject matter expert in that MS.
- although AOR presented hazards, it was considered that both were already generally well managed and that the actual degree of risk was relatively low and the AOR Directive should be rescinded.
- the AOR Directive was not relevant at present and that its relevance would reduce further with technological advances.

Effectiveness

Despite these disparate views, twelve stakeholder groups from six different MSs gave an average score of 4.3 (scale 1-5) on whether the AOR Directive had fulfilled its objective, indicating that, according to these national stakeholders, the Directive has fulfilled its objectives to a high extent. However, these six MSs should not necessarily be taken as representative of the wider EU-27.

Data on the effectiveness of the AOR Directive was of poor quality due to the low specificity of the classification used. Thus the most appropriate accident category was that of accidents caused by 'Effects of temperature extremes, light and radiation' encompassing the direct effect of heat (not restricted to IR radiation), cold and ionising radiation all of which are not applicable. It is therefore clear that a coordinated effort across the EU is required to improve the quality and availability of data pertaining to AOR-related accidents if the effectiveness of this directive is to be evaluated in the future.

Data from the EU-15, (1998-2012) indicated an overall decrease in the number of accidents resulting in more than three days of absence. However, as much of this decline preceded the presumed implementation of the provisions of the AOR Directive in most MSs, and the levels of accidents since that time have been relatively static, it seems unlikely that much (if any) of the decline can be attributed to the effective implementation of the AOR Directive.

More detailed analyses can be found in the Regulatory Impact Analysis (RIA) on the Control of Artificial Optical Radiation conducted by the Health and Safety Authority (HSA) in Ireland. This RIA concluded that, of approximately 8,000 injuries reported annually by employers from 2000 to 2009, none included any reference to the terms 'radiation' or 'laser'.

On health issues, although it is widely accepted that exposure to AOR can have adverse health effects, ranging from relatively minor problems such as skin reddening to significant diseases such as cataracts and skin cancer, no appropriate data sources on occupational diseases have been found. Current EU databases do not provide any classification appropriate for AOR. Searches for further sources of data from the published scientific literature showed that the majority of scientific papers tend to focus on other issues, such as solar UV. Whilst papers demonstrate the qualitative potential for health effects of AOR exposure none were identified which provided any quantitative assessment of risk. Clearly, to aid any future evaluation of the effectiveness and impact of the AOR Directive, improvements to data categorisation are required.

Coherence

Comparisons between the requirements of the AOR Directive and of those relating to other physical agents identified a number of differences and inconsistencies. Based on these a number of possible adjustments were identified. These encompassed:

- review of the risk assessment procedure to give particular attention to the extension of exposure beyond normal working hours under the employer's responsibility.
- review the AOR Directive to include an obligation to inform workers on the nature of the risks and to inform workers at particular risk.

- ensure that the procedure of adoption/amendment of limit values and action values is clarified and where relevant harmonised with the other physical agent directives.

However, it should be emphasised that these suggestions were based on a primarily legal appraisal of the duties imposed and could be subject to modification where harmonisation is not considered technically necessary or appropriate.

Overall conclusion and recommendations

The AOR Directive appears to attract more diverse and extreme views than most if not all of the individual Directives. There is clearly no consensus over this Directive; of the need for it, or of its value. Although it is recognised and accepted that AOR can generate hazards it would appear that some organisations at least are interpreting its provisions very widely, even considering office lighting as a potentially hazardous source. Given the lack of objective evidence it is difficult to reach a firm conclusion at this time as to the best way forwards. Although the hazards are recognised there is no substantial body of evidence to demonstrate the extent to which injuries or health problems are being caused as a result. Data from just one MS where data was systematically examined showed no recorded injuries, and even those which were recorded on other databases were not necessarily attributable to exposures to AOR.

Despite the data limitations it is clear that there is considerable uncertainty over the value of retaining this Directive, or whether it should be repealed or revised. In this respect the AOR Directive stands out from most of the other OSH Directives which seem to have a reasonable level of support. However, the data limitations mean that, at this stage it is not possible to make a firm recommendation for retention in its present form, revising it or repealing it.

The best recommendation is therefore that consideration should be given to initiating a debate on this Directive to determine whether it should be retained and, if so, to review its scope to consider, on the one hand, whether it can be restricted to remove known low-risk workplaces/sectors (thereby reducing the possibly unnecessary burden on industry) or to include additional sources of exposure such as external (solar) optical radiation.

As part of these deliberations, consideration should be given to the extent to which the emergence of harmonised standards on products potentially emitting AOR, which include health and safety considerations, reduces the need for the Directive by removing any risk at source.

This latter point provides further evidence for a need for a more in-depth exploration of the scientific evidence than can be provided by this review. Whilst a research group has advocated the inclusion of solar radiation (and provided published evidence in support of their argument) others have expressed a contrary view, again with supporting published evidence.

It is therefore suggested that a formal, independent, systematic evidence review of the topic is required to inform such a debate.

It is further recommended that consideration is given to collecting better quality, more appropriate data on accidents and acute health effects which can be directly attributed to AOR exposure to enable a more informed decision to be made over its retention or reintroduction in future reviews.

In addition, again if it is to be retained, consideration should be given to reviewing the legal inconsistencies identified between the AOR Directive and other physical agents Directives and considering whether they are necessary for technical reasons or if they should be resolved.

1 Introduction

About this report

This Directive-specific document forms part of the reporting of an overall evaluation of 24 Directives on Occupational Safety and Health (OSH) commissioned by DG Employment, Social Affairs & Inclusion. The report concerns Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (Artificial Optical Radiation) from here on referred to as "the AOR Directive".

The evaluation of 24 OSH Directives was initiated in 2013 and finalised in June 2015. The exercise produced cross-cutting findings on the implementation of the 24 Directives as an ensemble, which are documented in the Main Report. Annexed to this main report are Directive-specific reports for each of the 24 Directives (Appendix E) and reports on the implementation of the 24 Directives in the Member States (MSs) (Appendix G comprising 27 reports as Croatia was excluded from the study).

Objective of the evaluation

The objective was to evaluate the practical implementation of EU OSH Directives in the EU Member States with a view to assessing their relevance, effectiveness and coherence, with the aim of considering putting forward possible improvements to the regulatory framework. The evaluation was guided by a set of questions and evaluation criteria, which were to be addressed for all Directives and Member States. There are two main sets of questions.

The first set relates to the implementation of the Directives in the Member States:

- **Implementation**: MQ1-MQ7 are mapping questions that as part from addressing the overall implementation of the Directives look into specific implementation issues such as derogations, transitional periods, compliance and enforcement:

MQ1: Across the Member States, how are the different Common Processes and Mechanisms foreseen by the Directives put in place, and how do they operate and interact with each other?

MQ2: What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?

MQ3: What are the differences in approach to and degree of fulfilment of the

requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?

MQ4: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?

MQ5: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

MQ6: What are the differences of approach across Member States and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?

MQ7: What measures have been undertaken by the Member States to support SMEs and microenterprises (e.g. lighter regimes, exemptions, incentives, guidance, etc.)?

The second set addresses the three main evaluation criteria of relevance, effectiveness and coherence (a total of 11 evaluation questions):

› **Relevance:** EQR1-EQR2 relate to the extent to which the provisions of the Directive are relevant for the current as well as future risks and composition of industry sectors:

EQR1: To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?

EQR2: Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

› **Effectiveness:** EQE1-EQE7 explore whether the introduction of the Directive has led to changes to enterprise behaviour and the occupational safety and health of workers:

EQE1: To what extent has the Directive influenced workers' safety and health, the activities of workers' representatives, and the behaviour of establishments?

EQE2: What are the effects on the protection of workers' safety and health of the various derogations and transitional periods foreseen in several of the Directives concerned?

EQE3: How and to what extent do the different Common Processes and Mechanisms that were mapped contribute to the effectiveness of the Directives?

EQE4: To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directives?

EQE5: What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directives?

EQE6: To what extent do the Directives generate broader impacts (including side

effects) in society and the economy?

EQE7: To what extent are the objectives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the achievement of the objectives?

› **Coherence:** EQC1-EQC2 concern the extent to which the objectives and actions from a given OSH Directive interact or overlap with other OSH Directives and/or with other EU policies:

EQC1: What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

EQC2: How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive, Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

Methodology and sources of information

The overall methodology applied for the evaluation – and thus also for the analysis presented in this report – is presented in detail in Chapter 2 in the Main Report. However, relevant aspects are explained within this report.

The findings in this Directive report are based on the analysis of the OSH legislation in each of the MSs; official statistics at national and EU level; National Implementation Reports (NIRs) submitted to the Commission by each of the MSs by end of 2013 together with scientific articles, existing studies and interviews with both national and EU stakeholders (National and EU organisations representing one of four stakeholder groups: Employers, Workers, Authorities and others).

The report is structured according to the themes and issues listed above.

› Chapter 2 presents the overall understanding of the Directive, i.e. its rationale, its provisions, and its intervention logic, and introduces the issue of measuring the impacts of the Directive.

› Chapter 3 provides the relevant findings with regard to the implementation of the Directive in the MSs (addressing questions MQ1-MQ7).

› Chapter 4 provides the relevant findings with regard to the relevance of the Directive (addressing questions EQR1-EQR2).

› Chapter 5 provides the relevant findings with regard to the effectiveness of the Directive (addressing questions EQE1-EQE7).

› Chapter 6 provides the relevant findings with regard to the coherence of the Directive (addressing questions EQR1-EQR2).

› Chapter 7 draws the main conclusions emanating from the findings presented in Chapters 3-6

2 The Directive

2.1 Background and objective

Background

Article 137(2) of the Treaty establishing the European Economic Community, provides that the Council shall adopt, by means of Directives, minimum requirements for encouraging improvements, especially in the working environment, to ensure a better level of protection of the safety and health of workers. As part of this provision, Council Directive 89/391/EEC (Framework Directive) was adopted.

Against this general background the Council implemented the introduction of minimum health and safety requirements regarding the exposure of workers to the risks caused by physical agents[1].

From this, a Directive was conceived which laid down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to AOR during their work.

The Directive places obligations on the employer, in the case of workers exposed to artificial sources of optical radiation, to assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect.

Objective

The principle impact of the AOR Directive is intended to be a reduction in the incidence of injuries associated with AOR. The hazards are wavelength dependent (for example lasers of a certain frequency range will burn the retina whilst others will be absorbed by the cornea and lens and cause burn injuries or possibly cataracts).

Exposure to infrared radiation can present a risk of burn injuries. The nature of the injury depends on the temperature of the exposed body surface, which in turn is related to the wavelength and intensity of the radiation. Thus modest heating of

[1] Preamble to Directive 2006/25/EC

exposed skin will result in fully-reversible skin reddening (erythema) whilst slightly higher temperatures (but still below the burn threshold of about 42° C) will lead to the more permanent reddening known as *erythema ab igne*. Higher temperatures will result in skin burns of varying temperature-dependent depth and severity.

Skin exposures to ultraviolet (UV) AOR can lead to long-term effects such as a loss of skin elasticity (elastosis) or to the development of skin cancers.

Where a worker looks at a source of sufficiently intense AOR, injuries of increasing severity can be expected ranging from irritation of eye tissues (photoretinitis; photokeratitis; conjunctivitis) to burn injuries to the eye structures (e.g. corneal burns known as 'welders' flash'). As for lasers, the part of the eye affected (e.g. cornea, lens or retina) will be partly determined by the frequency of the AOR. Short exposures to intense AOR in the visible wavelengths can result in temporary blindness independent of any longer-lasting effect.

Both UV and infrared (IR) AOR can also lead to cataractogenesis, either by direct IR heating causing cloudiness of the lens or through UV-related cellular changes.

Fire and explosions resulting from heating of combustible materials by intense IR sources can also pose immediate safety risks to workers.

2.2 Risks

The main effects of exposure to excessive levels of artificial optical radiation relate the eyes and the skin, especially for workers belonging to particularly sensitive groups.

Workers' health and safety can also be affected by workplace interactions between optical radiation and photosensitising chemical substances.

Table 2-1 summarises the relevant possible adverse health and safety consequences which the AOR Directive addresses.

Table 2-1 *Injuries which might arise from AOR exposure*

Possible injuries
Acute injuries
Indirect effects such as temporary blinding, explosion or fire.
Erythema; burns; photoretinitis; photokeratitis; retinal burns; corneal burns; conjunctivitis
Long term injuries
cataractogenesis; elastosis; skin cancer.

Interaction with other Directives and international legislation

The AOR Directive is an individual Directive within the meaning of the Framework Directive (Council Directive 89/391/EEC). For cohesion, the Directive was considered in close conjunction with the other OSH and non-OSH Directives (especially the Directives addressing other physical agents such as noise and vibration) to establish a consistent legal approach where appropriate.

Coherence with other relevant Directives, OSH and non-OSH legislation is analysed further in Chapter 6.

2.3 Provisions

Scoping and definitions

The AOR Directive seeks to manage risks to health and safety arising from excessive exposure to AOR by:

- establishing wavelength-dependent exposure limits; and
- requiring employers to take measures to avoid and reduce such exposures.

It encompasses both laser and non-coherent radiation. AOR includes light emitted from all artificial sources in all its forms, such as UV, IR and laser beams.

The Directive adopts the following definitions:

'optical radiation' means any electromagnetic radiation in the wavelength range between 100 nm and 1 mm. The optical radiation spectrum is divided into ultraviolet radiation, visible radiation and infrared radiation:

> **'ultraviolet radiation'** means optical radiation of wavelength range between 100 nm and 400 nm. The UV region is sub-divided into UVA (315-400 nm), UVB (280-315 nm) and UVC (100-280 nm);
>
> **'visible radiation'** means optical radiation of wavelength range between 380 nm and 780 nm;
>
> **'infrared radiation'** means optical radiation of wavelength range between 780 nm and 1 mm. The IR region is sub-divided into IRA (780-1 400 nm), IRB (1 400-3 000 nm) and IRC (3 000 nm-1 mm).

'Laser' (light amplification by stimulated emission of radiation) means any device which can be made to produce or amplify electromagnetic radiation in the optical radiation wavelength range, primarily by the process of controlled stimulated emission.

'non-coherent radiation' means any optical radiation other than laser radiation.

CPMs and other KRs

In the process of analysing the implementation, relevance, effectiveness, and coherence of the many provisions of the AOR Directive, we focus on the most important ones – named key requirements (KR). Such KRs have – as explained in detail in the methodology chapter of the Main Report – been identified by the OSH experts within the evaluation team. Some of the KRs are the so-called Common Processes and Mechanisms (CPM) which are fundamental requirements placed upon the employer by the Framework Directive. These form the basis for the other KRs in the 24 Directives and thus comprise a useful structure of a comparative analysis across the whole set of Directives. The main Framework Directive CPMs relevant to the AOR Directive are described below, and shown in Table 2.2.

- **Conducting a risk assessment** is about the employers' obligation to assess risks at the workplace and be in possession of documentation of this assessment. This assessment then enables the employer to effectively take the measures necessary for the safety and health protection of workers.

- **Ensuring internal and/or external preventive and protective services** is the employer obligation to designate one or more workers to carry out activities related to the protection and prevention of occupational risks for the establishment. If there is a lack of competent personnel in the establishment, the employer has the obligation to enlist competent external services.

- **Information for workers** concerns the employer obligation to take measures to make sure that the workers who are exposed to risks from artificial optical radiation at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment provided for in Article 4

- **Training of workers** then focuses on the employers' obligation to ensure that each worker receives adequate safety and health training, in particular in the form of information and instructions specific to his workstation or job.

- **Consultation of workers** concerns the employer's obligation to consult workers and/or their representatives and allow them to take part in discussions on all questions relating to safety and health at work, including the planning and introduction of new technologies

- **Health surveillance** concerns providing appropriate health surveillance of workers with the objectives of the prevention and timely detection of any adverse health effects, resulting from exposure to optical radiation. Such health surveillance must be carried out by a doctor, an occupational health professional or a medical authority responsible for health surveillance in accordance with national law and practice. For each worker who undergoes health surveillance, individual health records must be made and kept up to date.

  Where exposure above the limit values is detected, a medical examination shall be made available to the worker(s) concerned in accordance with national law and practice. This medical examination shall also be carried out where, as a result of health surveillance, a worker is found to have an identifiable disease or adverse health effect which is considered by a doctor or occupational health professional to be the result of exposure to artificial optical radiation at work.

In addition to the above CPMs, other Directive-specific KRs as described below, are considered to be central in generating workplace and safety and health impacts.

- **Exposure Limit Values**

  The AOR Directive outlines a set of exposure limit values in respect of non-coherent radiation and laser radiation which are wavelength dependent.

› **Measures to avoid and reduce exposure**

In addition, the AOR Directive requires that, where there is any possibility that any limit values are exceeded, employers introduce measures to eliminate or reduce exposure. To assist employers, a set of principles to be taken into account in when selecting and implementing such measures aimed at preventing the exposure from exceeding the limit values. Where any limit value is exceeded, the employer must immediately establish and implement a programme of technical and/or organisational measures to reduce the exposure and to avoid its recurrence.

More detail on the presentation of the CPMs within the AOR Directive is also given the intervention logic figure (Figure 2-1). For example, employers are required to assess and, if necessary, measure or calculate worker exposure to optical radiation whilst carrying out the risk assessment.

Table 2-2 Key requirements for the AOR Directive

Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation)						
Key requirements: Scoping and definitions						
Scope of application Arts 1 and 2	The Directive relates to the protection of workers from risks to their health and safety arising or likely to arise from exposure to artificial optical radiation during their work. It relates to ultraviolet radiation, visible radiation and infrared radiation, both in diffuse (non-coherent) forms and lasers.					
Key requirements: Common processes and mechanisms						
CPM	Conducting a risk assessment	Ensuring internal and/or external preventive and protective services	Information for workers	Training of workers	Health surveillance	Consultation of workers
Relevant Articles	4	5	6	6	8	7
Key requirements: Directive-specific provisions						
Exposure limit values Art. 3	The Directive provides for a set of exposure limit values in respect of non-coherent radiation and laser radiation which are wavelength dependent.					
Measures to avoid and reduce exposure Art. 5	The Directive requires that, if there is any possibility that any limit values are exceeded, measures to eliminate or reduce exposure are introduced; and provides a set of principles to be taken into account in framing such measures aimed at preventing the exposure from exceeding the limit values. If any limit value is exceeded, the employer shall immediately establish and implement a programme of technical and/or organisational measures intended to reduce the exposure and to avoid its recurrence.					
Non-key Directive-specific provisions						

The following Directive-specific provisions are not considered to constitute key requirements in the context of the evaluation:

- provisions that do not have a direct impact on limiting the risk from exposure to artificial optical radiation, such as provisions of a technical nature (technical amendments (Art. 10), committee procedure (Art. 11), transposition (Art. 14), entry into force (Art. 15) and addressees (Art. 16);
- provisions addressed to the Commission, requiring the Commission to draw up practical guidelines to the implementation of the Directive (Art. 13).

2.4 Intervention logic

Impact logic

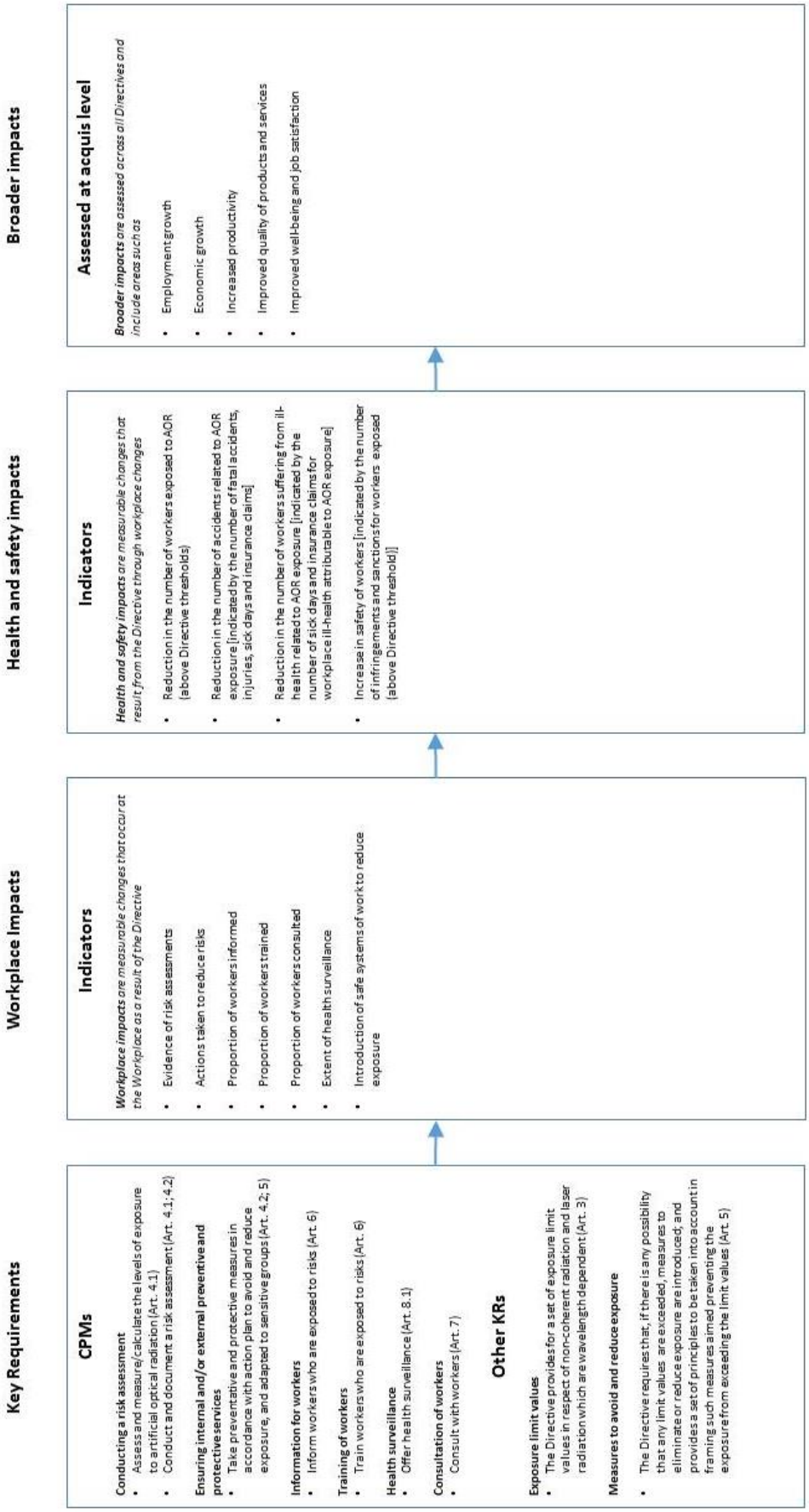
Figure 2-1 illustrates, in the form of an intervention logic, the conceptual steps of how the key requirements of the AOR Directive leads to impacts. This encompasses:

- **CPMs and other KRs**
- **Workplace impacts**
- **Safety and health impacts**
- **Broader impacts**.

Impact storyline

The intervention logic was used to generate an impact storyline which reflects the logic chain through which improvements in the health and safety of workers would be expected to be achieved. For example, risk assessments should be followed where appropriate by the introduction of a safe system of work to reduce exposure to AOR. These workplace impacts would in turn be expected to reduce the number of workers exposed to AOR above the exposure thresholds set by the Directive, leading to a reduction in AOR-exposure related accidents and ill-health.

Figure 2-1: AOR Directive Intervention Logic



2.5 Measuring impacts

Three levels of impacts

Based on this impact storyline, a series of potential workplace and safety and health impacts were identified. Whilst workplace impacts do not necessarily reflect specific improvements concerning eliminating or reducing occupational diseases arising from exposure to relevant risks, they are nevertheless important indicators of their implementation, i.e. the safety and health impacts from the Directive stem from the associated changes at the workplace.

Indicators must be quantifiable and available

This series represents the list of workplace and safety and health impacts that *ideally* should be considered in the evaluation of the Directive. These are presented in Table 2-3. However; measuring the impacts of the Directive on this basis requires that the indicators used for the analysis must be quantifiable via available statistics.

Table 2-3 Impact indicators

Workplace impacts	Safety and health impacts
Evidence of risk assessments	Reduction in the number of workers exposed to AOR (above Directive thresholds)
Actions taken to reduce risks	Reduction in the number of accidents related to AOR exposure
Proportion of workers informed	Reduction in the number of workers suffering from ill-health related to AOR exposure
Proportion of workers trained	Increase in the safety of workers
Proportion of workers consulted	
Extent of health surveillance	
Introduction of safe systems of work to reduce exposure	

Statistics available to analyse impacts

Searches revealed that there were no directly relevant data sets available to provide immediate insights into any of these impact indicators. Consequently, data sets that were available were examined for any material of at least some relevance. Table 2-4 provides an overview of those data variables and statistical sources identified that provide limited but useful information on safety and health impacts in the evaluation of the Directive. The limitations on these data sources are referred to at the appropriate points in the text. No data sources were identified relating to workplace impacts. In addition, limitations on the data sources meant that data collected outwith the formal review period of the study (2007-2012) was used where more timely data were not available. Whilst it is acknowledged that this is not ideal it was considered preferable to present slightly out-dated data than no data.

Table 2-4 Available statistics

Safety and health impacts	Variable	Source
Reduction in the number of workers exposed to AOR (above Directive thresholds)	Exposure at work to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams'*	EWCS (European Working Conditions Survey) 2005
Reduction in the number of accidents related to AOR exposure [indicated by the number of fatal accidents, injuries, sick days and insurance claims]	'Total number of accidents resulting in more than three days of absence caused by: 'Effects of temperature extremes, light and radiation'* 'Effects of radiation (non-thermal)'*	ESAW 1998 - 2012[2]
Reduction in the number of workers suffering from ill-health related to AOR exposure [indicated by the number of sick days and insurance claims for workplace ill-health attributable to AOR exposure]	Does your work give you problems with your vision?*	EWCS (European Working Conditions Survey) 2005

* Includes non-AOR effects, see following text

Data challenges

A very significant challenge associated with the variables identified in the above table is the determination of those injuries apparently or likely to have been caused by AOR-related activities, as the EWCS and ESAW databases do not include a more detailed attribution of any causal agent. Thus, as noted in the footnote to the table, all of the statistics identified will include non-AOR effects to an indeterminate extent. Nevertheless, in the absence of any, more specific data, these appear to provide the best available reflection of injuries possibly sustained due to AOR exposure. These limitations are discussed more fully where the data are used.

Additional data

Because of these shortcomings, qualitative information from studies and interviews are also used to assess the workplace impacts and the safety and health impacts in addition to statistical data sources. These sources are listed as used throughout the text. For a complete overview of these, see the references in the Appendix A.

[2] Eurostat (2015) http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

3 Implementation in MSs

Mapping the implementation

For the purpose of the evaluation, a mapping exercise of the implementation of the 24 Directives in the MSs has been conducted. Each Directive, including the AOR Directive, has been mapped according to seven MQs. This chapter provides a summary of the findings of the mapping exercise for the AOR Directive.

The National Implementation Reports (NIRs) have constituted an important data source for the mapping exercise, but other sources have also been consulted. Additional information on implementation in each of the MSs can be found in the individual country summary reports available in the Main Report. It should be noted that this chapter reflects only the Directive-specific data collected. For an overview of cross-Directive data, please refer to the main evaluation report.

Structure of this chapter

The chapter is structured in accordance with the seven MQs and presents data collected through the country-specific data collection exercise. Data are presented across MSs. For the purpose of presenting information across MSs, country codes are used in the tables in this chapter[3].

3.1 MQ1: Common Processes and Mechanisms

MQ1: Across the MSs, how are the different Common Processes and Mechanisms foreseen by the Directives put in place, and how do they operate and interact with each other?"

Summary of CPM implementation

Table 3-1 below shows an overview of data collected from the Country Summary Reports (see Main Report) regarding the CPMs and their transposition into national legislation.

Table 3-1 CPM implementation

[3] Eurostat country codes: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), United Kingdom (UK)

Member State	One (O) or several (S) laws	Observed discrepancies (Y/N)	More detailed requirements (Y/N)
BE	O	N	Y (Art. 4, 8)
BG	O	N	Y (Art. 8)
CZ	S	N	Y (Art. 4)
DK	S	N	Y (Art. 1, 2, 6)
DE	O	N	Y (Art. 4, 8)
EE	S	N	Y (Art. 4, 8)
IE	O	N	N
EL	O	N	Y (Art. 4, 8)
ES	O	N	N
FR	O	N	Y (Art. 4, 6, 8, Annex II)
IT	O	N	Y (Art. 4, 8)
CY	O	N	Y (Art. 4, 8)
LV	O	N	Y (Art. 4, 6, 8)
LT	O	N	Y (Art. 4, 8)
LU	O	N	Y (Art. 1, 2, 4, 8)
HU	O	N	Y (Art. 1, 2, 4, 7, 8)
MT	O	N	Y (Art. 4)
NL	O	N	Y (Art. 6, 7, 8)
AT	S	N	Y (Art. 4, 8)
PL	S	N	Y (Art. 8)
PT	O	N	Y (Art. 1, 2, 4, 8)
RO	S	N	Y (Art. 4, 8)
SI	O	N	Y (Art. 4, 8)
SK	S	N	Y (Art. 8)
FI	O	N	Y (Art. 4, 8)
SE	O	N	Y (Art. 4)
UK	O	N	Y (Art. 8)
Total	**S= 7 O= 20**	**Y= 0 N= 26**	**Y= 25 N= 2**

Source: Summary Reports on each Member State

Table 3-1 shows that most of the MSs have implemented the AOR Directive within one piece of legislation and fewer in several pieces. There have been no infringement proceedings initiated for non-communication of transposing measures for any of the MSs.

Although only very limited information is available, it appears that the implementation of the directive into a single piece of legislation has facilitated its application in a coherent manner. Limited information suggests that the requirements are applied coherently with the risk assessment and removal/reduction requirements functioning in the expected manner. Other requirements such as training, consultation and surveillance are often implemented within existing national structures and arrangements for such measures.

As shown in Table 3-1, there were no observed discrepancies (case of incorrect transposition) between the Directive and national legislation. In one MS, (Ireland), there is a subtle but important difference in that the national legislation requires the assessment to be 'competently carried out' as opposed to being carried out by 'competent services'. However, as this would seem to be likely to enhance the effectiveness of this measure, it was not regarded as a discrepancy.

The majority of the MSs have implemented more detailed requirements. This is in particular regard to Article 4 (Determination of exposure and assessment of risks), Article 8 (Health surveillance) and Article 6 (Worker information and training) as well as several other Articles. Specific examples of these more detailed requirements are given below by Article.

Article 4: Determination of exposure and assessment of risks

Ten MSs (CZ, DE, EE, FR, IT, LV, LT, MT, RO, SE) require employers to submit risk assessments to their relevant regulatory authority on request.

The risks to be taken into account in the assessment are described by three MSs (IT, LU, SE) in a more specific manner than in the Directive.

The overall risk assessment methodology is described in more detail within the legislation of six MSs (AT, CY, LV, HU, MT, SI) than in the Directive, with the content of the actual risk assessment defined more specifically by three MSs (LV, LU, SE).

The sources of information and persons in charge of the risk assessment are described in the legislation of nine MSs (AT, BE, EL, CY, EL, LT, LV, FI, SI) in a more specific manner than in the Directive. In the main, the additional detail specifies competence and accreditation requirements for persons and organisations involved in the risk assessment process and/ or measurements of exposure. Three MSs (AT, BE, LV) specify that risk assessments can only be carried out by experts or expert services, whilst another (LT) specifies that accreditation is required only for measurements and calculations of exposure to AOR.

Additional requirements mentioned by MSs included the requirement for appointment of a laser safety officer (1 MS, DE) and the specification of risk assessment/ measurement record retention times (2 MSs, LU, HU).

Article 8 Health surveillance

A requirement to provide health surveillance prior to workers commencing employment involving exposure to AOR was reported by eight MSs (AT, DE, FR, IT, LV, LU, PL, RO), with the form of health surveillance provision specified in the legislation of five MSs.

The periodicity of health surveillance is described more fully by 13 MSs (AT, BG, DE, EE, FR, IT, LV, LT, LU, HU, PL, PT, RO), with intervals ranging from annually to five years.

Continuation of health surveillance following cessation of AOR exposure is required by six MSs (BE, DE, FR, PT, SK, UK).

The arrangements for handling health surveillance records was specified within the legislation of 13 MSs (AT, DE, EE, EL, FR, IT, LV, LU, NL, PL, RO, SI, UK), for

example the inclusion of detail on retention times (from 5-30 years) and worker access to records.

In addition, one MS (FR) required employers to maintain a list of workers who were exposed to AOR in excess of the Exposure Limit Values (ELVs), whilst another MS (LU) required a list to be kept of workers who were required to wear personal protective equipment (PPE) to prevent or reduce AOR exposure during specified tasks.

Article 6 Worker information and training

In general, these requirements were transposed with little amendment into the national legislation of MSs; however four MSs reported implementing minor additional requirements. Two of these (LV, NL) specified trainer competence requirements, one (DK) related to tailoring information for specific workplace sizes; and the final one (FR) required workplaces to display specific information notices regarding use of equipment.

Many of these more detailed requirements appear to relate to measures implementing the transposed legislation within the existing national legal framework (e.g. existing provisions for health surveillance).

Answer to MQ1

There were no observed discrepancies in terms of incorrect transposition between the AOR Directive and national legislation. The national legislation of one MS requires the assessment to be competently carried out as opposed to being carried out by competent services. However, this was regarded as an additional requirement rather than a discrepancy. Limited information suggests that the requirements are applied coherently within MSs, with requirements such as training, consultation and surveillance often implemented within existing national structures and arrangements.

The majority of the MSs have implemented more detailed requirements. This is in particular regard to Article 4 (Determination of exposure and assessment of risks), Article 8 (Health surveillance) and Article 6 (Worker information and training) as well as several other Articles. Specific examples of these more detailed requirements are given below by Article.

Although many of the MSs have implemented similar additional requirements, it is likely that these simply reflect differences in approach to legislative activity. A number of the additions by MSs relate to more comprehensive descriptions of the Directive's requirements, for example provision of a risk assessment methodology or the periodicity of health surveillance. Amendment of the Directive to include such detail is considered unnecessary, although more guidance on the requirements may be of use.

In some instances, such as health surveillance and worker information and training, where national requirements are more detailed than those in the Directive, this arises out of a need to integrate the specific provisions of this directive into existing national systems and structures.

3.2 MQ2: Derogations and transitional periods

MQ2: "What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?"

Answer to MQ2

There are no provisions for transitional periods or derogations within the AOR Directive.

3.3 MQ3: Compliance

MQ3: What are the differences in approach to and degree of fulfilment of the requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?

Summary of compliance

Table 3-2 summarises the information available in terms of percentage of establishments which comply with the CPM requirements of the Directive. The table displays data only from the MSs for which data were available: the remaining MSs did not provide any data. Note that some of the numbers given are estimates provided by national experts who sometimes found it difficult themselves to differentiate between the different specific provisions of the Directive. In such cases the estimates were usually applied across all requirements.

Table 3-2 Compliance with key requirements in MSs (% of establishments)

Member State	Perform regular risk assessment[4]	Ensuring protective and preventive services	Information to workers	Training of workers	Health surveillance	Consultation of workers
ES	71%	-	-	-	-	-
RO	45%	45%	45%	45%	45%	45%
SK	45%	45%	45%	45%	45%	45%

Source: Country Summary Reports on each Member State

Table 3-2 illustrates two main findings. The first of these is that data on levels of compliance with the specific requirements of the AOR Directive are extremely sparse. Experience from conducting the studies at the national levels indicates that national authorities do not monitor levels of compliance in a directive-specific way, and, further, national stakeholders are reluctant to make concrete statements about levels of compliance during interviews as they consider their knowledge on these specificities to be limited. Whereas most interviewees were aware of general levels of compliance across all, or groups, of the directives, levels of knowledge regarding individual directive-level compliance were more limited.

Secondly, for those MSs where data were available, the level of compliance with the CPMs is assessed as moderate. Two (Slovakia and Romania) reported compliance levels of 45% across all of the articles, with Spain reporting 71%

[4] Is the risk assessment reviewed regularly and in any event when any changes occur in the conditions which may affect workers' exposure?

compliance with the requirement for risk assessments, but no further information was supplied regarding the other articles.

The national studies also sought to establish whether there are differences in levels of compliance depending on size of establishments and in respect of different sectors (particularly any differences between the public and private sectors). No data on size of establishment was available specific to the AOR Directive. However, general data on OSH compliance indicates that, in broad terms across the Directives, the level of compliance increases with the size of establishment. No data is available to differentiate levels of compliance between the public and private sector.

The NIRs[5] were also used to inform the evaluation of AOR Directive-specific compliance issues amongst Small and Medium Enterprises (SMEs). When answering the question regarding the AOR Directive, one third of the MSs have described specific issues experienced by SMEs. Excerpts from these are presented in Box 3-1 below.

Several MS did not provide a direct response to this question. However, amongst those who did, Austria, Czech Republic, Finland, Ireland and Luxembourg are amongst those who state that they have no evidence that SMEs experience greater difficulties.

In essence, the issue of AOR appears to be regarded as a complex and complicated area of occupational health and safety with considerable concerns regarding the understanding of the technicalities of the subject and of competence in its measurement and assessment.

[5] National Implementation Reports, 2007 - 2012

Box 3-1 *Examples of comments regarding compliance with the Directive for SMEs and microenterprises (from NIRs)*

EE - Awareness of sources of optical radiation, their impact on health and ways to prevent exposure is very low. No measurements are taken and nobody will start calculating radiation levels using the formulae.

DE - There tend to be shortcomings in SMEs in the form of inadequate protective equipment and work clothes, inadequate instruction or a total lack of risk assessment.

FR - It was stated that risk assessment would not get off the ground until it was possible to assess exposure levels; for the time being, measurement was still regarded as highly technical and treated with great caution.

Lastly, emphasis was placed on the difficulty involved in identifying competent bodies to perform the measurement.

MT - SMEs have reported a number of difficulties in the engagement of external experts, this being a very specialised subject.

RO - The main problem that SMEs are facing in applying the Directive is the lack of funds, namely purchasing performance work equipment of the latest generation that would ensure low levels of radiation.

SI - The inspections and targeted campaign showed that employers and workers are poorly informed about the issue of artificial optical radiation, including the Directive and the national regulations pertaining to the area. Only exceptionally did employers conduct measurements and/or calculations of artificial optical radiation. It should also be pointed out that Slovenia only has a few legal entities or natural persons that hold a permit to conduct specialist health and safety at work tasks in the area of artificial optical radiation. Measurements and/or calculations also represent a substantial financial cost for SMEs.

SK - Small and medium-sized enterprises may have difficulties with incomplete technical documentation (missing class labelling, documentation is not in Slovak, etc.).

SE – They [SMEs] have limited access to staff with expertise primarily in relation to lasers. There are also extremely few of them that have expertise on the subject of this exposure from a health and safety perspective.

UK - Particular difficulties of SMEs in implementing the requirements of the Directive include:

- The complexity of carrying out measurements to assess emissions from all sources of artificial optical radiation, including understanding the formulae used in the Directive.

- The duplication of risk assessments already required under Directive 89/391/EEC.

- Understanding what health surveillance means in practice under the directive, particularly as there are no recognised tests for ongoing surveillance of eye and skin conditions and long term surveillance following an accidental over-exposure is not considered scientifically appropriate.

Answer to MQ3

Data illustrating general levels of compliance with the Directives taken as a whole are limited in type and number, precluding comprehensive further analysis. AOR-Directive-specific data are even less common. For the three MSs that did provide data, two reported moderate (45%) overall compliance levels for the key requirements. A further MS reported 71% compliance with the requirement for risk assessment but no data on the other KRs.

The national studies have also sought to establish whether there are differences in levels of compliance depending on size of establishments. The data indicate that in general terms across the Directives the level of compliance increases with the size of establishment.

AOR Directive-specific compliance data relating to company size or sector could not be identified, thus separate consideration of public and private sectors or the various industrial sectors within this was not possible.

Compliance issues amongst SMEs were therefore identified using the responses in the NIRs. Specific issues included measurement method complexity, difficulty in appointing suitable competent assistance and health surveillance. Although only a limited number of MSs provided any data on SME-related issues, some stated that they have no evidence that SMEs experience greater difficulties than other organisational types in relation to the AOR Directive provisions.

3.4 MQ4: Accompanying actions

MQ4: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?"

In this section, we distinguish between actions at the MS level (data collected through the national studies) and actions at the EU level (data collected through desk-based research and interviews with EU level stakeholders).

3.4.1 Actions at Member State level

Summary of accompanying actions

Table 3-3 shows the type and number of actions undertaken in each MS to implement the AOR Directive. The emphasis is on key documents and actions, however in many MSs additional items, such as leaflets, posters etc., may have been produced.

Table 3-3 Type and number of accompanying actions in MSs

Member State	Guidance documents	Awareness raising campaigns	Support tools (possibly IT)	Education and training
BE	1	-	-	-
BG	1	-	-	-
CZ	-	-	-	-
DK	1	-	-	-
DE	2	-	1	1
EE	-	-	-	-
IE	1	-	-	-
EL	-	-	-	-
ES	2	-	-	-
FR	-	-	5	-
IT	2	-	1	-
CY	-	-	-	-
LV	1	-	-	-
LT	1	-	-	-
LU	1	-	-	-
HU	-	-	-	-
MT	1	1	-	-

Member State	Guidance documents	Awareness raising campaigns	Support tools (possibly IT)	Education and training
NL	4	-	1	-
AT	7	-	-	-
PL	1	1	1	-
PT	1	-	-	-
RO	-	-	-	-
SI	-	1	-	-
SK	1	-	-	-
FI	1	-	-	-
SE	1	-	-	-
UK	2	-	-	-
Total	**32**	**3**	**9**	**1**

Source: Country Summary Reports on each MS

Table 3-3 indicates that guidance documents, although not available in all MSs, are by far the most common action undertaken by MSs in respect to supporting the implementation of the legislation transposing the AOR Directive. Support tools are the next most common actions undertaken, followed by awareness raising campaigns; however, these are considerably less common. Education and training are provided very rarely. MSs were also asked whether financial incentives were used to support implementation, however no States reported using this action, thus for simplicity this column was not included in Table 3-3. Also, the table suggests that the MSs consider that available information and guidance are sufficient: when asked directly about whether there are gaps, none of the stakeholders responded 'yes'. However, as already noted above regarding compliance, some NIRs which highlighted challenges to SMEs mentioned a lack of knowledge about risk assessment, measurement methods and health surveillance. Additional accompanying actions in this area may therefore be required.

3.4.2 Actions at EU level

<u>European Commission</u>

Non-binding guide to good practice for implementing Directive 2006/25/EC, artificial optical radiation'[6]

The guide is primarily intended to assist employers, in particular SME employers. However, it is also appropriate for employee representatives and regulatory authorities in MSs. It aims to lead users through a logical path for assessing the risk from exposure of workers to AOR.

Data on the extent to which this non-binding guide is used by companies and establishments to pursue the objective of protecting the safety and health of workers from the risks of injury due to AOR hazards is not available. No NIRs refer

[6] European Commission (2011) http://bookshop.europa.eu/en/non-binding-guide-to-good-practice-for-implementing-directive-2006-25-ec-pbKE3010384/

to its use and no stakeholders, at EU or national level, commented on it as a resource.

The non-binding guide refers to the derivation of the exposure limit values (ELVs) from International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines. However, these guidelines are technical papers and, as such, have not been considered as resources for employers. They are however discussed in the context of the current relevance of the AOR Directive (Chapter 4.1).

Answer to MQ4

Guidance documents, although not available in all MSs, are by far the most common action undertaken by MSs in respect to supporting the implementation of the legislation transposing the AOR Directive. One non-binding guidance document has been produced by the European Commission. This outlines a method for assessing AOR risks and, although aimed at SME employers, may also be of use to employee representatives and regulatory authorities in MSs. Data on the usefulness and effectiveness of the document in the actual workplace were not available.

3.5 MQ5: Enforcement

MQ5: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

Summary of enforcement

The data from the national analyses show that the MSs typically have a general enforcement authority responsible for OSH enforcement and inspections related to all OSH matters, as well as for enforcement strategies. There are however exceptions. Table 3-4 below indicates whether there are:

- specific authorities (different from the general OSH enforcement authority) involved in relation to enforcement of the legislation transposing the AOR Directive (column 1)
- specific enforcement strategies, elements of strategies or procedures covering the implementation of the Directive (column 2)
- specific criminal or administrative sanctions which can be applied in cases of non-compliance with the Directive (column 3)

In the case where the answer to the questions is no, reference is made to the Directive report on implementation of the Framework Directive, which provides a summary of the general systems in force. For specific details, please see the individual country summary reports.

Table 3-4 Enforcement of the AOR Directive

Member State	Specific authorities relevant for Directive?	Specific strategic focus on Directive?	Specific criminal or administrative sanction?
BE	N	Y	Y
BG	N	N	N
CZ	N	Y	Y
DK	N	N	N
DE	N	Y	Y
EE	N	Y	Y
IE	N	N	Y
EL	N	N	Y
ES	N	N	Y
FR	N	N	N
IT	N	N	N
CY	N	N	N
LV	N	N	N
LT	N	N	N
LU	N	N	N
HU	N	N	N
MT	N	N	Y
NL	N	N	N
AT	N	Y	Y
PL	Y	N	N
PT	N	Y	Y
RO	N	N	Y
SI	N	Y	Y
SK	N	Y	Y
FI	N	N	N
SE	N	Y	N
UK	N	N	N
Sums	**Y= 1 N= 26**	**Y= 9 N= 18**	**Y=13 N= 14**

Source: Country Summary Reports on each Member State

Table 3-4 shows that only one MS (PL) has designated a specific authority responsible for the enforcement of the AOR Directive. The enforcement of the Directive typically comes under the general authority responsible for OSH inspection/ enforcement. Around one third of the MSs have a strategic focus on the AOR directive, with approximately half of the MSs implementing Directive-specific criminal or administrative sanctions.

Answer to MQ5

One MS has designated a specific authority responsible for the enforcement of the AOR Directive: for the others enforcement of the Directive's provisions typically comes under the general authority responsible for OSH inspection/ enforcement. Nine MSs have a strategic focus on the AOR Directive, with approximately 50% of the MSs implementing AOR Directive-specific criminal or administrative sanctions

3.6 MQ6: Vulnerable groups

MQ6: What are the differences of approach across MSs and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?"

Answer to MQ6

The findings from the national studies show that most MSs have general approaches to protecting vulnerable groups, i.e. which are not targeted at specific Directives (except for the specific provisions of the following Directives, which are designed to address vulnerable groups: Temporary Workers Directive; Pregnant/breastfeeding Workers Directive; Young People Directive). For the purposes of this report vulnerable groups include women (pregnant or breastfeeding); ageing workers; workers with disabilities; young workers; migrant workers; temporary workers and low-qualified workers[7]. There are no specific tools or approaches which focus expressly on vulnerable groups in relation to the risks detailed within the AOR Directive.

3.7 MQ7: SMEs and microenterprises

MQ7: What measures have been undertaken by the MSs to support SMEs and microenterprises (e.g. lighter regimes, exemptions, incentives, guidance, etc.)?

Answer to MQ7

Table 3-5 below indicates whether the MSs have developed particular measures to support SMEs and microenterprises in the implementation of the legislation transposing the Directive and the types of measures used. For brevity, the table displays data only from the MSs for which data were available: the remaining MSs did not report any data.

Table 3-5 Measures to support SMEs and microenterprises

Member State	Exemptions (Y/N)	Lighter Regimes (Y/N)	Incentives (Y/N)
CZ	Y	Y	N
DK	N	Y	N
EE	N	N	Y
FR	N	N	Y
Sums	**Y= 1 N= 26**	**Y= 2 N= 25**	**Y= 2 N= 25**

Source: Summary Reports on each Member State

Table 3-5 shows that few MSs have adopted special measures to assist SMEs, although the guidance material referred to above (3.4.1) may be of value to this

[7] European Parliament (2011) Vulnerable groups as defined within the report: Occupational health and safety risks for the most vulnerable workers http://www.europarl.europa.eu/RegData/etudes/etudes/join/2011/464436/IPOL-EMPL_ET%282011%29464436_EN.pdf

group. However, it should be taken into account that many MSs have developed various accompanying more generalised actions targeted at helping SMEs, see e.g. Directive report on the Framework Directive (89/391/EEC).

4 Assessment of relevance

Relevance in relation to relevant work and workforce

In this section, the relevance of the Directive in relation to the coverage of workforce and MSs, and the severity and extent of risks covered are investigated. The conclusions from the five parameters used to assess relevance are summarised in the table below.

Table 4-1 Summary of the five relevance parameters

Coverage of Workforce and MSs		**Accidents and health problems**		
Number of MS where the Directive is potentially relevant	Proportion of EU workforce to whom the Directive is potentially relevant	Fatal accidents at work (per 100-000 employed)	Non-fatal accidents at work (per 100-000 employed)	Work-related health problems
27	1.54 – 3.31%	n/a	See Section 4.1	See Section 4.1

Coverage of MSs

This Directive has been transposed into national legislation in all MS according to findings from the NIRs[8]. The first criterion to be applied is whether there are workers and/or sectors in each of the MSs where relevant AOR might be encountered. In doing this it is not necessary to identify all such sectors, simply that some at least exist in each MS. Commonly encountered sources of IR include those industries where red-hot (molten) materials are utilised such as furnaces in primary metal production (metal smelting and casting) and glass-making (and glass products) and as well as some specific occupations such as welders. The relevant NACE (Nomenclature statistique des activités économiques dans la Communauté européenne- Statistical Classification of Economic Activities in the European Community) codes are therefore C23 (Manufacture of other non-metallic mineral products) and C24 (Manufacture of basic metals). Eurostat data shows employment in industries under NACE Code 24 in all MS with the exception of Luxembourg and Malta.[9] The absence of entries for these two MS in this database

[8] Individual NIRs

[9] Eurostat (2010) http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Key_indicators,_manufacture_of_basic_metals_(NACE_Division_24),_EU-27,_2010.png

should not necessarily be construed as signifying an absence of employment in that sector.

A more detailed specific search of the Eurostat database indicates employment in the glass industry (NACE Code 23) in all MS with the exception of Malta.[10] However, further investigations revealed some craft production in this MS.[11] Additionally, welding is considered to be a common activity which is highly likely to be performed, to some extent, in all MSs. On this basis, it was concluded that occupational risks relevant to the AOR Directive are potentially experienced by some workers in all MS. On this basis the Directive can be regarded as relevant in all MS.

Workforce coverage

There are a variety of sectors and occupations where exposure to AOR is possible, usually for small, select sub-groups of the workforce. For example, discrete UV light sources are used in pharmaceutical and research (e.g. fluorescence and sterilisation systems); motor vehicle repairs (e.g. curing of paints); and printing (curing of inks) as well as medical and cosmetic treatments (e.g. laser surgery, blue light and UV therapies). However, each of these tends to represent a specialist sub-group within a sector making it difficult to establish the numbers of workers potentially exposed. In order to provide an approximate estimate of the proportion of the EU-27 workforce possibly exposed to AOR, without estimating numbers in such subsectors, a procedure was adopted whereby the whole employment figure was adopted for those sectors where the majority can be assumed to be at risk of exposure (not necessarily exposed) and to omit those in relatively small subsectors. This will clearly result in, on the one hand, an overestimate of those potentially at risk and, on the other hand, an underestimate. However, it was considered that this provided a reasonably accurate overall estimate where the intention was to provide a broad view of the proportion of the workforce covered, rather than any detailed calculation.

As noted above, sources of IR radiation include those industries in which red hot materials such as molten metal and glass are manufactured or processed. Another widely encountered group are those engaged in metal working – welding (both arc and oxy-fuel) and plasma cutting.

LFS & SBS data

Looking first at those exposed to primary red-hot materials, LFS (Labour Force Survey) data[12] document that, for 2012, a total of 215,678,600 people were employed within the EU-27 (15-74 years). Of these, 33,191,700 were employed within the manufacturing sector (NACE C). To calculate the proportion of workers in the manufacturing sector for whom the AOR Directive is relevant, SBS (Structural Business Statistics) data[13] were consulted. The most up-to-date data in the SBS database (recorded in 2010) were used. The estimated population of workers in the manufacturing sector was 30,000,000 (slightly lower than the LFS

[10] Eurostat (2015a) Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) [sbs_sc_sca_r2]

[11] Mdina Glass Handmade (2015) https://www.mdinaglass.com.mt/

[12] Eurostat (2015b) Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000 [lfsa_egan2]

[13] Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) [sbs_sc_sca_r2]

figure). The relevant sectors described above were estimated to include the following number of workers:

- C23 (Manufacture of other non-metallic mineral products) = 1,341,000
- C24 (Manufacture of basic metals) = 1,000,000

Therefore the AOR Directive is relevant to 7.8% of the workers in the manufacturing sector (NACE C). By applying this percentage to the number of workers in the manufacturing sector from the LFS data the AOR Directive can be regarded as relevant to 2,489,526 workers in the EU, which amounts to approximately 1.2% of the EU workforce. It must be recognised that many of those employed in these sectors will not be directly exposed to the molten material. For example, in the primary manufacture of float glass the glass is largely retained and enclosed within specialist insulated ovens and workers are only intermittently directly exposed. Nevertheless, the potential for exposure to the hazard exists and the AOR Directive is therefore of relevance to their employers, even if the proportion actually exposed is lower.

Specific subgroup

On the specific issues of welders (who are seen as a group at particular risk), a report financed by German Welding Society (DVS) and by European Federation for Welding, Joining and Cutting (EWF) states that, in 2007, there were nearly 837,000 welders, although the origins of this figure are not given[14]. This would increase the above figure to approximately 1.54% of the EU workforce.

Specialist users

A number of specialised applications of UV radiation can be found amongst a wide range of occupations from printers (where UV light is used to cure some inks) to dentists (where UV light is used to accelerate the setting of some tooth fillings). No statistics have been found to represent the numbers potentially affected. Similarly, in the healthcare sector, many different artificial sources of optical radiation are found, including: operating theatre lighting; special dermatologic and ophthalmic examination lamps; and sources used to provide ultraviolet (UV), photodynamic (PDT) and neonatal blue-light therapies. However, no statistics are available to provide any estimate of the proportion potentially at risk. As explained earlier, the expectation is that, at least to some extent, the underestimate arising from not including these sub-groups will be offset by the overestimate in assuming the potential for exposure of all workers in the selected sectors.

EWCS data

In an alternative approach, data was sought from the EWCS (European Working Conditions Survey) 2005 database[15] which, although falling outside the reference period for the study, provides the most up to date source. Again, from an examination of the more detailed coding, it appeared that many occupations likely to be exposed to forms of radiated energy other than AOR (such as X-Rays) were encompassed by codes other than Code 7. It was considered likely therefore that

[14] Middeldorf K (2009) The economic importance of welding and joining in Europe: Production values, values added and employees. DVS - Deutscher Verband für Schweißen und verwandte Verfahren e.V.(German Welding Society)

[15] http://nesstar.ukdataservice.ac.uk/webview/index.jsp?v=2&mode=documentation&submode=abstract&study=http://nesstar.ukdataservice.ac.uk:80/obj/fStudy/6971&top=yes

workers in occupations covered by Code 7 would be likely to be exposed to AOR exposures such as welding light or lasers rather than X-rays or radioactive radiation. A total of 3.31% of EWCS respondents indicated that they worked in an occupation coded within ISCO7 and that they were exposed to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams' for some of the time as part of their job.

To the extent that the EWCS sampling can be considered representative of the EU-27 workforce in terms of sectorial distribution this would seem therefore to provide a somewhat higher estimate of the proportion of the EU-27 workforce to whom the provisions of the AOR Directive are of possible relevance.

In summary, the AOR Directive is relevant to approximately 1.54 - 3.31% of the EU-27 workforce.

4.1 EQR1: Current relevance

EQR1: To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?

AOR and types of injury or ill-health

As noted in the Directive text, artificial optical radiation can be divided into three categories: UV, visible, and IR. These, in the form of 'non-coherent radiation', together with the focussed or coherent laser radiation, are the target of this Directive. The main health effects relate to the skin and eyes.

With the skin, UV is recognised as a carcinogenic agent (Group 1)[16] and exposure can also lead to the comparatively minor problem of a loss of skin elasticity (elastosis). IR exposure usually has an effect through heating, with a range of outcomes from the skin mottling known as *erythema ab ligne* to full thickness burns.

With the eyes, either UV or IR exposure can lead to cataract formation and IR can lead to injuries relating again to tissue heating, ranging from irritant conditions such as photoretinitis, photokeratitis, or conjunctivitis to burn injuries to the eye structures (e.g. corneal burns known as 'welders' flash').

This section will explore the extent to which the directive fulfils its overall aim of protecting the health and safety of workers, as demonstrated by what evidence there is regarding the current incidence of relevant accidents or injuries. First however, there have been developments in terms of the scientific basis for the exposure limits which form a core element of the directive and these will briefly be examined.

Basis of protection

Although the provisions of the directive are intended to function as a coherent suite of provisions, the core element can be seen as the exposure limit values, provided

[16] El Ghissassi et al. (2009) Special Report: Policy. A review of human carcinogens—Part D: radiation.

for in Article 3 and detailed in the two accompanying annexes. As with other physical agents directives these provide the technical core of the directive. In this instance they consist of exposure limits (rather than, for example, the two-tier process embodied in the Noise Directive). Other actions required of employers are then aimed at ensuring that these limits are not exceeded and in taking actions to reduce exposure to below these limits where they are.

The origin of these limits is not detailed in the Directive. However, the non-binding guide on good practice for implementing Directive 2006/25/EC[17] indicates that they are based on the guidelines published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), citing the source documents.

The guide also indicates that should these guidelines be altered by ICNIRP, the ELVs in the Directive may subsequently be modified. The directive itself provides the mechanism for such modifications in Article 10, although providing no detail for the source on which any such changes might be based.

Since the adoption of the AOR Directive, such changes to the ICNIRP guidelines have indeed been published. Although beyond the reference period of this review (both were published in 2013) they will be briefly considered here.

Two revisions have been published relating to incoherent visible and infrared radiation[18] and laser radiation[19]. In both cases, the rationale for the changes is explained in some detail, summarising the developments in research knowledge since the guidelines were published (in 1997).

A detailed critique of these changes is beyond the scope of this report. However, it should be noted that, in most, if not all, cases, the changes have resulted in an increase in the permitted thresholds. Such changes often stem from resolving earlier uncertainties that had resulted in the adoption of what are now recognised as conservative limits. The implication of this is that the equivalent limits in the current directive are excessively conservative and can be considered to be unnecessarily restricting employers.

It is not possible to gauge the likely impact of such differences in terms of the extent to which the changes influence working practices and procedures. Nevertheless, as flagged by the non-binding guide, the ICNIRP guidelines have been changed and these changes should be reviewed by the Commission to determine whether or not the defined procedure for changes to the ELVs should be invoked and the Directive amended accordingly.

[17] http://bookshop.europa.eu/en/non-binding-guide-to-good-practice-for-implementing-directive-2006-25-ec-pbKE3010384/

[18] ICNIRP guidelines on limits of exposure to incoherent visible and infrared radiation. Health Physics 105(1):74-96; 2013

[19] ICNIRP guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 µm. Health Physics 105(3):271-295; 2013

Fatal and non-fatal accidents at work

The European Statistics on Accidents at Work (ESAW) database (2008 onwards[20]) includes two classes of type of injury[21]: 'Burns, scalds and frostbites' and 'Effects of temperature extremes, light and radiation' which could encompass injuries from AOR exposure. However, neither are sufficiently exclusive (e.g. burn injuries will include contact burns as well as the scalds and frostbite; 'radiation' will include bot ionising and non-ionising radiation) to provide any insight into the relevance of the AOR Directive.

The ESAW database of data from earlier years offers slightly more focussed categories for 'type of injury' (for example separating thermal and chemical burns as well as frostbites and 'Other types of burns, scalds and frostbites'). Although these do not enable injuries attributable to radiated heat (IR) to be identified, the data includes separate categories of 'effects of radiation (non-thermal)' and 'effects of temperature extremes, light and radiation'. According to the ESAW database for 2007[22], there were just 70 injuries entailing four or more days off work, and no fatalities across the EU-15 for 'effects of temperature extremes, light and radiation'. For 'effects of radiation (non-thermal)' there were again no fatalities and a total of 1,481 injuries, again across the EU-15. It is not possible to separate ionising and non-ionising radiation from these figures. Clearly these statistics are not entirely satisfactory as measures of AOR-related injuries. However, even if all of these injuries were attributable to agents covered by the AOR (which seems unlikely) they clearly suggest a very low level of relevant injuries.

For mode of injury, the more detailed analysis of the 2005 data (ESAW III) includes 'contact with electrical voltage, temperature, hazardous substances – not specified' as a contact mode of injury whilst the classification of 'deviations' provides no relevant categories.

These figures primarily record what might be thought of as injuries arising from acute exposures. Less likely to be recorded as workplace 'injuries' are those developing more gradually such as cataracts or cancers. No statistics are available to document the number of cases of such diseases which have been attributed to workplace exposures. Data on cataracts in the general population do not examine the extent to which such cataracts might be work-related.

The Labour Force Survey (LFS) database also includes material on accidents at work, but the classification of data by work sector[23] or type of physical exposure[24] is not sufficiently specific to allow data relating to AOR exposures to be extracted.

[20] Eurostat (2014a) Accidents at work by economic activity and type of injury [hsw_n2_07]
[21] Eurostat (2014b) Accidents at work by type of injury and severity (NACE Rev. 2, A, C-N) [hsw_mi07]
[22] Number of accidents at work by type of injury and severity [hsw_aw_ninsv]
[23] Eurostat (2013a) Persons reporting an accident at work in the past 12 months, by sex, age and economic activity sector [hsw_ac5]
[24] Eurostat (2013b) Persons reporting the physical factor they were most exposed to by type [hsw_exp4]

Work-related health problems

As with the injury data, LFS data on work-related health problems (self-reported) include material on type of problem[25] but the categories used do not provide any material from which relevant statistics relating to AOR exposures can be derived.

The EWCS 2005[26] contains material relating to the employment environment and employment health. One question on the employment environment of potential relevance to the AOR Directive relates to exposure at work to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams'. A total of 13.8% of respondents answered positively to this question. Clearly, with such a variety of types of exposure source included in this question it cannot be assumed that all respondents were exposed to sources encompassed by the provisions of the AOR Directive.

To refine this estimate further therefore, data on occupational group was sought from the same database. The 2005 survey was limited to using the first level ISCO Codes. However, an appraisal of the more detailed levels indicated a series of occupational groups within ISCO7, including specifically welders and flamecutters, who it was considered likely could work with or in close proximity to welding activities on occasions (e.g. codes 7211-7215, & 7221). It was therefore considered that there was a good chance that those within Code 7 who indicated exposure to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams' would work with exposures such as welding light or lasers rather than X-rays or radioactive radiation.

The EWCS 2005 also included a question (in the category on employment health) which asked respondents if their work gave them problems with their vision. The survey text does not define 'problems' but, in the context of the survey, it can be assumed to relate to health problems of some description.

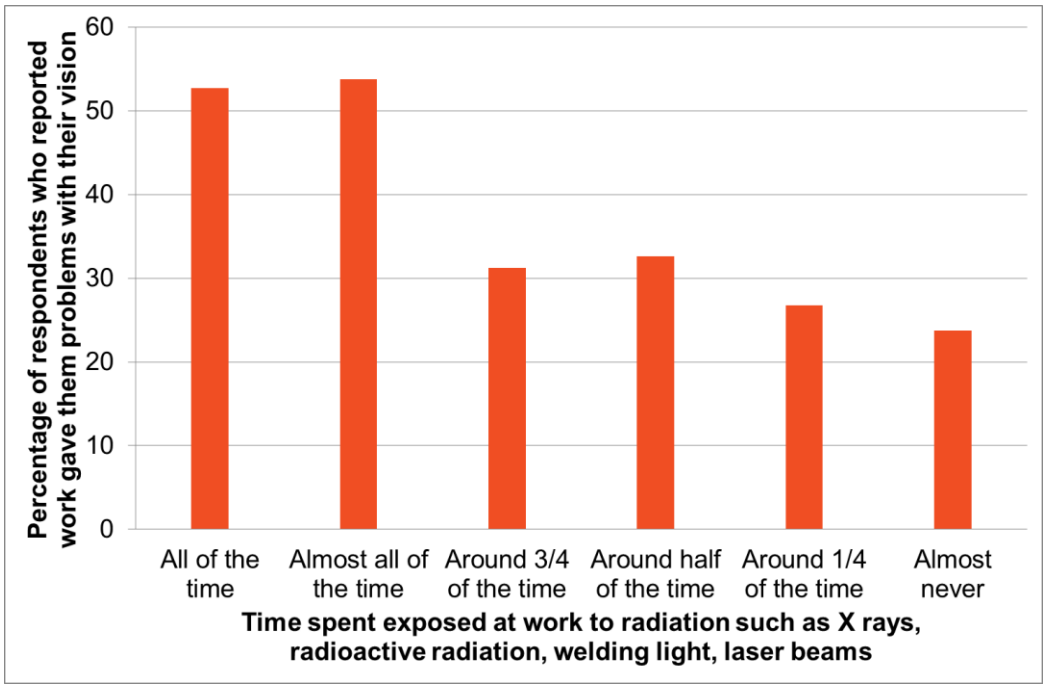
Clearly, visual problems can arise for many reasons, other than exposure to AOR. To provide some insight therefore, the responses to the EWCS were further analysed to identify those from the ISCO7 subgroup who indicated that they were exposed to 'Radiation etc.' who also indicated that their work gave them problems with their vision. A total of 21.82% of the radiation-exposed group (0.72% of the total dataset) indicated that they worked in the qualifying occupational group; that they were exposed at all to 'Radiation, etc.'; and that their work gave them visual problems. Figure 4-2 presents a breakdown of this data set, with the percentage reporting visual problems subdivided according to the extent of their 'Radiation, etc.' exposure. It is unlikely that X-rays or radioactive radiation would give rise to visual problems. In addition, given existing protection for workers exposed to ionising radiation such as the basic safety standards laid down by Directive

[25] Eurostat (2013c) Persons reporting their most serious work-related health problem work in the past 12 months, by type of problem [hsw_pb5]

[26] http://nesstar.ukdataservice.ac.uk/webview/index.jsp?v=2&mode=documentation&submode=abstract&study=http://nesstar.ukdataservice.ac.uk:80/obj/fStudy/6971&top=yes

96/29/Euratom[27] (due to be repealed by Directive 2013/59/Euratom), exposure 'all of the time' seems particularly unlikely. On this basis, this would seem to be an appropriate subgroup for analysis. As explained earlier, the restriction of this analysis to those within the ISCO7 group means that, although theoretically including those exposed to X-rays and radioactive radiation it would seem likely that the majority of respondents in this figure would be exposed to visible radiation.

Figure 4-2: Percentage of respondents who reported work gave them problems with their vision by time exposed at work (ISCO7 occupational group)



Source: EWCS 2005

This graph shows a virtual bimodal distribution in which more than half of those who reported relevant exposures almost all or all of the time also reported work-related visual problems, whilst markedly fewer (around 30% or less) of those reporting less exposure (no more than around 75% of the time) did so. Although the percentage of people reporting problems diminished slightly as exposure fell to below half of the time, there was no clear dose-response relationship. As noted above, it would seem likely that most respondents were referring to visible radiation although the possibility cannot be excluded that some worked with other forms but attributed their visual problems to ancillary tasks (e.g. X-Ray technicians viewing X-Ray plates).

One aspect of these figures is the substantial minority (~25%) who report that their work gave them problems with their vision but who reported 'almost never' working exposed to some form of 'radiation'. This could indicate that their problems were unrelated to any such exposure (although of course exposure to welding flash or laser light would only need to be 'momentary' in some instances to cause

[27] Directive 96/29/Euratom - ionizing radiation laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

problems). However, even offsetting 20-30% as some form of 'base load', the substantial increase in problems amongst those spending all or almost all of their time exposed to radiation does seem to indicate a relationship between the exposure and the problems. Thus, although these figures are subject to a number of caveats and assumptions, they seem to provide what appears to be the closest available indication of the current relevance of the AOR directive. Thus those reporting themselves most exposed to radiation at work, selected to prioritise groups where such exposure is likely to be optical radiation (AOR), appear to be more likely than not (i.e. >50%) to experience visual problems as a result of their work. Clearly however there can be many possible explanations for this, related to other aspects of their work.

A recent EU-OSHA European Risk Observatory report on current and emerging issues in the healthcare sector[28] focussed on ionising radiation rather than the non-ionising forms of radiation covered by the AOR Directive (although it did include a short descriptive section on the risks arising from UV exposure). AOR did not feature in the results of a survey amongst national OSH experts of emerging or new risks or in an overview of current risks.

EU stakeholder interviews

EU stakeholders (representing employer, worker or government groups at EU level), were asked during interviews, how relevant are the Directives for improving/safeguarding the health and safety of workers in the EU (rate on a scale of 1-5) and why? On the AOR Directive, one stakeholder commented that the relevance of some of the Directives (for example the AOR Directive) is negatively influenced by the very prescriptive approach used. They felt that the Directives should be more goal-oriented rather than being purely prescriptive. In addition, this stakeholder felt that the provisions stipulated were disproportionate to the risks from AOR, which were perceived to be of low risk and low frequency but very high in terms of cost. This had resulted in high levels of non-compliance with the Directive requirements within this employer stakeholder's organisation. Finally, this stakeholder emphasised the importance of basing any new directives on evidence, rather than adopting what was seen as a precautionary approach.

Answer to EQR1

The question regarding the extent to which the AOR Directive remains relevant; and adequately addresses current occupational risk factors in order to protect the safety and health of workers, has been addressed in a number of ways. Firstly, confirmation was sought that the Directive remained relevant at MS level; explored by confirming that each MS had workers to whom the provisions of the Directive probably applied. This was confirmed by demonstrating that each MS had workers in industries where AOR exposure, at least to some workers, was a strong possibility.

The next step was to provide some form of estimate of the proportion of the EU workforce to whom the provisions of the AOR Directive were of possible relevance. Two approaches were adopted to address this, one sector-based approach, the second based on self-reported exposure to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams' and selecting industrial sectors where such

[28] EU-OSHA (2014) Current and emerging issues in the healthcare sector, including home and community care.

exposures were likely to be AOR. These two approaches yielded estimates of between 1.54 and 3.31%. These estimates therefore give some idea of the proportion of the EU workforce to whom the AOR is of possible relevance.

As part of exploring the extent to which the AOR Directive adequately addresses current risk factors and protects workers, attention was paid to the exposure limits which are at the core of the AOR Directive and on which many of the other requirements depend. The ELVs within the AOR Directive are derived from earlier (1997) guidance from the ICNIRP. Recent (2013) revisions of that guidance state that the previous guidance values were too low and that higher levels of exposure are acceptable, without risk of injury. It is suggested that the evidence from the ICNIRP regarding these revisions is reviewed, and an equivalent revision of the equivalent ELVs within the AOR Directive adopted.

In terms of injury caused by AOR exposure there is very little evidence appropriate to use, but what little there is appears to suggest a very low level of actual injury. Across the EU-15, the ESAW database for 2007 records just 70 injuries entailing four or more days off work, and no fatalities across the EU-15 for 'effects of temperature extremes, light and radiation' whilst for 'effects of radiation (non-thermal)' there were again no fatalities and a total of 1,481 injuries. It is not possible to separate ionising and non-ionising radiation from these figures, or to determine in any other way the proportion of these attributable to exposure to AOR. Care should be taken in concluding that these figures indicate that AOR exposure is of only limited relevance to the EU workforce, because there are a number of longer-term consequences, such as cataracts and skin cancer, which are not captured by these figures.

Other statistics, documenting less-specific 'health problems' give a slightly different picture. EWCS 2005 statistics indicate that those who report working most of the time exposed to 'Radiation such as X-rays, radioactive radiation, welding light, laser beams' (again selected to those industrial sectors where such exposures are likely to be AOR) are more likely than those less exposed to report that their work gives them problems with their vision. The nature of the problems experienced is not known. To the extent that these problems relate to AOR exposure (which is not known), these figures might provide some limited justification for the ongoing relevance of the AOR Directive in terms of workers possibly at risk. However, given the tenuous nature of any presumed connection; and the clear evidence from authoritative reviews such as that from EU-OSHA, there must be at least some doubt over the current relevance of the AOR Directive.

4.2 EQR2: Future relevance

EQR2: Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

EU stakeholder interviews

EU stakeholders were asked during interviews 'Do you think that there are any new or emerging risks which should be (but are not) covered by these Directives? If so, please give details'. The single EU stakeholder who commented on this in relation to the AOR Directive indicated that all covered risks are relevant (with exception of the more recent ones such as AOR), and did not foresee any new risks on the horizon which would necessitate the development of new Directives.

National stakeholder and expert interviews

A number of national stakeholders indicated that the AOR Directive was insufficient in that it did not cover outdoor work and the associated increased risk of skin cancer; i.e. the Directive should be extended to include natural as well as artificial optical radiation. Inclusion of natural optical radiation would require more detailed consideration of recreation time, for example in non-exposed areas, such as in shadow and inside buildings.

It was felt by others that awareness-raising via guidelines would have been preferable to implementation of regulations. A different stakeholder felt that the AOR Directive had great ongoing relevance, in particular for the health sector, where the problem was prevalent in their MS. As noted above, although it is recognised that exposure to AORs is a potential risk in some sub-sectors of the healthcare sector it is not possible to estimate the proportion of workers within this sector affected.

Interviewees were also asked if they felt that there were any requirements of the AOR Directive which they considered to be obsolete or less relevant because they do not reflect current working methods or available techniques in their MS. Where they answered positively they were asked to indicate the specific provisions they had in mind.

An employer's representative from one member state reiterated a point from their regulatory authority that the AOR Directive brought no additional benefit to their MS, an opinion which was echoed by a subject matter expert from that MS. Although AOR presented hazards, it was considered that both were already generally well managed and that the actual degree of risk was relatively low. On that basis, this MS had recommended that the AOR Directive should be rescinded. The interviewees preferred a risk management approach rather than one based on risk assessment.

Finally, interviewees were asked whether they felt that the relevance of the AOR Directive would continue at same level as today or change. One expert interviewee indicated that, in their opinion, the Directive was not relevant at present and that its relevance would reduce still further with technological advances.

Comments from National Implementation Reports (NIR)

In response to the question: "Has the Member State taken additional measures not included in the [AOR] Directive? If yes, please describe them and give reasons why these additional measures were taken." a number of MSs reported that they had implemented additional measures, including the extension of the requirements to include natural optical radiation (either for the first time, or as a consequence of existing legislation). These are described below in considering whether any of the additional measures should be considered for EU-wide adoption as a means of enhancing the future relevance of the AOR Directive.

Another MS reported that they restricted welding and cutting of metal to workers who have attended a special training course approved by the regulatory authority. This course includes information on the harmful effects of exposure to welding arcs and protective measures.

One MS also requires the appointment in writing of a laser protection officer, before commencing operation of class 3R, 3B and 4 lasers, unless the operator has the necessary expertise. Expertise is obtained by passing a course. Working in conjunction with the OSH officer and occupational physician, the laser protection officer must assist the employer in implementing the necessary precautions and supervise the safe operation of the lasers.

This MS also specifies a retention time for assessment data, including exposure measurements and/or calculations and health surveillance documents. Employers must keep documentation on the results of measurements and calculations in a form which allows for later inspection. For exposure to artificial UV radiation, the documents must be kept for a minimum of 30 years.

In relation to Article 8, another MS specifies the requirements for 'Health surveillance' by stipulating that: 'the results of health surveillance shall be entered in the medical records as soon as possible and, in any event, within fifteen (15) days from the respective checks and tests and shall be kept for at least twenty (20) years. After the end of this period, the records shall be sent, at the responsibility of the employer, to the competent Labour Inspectorate for research purposes, without giving rise to any medical confidentiality issues. Where an undertaking ceases to trade, the personal medical records shall be handed to the competent Labour Inspectorate'. This arrangement has not produced any results for assessment.

One MS allows sources where emission levels are considered non-significant to be exempted from the assessment of the radiation levels in order to reduce the potential costs to the employer of unnecessary risk assessment. As it is not always possible to establish the significance of a source without determination of the exposure level, the Regulation specifies that optical radiation is not considered as a harmful agent when the level of exposure does not exceed 0.4 of the MPE value (Maximum Permitted Exposure); exposure does not affect workers from the special risk groups and, furthermore, when there are no other agents present resulting in greater risk for workers.

In relation to Article 4 (5), one MS stipulates that the measuring equipment used by specialist workers or services that conduct assessments and measurements and/or calculations relating to optical radiation must comply with the SIST EN 14255 or SIST EN 60825 standard series with regard to the investigation type, assessment method, measurement technique and calculation procedure. This requirement thus details more clearly the methods and equipment to be used for assessing AOR and links to more general national legislation pertaining to conditions for acquiring and renewing permits for performing specialist health and safety at work tasks.

To a large extent, the listed additional measures primarily reflect national differences in the approach to risk management and would not appear to offer

substantial additional benefit in terms of enhanced relevance. The exception would seem to be the extension of the scope of national legislation to encompass natural optical radiation (sunlight) which is discussed further below.

Recommendations from National Implementation Reports (NIR)

One explicit recommendation for repeal was offered by one MS (UK): 'Repeal in its entirety. It is considered that the risks from artificial optical radiation can be adequately managed under the requirements of Directive 89/391/EEC.'

Additional representations

Detailed representations were received from one expert research group in respect of exposure to UV from solar radiation. They indicate that skin cancer is the most common cancer in Europe and that a growing body of research demonstrates that occupational UV exposure of outdoor workers is a highly relevant occupational hazard in Europe. According to figures they cite, outdoor workers are at a markedly increased risk for basal cell carcinoma, and at a doubled risk for squamous cell carcinoma compared to indoor workers and the general population.

One issue, shared with some other workplace hazards, is that solar UV exposure is clearly not only derived from occupational exposures. In response to this, the expert group cite detailed measurements from a small group of workers which suggest that, compared to indoor workers, outdoor workers receive much higher doses of UV. Additionally, solar UV is at a maximum from 11.00 – 14.00, a time period when most employees are in work, rather than receiving leisure exposures.

The research group also indicate that, in some member states (e. g. Austria, Croatia, Denmark, Portugal and most recently Germany) sun exposure at workplaces has been recognised as a relevant occupational hazard and consequently incorporated into specific national legislation.

As a partial counter to this, Young et al (2012) cite studies which suggest that increased risk for melanoma is most strongly linked to intermittent exposure to high-intensity sunlight (i.e., usually recreational exposure resulting in sunburn), rather than the chronic exposure typical of outdoor occupations[29].

This work, amongst others, is cited in a very recent (2015) study which estimated the contribution of occupational exposures to solar radiation on the incidence of cutaneous malignant melanoma in the UK. This research suggests that 2% of all cases of cutaneous malignant melanoma in Britain can be attributed to occupational exposure to solar radiation giving, in a single typical year in the UK (based on 2011/2012), 46 deaths and 239 new cases of malignant melanoma[30].

It seems therefore that there is a considerable spread of views regarding the future relevance of the AOR Directive. These are discussed further in Chapter 7.

Answer to EQR2

There were very mixed responses from the interviewees and within the NIRs regarding the future relevance and worth of the AOR Directive. Some stakeholders

[29] Young C et al (2012) Occupational cancer in Britain: Skin cancer. British Journal of Cancer, 107, S71 – S75

[30] Rushton & Hutchings (2015) The burden of occupational cancer in Great Britain. Cutaneous malignant melanoma and occupational exposure to solar radiation

felt that the AOR Directive was not relevant at present and that this situation would be unlikely to improve in the future, whilst others stated that (unspecified) technological changes would reduce any relevance in the future. A different stakeholder felt that the AOR Directive had great relevance, in particular for the health sector, where the problem was prevalent in their MS. In contrast, another stakeholder recommended that the AOR Directive was not relevant and would remain so and should be repealed in its entirety. None presented any expectations of major changes in technology which would result in a significant increase in exposures although, perhaps with the benefit of hindsight, few could have foreseen the growing use of lasers and other high power optical devices in the entertainment industry.[31] Some concerns have also been expressed that the growing use of LED lighting may result in increased risks, although this has yet to be proven[32].

One area where there was quite widespread concern related to natural radiation. A number of national stakeholders indicated that the AOR Directive was insufficient in that it did not cover outdoor work and the associated increased risk of skin cancer; i.e. the Directive should be extended to include natural as well as artificial optical radiation.

Differing representations about the level of risk to such workers were received. One expert research group postulated that occupational UV exposure of outdoor workers is a highly relevant hazard in Europe with outdoor workers at a markedly increased risk. This reflects the concerns from some MSs where, in some instances, workplace sun exposure has already been incorporated into their national legislation. In contrast, another study has suggested that the risk of melanoma is strongly linked to high-intensity intermittent exposure, rather than the chronic exposure typical of outdoor occupations.

No representations were made regarding any expectations of significant changes in sectoral composition which might impact on the future relevance of the AOR Directive.

EU-level action does not necessarily entail the adoption of Directives and it was felt by some stakeholders that awareness-raising via guidelines would have been preferable to the implementation of regulations. Some stakeholders felt that the risks covered by the AOR Directive were already adequately addressed and managed, without additional legislation being required. This was reflected in the NIR from one MS which recommended that the AOR Directive should be repealed.

Thus, on the one hand, representations have been received for widening the scope of the AOR Directive whilst, on the other hand, it has been suggested that the Directive is unnecessary and should be repealed.

It has not been possible within the resources available for this review to carry out a comprehensive evaluation and weighing of the relative arguments for these two

[31] O'Hagan JB, Khazova M. (2010) Assessment of personal exposures to non-laser optical radiation in entertainment. Didcot, UK, Health Protection Agency

[32] Behar-Cohen F, *et al* (2011) Light-emitting diodes (LED) for domestic lighting: Any risks for the eye? Progress in Retinal and Eye Research, 30, 239–257.

positions. There is very little evidence of reported injuries possibly arising from AOR exposure, although this does not encompass chronic exposure effects. This raises the issue of whether the burden placed on employers in complying with the Directive is proportionate to the benefits derived in terms of any reduction in injury and ill-health as a result. Such arguments could call into question the future need for this Directive. In contrast, it is widely accepted that exposure to natural light (sunlight) carries a risk to the safety and health of those exposed and some evidence to support the suggestion that the effects of work-related exposures can be differentiated from other non-work exposures and should therefore be regulated. Again, if accepted, such arguments could suggest a need for maintaining the Directive with an enlarged scope.

It is therefore suggested that there is a need for the Commission to open a debate on the future of this Directive.

5 Assessment of effectiveness

Overall approach to effectiveness

In the context of the AOR Directive, effectiveness broadly refers to the extent to which the exposure to artificial optical radiation by EU workers has been reduced below exposure limit values, that employers and workers become aware of the risks and that occupational accidents and diseases resulting from AOR have been reduced.

In each case, statistical evidence was sought, supplemented by analysing stakeholder assessments of the effectiveness of the AOR Directive.

One immediate shortcoming in the data identified to inform this assessment is that it was not possible to divide this in any manner which would allow the meaningful analysis of effectiveness across different sectors.

5.1 EQE1: Effect on occupational safety and health

EQE1: To what extent has the Directive influenced workers' safety and health, the activities of workers' representatives, and the behaviour of establishments?

Legislation fulfilling its objectives

Four main groups of stakeholders were identified for the study (authorities, employers, workers and others e.g. experts). From these sets, twelve stakeholders from six different MSs, covering all of the four groups, were interviewed about the AOR Directive. As part of these interviews, they were asked to give their opinions on the extent to which their national transposed AOR legislation had fulfilled its overall objective (of protecting workers from the risks associated with optical radiation, owing to its effects on the health and safety of workers, in particular damage to the eyes and to the skin)[33]. Specifically they were asked to rate the extent of this fulfilment on a scale of 1 (very low) to 5 (very high). Figure 5-1 shows the overall outcome, averaged across the four stakeholder groups.

[33] Preamble to Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).

The total average score of 4.3 indicates that, according to national stakeholders, the AOR legislation has fulfilled its objectives to a large extent. The Authorities were generally slightly more sceptical than the other stakeholder groups, providing an average score of 4.1. Nevertheless it will be seen that all four groups gave average scores of more than four, suggesting a generally high opinion of their legislation. These and subsequent results from these six MSs should not necessarily be assumed to be representative of the wider EU-27.

Figure 5-1: Extent to which transposed legislation has fulfilled its objectives, according to national stakeholders

Source: National stakeholder interviews. (n=12 from 6 MSs: Bulgaria, Cyprus, Germany, Lithuania, Romania, Slovakia)

Note: The graph depicts the average score provided by national stakeholders according to stakeholder groups when answering the question "Has the transposed legislation fulfilled its objective?", rated on a scale of 1 (to a very low extent) to 5 (to a very high extent).

5.1.1 Workplace impacts

During national stakeholder interviews, interviewees were asked to what extent the national transposition of the AOR Directive had achieved any general impact in the workplace by influencing establishment behaviour in the MSs in respect to the risks covered by the AOR Directive. Again they were asked to utilise a five-point scale from 1 (low impact on behaviour) to 5 (high impact). Stakeholders found it difficult to specify but the overall opinion was that the impact increased with the size of the establishment, with relatively little effect on behaviour in microenterprises (an average score of 2.3 on a scale from 1 to 5), a slightly improved effect in SMEs (3.5), and the largest effect in large companies (4.1).

5.1.2 Safety and health impacts

Very little quantitative data exist that could possibly be used to assess the impact of Artificial Optical Radiation on the health and safety of workers. The most appropriate data identified seemed to be the harmonised data on accidents at work collected in the framework of the European Statistics on Accidents at Work (ESAW). However, although useful at a general level, this data has a considerable number of limitations which undermine its utility for this purpose.

The first challenge relates to the nature of the data grouping available. Eurostat have to operate within the constraints imposed by the limitations of the national data sets made available to them. In this case, the most appropriate data classification would seem to be that described as 'Effects of temperature extremes, light and radiation' amongst the classifications of ‘type of injury’. Interestingly, ‘temperature extremes’ is classified separately from burns, which come into a different grouping. Injuries such as those related to heat strain would therefore seem to qualify under 'Effects of temperature extremes’. The nature of injuries associated with ‘light’ in this group is also not clear. Probably the main issue will be the extent to which any injuries associated with exposure to natural light (not covered) are included alongside those attributable to artificial light (covered). Finally, the classification includes but does not define ‘radiation’. Furthermore, the data are only available as the ‘number’ of reported accidents in any year without any reflection of the incidence. Thus changes could simply arise from a reduction in the number of workers in relevant industries.

Of course, it could be decided that such flawed data were better than no data at all. The next challenge therefore is that the existing EU data are highly fragmented, missing reports from several MSs and entries from several years. A full overview cannot therefore be presented, with MSs selected for analysis on the basis of data availability rather than representativeness etc.

Next, the dataset includes a number of excessive rises or falls in data numbers. These are more likely to have resulted from changes in reporting methods, entry mistakes or external/unrelated factors rather than as a consequence of any genuine change such as could be attributed to the impact of the AOR Directive. One such example includes the number of accidents resulting in more than three days of absence caused by 'Effects of temperature extremes, light and radiation' reported in Czech Republic from 2008-2012. Figures from 2008 to 2012 show a fall from 59 accidents to eight accidents, apart from the entry for 2009, which indicates that 1392 such accidents occurred that year. Of course, this number may indeed be a valid result and not necessarily be a data error, although this seems unlikely.

One consequence of these vagaries is that reported accidents in this category across the EU-15 (the most complete data set) appeared to largely cease between 2005 and 2008 before restarting in 2009 at much the same level as in 2004.

A final problem observed relates to chronology: the Directive was adopted in 2006 but only required compliance by 2010. Possible effects of the provisions of the Directive, therefore, will hardly have been realised and may not necessarily be manifested in the accident figures to date. It may in other words be too early to quantitatively assess the impact of the AOR Directive, even if good quality data were available.

Even were these shortcomings to be ignored, variations in data between MSs makes analysis of any changes over the period of interest across the EU problematic. Thus, setting aside the apparently anomalous absence of any accidents in 2008 and the preceding few years, there would appear to have been a

broad fall in accidents from 2009 – 2012 (with a dip in 2011)[34]. However, more detailed analyses suggests that this is largely driven by changes in one MS (DE) who account for a large proportion of the reported accidents and masks increases in some MSs, decreases in others and no change in a third sub-set (in some cases, the low number of reported accidents leads to considerable fluctuation in reported numbers from year to year). In other words, there is no consistent pattern across a sample of EU MSs which would suggest any systematic change.

EU statistics relating to the number of fatal accidents caused by 'Effects of temperature extremes, light and radiation', were similarly flawed. In any case, there were too few such fatalities for formal analysis. In addition, although exposure to UV can result in the development of carcinomas, such incidents are unlikely to be recorded as fatal accidents. Thus the fatalities are likely to include some irrelevant cases but exclude some relevant cases.

One source of information was that reported earlier in the form of a Regulatory Impact Analysis (RIA) on the Control of Artificial Optical Radiation Regulations, conducted by the Health and Safety Authority (HSA) in Ireland in 2009[35]. This RIA, concluded that, of approximately 8,000 injuries annually, reported by employers from 2000 to 2009, none included any reference to the terms 'radiation' or 'laser'.

Answer to EQE1

During national interviews, twelve stakeholder groups from six different MSs provided a score from 1–5 on the extent to which the AOR Directive was considered to have fulfilled its objectives in protecting the safety and health of workers. The mean score of 4.3 indicates that the AOR legislation, according to these national stakeholders, has considered to have largely fulfilled its objectives.

As an adjunct to this, interviewees were also asked to what extent the national transposition of the AOR Directive had affected the behaviour of establishments. Generally, stakeholders found it difficult to specify but the overall view was that there had been a small impact on behaviour in microenterprises (an average score of 2.3/5), some impact in SMEs (3.5), and a considerable impact in large companies (4.1). The results from these six MSs should not necessarily be assumed to be representative of the wider EU-27.

No information was available regarding individual aspects of the Directive. In particular, whilst stakeholders had a view on the general role and function of worker representatives in their MS, it was not possible to determine whether worker representatives have adopted a particular role or participated in any other directive-specific activities.

Beyond these subjective opinions, very little quantitative data exists for objective assessment of the impact of Artificial Optical Radiation on the health and safety of workers. What data are available are not entirely satisfactory in that the recorded

[34] Source: ESAW [hsw_aw_ninsv] and [hsw_n2_07]

[35] Health and Safety Authority, Ireland (2009), Regulatory Impact Analysis (RIA), Safety, health and welfare at work (general application) (amendment) regulations 2009, Control of Artificial Optical Radiation at work http://www.hsa.ie/eng/Legislation/Regulatory_Impact_Analysis/RIA_Optical_Radiation.pdf

accidents are not necessarily uniquely attributable to AOR exposure, are incomplete, and it is not possible to determine causal agents from the records. It is also not possible to differentiate any changes attributable to the influence of the AOR Directive from the many other external factors which could contribute to change. For example, the best available data documents solely number of accidents. Thus, any apparent change might be attributable to a change in the number of workers engaged in relevant work activities. Additionally, overall statistics are strongly influenced by the data from one MS who account for a significant proportion of the recorded accidents.

One source of AOR-specific accident information, a Regulatory Impact Analysis (RIA) carried out by one MS specifically on the Artificial Optical Radiation Regulations, concluded that, of approximately 8,000 injuries reported annually across the period 2000-2009, none included any reference to the terms 'radiation' or 'laser'.

Even accepting the limitations of the data they present a confusing picture, with numbers of accidents from some MSs suggesting an increase, some a decrease, and a third group no change.

On health issues, although it is widely accepted that exposure to AOR can have adverse health effects, ranging from relatively minor problems such as skin reddening, to significant diseases such as cataracts and skin cancer, no appropriate data sources on occupational diseases have been found. Current EU databases do not provide any classification appropriate for AOR and the majority of scientific papers tend to focus on other issues such as solar UV. Clearly, to aid any future evaluation of the effectiveness and impact of the AOR Directive, improvements to data categorisation are required.

5.2 EQE2: Effect of derogations and transitional periods

EQE2: What are the effects on the protection of workers' safety and health of the various derogations and transitional periods foreseen in several of the Directives concerned?

Answer to EQE2

As there are no transitional periods or provisions for derogations within the AOR Directive, assessment of their effect on workers' safety and health protection is not appropriate.

5.3 EQE3: Effect of Common Processes and Mechanisms

EQE3: How and to what extent do the different Common Processes and Mechanisms that were mapped contribute to the effectiveness of the Directives?

Answer to EQE3

As highlighted in Chapter 2, Table 2-1, a number of Common Processes and Mechanisms (CPMs) can be identified as being primarily relevant to the AOR directive, namely: Conducting a risk assessment; Ensuring internal and/or external preventive and protective services; Information for workers; Training of workers; Health surveillance and Consultation of workers. In the interviews with EU and national stakeholders, interviewees were asked to make an assessment of the relative importance of total identified CPMs in the context of the AOR Directive. However, both EU and national stakeholders found it very difficult to make this assessment, perhaps because of the relatively brief period of implementation. No studies on the subject have been made (or identified) neither at EU nor at national level. Although inquiries have been made, experience and knowledge of the effect of the AOR Directive seems limited across the MSs.

The requirement of MSs to provide a five-yearly report on the practical implementation of the AOR Directive to the Commission (article 12) was removed from the Directive with Amendment 2007/30/EC from 20 June 2007. It could be argued that this action may therefore have had an impact on, or attributed to, the limited current levels of specific knowledge about the AOR Directive.

At national level, some estimation on the part of the interviewed stakeholders pointed to training and information of workers as the most important CPMs. Likewise, health surveillance and risk assessments were cautiously highlighted. However, in the opinion of the authors, it is felt that many interviewees made estimations based on a more general knowledge of 'what usually works' when implementing OSH provisions, rather than reporting specific evidence-based or qualitative insight into the practical implementation of the AOR Directive. As such, it is not possible to assess the manner and extent to which the different CPMs have contributed to the AOR Directive's effectiveness.

5.4 EQE4: Effect of enforcement

EQE4: To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directives?

Answer to EQE4

The limited knowledge of the practical implementation of the AOR Directive in MSs, is mirrored by the limited amount of data available on the effect of enforcement measures. For instance, three different EU stakeholders, all representing businesses, provided scores of 2, 4 and 5 (average: 3.7) respectively, when asked to score the extent of compliance with the Directive in European companies. The variability in response makes meaningful assessment of these results difficult. Interviews with EU stakeholders did however point consistently to the fact that enforcement measures play an important role in ensuring compliance (average score of 4 on a scale from 1-5).

National stakeholders were also asked their opinions regarding the relative importance of enforcement measures. It should be noted that the question relates to sanctions and other enforcement activities, with no caveats regarding 'as required by the AOR Directive'. The Directive makes no specific requirements in

this regard, referring solely to a need for 'adequate penalties…..in the event of infringement of the national legislation adopted'.

Figure 5-2 summarises the scores provided by national stakeholders. It should be noted that only four MSs provided replies and thus the results cannot be viewed as either statistically robust or representative of the collective MSs. These limited responses do however support those limited replies received from EU stakeholders, namely that enforcement measures are generally of high importance for ensuring compliance with the AOR Directive.

Figure 5-2 Relative importance of enforcement measures according to national stakeholders

Source: Member State interviews. (n=10 from 4 MSs: Cyprus, Germany, Lithuania, Slovakia)

Note: Average scores, by stakeholder groups across MSs, to the question: "Do you consider the following enforcement measures and sanctions to be effective?" rated on a scale of 1 (to a very low extent) to 5 (to a very high extent).

5.5 EQE5: Benefits and costs

EQE5: What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directives?

Answer to EQE5 This question is addressed in the Main Report in a cross-Directive perspective.

5.6 EQE6: Broader impacts

EQE6: To what extent do the Directives generate broader impacts (including side effects) in society and the economy?

Answer to EQE6 This question is addressed in the Main Report in a cross-Directive perspective.

5.7 EQE7: Objective achievement

EQE7: To what extent are the Directives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the achievement of the objectives?

Answer to EQE7

This question is addressed in the Main Report in a cross-Directive perspective.

6 Assessment of coherence

With regard to internal coherence, this section focuses primarily on coherence between the AOR Directive and the other three Physical Agents Directives on vibration, noise and electromagnetic fields (EMFs).

Some inconsistencies have been identified between the four directives, in particular with regard to the provisions on risk assessment and derived risk management measures; information; training; health surveillance and the procedure for adoption of limit values.

Findings related to coherence between AOR Directive and the Framework Directive are described and addressed in the Directive report on the Framework Directive itself. These findings are limited to some questions of overall coherence of the OSH body of legislation, whereby provisions of a general nature which could be considered as part of a framework have been introduced in the different individual directives.

The review of coherence with non-OSH EU instruments has not revealed any overlaps or inconsistencies, but identified some synergies with Directive 2006/42/EC (machinery), Directive 2014/35/EU (electronic equipment with certain voltage), Directive 93/42/EEC (medical devices) and Directive 98/79/EC (in-vitro medical devices) (see references).

6.1 EQC1: Coherence and complementarity between the AOR Directive and the other OSH Directives (Internal coherence)

EQC1: What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

Scope of application

The AOR Directive lays down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to AOR

during their work. It refers to the risk to the health and safety of workers due to adverse effects caused by exposure to artificial optical radiation to the eyes and to the skin. Its scope covers UV radiation, visible radiation and IR radiation, both in diffuse (non-coherent) forms and lasers.

Risk assessment

The AOR Directive, as for the majority of OSH Directives, contains provisions on risk assessment. It cross-refers to, and specifies, the provisions of the Framework Directive on risk assessment in order to cover the particular risks caused by AOR. The risk assessment procedure is very similar to the one set by the other three Physical Agents Directives. Specific provisions related to AOR are also included, for example possible effects on workers' health and safety resulting from workplace interactions between optical radiation and photosensitising chemical substances. There is a provision in the Noise Directive requiring employers to give particular attention to the extension of exposure beyond normal working hours under the employer's responsibility. Thus, the exposure limits are based on the assumption of a notional eight-hour working day. Where that working day is extended (e.g. to ten hours) then the limit must be revised accordingly. This should not be confused with any exposures outside work. Some adverse effects of AOR exposure relate to the effects of chronic rather than acute exposures, thus the exposure limit values for various UV wavelengths are based on an 8-hour exposure. In parallel to the provision in the Noise Directive regarding longer periods of working, a similar provision could also apply to workers exposed to AOR.

Preliminary conclusions:

› Consider the review of the risk assessment procedure of the AOR Directive to include the provision of the Noise Directive requiring employers to give particular attention to the extension of exposure beyond normal working hours under the employer's responsibility.

Risk management measures derived from the risk assessment

The four Physical Agents Directives adopt similar approaches to exposure risk control. All of the Directives mention that the risk arising from exposure must be eliminated or reduced to a minimum. The Directives relating to noise, vibration and electromagnetic fields set two types of management measures derived from the risk assessment procedure depending on either the exceedance of action limit values/action levels, or exceedance of exposure limit values. These requirements are not implemented within the AOR Directive, which requires employers to take risk management measures only if the risk assessment indicates that exposure limit values may be exceeded and in cases where they are exceeded.

Although there are certain requirements for particular physical hazards, the risk management measures specified are generally similar across the four Directives. It is difficult to consider this as a potential overlap since the risk management measures must be adapted to each specific physical hazard. Merging the sections relating to risk assessment (see above) and derived risk management measures across the four Directives on physical agents may increase coherence.

Preventive and protective services

As for the other Physical Agents Directives, the AOR Directive requires that the risk assessment and measurements shall be planned and carried out by competent services at suitable intervals, taking particular account of the provisions of Article 7 of the Framework Directive concerning the necessary internal or external

competent services or persons. This does not create any coherence issues, as the AOR Directive simply specifies the duties of the services for the risk it covers.

Information to workers

In relation to information to be provided to workers, the AOR Directive contains a 'without prejudice' clause referring to the relevant Article of the Framework Directive. Additional generalised requirements found in an almost systematic way in all Physical Agents Directives are also included.

The wording regarding information and training differs somewhat between the different physical agents directive. Thus, the Noise Directive requires employers to provide information relating to 'the nature of the risks' whilst the AOR Directive requires them to cover 'the exposure limit values and the associated potential risks'. Although subtly different these probably have the same effect.

The EMF Directive makes a specific information requirement concerning workers at particular risk. No such provision is made under the AOR Directive, although Article 4 does refer to the health and safety of workers belonging to particularly sensitive risk groups. Such provisions could also apply to workers exposed to AOR.

Preliminary conclusions:

› Consider the review of the AOR Directive to include an obligation to inform those workers at particular risk.

Training of workers

All four Physical Agents Directives include a common provision for information and training, without distinguishing what should constitute the object of the information and what should be part of training. The above findings on information for workers therefore also apply as regards training.

Health surveillance

The AOR Directive is one of the fourteen Directives that set requirements on health surveillance. The relevant provision contains a 'without prejudice' clause referring specifically to Article 14 of the Framework Directive whilst at the same time establishing more detailed requirements regarding health surveillance.

The AOR Directive requirements in relation to health surveillance are very similar to those set by the other three Physical Agents Directives, in some cases identical and would appear to have the same effect.

Health records

The Framework Directive does not regulate health records, whereas almost all individual directives which contain a provision dedicated to health surveillance, including the AOR Directive, contain specific requirements and specifications relevant to health records. The relevant requirements are approached in a common way throughout the Physical Agents Directives.

Consultation of workers

The AOR Directive, like a majority of Directives (15) regulating specific risks and categories of workers does not contain specific worker consultation requirements but mentions that 'consultation and participation of workers and/or of their representatives shall take place in accordance with Article 11 of the Framework Directive on the matters covered by this Directive'.

Adoption of limit values

In contrast to the other Physical Agent Directives, the AOR Directive explicitly mentions that any modification of the exposure limit values set out in the Annexes must be adopted by the European Parliament and the Council in accordance with the procedure laid down in Article 137(2) of the Treaty establishing the European Economic Community.

Preliminary conclusions:

› Ensure that the procedure for the adoption/amendment of limit values is harmonised in the other Physical Agents Directives (including action values in those Directives where they are specified).

Workers at particular sensitive risk

The AOR Directive, like the other Physical Agent Directives, requires employers to pay special attention to any effects concerning the health or safety of workers at particular risk when carrying out the risk assessment. The AOR Directive, as in the Noise and Vibration Directives, requires that pursuant to Article 15 of the Framework Directive, the employer must adapt the measures derived from the risk assessment to the requirements of "workers at particular risk". Such provisions could overlap with the Framework Directive provisions on workers at particularly sensitive risks; however this potential overlap does not entail double regulation in practice.

Other aspects

› Reporting obligations.

› None identified

› Inspection and enforcement measures

Out of the four Physical Agents Directives, only the AOR and EMF Directives provide for adequate penalties to be applicable in the event of infringement of the national transposing legislation. This does not seem to be justified by the scope of the two aforementioned Directives and such requirements should cover the OSH acquis as a whole (see relevant analysis in the Framework Directive report).

› Use of Personal Protective Equipment

The AOR Directive requires that employers must take into account the availability of personal protective equipment to reduce the level of radiation. The Use of PPE Directive[36] includes a list of personal protective equipment, which includes laser-beam goggles, UV, IR, visible radiation goggles and clothing to provide protection from IR.

EU stakeholders' views

None of the EU stakeholders interviewed identified any internal coherence issues with regard to the AOR Directive. Some EU stakeholders referred to *'general interfaces relations'* between the Use of PPE Directive and the Physical Agents Directives. One stakeholder identified potential overlaps among the above

[36] Council Directive of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of
Directive 89/391/EEC)

directives, notably as regards risk assessment and necessary training. However, the Use of PPE Directive does not contain any specific provision for a risk assessment. Any duplication of training requirements is unlikely to result in any duplication of effort.

Information from the NIRs

One MS pointed out that there was no single/consistent system of limit values for physical effects. This is technically incorrect although the reference is probably combining, for example, action values and limit values under the same term. The system requiring action incorporates one limit value for any type of optical radiation, two values, per vibration medium for vibration (action and exposure) and three values (two action values and a limit value) have been set for noise. They stated that, in their opinion, there was no justification for these differing systems and that it would be simpler, for the purpose of both transposition and implementation in practice (e.g. for SMEs), if just one similar type of limit value was set for all these effects.

However, this was not a view reflected in other NIRs and it is clear that issues such as distinguishing between the effects of acute and chronic exposures mean that this view might not be entirely correct.

Another MS emphasised the number of overlapping requirements between the various Physical Agents Directives, which it was felt hindered their implementation. It was observed that consolidation and improved clarity of presentation of requirements that are similar across the Physical Agents Directives, together with additional explanatory instructions, would be of particular benefit to SMEs. Earlier sections of this chapter have addressed these overlaps and, where appropriate, presented preliminary conclusions.

Answer to EQC1

An inconsistency was noted between the AOR and Noise Directives relating to the risk assessment procedure. Whilst the Noise Directive requires the employer to give particular attention to the effects of extending exposure when working for more than eight hours under the employer's responsibility, this is not required by the AOR Directive. Consideration should therefore be given to the inclusion of a similar provision in the AOR Directive.

Unlike the Noise Directive, the requirement for information and training under the AOR Directive does not impose any specific obligation on employers to inform those workers at particular risk, although elsewhere in the Directive such workers are referred to. Consideration should be given to rectifying this.

The AOR Directive is alone amongst the physical agents directives in detailing the procedure for the adoption/amendment of limit values. Consideration should be given to ensuring that this is harmonised in the other Physical Agents Directives (including action values in those Directives where they are specified).

In summary, it is felt that addressing the above inconsistencies could improve the legal clarity and coherence of, and thus compliance with, the requirements of the four Physical Agents Directives.

6.2 EQC2: Coherence between the AOR Directive and other EU measures and policies/international instruments (External coherence)

EQC2: How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive, Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

Other EU legal acts

› Directive 2006/42/EC (machinery)

Directive 2006/42/EC (the Machinery Directive) applies to machines which include interchangeable equipment, safety components, lifting accessories, chains ropes and webbing and removal mechanical transmission devices. In order to be allowed to place machinery on the market, the employer must ensure, amongst other requirements, that it complies with the relevant health and safety requirements set under Annex I of the Directive.

Annex I Point 1.5.10 to the Machinery Directive contains several requirements applicable to artificial optical radiation. It provides that undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons. In addition, it requires any functional non-ionising radiation emissions[37] during setting, operation and cleaning to be limited to levels that do not have adverse effects on persons. Annex I Point 7.4.2 (v) requires that each instruction manual must contain information concerning the radiation emitted for the operator and exposed persons, at least where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices.

Annex I point 1.5.12 of the Machinery Directive sets requirements to limit AOR from lasers incorporated into machines. For example, it requires laser equipment on machinery to be designed and constructed in such a way as to prevent any accidental radiation emission.

These requirements have a positive effect for the reduction of worker exposure to AOR. Furthermore employers can rely on information generated under the Machinery Directive when carrying out a risk assessment related to AOR.

› Directive 2014/35/EU (electronic equipment with certain voltage)

Directive 2014/35/EU (electronic equipment with certain voltage) applies to electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current. The purpose of this Directive is to ensure that electrical equipment on the market fulfils the requirements providing for a high level of protection of health and safety of

[37] Non-ionising radiation includes AOR

persons, and of domestic animals and property, while guaranteeing the functioning of the internal market. Annex I to this Directive sets out principle elements of the safety objectives for these types of electronic equipment, which require technical measures to be laid down to ensure that radiations which would cause danger are not produced. Such safety requirements have a positive effect for the reduction of worker exposure to AOR.

› Directive 93/42/EEC (medical devices)

This Directive applies to medical devices and their accessories. Annex I to the Directive sets out essential requirements, taking into account the intended purpose of the devices concerned. As a general principle, Point 11.1.1 of this Annex provides that devices must be designed and manufactured in such a way that exposure of patients, users and other persons to radiation must be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. In case of intended generation of radiation, it requires that it must be possible for the user to control the emissions. Concerning unintentional radiation generation, it requires that devices must be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Such safety requirements have a positive effect for the reduction of worker exposure to AOR.

› Directive 98/79/EC (in-vitro medical devices).

This Directive applies to in vitro diagnostic medical devices and their accessories. Devices must meet the essential requirements set out in Annex I to this Directive, taking into account the intended purpose of the devices concerned.

Point 5 to this Annex regulates radiation emissions from these devices. They must be designed, manufactured and packaged in such a way that the exposure of users and other persons to the emitted radiation is minimised. It also requires that when devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted, fitted with visual displays and/or audible warnings of such emissions.

Finally, manufacturers must provide instructions with detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.

These requirements have a positive effect for the reduction of worker exposure to AOR. Furthermore, employers can rely on information generated under Directive 98/79/EC (in-vitro Directive) where carrying out risk assessments related to AOR derived from these devices.

Other EU policies

None identified.

Relevant European Social Partners Agreements	None identified.
Other international instruments	None identified.
European and International Standards	Because they are not freely available, the texts of European and International Standards were not systematically examined as part of the study. Such Standards have no legally-binding status in MSs, although individual MSs might choose to encapsulate certain provisions from these Standards in national law. However, various Standards are cited in the AOR Directive and, to that extent, their content is of direct consequence. For example, Article 4(1) states that: "The methodology applied in assessment, measurement and/or calculations shall follow the standards of the International Electrotechnical Commission (IEC) in respect of laser radiation and the recommendations of the International Commission on Illumination (CIE) and the European Committee for Standardisation (CEN) in respect of noncoherent radiation." Article 4(3)i refers to: "a classification applied to a laser as defined in accordance with the relevant IEC standard and, in relation to any artificial source likely to cause damage similar to that of a laser of class 3B or 4, any similar classification." As these citations refer to undated (and unspecified) standards and defer wholly to the relevant content of those standards there are no coherence issues. A number of CEN Standards can be identified relating to electrical products such as EN 62471:2008 "Photobiological safety of lamps and lamp systems" and EN 60825-1:2007 "Safety of laser products. Equipment classification and requirements". Some of these, such as EN 62471, are targeted at manufacturers of such devices and employers would need to consider the circumstances and manner in which they are being used in assessing any risk to health. Others, such as EN 60825-1 are intended for users and employers can use this to 'make informed decisions regarding the risks associated with intentional and unintended exposure to laser radiation'. Indications of compliance with the latter Standard could be used by employers as "information provided by the manufacturers of optical radiation sources and associated work equipment" in carrying out any risk assessment (Article 4(3)j).
EU Stakeholders' views	Non-identified

National stakeholders and experts' views

One stakeholder mentioned that there were overlaps between EU minimum quality standards and various OSH Directives. They felt that a clear linkage between EU legislation setting minimum quality standards of equipment and the physical agents Directives should be made following the model of Directive 89/656/EC (Use of PPE). It was felt that this would simplify the understanding and application of the aforementioned OSH Directives. However, the parallels are not immediately clear as, unlike the Use of PPE Directive, the physical agents directives do not relate directly to the use of specific equipment.

Information from the NIRs

One Member State pointed out that there were some discrepancies between the AOR Directive and EN 62471: Photobiological safety of lamps and lamp systems, in relation to classification, although no details of these perceived discrepancies were provided in the NIR. EN 62471 has wider application as it is a parallel standard with IEC 62471. It includes a four level risk classification system (no photobiological hazard; no photobiological hazard under normal behavioural conditions; does not pose a hazard due to aversion response to bright light or thermal discomfort; hazardous even for momentary exposure). These are stated as being based on ICNIRP guidelines. However, this classification relates to the lamps themselves, not workplaces where they are used. It is not apparent whether any differences cause confusion or uncertainty amongst employers or whether any action is necessary as a result of this comment.

Answer to ECQ2

There are a number of EU Directives which are of relevance in terms of interactions with the provisions of the AOR Directive: Directive 2006/42/EC (machinery); Directive 2014/35/EU (electronic equipment with certain voltage); Directive 93/42/EEC (medical devices) and Directive 98/79/EC (in-vitro medical devices). All of these Directives provide positive effects in relation to reducing worker exposure to AOR by the design, operation and maintenance of AOR-generating equipment. The requirements on manufacturers to provide emission information to purchasers of the equipment are also of use to organisations when assessing risks from AOR.

One stakeholder suggested that clarification of the linkage between EU legislation setting minimum quality standards of equipment and all of the Physical Agents Directives would increase understanding and application of the aforementioned OSH Directives. However, it is not clear how such linkages could be drawn.

One MS also reported discrepancies between the AOR Directive and the standard EN 62471: Photobiological safety of lamps and lamp systems, in relation to classification. It is not apparent whether any differences cause confusion or uncertainty amongst employers or whether any action is necessary as a result of this comment.

7 Conclusions and recommendations

7.1 Implementation

There were no observed discrepancies in terms of incorrect transposition between the AOR Directive and national legislation.

Although only very limited information is available it appears that the implementation of the directive into a single piece of legislation has facilitated its application in a coherent manner. Limited information suggests that the requirements are applied coherently with the risk assessment and removal/reduction requirements functioning in the expected manner. Other requirements such as training, consultation and surveillance are often implemented within existing national structures and arrangements for such measures.

The majority of the MSs have implemented more detailed requirements. This is in particular regard to Article 4 (Determination of exposure and assessment of risks), Article 8 (Health surveillance) and Article 6 (Worker information and training). Many of these more detailed requirements appear to relate to implementing the transposed legislation within the existing national legal framework (e.g. existing provisions for health surveillance).

In relation to the AOR Directive, the CPMs have therefore generally been implemented in a consistent manner across the MSs, with some exceptions in relation to health surveillance and worker information and training, where national requirements are more detailed than those in the Directive. For example, where the Directive requires health surveillance a commonly applied more detailed requirement is to specify the frequency of such surveillance rather than introducing additional measures. This arises out of a need to integrate the specific provisions of this directive into existing national systems and structures.

There are no provisions for transitional periods or derogations within the AOR Directive.

Data illustrating general levels of compliance with the Directives taken as a whole are very limited in type and number, precluding comprehensive further analysis.

AOR Directive-specific data are even less common. For the three MSs that did provide data, two reported moderate (45%) estimated overall compliance levels for the key requirements. A further MS reported 71% compliance with the requirement for risk assessment but no data on the other CPMs or KRs.

The national studies also sought to establish whether there are differences in levels of compliance depending on size of establishments and in respect of different sectors (particularly any differences between the public and private sectors). No data on size of establishment was available specific to the AOR Directive. However, general data on OSH compliance indicates that, in general terms across the Directives, the level of compliance increases with the size of establishment. No data is available to differentiate levels of compliance between the public and private sector.

Compliance issues amongst SMEs were therefore identified using the responses in the NIRs. Specific issues included measurement method complexity, difficulty in appointing suitable competent assistance and health surveillance. Although only a limited number of MSs provided any data on SME-related issues, some stated that they have no evidence that SMEs experience greater difficulties than other organisational types in relation to the AOR Directive provisions.

One non-binding guidance document (Non-binding guide to good practice for implementing Directive 2006/25/EC, artificial optical radiation') has been produced by the Commission. This outlines a method for assessing AOR risks and, although aimed at SME employers, may also be of use to employee representatives and regulatory authorities in MSs. Data on the extent to which this non-binding guide is used by companies and establishments to pursue the objective of protecting the safety and health of workers from the risks of injury due to AOR hazards is not available. No NIRs refer to its use and no stakeholders, at EU or national level, commented on it as a resource.

The non-binding guide refers to the derivation of the exposure limit values (ELVs) from International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines. However, these guidelines are technical papers and, as such, have not been considered as resources for employers. They are however discussed in the context of the current relevance of the AOR Directive.

One MS has designated a specific authority responsible for the enforcement of the AOR Directive: for the others enforcement of the Directive's provisions typically comes under the general authority responsible for OSH inspection/ enforcement. No specific tools or approaches relating to vulnerable groups were identified within the AOR Directive.

Although many MSs have implemented general methods to assist SMEs to comply with OSH requirements, with the exception of some guidance documentation, no AOR Directive-specific incentives or approaches were identified.

7.2 Relevance

According to the NIRs, the AOR Directive has been transposed into national legislation in all MSs. There are industrial sectors in which AOR is likely to be encountered in all MSs meaning that, in that respect, the Directive is of current relevance in all MSs.

Estimates of the proportion of the EU workforce potentially at risk from AOR exposure and to whom the Directive is therefore relevant are difficult because no specific statistics can be identified. Estimates using two different approaches suggest a range of 1.54-3.31% of the EU workforce.

As part of exploring the extent to which the AOR Directive adequately addresses current risk factors and protects workers, attention was paid to the exposure limits which are at the core of the AOR Directive and on which many of the other requirements depend. The ELVs within the AOR Directive are derived from earlier (1997) guidance from the ICNIRP. Recent (2013) revisions of that guidance indicate that the previous guidance values were too low and that higher levels of exposure are acceptable, without risk of injury. It is suggested that the scientific evidence from the ICNIRP regarding these revisions is reviewed, and an equivalent revision of the equivalent ELVs within the AOR Directive adopted.

One approach adopted with the various OSH directives has been to determine the extent of current illness attributable (or potentially attributable) to the subject matter of the Directive (or as current as possible given the availability of statistics). Very little appropriate data could be identified relating to the AOR Directive. One dataset (EWCS, 2005) provided some data. Data extracted for a subset who, it appeared possible, were exposed to AOR in the course of their work suggested that those who were exposed for longest were more likely to report problems with their vision that they attributed to their work. Although there were no assurances that this data covered AOR exposures or that the visual problems experienced could be attributed to such exposures this analysis provided the best available objective material.

There were very mixed responses from the interviewees and within the NIRs regarding the current relevance and worth of the AOR Directive.

Turning to more subjective sources, some stakeholders interviewed for the study felt that the AOR Directive was not relevant at present, whilst others stated that technological changes would reduce any relevance in the future although the nature of these anticipated changes was not detailed. A different stakeholder felt that the AOR Directive had great relevance, in particular for the health sector, where the problem was prevalent in their MS. Again, the nature of the problems experienced were not explained. Another stakeholder felt that the AOR Directive should be repealed in its entirety.

A number of national stakeholders indicated that the AOR Directive was insufficient in that it did not cover outdoor work and the associated increased risk of skin cancer.

It was felt by others that awareness-raising via guidelines would have been preferable to implementation of national legislation. Some stakeholders felt that the risks covered by the AOR Directive were already adequately addressed and managed, without additional legislation being required and that, in any case, the actual degree of risk was relatively low. On that basis, this MS had recommended that the AOR Directive should be rescinded.

Additional actions noted in the NIRs included extension of the AOR Directive to natural sources (solar radiation); the requirement to appoint a laser protection officer and specific training requirements for welders.

Differing representations about the level of risk to workers from solar UV radiation were received. One expert research group postulated that occupational UV exposure of outdoor workers is a highly relevant hazard in Europe. The group also noted that workplace sun exposure has already been recognized as a relevant occupational hazard and consequently incorporated into specific national legislation of a number of MSs.

In contrast, another study suggested that the risk of melanoma is strongly linked to high-intensity intermittent exposure, as for example received during recreational/ holiday activities resulting in sunburn, rather than chronic exposure typical of outdoor occupations.

There were very mixed responses from the interviewees and within the NIRs regarding the future relevance and worth of the AOR Directive. Some stakeholders felt that the AOR Directive was not relevant at present and that this situation would be unlikely to improve in the future, whilst others stated that (unspecified) technological changes would reduce any future relevance. A different stakeholder felt that the AOR Directive had great relevance, in particular for the health sector, where the problem was prevalent in their MS. In contrast, another stakeholder recommended that the AOR Directive was not relevant and would remain so and should be repealed in its entirety.

No stakeholders presented any expectations of major changes in technology which would result in a significant increase in exposures although, perhaps with the benefit of hindsight, few could have foreseen the growing use of lasers and other high power optical devices in the entertainment industry. Some concerns have also been expressed that the growing use of LED lighting may result in increased risks, although this has yet to be proven

It seems therefore that there is a considerable spread of views regarding the future relevance of the AOR Directive. These are discussed further below.

7.3 Effectiveness

During national interviews, twelve stakeholder groups from six different MSs provided a score from 1–5 (low to high) on the extent to which the AOR Directive was considered to have fulfilled its objectives. The mean score of 4.3 indicates that

the AOR legislation, according to these national stakeholders, has fulfilled its objectives to a large extent.

Interviewees were also asked to what extent the national transposition of the AOR Directive had achieved any general impact in the workplace by influencing the behaviour within establishments in the MSs in respect to the risks covered by the AOR Directive. They were also asked to take size of establishment into account in this rating. Again they were asked to utilise a five-point scale from 1 (low impact on behaviour) to 5 (high impact). Stakeholders found it difficult to specify but the overall opinion was that the impact increased with the size of the establishment, with relatively little effect on behaviour in microenterprises (an average score of 2.3 on a scale from 1 to 5), a slightly improved effect in SMEs (3.5), and the largest effect in large companies (4.1). The results from these six MSs should not necessarily be assumed to be representative of the wider EU-27.

Very little quantitative data exists for objective assessment of the impact of Artificial Optical Radiation on the health and safety of workers. What data are available are not entirely satisfactory in that the recorded accidents are not necessarily attributable to AOR exposure and it is not possible to determine causal agents from the records. Subject to these profound limitations, which were considered to render detailed analysis virtually meaningless, it appears superficially as if the incidence of accidents within this category has fallen within the EU-15 since the start of the millennium but remained relatively static in more recent years. As much of this decline preceded the presumed implementation of the provisions of the AOR Directive in most MSs, this suggests that the decline cannot be attributed to the effective implementation of its provisions. Additionally, any trends in these data appear to be strongly influenced by changes in a single MS and there is no consistent pattern across a sample of EU MSs which would suggest any systematic change.

One MS reported on a Regulatory Impact Analysis (RIA) specifically on the AOR. The authors concluded that, of approximately 8,000 injuries reported annually, none included any reference to the terms ‘radiation’ or ‘laser’. This may indicate either that reported accidents are caused by other factors than AOR exposure or that AOR-related accidents are currently not reported.

On health issues therefore, although it is widely accepted that exposure to AOR can have adverse health effects, ranging from relatively minor problems such as skin reddening to significant diseases such as cataracts and skin cancer, no appropriate data sources on occupational diseases have been found. Current EU databases do not provide any classification appropriate for AOR.

There are no transitional periods or provisions for derogations within the AOR Directive.

Evaluation of the extent to which the different CPMs contributed to the effectiveness of the AOR Directive is challenging. Stakeholders at national level indicated that they considered provision of information and training to workers, health surveillance and risk assessment to be the most important CPMs although it

is not possible to assess the manner and extent to which the different CPMs have contributed to the AOR Directive's effectiveness.

A number of stakeholders felt that sanctions and other enforcement activities were of significant importance in ensuring compliance of the AOR Directive, however it was not clear if these responses related to the general effectiveness of such actions, or were AOR Directive specific.

7.4 Coherence

An inconsistency was noted between the AOR and Noise Directives relating to the risk assessment procedure. The requirements under the Noise Directive to inform workers on the nature of the risks, and within the EMF Directive to inform workers at particular risk, are not incorporated into the AOR Directive. The procedures for the adoption and amendment of limit values and action values differ for the AOR Directive in comparison with the other Physical Agents Directives.

Based on these legal inconsistencies, three preliminary suggestions for change were identified:

› Consider the review of the risk assessment procedure of the AOR Directive to include the provision of the Noise Directive requiring employers to give particular attention to the extension of exposure beyond normal working hours under the employer's responsibility.

There is a provision in the Noise Directive requiring employers to give particular attention to the extension of exposure beyond normal working hours under the employer's responsibility. Thus, the exposure limits are based on the assumption of a notional eight-hour working day. Where that working day is extended (e.g. to ten hours) then the limit must be revised accordingly. This should not be confused with any exposures outside work. Some adverse effects of AOR exposure relate to the effects of chronic rather than acute exposures, thus the exposure limit values for various UV wavelengths are based on an 8-hour exposure. In parallel to the provision in the Noise Directive, a similar provision could also apply to workers exposed to AOR and would enhance the protection provided to such workers.

› Consider the review of the AOR Directive to include an obligation to inform those workers at particular risk.

The EMF Directive makes a specific information requirement concerning workers at particular risk. No such provision is made under the AOR Directive, although Article 4 does refer to the health and safety of workers belonging to particularly sensitive risk groups. Such provisions could therefore also apply to workers exposed to AOR ensuring that those at particular risk were aware of this and of any additional precautions they or their employer should adopt.

› Ensure that the procedure for the adoption/amendment of limit values is harmonised in the other Physical Agents Directives (including action values in those Directives where they are specified).

Amongst the various Physical Agent Directives, the AOR Directive is the only one which explicitly states the procedure to be followed in respect of any modification of the exposure limit values set out in the Annexes. Such a provision could be considered for the other Physical Agents Directives and might help to regularise the amendment process.

In summary, it is felt that addressing the above inconsistencies could improve clarity of, and thus compliance with, the legal requirements of the four Physical Agents Directives.

7.5 Overall discussion

It is clear from this appraisal that the justification for the AOR Directive does not seem to have a strong evidence base in terms of objective data on AOR-related accidents or ill-health. However, the absence of data should not necessarily be regarded as indicating the absence of a problem. Some specific adverse effects of AOR exposure, especially those affecting the eyes, are well documented. It is possible that the view expressed by some that such problems are well-known and well addressed without the need for recourse to a Directive has some merit. However, the complexities and complications associated with measuring and assessing exposure should not be regarded as a reason for not having a Directive where there is a recognised and poorly controlled hazard.

Given the apparently relatively low level of accidents and injuries (as distinct from health effects which tend to be longer-term) it would seem that more chronic effects should be given more attention. The carcinogenic effects of UV exposure are well documented and recognised. Some experts advocate the extension of the AOR Directive to include a non-artificial source – sunlight and some MSs have already legislated to protect workers from this source. However, others are less convinced that occupational exposure to solar UV can be so readily distinguished from leisure exposures and that consequent attribution of risk is less clear. One recent estimate suggests that approximately 2% of cutaneous melanoma deaths (~50 per year, based on UK data) are attributable to occupational exposures to solar radiation.

7.6 Overall conclusions and recommendations

All MSs have implemented the provisions of the AOR Directive in a consistent manner. Data on compliance is very limited but would appear to be moderately implemented, with the generally-held opinion that compliance increases with the size of establishment. There are no objective data sources to support or refute this view which is based on 12 interviews with national stakeholder groups drawn from six MSs .

In keeping with other individual Directives, there is no data available regarding the impact and influence of specific CPMs within the Directive.

As part of exploring the extent to which the AOR Directive adequately addresses current risk factors and protects workers, attention was paid to the exposure limits which are at the core of the AOR Directive and on which many of the other requirements depend. The ELVs within the AOR Directive are derived from earlier (1997) guidance from the ICNIRP. Recent (2013) revisions of that guidance indicate that the previous guidance values were too low and that higher levels of exposure are acceptable, without risk of injury. **It is suggested that the scientific evidence from the ICNIRP regarding these revisions is reviewed, and an equivalent revision of the equivalent ELVs within the AOR Directive adopted.**

Opinions, drawn from interviews with stakeholder and expert groups from a number of MSs, together with material and recommendations from NIRs and representations by expert research groups as to the future relevance of the Directive are mixed. Some evidence suggests that the AOR Directive is not at all relevant at present (including one MS providing objective evidence that AOR exposure did not appear to have contributed to any workplace accidents), with some stakeholders suggesting that technological changes would reduce its relevance still further. One stakeholder went so far as to recommend that the AOR Directive should be repealed in its entirety. This recommendation was also formally made by one MS in its NIR.

In contrast, another stakeholder felt that the AOR Directive had great relevance, in particular for the health sector, whilst a number of national stakeholders indicated that the AOR Directive was insufficient in that it did not cover outdoor work and the associated increased risk of skin cancer. This latter view was endorsed by representations from a scientific and medical research group concerned with skin cancers, although the views of this group were again countered by other evidence.

The AOR Directive appears to attract more diverse and extreme views than most if not all of the individual Directives. There is clearly no consensus over this Directive; of the need for it, or of its value. Although it is recognised and accepted that AOR can generate hazards it would appear that some at least are interpreting its provisions very widely, even considering office lighting as a potential hazardous source.[38] Given the lack of objective evidence it is difficult to reach a firm conclusion at this time as to the best way forwards. Although the hazards are recognised there is no substantial body of evidence to demonstrate the extent to which injuries or health problems are being caused as a result. Data from just one MS where data was systematically examined showed a very low level of recorded injuries, and even those which were recorded were not necessarily attributable to exposures to AOR.

Despite the data limitations it is clear that there is considerable uncertainty over the value of retaining this Directive, or whether it should be repealed or revised. In this respect the AOR Directive stands out from most of the other OSH Directives which seem to have a reasonable level of support. However, the data limitations mean that, at this stage, it is not possible to make a firm recommendation for retention in its present form, revising it or repealing it. The best recommendation is therefore

[38] Coleman et al (2010) A survey of the optical hazards associated with hospital light sources with reference to the Control of Artificial Optical Radiation at Work Regulations 2010

that consideration should be given to initiating a debate on this Directive to determine whether it should be retained and, if so, to review its scope to consider, on the one hand, whether it can be restricted to remove known low-risk workplaces/sectors (thereby reducing the possibly unnecessary burden on industry) or to include additional sources of exposure such as external (solar) optical radiation. As part of these deliberations, consideration should be given to the extent to which the emergence of harmonised standards on products potentially emitting AOR which include health and safety considerations reduces the need for the Directive by removing any risk at source.

This latter point provides further evidence for a need for a more in-depth exploration of the scientific evidence than can be provided by this review. Whilst a research group has advocated the inclusion of solar radiation (and provided published evidence in support of their argument) others have expressed a contrary view, again with supporting published evidence. **It is therefore suggested that a formal, independent, systematic evidence review of the topic is required to inform such a debate.**

It is further recommended that consideration is given to collecting better quality, more appropriate data on accidents and acute health effects which can be directly attributed to AOR exposure to enable a more informed decision to be made over its retention or reintroduction in future reviews.

Finally, the review of legal coherence (Chapter 6) identified a number of apparent consistencies in the requirements of employers imposed by the AOR Directive compared to those relating to other physical agents. **If the AOR Directive is to be retained, consideration should be given to reviewing the legal inconsistencies identified between this and other physical agents Directives and considering whether they are necessary for technical reasons or if they should be resolved to remove apparent anomalies.**

Appendix A References

Coleman A, Fedele F, Khazova M, Freeman P, Sarkany R. (2010) A survey of the optical hazards associated with hospital light sources with reference to the Control of Artificial Optical Radiation at Work Regulations 2010. J. Radiol. Prot. 30 469-89

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast).

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

El Ghissassi, F., Baan, R., Straif, K., Grosse, Y., Secretan, B., Bouvard, V., Benbrahim-Tallaa, L., Guha, N., Freeman, C., Galichet, L. and Cogliano, V. (2009) 'A review of human carcinogens - Part D: radiation.' *The Lancet Oncology*, 10(8), 751–752.

EU-OSHA (2014) *Current and emerging issues in the healthcare sector, including home and community care*. Luxembourg: Publications Office of the European Union.

European Commission (2011) *Non-binding guide to good practice for implementing Directive 2006/25/EC - artificial optical radiation* [online], available: http://bookshop.europa.eu/en/non-binding-guide-to-good-practice-for-implementing-directive-2006-25-ec-pbKE3010384/ [accessed 21 January 2015].

European Parliament (2011) *Vulnerable groups as defined within the report: Occupational health and safety risks for the most vulnerable workers* [online], available: http://www.europarl.europa.eu/RegData/etudes/etudes/join/2011/464436/IPOL-EMPL_ET%282011%29464436_EN.pdf [accessed 19 January 2015].

Eurostat (2010) *Key indicators, manufacture of basic metals (NACE Division 24)* [online], available: http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Key_indicators,_manufacture_of_basic_metals_(NACE_Division_24),_EU-27,_2010.png [accessed 21 January 2015].

Eurostat (2013a) *Persons reporting an accident at work in the past 12 months, by sex, age and economic activity sector [hsw_ac5]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_ac5 [accessed 21 January 2015].

Eurostat (2013b) *Persons reporting the physical factor they were most exposed to by type [hsw_exp4]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_exp4 [accessed 21 January 2015].

Eurostat (2013c) *Persons reporting their most serious work-related health problem work in the past 12 months, by type of problem [hsw_pb5]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_pb5 [accessed 14 January 2015].

Eurostat (2013d) *Number of accidents at work by type of injury and severity [hsw_aw_ninsv]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_aw_ninsv [accessed January 21 2015].

Eurostat (2014a) *Accidents at work by economic activity and type of injury [hsw_n2_07]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_n2_07&lang=en [accessed 21 January 2015].

Eurostat (2014b) *Accidents at work by type of injury and severity (NACE Rev. 2, A, C-N) [hsw_mi07]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hsw_mi07 [accessed 21 January 2015].

Eurostat (2015a) *Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) [sbs_sc_sca_r2]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=sbs_sc_sca_r2&lang=en [accessed 20 January 2015].

Eurostat (2015b) *Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000 [lfsa_egan2]* [online], available: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=lfsa_egan2&lang=en [accessed 20 January 2015].

Health and Safety Authority, Ireland (2009) *Regulatory Impact Analysis (RIA), Safety, health and welfare at work (general application) (amendment) regulations 2009, Control of Artificial Optical Radiation at work* [online], available:

http://www.hsa.ie/eng/Legislation/Regulatory_Impact_Analysis/RIA_Optical_Radiation.pdf [accessed 21 January 2015].

HSE (2013) *Follow-up and assessment of self reports of work-related illness in the Labour Force Survey.* Health and Safety Executive, RR970.

Johansen, C. Olsen, J. H. (1999) Risk of cancer among Danish electricity workers. A cohort study. *Ugeskr Laeger,* 161(14), 2079-85.

Mdina Glass Handmade (2015) [online], available: https://www.mdinaglass.com.mt/ [accessed 21 January 2015].

Middeldorf IK. (2009). The Economic Importance of Welding and Joining in Europe Production Values, Values Added and Employees. Proceedings of the Eurojoin 7, Venice, Italy.

O'Hagan JB, Khazova M. (2010) Assessment of personal exposures to non-laser optical radiation in entertainment. Didcot, UK, Health Protection Agency

Rushton L, Hutchings S. (2015) The burden of occupational cancer in Great Britain. Cutaneous malignant melanoma and occupational exposure to solar radiation. Leicester: IOSH, Research report 15.3

Wilkins 3rd, JR. Wellage, LC. (1996) 'Brain tumor risk in offspring of men occupationally exposed to electric and magnetic fields.' *Scandinavian Journal of Work, Environment & Health*, 22(5), 339-345.

Young C, Rushton L, et al (2012) Occupational cancer in Britain: Skin cancer. British Journal of Cancer, 107, S71 – S75