European Radiation Dosimetry Group e. V.

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Neuherberg, January 2021

13th EURADOS Winter School
Eye Lens Dosimetry

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E.A. Ainsbury[1], R. Behrens[2], E. Carinou[3], O. Ciraj Bjelac[4], I. Clairand[5], J. Dabin[6], T.W.M. Grimbergen[7], S. Jacob[5], R. Kollaard[8], M. Nesti[9], L. Struelens[6].

[1]Public Health England (PHE), United Kingdom.

[2]Physikalisch-Technische Bundesanstalt (PTB), Germany.

[3]Greek Atomic Energy Commission (EEAE), Greece.

[4]Vinca Institute of Nuclear Science, University of Belgrade, Serbia.

[5]Institute for Radiological Protection and Nuclear Safety (IRSN), France.

[6]Belgian Nuclear Research Centre (SCK CEN), Belgium.

[7]Mirion Dosimetry Services, Arnhem, The Netherlands.

[8]Nuclear Research and Consultancy Group (NRG), The Netherlands.

[9]Department of Cardiology, S. Donato Hospital (Arezzo), Italy.

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EDITORIAL GROUP

This report was prepared by the following members of EURADOS:

E.A. Ainsbury, Public Health England (PHE), United Kingdom

I. Clairand, Institute for Radiological Protection and Nuclear Safety (IRSN), France

M. Ginjaume, Universitat Politecnica de Catalunya (UPC), Spain

E. Fantuzzi, Agenzia nazionale per le nuove tecnologie, l'energia e lo sviluppo economico sostenibile (ENEA), Italy

F. Rossi, Azienda Ospedaliero Universitaria Careggi (AOU-Careggi), Italy

H. Schuhmacher, retired from Physikalisch-Technische Bundesanstalt (PTB), Germany

Content

Abstract

The Council Directive 2013/59/EURATOM of 5 December 2013 lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation. It includes a new dose limit for the eye lens, with a reduction from 150 to 20 mSv per year (average over five years, with no single year exceeding 50 mSv), that is to say 7.5 times lower than it was. The member states had four years (deadline February 2018) to implement the Directive into their legislation. The lowered dose limit raised a lot of issues, concerning the need for a dedicated eye lens dose monitoring, the choice of monitoring programme and the workers needing it, etc. Consequently, research studies and monitoring surveys were performed in the recent years, and in some member states new regulations and associated guidance were developed according to the new directive.

The medical field is without a doubt the most affected, in particular interventional radiology and cardiology, thus input is needed from surgeons who now find themselves wearing another dosemeter. Dosimetry services are also stakeholders, not only in terms of dosemeter supply but also for other organisational issues, including dose recording and record keeping, dose reporting, etc. The course will give an overview regarding the scientific background for the changes in legislation, the current status of regulations and guidance, what is currently available to support radiation protection of the lens and identify the questions that at yet remain to be fully answered.

The following papers are based on the presentations given in the EURADOS Winter School 2020 held in Florence (Italy) on January 30th 2020.

Winter school scientific committee:

- Liz Ainsbury (PHE, UK),
- Isabelle Clairand (IRSN, France),
- Elena Fantuzzi (ENEA, Italy),
- Mercè Ginjaume (UPC, Spain),
- Francesco Rossi (AOU-Careggi, Italy).

1. Eye lens exposure to ionising radiation: current radiobiological understanding

Elizabeth A. Ainsbury, Public Health England (PHE), UK; **Claudia Dalke,** Helmholtz Zentrum München GmbH, Germany; **Nobuyuki Hamada**, Radiation Safety Research Center, Japan ; **Roy Quinlan,** University of Durham, UK; **Munira Kadhim,** Faculty of Health and Life Sciences, UK; **Maria Teresa Mancuso,** Agenzia Nazionale per le Nuove Tecnologie, l'Energia e lo Sviluppo Economico Sostenibile (ENEA), Italy and **The LDLensRad Consortium** (https://www.researchgate.net/project/LDLensRad-the-European-CONCERT-project-starting-in-2017-Towards-a-full-mechanistic-understanding-of-low-dose-radiation-induced-cataracts).

1.0 Abstract

The International Commission on Radiological Protection (ICRP, 2012) recently concluded that the lens of the eye is more radiosensitive than previously thought. The recommendation of a new threshold of 0.5 Gy for ionising radiation cataract discussed in detail in ICRP Publication 118 (ICRP, 2012) has resulted in a large reduction in the occupational lens dose limit from 150 mSv year^{-1} to 20 mSv year^{-1} averaged over 5 years with no one year exceeding 50 mSv, in order to limit the chances of lifetime cumulative dose approaching the stated threshold.

However, ICRP 118 clearly states that this recommendation was based almost solely on the epidemiological population risk-based evidence, as mechanistic understanding of the role of ionising radiation in cataract formation is significantly lacking, especially at low doses. The need for further radiobiological research to underpin adequate protection legislation and guidance is clear.

This chapter reviews current understanding in terms of the radiobiological effects of ionising radiation on the lens, and considers in brief the research needs and the implications for radiological protection.

1.1 Introduction

1.1.1 Current radiological protection regulations

Following a detailed review of the relevant literature, in 2012, the International Commission on Radiological Protection (ICRP) produced Publication 118, which concluded that the lens of the eye is more radiosensitive than previously thought. Using data from a number of epidemiological publications, looking at cataract risk in a variety of different exposure scenarios, it was recommended that the threshold for ionising radiation (IR) cataract should be 0.5 Gy independent of rate of dose delivery. Further, to limit the chances of lifetime cumulative dose approaching the stated threshold, it was recommended to reduce the occupational lens dose limit from 150 mSv year^{-1} to 20 mSv year^{-1} averaged over 5 years with no one year exceeding 50 mSv (ICRP, 2012). This recommendation was formally incorporated into the revised EU Basic Safety Standards which came into force in February 2018 (EU, 2014). EU member states are thus now expected to be complying with this lens dose limit.

However, ICRP 118 plainly stated that the above recommendations were based almost solely on the epidemiological population risk-based evidence. This was because mechanistic understanding of the role of IR in cataract formation was lacking, especially at low doses and low dose rates. The need for further radiobiological research to underpin adequate protection legislation and guidance was clearly outlined (ICRP, 2012).

This chapter reviews current understanding of the different radiobiological effects of IR in the lens and their hypothesised relationship with cataract initiation and progression. The knowledge gaps and research needs are considered in the light of this knowledge, together with the implications of these for radiological protection in the context of the new ICRP recommendations (ICRP, 2012) and the revised EU basic safety standards (EU, 2014).

1.1.2 Lens and cataract

The lens of the eye is a small, avascular tissue, surrounded by the aqueous and vitreous humours. The lenses of human adult are on the order of 9-10 mm in diameter, and around 4.5 mm in thickness. The lens is a key optical element for vision. Lens fibre cells are anuclear; throughout life new lens fibre cells are added as a result of lens epithelial cells (LEC) differentiation and exiting from the lens epithelium at the meridional rows proximal to the germinative zone at the equator of the lens. Fibre cell formation is a tightly regulated process, both temporarily and spatially, and its deregulation manifests itself in fibre cell disorganisation, both spatially, biochemically and cell biologically, leading to cataract formation. Cataracts disrupt the refractive properties of the lens compromising vision and requiring surgical intervention for its correction.

Cataract is the most frequent cause of blindness worldwide (Bourne et al., 2013). Cataract has a multifactorial aetiology, the relationship with age is clear (e.g. Asbell et al., 2005; Uwineza et al., 2019), and the genetic component has been chiefly studied through investigation of congenital cataracts (Shiels and Hejtmancik, 2017). In addition, factors including ultraviolet (UV) radiation from sunlight (McCarty and Taylor, 2002), alcohol intake, nicotine consumption, several medical conditions including diabetes (Abraham et al., 2002; West, 2007), and persistent use of drugs such as corticosteroids (James, 2007), all have an influence on cataract development.

1.1.3 Radiation Cataract

The link between IR exposure and effects in the lens was first noted soon after the discovery of x-rays (Rohrschneider, 1929). Since then, work to understand this link has chiefly focused on high dose exposures, both in radiobiological and epidemiological studies, because until very recently, it was thought that doses lower than approximately 2 Gy did not lead to lens changes (e.g. ICRP, 1990). Now, however, the weight of evidence indicates that the latency period (time from exposure to onset) is inversely related to the exposure dose, i.e., the lower the dose, the longer it will be until IR has an effect (Ainsbury et al., 2016; Uwineza et al., 2019).

Even though cataract treatment is relatively simple and relatively available in many parts of the world, many people are unable to access ophthalmological specialist surgery, and thus have to live with the consequences of lens changes without intervention (Bourne et al., 2013). As with all IR effects, it is the responsibility of the entire community to ensure that data and scientific understanding underpins adequate IR protection regulations and guidance to guard against the risk of cataracts in a proportionate manner.

1.2 Current mechanistic understanding

This section provides a summary of the current status of our understanding. The mechanisms associated with radiation cataract were recently reviewed in full in Ainsbury et al. (2016). For further details, readers should consult this paper and the more recent references given below.

1.2.1 Oxidation

IR-induced oxidation is a well reported mechanism implicated in a number of different radiation-related health effects (reviewed in Wei et al., 2019). Oxidation is known as the “hallmark” of age related nuclear cataract (Truscott and Friedrich, 2019), not least due to the reduced levels of the antioxidant glutathione which starts to occur around middle age.

It is known that UV exposure generates reactive oxygen species (ROS) in the lens, which in turn causes “degradation, cross-linking and aggregation of lens proteins” (Hamada et al., 2014). As well summarised by Hamada and colleagues, it is currently hypothesised that the production of ROS by IR (as well as a number of other factors) leads to direct and indirect DNA damage, further leading to aberrant LEC division, migration and differentiation as well as protein degradation, cross-linking and aggregation (see also Moreau and King, 2012; Truscott and Friedrich, 2019).

1.2.2 DNA damage

The role of DNA damage in IR responses is generally well understood (Hall and Angele, 1999; Nickoloff et al., 2017); however, until recently, this had not been studied in any detail in the lens. In recent years, Markiewicz and colleagues (2015) demonstrated non-linear dose responses terms of DNA damage markers in LEC following low dose IR exposure; Barnard and colleagues (2018) showed the strain-dependence of DNA damage response in mouse lenses exposed in vivo, and Barnard et al. (2019) found evidence of an apparent inverse dose-rate response relationship for markers of DNA damage response, with the same (low) doses delivered at lower dose rates, leading to higher levels of residual damage at 4 and 24 hours post exposure.

It is also important to note that high linear energy transfer (LET) radiations are more effective at inducing cataract compared to low LET X-rays (e.g. Baumstark-Khan, 2003; Hamada and Sato, 2016).

1.2.3 Cellular proliferation and differentiation

In ICRP (2003), it was first proposed that cataract formation may be due to abnormal differentiation, rather than cell killing (for other “deterministic” effects). The majority of information on this in the literature comes from animal models and at relatively high doses, for example, 15 Gy x-irradiation caused a temporary decrease in cell density, followed by increased proliferation, in the germinative zone of rabbit lenses (von Sallmann, 1952). Markiewicz and colleagues (2015), however, found increased proliferation and cell density for doses < 0.5 Gy in human LEC lines. A recent study of the genetic factors associated with lens epithelial cellular proliferation has also indicated that the responses are clearly dose dependent (Fujimichi and Hamada, 2014; Hamada, 2017).

1.2.4 Genetics

Human genetics is highly complex. The Human Genome Project estimate that there are between 20,000 and 25,000 genes, and approximately 1% of genetic material varies on an interindividual basis (US National Library of Medicine, 2020). This is clearly manifested in the phenotypic variability of cataract itself (Shiels and Hetjmancik 2017) demonstrating that however much of the human genome has been characterised, the contribution of individual heterogeneity has yet to be understood. This makes study of genetic involvement in any disease complex.

However, there is evidence that those with heterozygous mutations (i.e. those having two different alleles of a particular gene) of the ATM, RAD9 and BRCA1 genes, for example, are at increased risk of certain health effects. For example, Kleiman et al. (2007) looked at cataract in mouse models heterozygous for the Rad9 and Atm genes. Posterior subcapsular opacities were found to develop earlier in X-irradiated double heterozygotes ($Atm^{+/-}/Rad9^{+/-}$) than either of the single heterozygotes ($Atm^{+/-}/Rad9^{+/+}$ or $Atm^{+/+}/Rad9^{+/-}$), which again developed earlier than in wild-type mice ($Atm^{+/+}/Rad9^{+/+}$).

In a recent mechanistic review, Hamada and Fujimichi (2015) identified a number of genes associated with carcinogenesis (oncogenes), tumour suppression, DNA repair, intercellular interactions and inflammation which are involved in cataract development. While questions remain, it is clear that there is now a weight of evidence in support of genetic susceptibility as key to understanding radiation-induced cataractogenesis.

1.2.5 Aging

The lens continues to grow throughout life, and thus the integrity of the functional structure is highly dependent on continuation of the intrinsic homeostatic functions. Truscott and Friedrich (2019) and Michael and Bron (2011) clearly described the loss of antioxidant functionality with age. Other 'aging' type processes (racemisation, deamidation, protein insolubility, covalent cross-linking) accompany oxidation in the progression to cataractogenesis (Truscott and Friedrich, 2019; Uwineza et al., 2019). For example, loss over time of the lens cells' ability to divide, is known as replicative senescence. This has been hypothesized that this might be associated with shortening of telomeres, the regions at the end of chromosomes, due to increased oxidative stress and reduced inherent antioxidant capabilities leading to chromosomal damage (Babizhayev et al., 2011).

The "accelerated aging" hypothesis, whereby IR exposure causes cataracts that would have appeared anyway in old age to manifest at an early time point, has been gaining popularity in recent years (e.g. Chodick et al., 2008).

Uwineza and colleagues (2019) have looked at this in detail, with a particular focus on protein and lipid modification. The authors conclude that the combination of the effects of DNA damage, aberrant proliferation and differentiation, altered transcription (gene responses), as well as direct effects on the lens proteins and lipids, all contribute to the individual "cataractogenetic load" which manifests as acceleration of appearance of cataracts that might otherwise have occurred as part of the normal aging process (Uwineza et al., 2019).

Finally, in terms of cataract development, Pawliczek and colleagues recently reported that cataracts form in a mouse model in response to IR in a dose and age dependent manner (Pawliczek et al., 2019).

1.2.6 Other potential mechanisms

Within the wider literature, a number of other potential competing/parallel mechanisms are discussed in the context of cataract formation. In terms of post translational modifications, which occur after the LEC have differentiated into fully functional lens fibre cells, radiation-induced oxidative stress causes aberrant protein aggregation (Moreau and King, 2012; Hamada et al., 2014). In addition, cataract patients have been shown to have increased levels of lipid peroxidation products compared to age matched controls (Girao et al., 1998). Uwineza and colleagues (2019) consider in detail the role of lipid and proteins in the radiation response in the lens. The implications of this for lenses exposed to IR are currently under investigation.

The involvement of the extra cellular matrix (ECM) has also been discussed in the literature, for example, it has been shown that IR-induced alterations in the misregulation of MMP expression, which may impact the ECM as well as cellular differentiation (Chang et al., 2007).

It is also worth noting that in contrast to carcinogenesis, there is very little information in the literature on the role of epigenetic mechanisms (e.g. DNA methylation, histone modification, regulation of miRNA, as discussed in Wei et al., 2019) in cataract formation.

In addition to age, sex, genotype, epigenotype and environment, the co-morbidity will be important in considering individual responses, e.g., recent epidemiological studies have suggested that people with diabetes have higher risk for radiation cataracts (Little et al., 2018, 2020).

Finally, it has been hypothesised that non-targeted effects may play a role in radiation cataract formation, for example through induction of genomic instability or through indirectly targeting intracellular communication (Hamada et al., 2011; Ainsbury et al., 2016).

More work is needed to fully understand each of the observations detailed in this section, and how they relate to radiation cataract.

1.3 Discussion and conclusions

Figure 1.1 summarises at a high level current understanding regarding different aspects of radiological responses in the lens which may be involved in radiation cataract formation. There are still open questions particularly regarding the link between the different radiobiological mechanisms and radiation cataract; however, overall, mechanisms of cataract are beginning to be more clearly understood (e.g. Ainsbury et al., 2016; Uwineza et al., 2019).

In addition, there is a good level of understanding of lens biology (structure, physiology, process of fibre cell formation) and the effects of IR at high doses (the studies by Worgul and colleagues, for example, as discussed above). The weight of evidence regarding the impact of age, genetic background, wider lifestyle factors and indeed sex for cataract formation in general is good, and mechanistic studies also mean that the impact and/or interaction of these factors on mechanisms of radiation cataract is becoming clearer.

1.3.1 Summary of current understanding

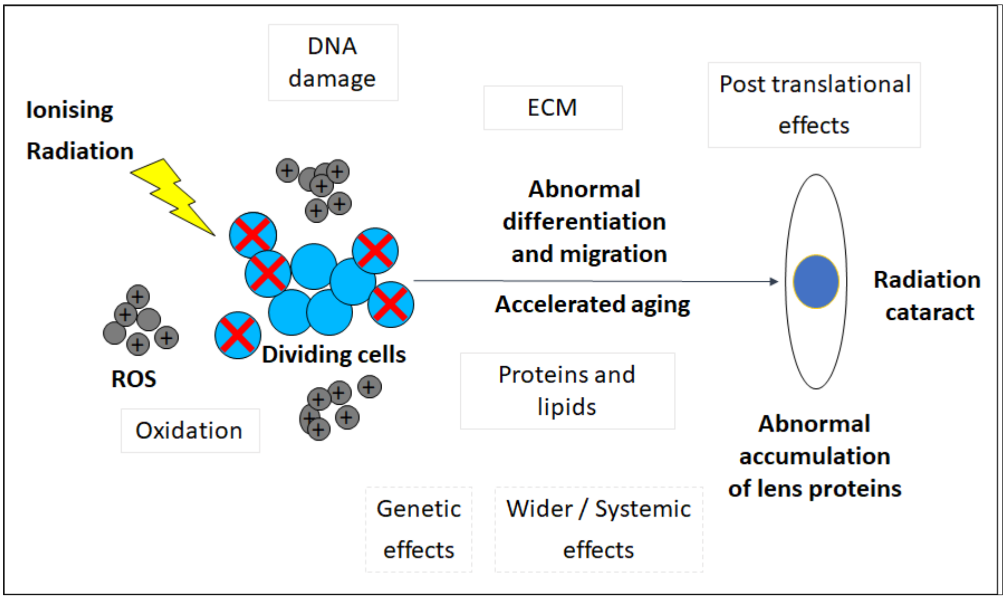

Figure 1.1: Simplified summary of aspects of current mechanistic understanding for radiation cataract initiation and progression. Arrow (loosely) indicates time post exposure, which is hypothesised to be inversely proportional to dose. Further details

given in the main text.

1.3.2 Ongoing and future research

For radiological protection purposes, ICRP divides IR-induced health effects into two different types:

- Deterministic effects or tissue reactions

  Those for which there is a defined threshold below which the effect does not occur; severity of effect increases with dose.

- Stochastic effects

  Those for which there is no threshold, risk (but not severity) increases with dose.

For radiological protection purposes, as discussed above, radiation cataract is currently classified as a “tissue reaction” as the epidemiological evidence suggests a threshold on the order of 0.5 Gy, and the severity of effect appears to increase with dose. However, there is a growing body of mechanistic evidence in support of DNA damage related, stochastic, responses in terms of lens opacification. For example, in a recent report on cataract phenotypes, Pawliczek and colleagues reported that the existence of an IR response threshold was time-dependent and indeed the threshold disappeared, i.e. the response became stochastic, with enough time post IR (Pawliczek et al., 2020). The concept of opacification vs cataract, i.e. the point at which changes to the lens become vision-impairing, has been widely discussed in the literature (Hamada et al., 2014), but further consideration of this is needed in the light of the most recent findings.

Most recent, lower dose, studies have also focused on low-LET radiations such as X- and gamma rays; there is a need also to consider the mechanisms of response in the lens to more effective high-LET radiations, in support of novel medical uses of IR and space travel.

Current radiological protection practices would seem to be pragmatic in the absence of complete mechanistic understanding of radiation-induced cataract. However, as more data are gathered, the increasing evidence for a stochastic-like response, for example, might well eventually compel a full review of the data to ensure that the system of radiological protection is sufficient and remains grounded in the state of the art in terms of knowledge and understanding.

Further, for adequate radiological protection, it is very important to consider the radiobiological, mechanistic, data together with information from epidemiological and dosimetric studies. These suggest that IR is most commonly associated with posterior subcapsular cataracts, but the reliability of the extrapolation of this to low dose exposures remains unclear. In addition, cataract detection, assessment and treatment are all important aspects related to the wider radiological protection picture. Each of these are discussed in detail in further sections of this report.

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2. Risk of radiation-induced cataract and lens opacities: results from epidemiological studies

Sophie Jacob, Institute for Radiological Protection and Nuclear Safety (IRSN), France.

2.0 Abstract

The lens of the eye is among the most sensitive organs to ionizing radiation in the human body. Historically, it was believed that the acute threshold dose for cataract formation was 5 Gy, and annual dose limits to the lens were set at 150 mSv. Recent epidemiological studies, performed on populations exposed to lower radiation doses than those previously considered as cataractogenic, have led the International Commission on Radiological Protection (ICRP) in April 2011 to reduce its eye dose threshold for cataract induction from 2 Gy to 0.5 Gy, and the occupational annual dose limit from 150 mSv to 20 mSv year^{-1}. In this presentation, we will review the current knowledge on radiation-induced cataract including the main recent epidemiological studies. Data from a variety of exposure cohorts will be reviewed, including atomic bomb survivors, Chernobyl liquidators, astronauts and pilots, populations living in the contaminated territories of Chernobyl, patients exposed to computed tomography, radiotherapy patients and medical personnel, such as radiology technicians and interventional cardiologists.

While posterior subcapsular cataracts are characteristic of radiation exposure, several sets of data suggest that the broader category of posterior cortical cataracts may also be regarded as radiation-associated. Increased risks of lens opacities (including posterior subcapsular, cortical, nuclear, and mixed cataracts) have been reported in these different populations. However, we will see that combining all these studies in order to provide an overall risk model is challenging due to inconsistencies with dosimetry, sample size, and scoring metrics but also radiation quality, age at exposure and latency period. For future studies, reliable dosimetry and grading methods for lens opacities is important in order to determine an appropriate level for dose threshold and exposure limit. Nevertheless, the question as to whether radiation-induced cataract is a deterministic event, meaning a threshold dose must be exceeded in order for it to develop or a stochastic effect (linear non-threshold) still remains…

2.1 Introduction

Cataract is an eye lens opacification causing reduced visual acuity. Lens opacities are regarded as earlier forms of cataract, with little interference of visual acuity. They can be detected by examination and several scoring systems have been developed for grading their severity. Cataracts are divided into sub-groups according to their location. Nuclear cataracts (centre of lens) are strongly age-related and associated with light/UV. Cortical cataracts (edge of lens) are the second most common subtype. Posterior subcapsular cataracts (back of lens) are less common and have been associated with exposure to ionising radiation. Several classification systems have been developed for ranking the severity of cataracts based on slit-lamp examination. One of the most common classification is the Lens Opacities Classification System (LOCS) with different versions from I to III the most recent (Chylack et al., 1993). The World Health Organization (WHO) also developed a grading system for scoring the three classes of cataracts (Thylefors et al., 2002). Merriam and Focht (Merriam and Focht, 1962) classification, much simpler than the others, was specifically designed for radiation-induced cataracts. The Focal Lens Defect (FLD) system (Day et al., 1995) was designed for minor subclinical opacities. Self-reported presence or absence of cataracts without any ranking is also considered in some studies.

The lens of the eye is among the most sensitive organs to ionizing radiation in the human body. Historically, it was believed that the acute threshold dose for cataract formation was 5 Gy, and annual dose limits to the lens were set at 150 mSv (ICRP, 2007). However, the exact mechanisms underlining this pathology have yet to be uncovered. In particular, the question as to whether radiation-induced cataract is a deterministic event, meaning a threshold dose must be exceeded in order for it to develop, still remains. Recent epidemiological studies, performed on populations exposed to lower radiation doses than those previously considered as cataractogenic, have led the International Commission on Radiological Protection (ICRP) in April 2011 to reduce its eye dose threshold for cataract induction from 2 Gy to 0.5 Gy, and the occupational annual dose limit from 150 mSv to 20 mSv $year^{-1}$ (ICRP, 2011).

The ICRP have yet to support a stochastic effect (linear non-threshold) for radiation- induced cataract, although this has been suggested by several studies. In this short report, we will review the current knowledge on radiation-induced cataract including the main recent epidemiological studies covering a wide range of different exposure and radiation quality cohorts including atomic bomb survivors, Chernobyl liquidators, astronauts and pilots, populations living in the contaminated territories of Chernobyl, patients exposed to computed tomography, radiotherapy patients and medical personnel, such as radiology technicians and interventional cardiologists.

2.2 Environmental exposure.

2.2.1 Atomic bomb survivors

The risk of eye lens opacities and cataract in the population of atomic bomb survivors, with an acute exposure to neutron and gamma radiation, has been widely investigated. Recent studies have analysed long-term effects in this population (>40 years after exposure), however, a large number of the individuals considered were children at the time of exposure. A study (Minamoto et al., 2004) examined 873 survivors based on LOCS II classification and found an increase in cortical and PSC opacities with an OR (Odds Ratio) at 1 Sv of 1.29 (1.12–1.49) and 1.41 (1.21–1.64), respectively. These results were reanalysed, and a threshold of 0.6 Sv (<0–1.2) was calculated for cortical opacities and 0.7 Sv (<0–2.8) for PSC opacities (Nakashima, Neriishi and Minamoto, 2006). Based on confidence intervals, the authors concluded that this threshold was not significantly different from zero. The prevalence of more severe cataracts requiring surgery was examined (Neriishi et al.,, 2007), founding an OR at 1 Gy of 1.39 (1.24–1.55) and a threshold dose of 0.1 Gy (<0–0.8). Further analysis on the subgroup of individuals with lens dose <1 Gy was performed and no statistically significant threshold could be found. A higher threshold of 0.5 Gy (0.1–0.95) was identified in a study of incidence of cataract surgery that included 6006 subjects (Neriishi et al., 2012).

2.2.2 Contaminated Chernobyl territories

The incidence of lens opacities using the LOCSII classification in 1,787 children (5–17 years) residing near Chernobyl (996 children exposed/ 791 not exposed) was studied (Day, Gorin and Eller 1995). Whole-body effective dose estimates were between 29 and 86 mSv. A small 3.6% increase was found in subclinical PSC lens changes in the exposed group, but no dose threshold was calculated.

2.2.3 Contaminated building

In Taiwan, the population of occupational buildings accidently constructed in 1983-1984 with steel that was contaminated with ^{60}Co was investigated, more than a decade after several years of chronic, low-dose exposure. A study performed in 2001 (Chen et al., 2001) found no significant dose-response when cataracts were scored using the LOCS III system, but a correlation was identified between dose and non-vision impairing FLD scores in younger individuals (<20 years). No radiation effects were found in older age groups where some individuals had cumulative effective doses up to 1.5 Sv. A follow-up study was then conducted 5 years later looking only at individuals under the age of 20 (Hsieh et al., 2010). FLD scores were higher compared to the earlier data suggesting a progression of opacities with time. However, no dose-response relationship was found when the LOCS III scoring method was used.

2.3 Medical exposure

A small number of studies have looked at cataract formation following diagnostic imaging procedures and most of these studies were based on self-reporting with no estimation of radiation doses. A study (Klein et al., 1993) found a relationship between head and neck computed tomography (CT) scans and PSC opacities with an OR of 1.45 (1.08–1.95) in the Beaver Dam Eye Study Cohort. An increase was also found in nuclear opacities. Taiwanese researchers (Yuan et al., 2013) examined medical records from individuals receiving at least one head CT scan: 2776 patients exposed to head CT and 27 761 non-exposed (based on Taiwan registry 1995-2009). They evaluated that 1 CT corresponded to 50 mSv to the lens. A Hazard Ratio (HR) of 1.76 (1.18–2.63) in the exposed population compared to the unexposed population was found. Moreover, a correlation was also found between the number of CT scans received and cataract risk.

2.4 Occupational exposure

2.4.1 Chernobyl liquidators

The risk of cataract has also been examined in the population of Chernobyl clean-up workers, who were exposed to protracted exposure to individuals exposed beta and gamma radiation. In a study including 8607 liquidators aged 33 years at mean at exposure, estimated lens dose ranged from 0 to >1 Gy with a median of 123 mGy. Based on the Merriam-Focht scale, the OR at 1 Gy was 1.70 (1.22–2.38) for all types of early stage of cataract and a threshold of 0.34 Gy (0.19–0.68) (Worgul et al., 2007). For PSC cataract, they found an OR at 1 Gy of 1.42 (1.01–2.00) and a threshold of 0.35 Gy (0.19–0.66).

2.4.2 Astronauts

Astronauts represent a unique population for studying the impacts of high linear energy transfer exposure to the eye. Although relevance of high LET space radiation to exposure scenarios on Earth remains an issue, and the size of investigated population was limited due small sample size of people who have travelled to space astronauts with a protracted exposure to cosmic radiation were also considered in studies. A first study (Cucinotta et al., 2001) examined 295 NASA astronauts up to 30 years post spaceflight. Individuals were divided into high dose category (>8 mSv, average of 45 mSv) and low dose category (<8 mSv, average of 3.6 mSv). The high dose group had a significantly elevated HR for cataract formation of 2.35 (1.01–5.51) compared to the low dose group. A smaller study (Rastegar, Eckart and Mertz, 2002) examined 21 astronauts and cosmonauts and an unexposed group of 395 individuals. An increase in PSC opacities was found compared to a reference population but statistical testing was not performed. More recently, the NASA Study of Cataracts in Astronauts study group was created (Chylack et al., 2009). Cataracts were scored using the LOCS III method. A significant correlation was found between radiation and PSC opacities with an OR at high exposures (>10 mSv) of 2.23 (1.16–4.26). These findings were updated in 2012, examining the longitudinal progression of cataracts (Chylack et al., 2012) and no relationship was found between dose and progression rate for PSC or nuclear opacities.

2.4.3 Airline pilots

Airline pilots can receive a protracted exposure to cosmic radiation due to high altitude travel. A case-control study (Rafnsson et al., 2005) was performed on 205 cases (71 nuclear, 102 cortical and 32 PSC) and 374 controls among Icelandic pilots. The WHO classification was used. An OR for nuclear cataracts at 1 mSv of effective dose was calculated as 1.02 (1.00–1.03). The highest exposure group (22–48 mSv) had a nuclear cataract OR of 4.19 (1.04–16.86). Surprisingly, no significant increase in risk was found for cortical or PSC cataracts.

2.4.4 Industry radiographers

A study based on a cohort of 1401 industry radiographers and 1878 unexposed workers in China followed for 12 years was performed (Lian et al., 2015). The lens doses were based on individual monitoring. Presence of cataract was assessed based on LOCSIII classification. Industry radiographers were significantly more likely than unexposed workers to develop cortical (HR=2.58, 95% CI 1.36 to 3.82), posterior subcapsular (PSC) cataract (HR=3.57, 1.27-4.79) and mixed cataract (HR=3.25, 1.20-6.78), but not nuclear cataract (HR=0.93, 0.78-1.11). However, no dose-effect relationship could be observed.

2.4.5 Medical professionals

Lens opacities have been examined in physicians, nurses, and technologists receiving occupational exposures. A large cohort of 67,246 US radiation technologists (US cohort of technologists) was followed for 12 years with an estimated mean lens dose of 55.7 mGy (Little et al., 2018). In this study, Little et al. calculated a HR of cataract (self-reported) ranging from 1.11 to 1.76 (1.29–2.40) for individuals having received at least 10 mGy to the eye lens compared to the lower exposed group. A subgroup of technologists working with nuclear medicine procedures was analysed (Bernier et al., 2018) and an increased risk of cataract associated with nuclear medicine diagnostic and therapeutic procedures was observed. Many studies have been performed in the population of catheterisation laboratory staff. A group of 57 Finnish physicians (mainly of radiologists) with an average effective dose of 60 mSv was studied (Mrena et al., 2011). Opacities were detected with LOCSII classification but were mostly nuclear, and it was concluded that they were not radiation based. A follow-up study confirmed these results finding no increase in PSC or cortical cataracts, based on LOCSII, in 47 exposed physicians with a mean whole-body effective dose of 102 mSv (Auvinen et al., 2015). Some of the largest medical occupational exposures are to interventional cardiologists and radiologists. A study (Ciraj-Bjelac et al., 2010) examined a group of cardiologists and nurses in Malaysia whose average lens doses were 3.7 Gy and 1.8 Gy, respectively. The RR (Relative Risk) for early PSC opacities (not vision impairing), compared to a control population, was 5.7 (1.5–2.2) for cardiologists and 5.0 (1.2–2.1) for nurses. However, a follow-up study 2 years later calculated a lower RR by nearly half (Ciraj-Bjelac et al., 2012). In another study (Vano et al., 2010), it was found a significant increase in PSC opacities in South American cardiologists who received an average lens dose of 6 Sv compared to a control population, equating to a RR of 3.2 (1.7–6.1). A follow-up study on a second South American cohort found a higher frequency of PSC opacities in nurses compared to a control population, but no risk calculation was included (Vano et al., 2013). An increase in PSC frequency was found in the O'CLOC study of French cardiology unit workers, with an OR of 3.56 (1.25–10.13) using LOCSIII classification, with eye lens dose eye lens dose that ranged from 25 mSv to more than 1600 mSv; the mean+SD was 423+359 mSv. (Jacob et al., 2012; Jacob et al., 2013). In contrast, no increase in lens opacities in exposed Greek interventional cardiologists was found (Thrapsanioti et al., 2017).

Due to the differences in methodology in these various studies on interventional cardiologists, it is difficult to pool data for comparison purposes. For this reason, the EURALOC (European epidemiological study on radiation-induced lens opacities among interventional cardiologists) project was launched, aiming to provide the best uniform methodology currently available and to establish a dose–response relationship in the low-dose range of exposure to ionising radiation. Eleven European countries joined this epidemiological study by recruiting a cohort of interventional cardiologists (ICs) using a common protocol allowing both the comparison of information on confounders for cataract and retrospective evaluation of the eye lens doses. Some 393 interventional cardiologists and 243 non-exposed individuals were included in this study, using LOCSIII classification. Median lens doses was 151 mSv (max 2815 mSv) for left eye (Struelens et al., 2018) (Domienik-Andrzejewska et al., 2019). First results indicated an increased risk of PSC in the interventional cardiology group compared to the unexposed group and the dose-response relationship analysis for PSC may indicate a linear non-threshold relationship.

2.5 Conclusion

In summary, data from a wide range of different exposure and radiation quality cohorts have been collected and analysed. While posterior subcapsular cataracts are characteristic of radiation exposure, several sets of data suggest that the broader category of cortical cataracts may also be regarded as radiation-associated. Increased risks of lens opacities (including posterior subcapsular, cortical, nuclear, and mixed cataracts) have been reported in these different populations. However, the papers reviewed in this manuscript vary quite widely in terms of radiation exposure characteristics. As a consequence, combining all these studies in order to provide an overall risk model is challenging due to inconsistencies with dosimetry, sample size, and scoring metrics but also radiation quality, age at exposure and latency period.

For future studies, reliable dosimetry and grading methods for lens opacities are important in order to determine an appropriate level for dose threshold and exposure limit. Nevertheless, the question as to whether radiation-induced cataract is a deterministic event, meaning a threshold dose must be exceeded in order for it to develop, or a stochastic effect (linear non-threshold) still remains as remains the difficulty of carrying out future epidemiological studies that could provide clear answers to this question.

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3. Eye lens dosimetry approaches within the European EURALOC epidemiology project

Lara Struelens, Belgian Nuclear Research Centre (SCK CEN), Belgium.

3.0 Abstract

The European epidemiological study EURALOC aimed to establish a dose-response relationship for low dose radiation induced eye lens opacities using interventional cardiologists as the study group.

Large efforts have been made to develop two retrospective lens dose calculation methods and to apply them within the epidemiological study. While one approach focuses on self-reported data regarding working practice in combination with available procedure-specific eye lens dose values, the second approach focuses on the conversion of the individual whole-body dose to eye lens dose. In contrast with usual dose reconstruction methods within an epidemiological study, a specific methodology is applied resulting in an individual distribution of possible cumulative lens doses for each recruited cardiologist, rather than a single dose estimate. In this way, the uncertainty in the dose estimate (from measurement uncertainty and variability among cardiologists) is represented for each individual.

Eye lens dose and whole-body dose measurements have been performed in clinical practice to validate both methods, and it was concluded that both produce acceptable results which can be used as input for a dose-risk evaluation study. Optimal results were obtained for the dose to the left eye using procedure-specific lens dose data in combination with information collected on working practice. This method is applied to 421 interventional cardiologists, resulting in a median cumulative eye lens dose of 151 mSv for the left eye and 114 mSv for the right eye. From the individual cumulative eye lens dose distributions obtained for each cardiologist, maxima up to 9-10 Sv were observed, although with low probability. Since whole-body dose values above the lead apron are available for only a small fraction of the cohort and in many cases not for the entire working career, the second method has only been used to benchmark the results from the first approach. This study succeeded in improving the retrospective calculation of cumulative eye lens doses in the framework of radiation-induced risk assessment of lens opacities, but it remains dependent on self-reported information, which is not always reliable for early years.

However, besides being the cornerstone of the epidemiological part of the project, these dosimetry methodologies were also used to develop two calculation tools, “mEyeDose” and “mEyeDose_X” which enable to track, calculate, optimize and analyze eye lens doses in interventional cardiology. mEyeDose was developed as a Mobile Web App and serves as a readily accessible, highly effective educational tool for interventional cardiologists, whereas the user-friendly desktop application mEyeDose_X is designed for radiation protection professionals. Both tools are freely available and can be used for a wide range of purposes such as optimization of practices, calculation of cumulative eye lens doses or risk assessment prior to routine eye lens dose monitoring.

3.1 Introduction

The EURALOC study (European epidemiological study on radiation-induced lens opacities among interventional cardiologists) examines the effects of low-dose radiation on risk of eye lens opacities as a major non-cancer effect of ionising radiation.

The rationale of EURALOC is to combine epidemiological, ophthalmological and dosimetry data for analysis of the dose-response relationship for cataract formation at low doses. The study design involves construction of an exposed cohort with interventional cardiologists and a reference cohort of non-exposed subjects. Previously published studies have already suggested an increased risk of lens opacities for this population (Vaño et al., 2013; Ciraj-Bjelac et al., 2010; Jacob et al., 2013), but a dose-response relationship has not been established. One of the challenges, but also strengths, of the EURALOC project was to provide not only a single-point dose estimate for each recruited interventional cardiologist, but a distribution of possible eye lens doses for each of them which permits a detailed and quantitative investigation of the impact of the cumulated absorbed dose to the lens of the eye on the occurrence of lens opacities.

A total of 393 exposed subjects working with interventional cardiology have been recruited from 11 European countries. They have completed study questionnaires on work history and risk factors for lens opacities. Each of them had an eye examination performed by a national ophthalmologist using a slit lamp microscope after pupil dilatation and the LOCSIII grading guideline (Chylack et al., 1993) was used for opacity classification. The recruitment has been performed in a harmonised way over the different centres and participating countries to allow pooling of data.

The focus of this report is to describe the retrospective dosimetry methods developed within the project, to validate the dose reconstruction strategy by performing measurements in routine clinical practices and to apply them to each recruited interventional cardiologist to obtain individual eye lens dose distributions. And, finally, to use those as input for the statistical design to investigate a possible dose-response relationship.

3.2 Methodology

A common dosimetry protocol consists of two different, but complementary approaches:

1. If estimates of average eye lens dose for a specific type of procedure are available, one can calculate the cumulative dose as the sum of the average dose incurred during each type of procedure ($H_p(3)_{proc,j}$) multiplied by the number of procedures of each type performed during the cardiologist's career ($N_{proc,j}$): $H_{\mathrm{p}}(3)_{\mathrm{cum}} = \sum_{\mathrm{proc,j}} H_{\mathrm{p}}(3)_{\mathrm{proc,j}} \ x \ N_{\mathrm{proc,j}}$
2. If annual records of the whole-body (WB) dose ($H_p(10)_{,j}$) covering the complete cardiologist's career can be obtained, one might consider converting the WB dose into eye-lens dose using conversion coefficients from whole-body to eye-lens dose ($C_{WB\rightarrow E}$): $H_{\mathrm{p}}(3)_{\mathrm{cum}} = \sum_{\mathrm{j}} H_{\mathrm{p}}(10)_{\mathrm{j}} \ x \ C_{\mathrm{WB}\rightarrow\mathrm{E}}$

However, $H_p(3)_{proc,j}$ is rarely, if ever, available on an individual basis in practice, nor is $C_{WB\rightarrow E}$. The usual dose reconstruction strategy for an epidemiology study would then consist in using single point estimates (usually, a mean or median value) as surrogates for the unknown values ($H_p(3)_{proc.j}$ or $C_{WB\rightarrow E}$). For instance, the mean value of a set of measurements performed during coronary angiography (CA) would be used as the estimate of the dose incurred during similar procedures ($H_p(3)_{CA}$) for all cardiologists in the cohort, irrespective of operator's skills. Hence, using such strategy would equate to ignore the dose variability between operators, but also the uncertainty in the dose measurement. The uncertainty in the reconstructed dose would be particularly difficult to quantify and, consequently, any conclusions on the possible dose-risk relationship would suffer from the same shortcomings. Therefore, it was decided to implement an approach which makes use of the complete distribution of available data, and which results in an individual distribution of possible cumulative eye lens doses for each cardiologist, rather than a single dose estimate. The advantage of such strategy is evident: for each individual, the uncertainty in the dose estimate is represented by the dose distribution.

3.2.1 From procedure-specific eye lens dose to cumulative eye lens dose

3.2.1.1 Information on working history

The information on working history has been collected through an extensive questionnaire. Information has been collected per decade on

a. different working periods, corresponding to the different centers where a cardiologist worked
b. the use of individual protective equipment (lead glasses, face shield, apron, etc.) and individual dosimetry methods (single/double dosimetry (defined below), position of dosemeter, etc.)
c. type of interventional cardiology procedure: workload, x-ray system, collective protective equipment (ceiling-mounted shield, lead curtains, radiation protection cabin, etc.)

A joint database has been constructed for collection of the data and screenshots of this database are illustrated in Figure 3.1.

3.2.1.2 Eye lens dose data collection

Doses to the eyes during cardiac procedures were collected from the literature complemented, where necessary by additional in-hospital measurements. More than 82 papers were read and, after careful evaluation, raw data from 7 papers (Vanhavere et al., 2011; Efstathopoulos et al., 2011; Antic et al., 2013; Ciraj-Bjelac et al., 2013; Domienik et al., 2014; Kollaros et al., 2014; Principi et al., 2015) and 4 unpublished studies were selected; These included 580 measurement data from the European ORAMED project (Vanhavere et al., 2011). Additional measurements were performed for 5 procedures. Data were sorted according to 8 types of procedures (coronary angiography, CA; percutaneous transluminal coronary angioplasty, PTCA; pacemaker implantation, PM; cardiac resynchronisation therapy, CRT; radiofrequency catheter ablation, RFCA; pulmonary vein isolation, PVI; valvuloplasty, VP; chronic total occlusion angioplasty, CTO), 3 tube configurations (tube below, tube above and biplane) and the use of ceiling suspended screen or not. This was done for the left and right eye, separately. An example for the left eye is shown for the CA procedure performed with a tube below configuration and using a ceiling suspended screen in Figure 3.2 (left). In practice, for each exposure configuration, 500,000 values were randomly sampled from the doses collected in the literature. For each sampled dose value, the uncertainty in the dose measurement was accounted for by randomly sampling a value from a truncated normal distribution (defined from 0 to infinity) with a mean equal to the sampled dose itself and a standard deviation attributed according to expert estimate. As a final step, a kernel density estimate is performed, resulting in a smoother eye lens dose probability density function (PDF) (Figure 3.2, right).

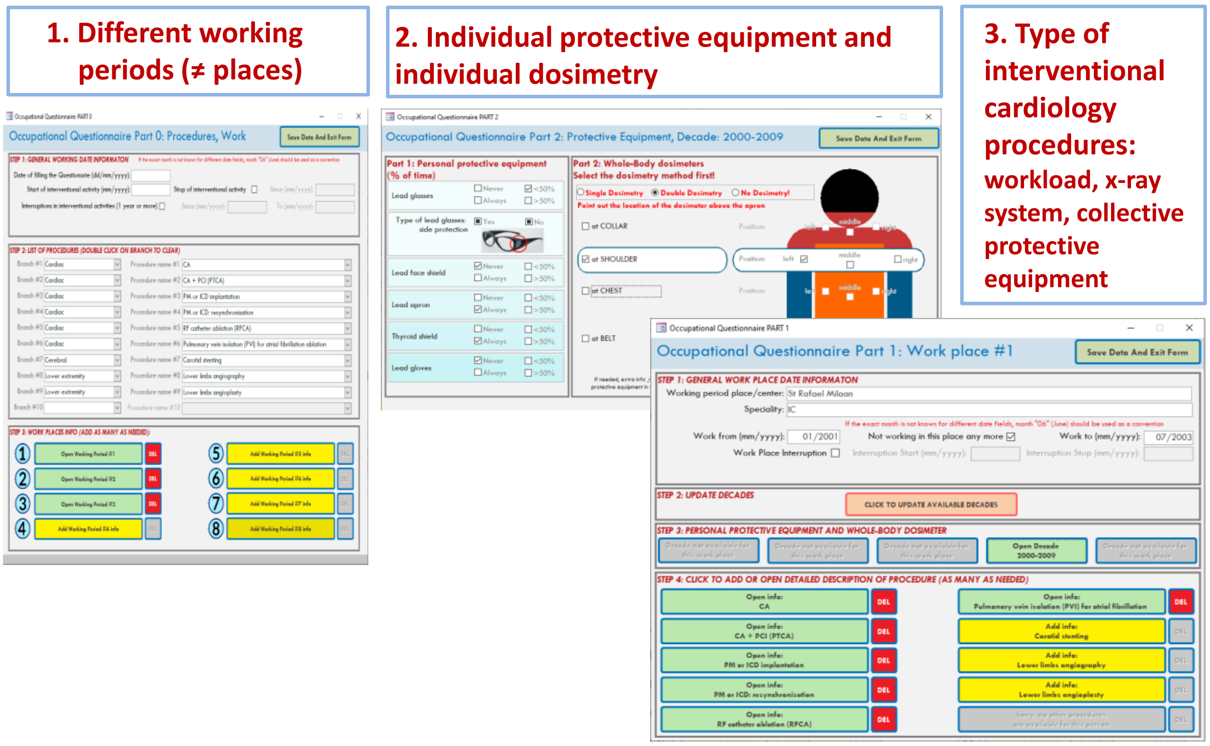

Figure 3.1: Screenshots of the database, collecting the occupational working history of each recruited interventional cardiologist per decade.

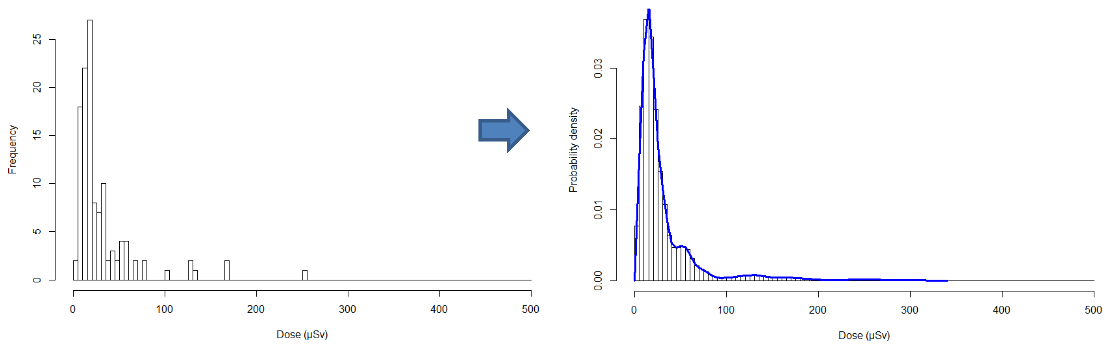

Figure 3.2: Frequency histogram of literature left eye lens dose data collected for CA (coronary angiography) procedure with tube below configuration and the use of a ceiling suspended shield (left); Probability density function of the dose per procedure estimated using the sampling and kernel density method (right).

3.2.1.3 The effect of lead glasses

The published eye lens dose data do not account for the attenuation from wearing lead glasses. There are numerous studies, however, that have computed the efficiency of lead glasses by performing Monte Carlo simulations, including parameters like the shape of glasses, the position and rotation of the operator with respect to the x-ray beam, lead thickness, beam projections, etc. A real procedure, however, consists of a specific combination of many of these different parameters. For each procedure type, the contribution of each x-ray beam projection to the total procedure dose (represented by the dose-area-product DAP) has been determined from procedure-specific dose reports. The lead glasses efficiency factors from the study of Koukorava et al. (2014) for a specific procedure were determined by combining the beam projection-specific efficiency factors, considering the weight of each beam projection for that specific procedure; while the different operator's head orientations and lead glasses shapes were considered as equally likely. Moreover, only efficiency factors were considered for operator positions relevant for the specific procedure. For each combination of procedure and equipment, the dose PDF calculated without glasses were used to sample randomly 500,000 dose estimates which were multiplied with as many glass shielding efficiency factors randomly sampled from the procedure-and-equipment-specific shielding factors. Kernel density estimation was then used to determine the PDF.

3.2.2 From annual whole-body dose to cumulative eye lens dose

A thorough study of the relationship between eye lens and whole-body dose was performed by means of phantom measurements within the framework of the ELDO project (Farah et al., 2013). This study has the advantage of being a quite comprehensive list of exposure situations that could be encountered within the cathlab; one can combine these situations to reconstruct possibly any type of procedure for each possible position of the WB dosemeter. WB to eye-lens dose conversion coefficients were experimentally determined for different WB dosemeter positions and procedure parameters: x-ray beam projections, operator positions, x-ray tube voltage and mono-plane and bi-plane x-ray systems. A real procedure, however, consists of a specific combination of many of these different parameters. Therefore, the procedure-specific WB to eye-lens conversion coefficients were determined using a similar strategy to the one used for the procedure-specific glass efficiency factors. For a specific procedure, frequency distributions of the conversion coefficients have been established by combining the conversion coefficients of the relevant x-ray beam projections and operator positions for that specific procedure and this was done for each possible WB dosemeter position separately. It must be noted, that the conversion from whole-body to eye lens dose, is only feasible for whole-body dosemeters worn above the lead apron. For each procedure and WB dosemeter position, 500,000 coefficient values were randomly selected from the frequency distributions, representing the relevant projection-specific coefficients, and combined into procedure specific-coefficients as described above. To account for the lead glasses, each sampled projection-specific whole-body to eye lens dose conversion coefficient is first multiplied with a lead glasses shielding factor randomly sampled from the relevant projection-specific factors.

3.2.3 Validation of dosimetry methodology

Eye lens dose measurements have been performed in clinical practice by measuring the cumulative eye lens doses of interventional cardiologists with commercially available dedicated eye lens dosemeters during 1 or 2 months for both left and right eye. Additionally, the relevant occupational information was collected for the specific measurement period, as well as the corresponding whole-body dose value, measured above the lead apron at chest level. In total 230 sets of measurements were obtained in different hospitals from 8 different countries. From the collected information, cumulative eye lens doses were calculated using both described approaches, but by using the mean and median values of the relevant probability density functions. In that case, single eye lens dose values were obtained for easy comparison with the measured eye lens dose values. In order to compare the data sets (i.e. measured values against calculated values of both approaches) data were transformed using the logarithmic function and the respective distributions were checked for normality. The Anderson-Darling test was used to compare the empirical cumulative distribution function of the sample data sets with the distribution expected if the data sets were normal.

3.3 Results and discussion

3.3.1 Validation of dosimetry methodology

The mean ratios of the measured and calculated data for the left and right eye are shown in Table 3.1.

Table 3.1: Mean ratios of the eye lens doses measured and calculated for both left and right eye.

Mean $H_p(3)_{meas}$ / $H_p(3)_{calc}$				
	Left eye		Right eye	
	Approach 1	Approach 2	Approach 1	Approach 2
Mean values of PDFs	0.56	0.76	0.26	0.44
Median values of PDFs	0.97	0.79	0.50	0.45

As it can be observed, the measured values are generally lower compared to the calculated ones. For the left eye, the calculated eye lens doses when using the median values of the PDFs according to approach 1 agree best with the measured eye lens dose data, with a ratio of 0.97. And both data sets are considered not significantly different according to a t-test (p: 0.613). For all the other data sets a significant difference is observed ($p<0.05$; CI=95%). For the left eye, the second approach (converting WB dose into eye lens dose) underestimates the measurements by 21-24%, which can be considered acceptable for radiation protection measurements and as input for epidemiological studies. On the other hand, the right eye measurements are systematically underestimated compared to the calculated values using both approaches. These large discrepancies found for the right eye can to some extent be explained by the position of the eye lens dosemeters when measurements are performed. These dosemeters are positioned on the temple and not on the forehead at the level of the eyes. Studies of Domienik et al. (2012; 2014) demonstrated that for the left eye the difference in dose between those 2 positions is comparable, while for the right eye the dose at the temple position is significantly lower compared to the dose on the forehead above the right eye. The calculated doses considered the position on the forehead for the right eye, by using conversion coefficients from left eye to right eye from the study of Domienik et al. (2012; 2014). This explains the larger overestimation of the calculated dose to the right eye compared to the measured dose with a dosemeter positioned on the right temple.

Aside from validation of the reconstruction approaches, the measurements performed in the validation study could also be used to calculate conversion coefficients from whole-body to eye lens dose from data in clinical practice with a whole-body dosemeter positioned at chest level and compare them against those obtained by using the data from Farah et al. (2013) from phantom measurements (Figure 3.3). It can be observed that the ratios $H_p(3)/H_p(10)$ from the phantom study are larger than those obtained from clinical practice. The latter are considered more appropriate to calculate eye lens dose from whole-body dose.

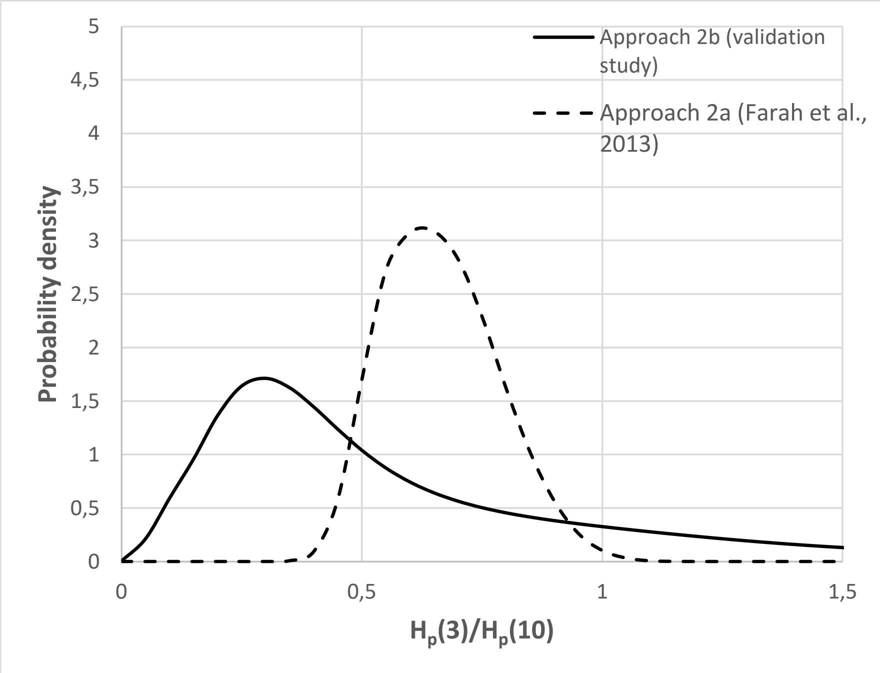

Figure 3.3: The ratio whole-body dose to eye lens dose from the study of Farah et al. (2013) obtained by phantom studies (dotted line) compared to the ratio from this study obtained from clinical practice, for a whole-body dosemeter positioned at chest level.

3.3.2 Retrospective dose calculations

Both dosimetry methodologies have their pros and cons. While the first approach uses direct eye lens dose data obtained from clinical practice combined with individual occupational history, including the number of procedures performed per type, one still has to consider that not only a large spread is observed in the available eye lens dose data (even for similar practices), one also has to rely on the self-reported data from the cardiologists, which may be less reliable for the early years. The positive side from approach 2 is that personal dose information is used from the recruited cardiologist (personal whole-body doses). However, these data need to be converted to eye lens dose, not a lot of $H_p(10)$ data is available measured above the lead apron and we have very low confidence in the correct use of the whole-body dosemeter in the early years. Because whole-body dose values, measured above the lead apron, were only available for a small part of the cohort and often only for a part of their working career, only eye lens dose data, calculated from approach 1 were used as input for the statistical design to investigate the dose-response relationship.

For approach 1, we defined in total 192 different exposure configurations per eye and PDFs have been determined for all of them. The cumulated eye lens dose distributions for each cardiologist was calculated by sampling the specific exposure configuration PDFs 100,000 times. Each sampled dose is then multiplied with the number of procedures performed for that specific configuration and year and summed over the total number of years in the working career of that individual cardiologist. It has to be mentioned that for each sample realisation, one identical dose value per exposure configuration is used for all cardiologists. In this way, the uncertainties in the individual dose assessment are correctly taken into account, as it maintains the shared errors among the cardiologists, e.g. errors in dose estimates for a specific exposure configuration in a specific period affect all cardiologists who performed that particular procedure in that period. An example of the complete cumulative eye lens dose distribution for one of the recruited interventional cardiologists is shown in Figure 3.4.

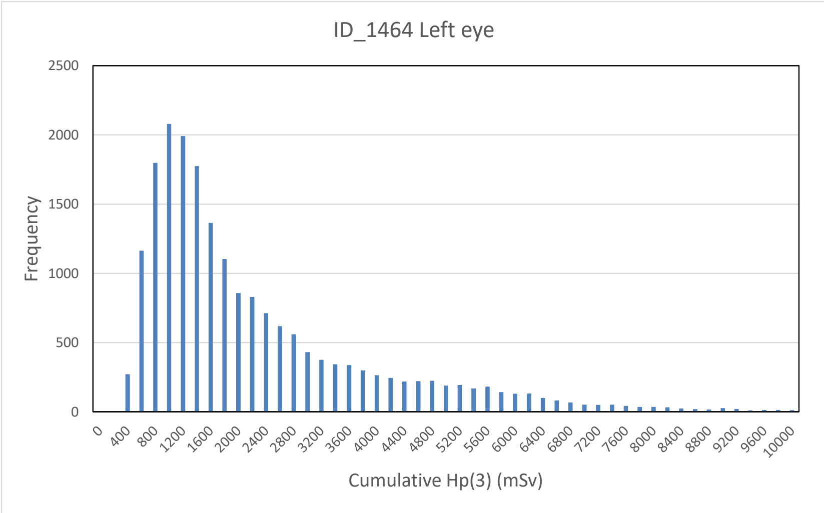

Figure 3.4: Individual cumulative eye lens dose distribution for the left eye for one cardiologist.

When considering the dose values calculated for the entire cohort by using the median values of the PDFs from the first approach (as this was best evaluated after the validation study), a median eye lens dose value of 151 mSv and 114 mSv was obtained for the left and right eye, respectively. For the left eye a maximum dose of 2.8 Sv was obtained with 68% of the cohort having a dose to the left eye lower than 300 mSv. We have to mention that much higher maximum dose values were observed in the individual dose distributions, up to 9-10 Sv, with very low probability of course.

More information on the methodologies developed and a more complete overview of the obtained dosimetry data can be found in (Struelens et al., 2018).

3.4 Conclusions

Two methodologies for retrospective calculation of cumulative eye lens doses for interventional cardiologists have been developed within the EURALOC project. A big effort was made to provide a distribution of possible eye lens doses for each cardiologist. Median cumulative eye lens doses of 151 mSv for the left eye and 114 mSv for the right eye were obtained with individual maximum eye lens doses up to 10 Sv. A validation study, collecting reliable information, positively benchmarked the established methodology. The biggest limitation of the study is that it relies on self-reported data. But it can also be used for prospective assessment of eye lens doses. Therefore, within the project a desktop application has been developed in Microsoft Access "mEyeDose_X" that uses the full EURALOC dose calculation methodology. It can store and calculate a large amount of data of multiple cardiologists and has additional features, such as an interface to export the calculated data and call tutorial screens during all processes embedded. More information can be found in (Covens et al., 2018).

3.5 Acknowledgement

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4. Interventional cardiology procedures involving eye lens exposure

Martina Nesti, Department of Cardiology, S. Donato Hospital (Arezzo) – Italy

4.0 Abstract

Interventional cardiology (IC) is an area of medicine within the subspecialty of cardiology. IC uses specialized imaging and other diagnostic techniques to evaluate blood flow and pressure in the coronary arteries and chambers of the heart, as well as technical procedures and medications to treat abnormalities that impair the function of the cardiovascular system. The main procedures performed by interventional cardiologists are: coronary angiography, electrophysiology studies, pacemaker implantation, percutaneous transluminal coronary angioplasty and radiofrequency catheter ablation.

The radiation dose received by cardiologists during these interventions can vary by more than an order of magnitude for the same type of procedure and for similar patient doses. In the light of the recently updated occupational dose limits, there is particular concern regarding dose to the lens of the eye. A number of different methods are available to minimize occupational radiation doses. In addition to adequate monitoring, provision and use of appropriate personal protective and workplace equipment must be complemented by education with training in radiation protection for all IC personnel.

4.1 Introduction

This chapter describes the main procedures involving the use of x-rays in interventional cardiology (IC). The aim is to give an overview, without describing the dosimetric nor the medical details, in order to explain the use of radiation in the work carried out by interventional cardiologists. The intention is to show why a cardiologist needs x-rays for his or her work.

4.2 Interventional Cardiology

The general term for cardiological procedures involving the use of x-rays is Interventional Cardiology (IC). IC procedures can be divided into two subcategories: those which take place in the electrophysiology (EP) laboratory and catheterization (cath) procedures which take place in the cath lab. In the simplest possible way, EP specialists can be thought of as the “electricians” of the heart; cath specialists as the “plumbers”.

Both EP and cath procedures need dedicated surgical rooms equipped with radiological equipment, and at least 4 professionals present for each case: a doctor, a medical physicist, a radiological technician and a nurse, all of whom may have some level of radiation exposure (ref).

4.2.1 Electrophysiology

Electrophysiology first started in 1958, when Dr Åke Senning and his team carried out the first successful pacemaker implantation for a patient named Arne larsson who had Stroke-Adam syndrome (intermittent complete heart block or other high-grade arrhythmia that results in loss of spontaneous circulation and inadequate blood flow to the brain, characterised by periodic fainting spells (Cooley, 2000; Konstantinov et al., 2004; Aquilina, 2006)).

Two main procedures are commonly used in Electrophysiology: pacemaker implantation and ablation. For illustrative purposes, Figure 4.1 presents the numbers and types of procedures performed in the Department of Cardiology of S. Donato Hospital (Arezzo, Italy) in 2017 and 2019.

Procedure	2017	2019
PM implantation	282	285
ICD implantation	48	58
CRT	17	23
Ablation with NAVEX	23	1
Ablation with CARTO	64	101
Mapping	0	3
SEF	13	23
EPS+CARTO	5	5
Ablation with radiation exposure	14	21
Total	466	520

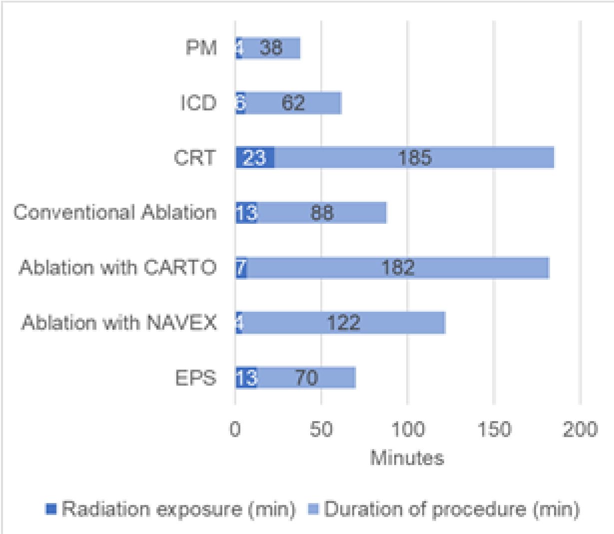

Figure 4.1: Numbers and types of procedures performed in 2017 and 2019 in the Department of Cardiology, S. Donato Hospital, Arezzo, Italy.

4.2.1.1 Pacemaker implantation

A pacemaker implantation (Figure 4.2) is, in simple terms, the introduction into the body of a device that will help the heart function when it is affected by certain pathologies. The device is connected to an electrode that passes through the veins and ends inside the heart. The procedure requires a catheter, a programmer and the device itself. The catheter is composed of body, a fixing mechanism and a connector.

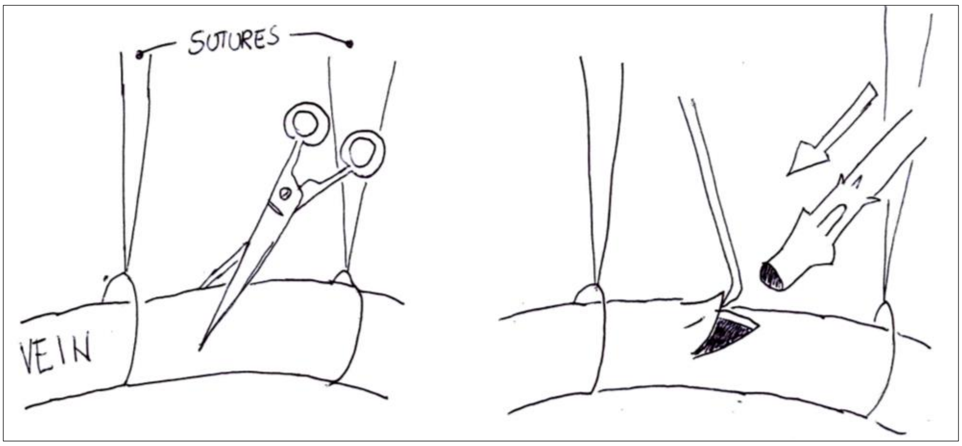

Figure 4.2: Principle of pacemaker implantation: the electrode is introduced into the vein with the aid of a vein retractor.

The implantation, in transvenous access, may start with either the puncture of the subclavian or axillary veins or isolation of the cephalic vein. The device can be a singular (for atrial or ventricular stimulation) or a dual chamber device. An automatic implantable cardioverter defibrillator (AICD; Figure 4.3) device is a pacemaker plus an external automatic defibrillator (EAD), which is used to monitor and help control the heart rate as needed.

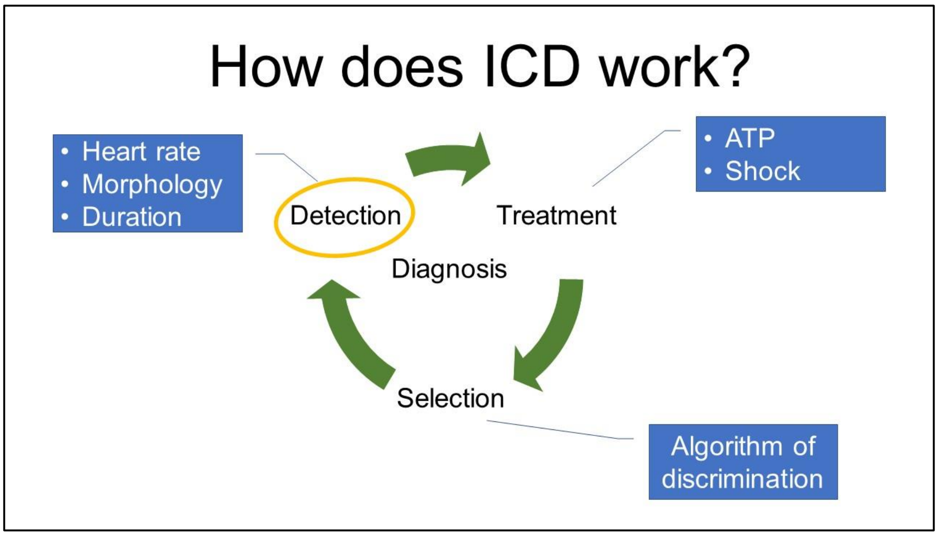

Figure 4.3: The principle functions of an AICD (automatic implantable cardioverter defibrillator).

4.2.1.2 Ablation

Ablation is the second main procedure in electrophysiology. In contrast to pacemaker implantation, ablation is used to gather information on how each part of the heart is functioning, and then to correct the problem using electrodes to introduce scarring which then corrects the arrhythmia.

Figure 4.4 shows (a) the schema of the different techniques for the transvenous access, (b) what the surgeon sees, (c) what a catheter looks like, and how it could be inserted inside the heart, (d) what the electrophysiologist sees on the monitor of the x-ray machine, to help guide positioning of the electrodes.

As is clear from Figure 4.4, in both ablation and pacemaker implantation, x-rays fluoroscopy is required in order to allow the surgeon to follow the progress of the inserted electrodes and check they are correctly positioned prior to the ablation. The fluoroscopy time, and thus radiation doses, can vary a large amount due to the complexities of the procedures, the variation in position and ease of passage through the veins, the size of the patient and the status of his or her vessels. The exposure parameters also may vary, chiefly on the basis of the size and weight of the patient. Casella et al. (2018), for example, found effective doses of between 8.2 and 28.8 mSv for 2416 atrial fibrillation ablation procedures performed between 2010 and 2016 inclusive.

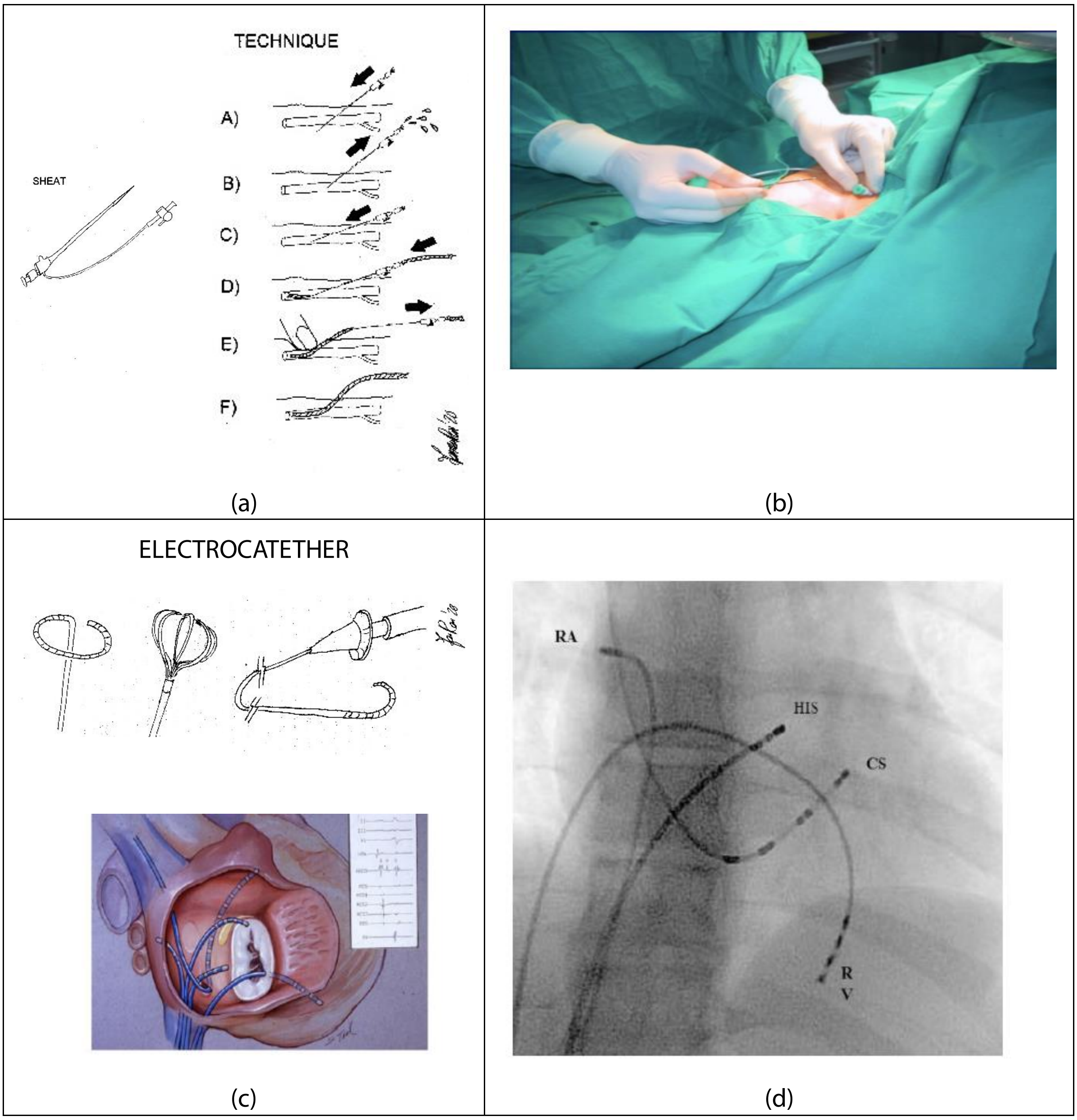

Figure 4.4: (a) schema of the different techniques for the transvenous access, (b) how it looks in the surgical scenario, (c) how a catheter looks like, and how it could be inserted inside the heart, (d) what the electrophysiologist sees on the monitor of the x-ray machine

4.2.2 Cath lab procedures

The first coronary angioplasty was carried out approximately 40 years ago (Barton et al., 2014). It was carried out by Andreas Grüntzig who then, in 1977, performed the first coronary angioplasty with a polyvinyl chloride balloon catheter with short guidewire attached to its tip.

The main cath laboratory procedure is the coronarography. As illustrated in Figure 4.5, coronarography is intended to solve problems due to a stenosis in coronary vessels (a). Coronarography starts with transvenous access, either femoral or radial (b). One of the number of different catheter types is then inserted (c), depending on the access and on the coronary issue (d).

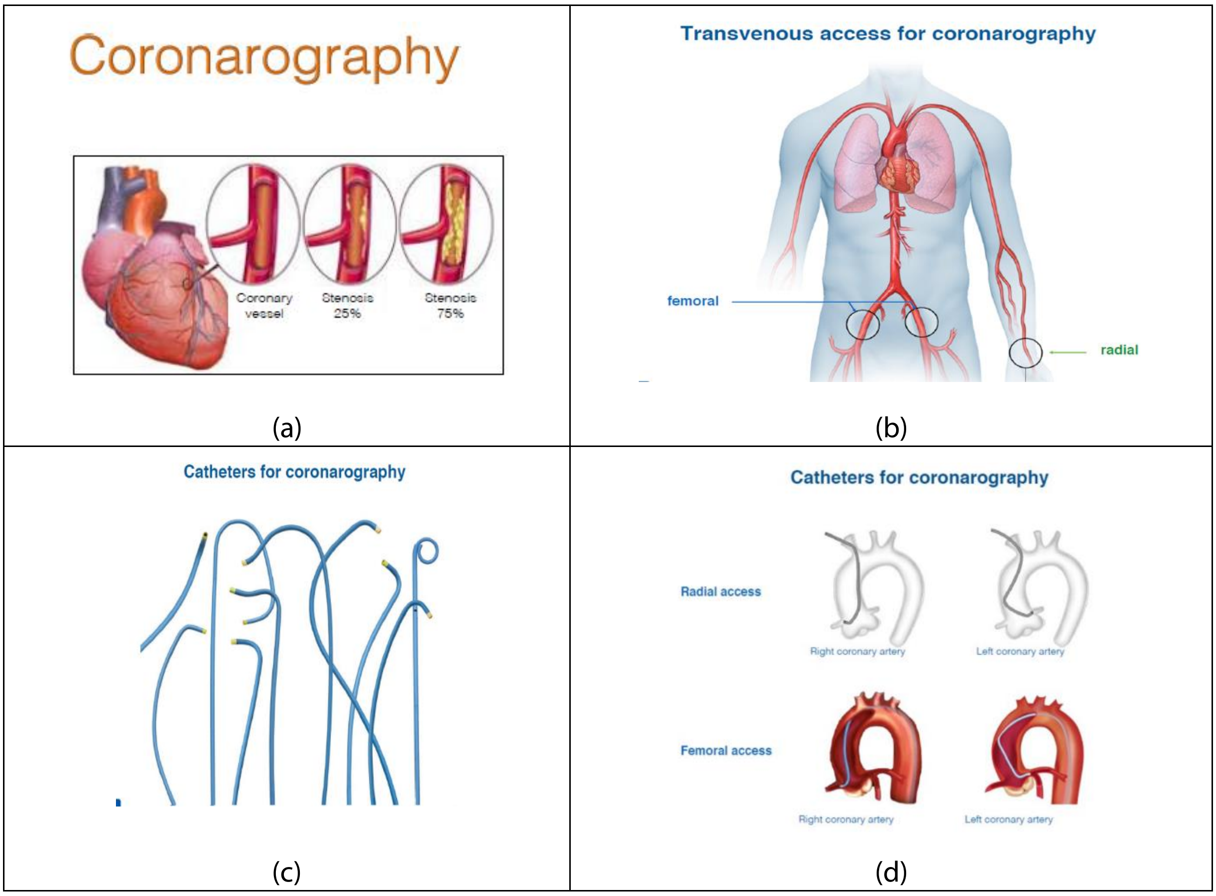

Figure 4.5: (a) stenosis in coronary vessels, (b) transvenous access, either femoral or radial, (c) and (d) catheter types.

As with EP, x-rays are then used to carefully follow the transition of the catheter, as well as to have better identify the position and shape of the stenosis. To facilitate this, x-ray images need to be taken from several different angles. Thus, when coronarography is performed, the x-ray tube must be moved to different positions. Figure 4.6 illustrates the importance of this, and why the time for the procedure and thus the dose delivered to the patient and staff members can vary a large amount depending on the individual patient characteristics, the pathology and the machine itself.

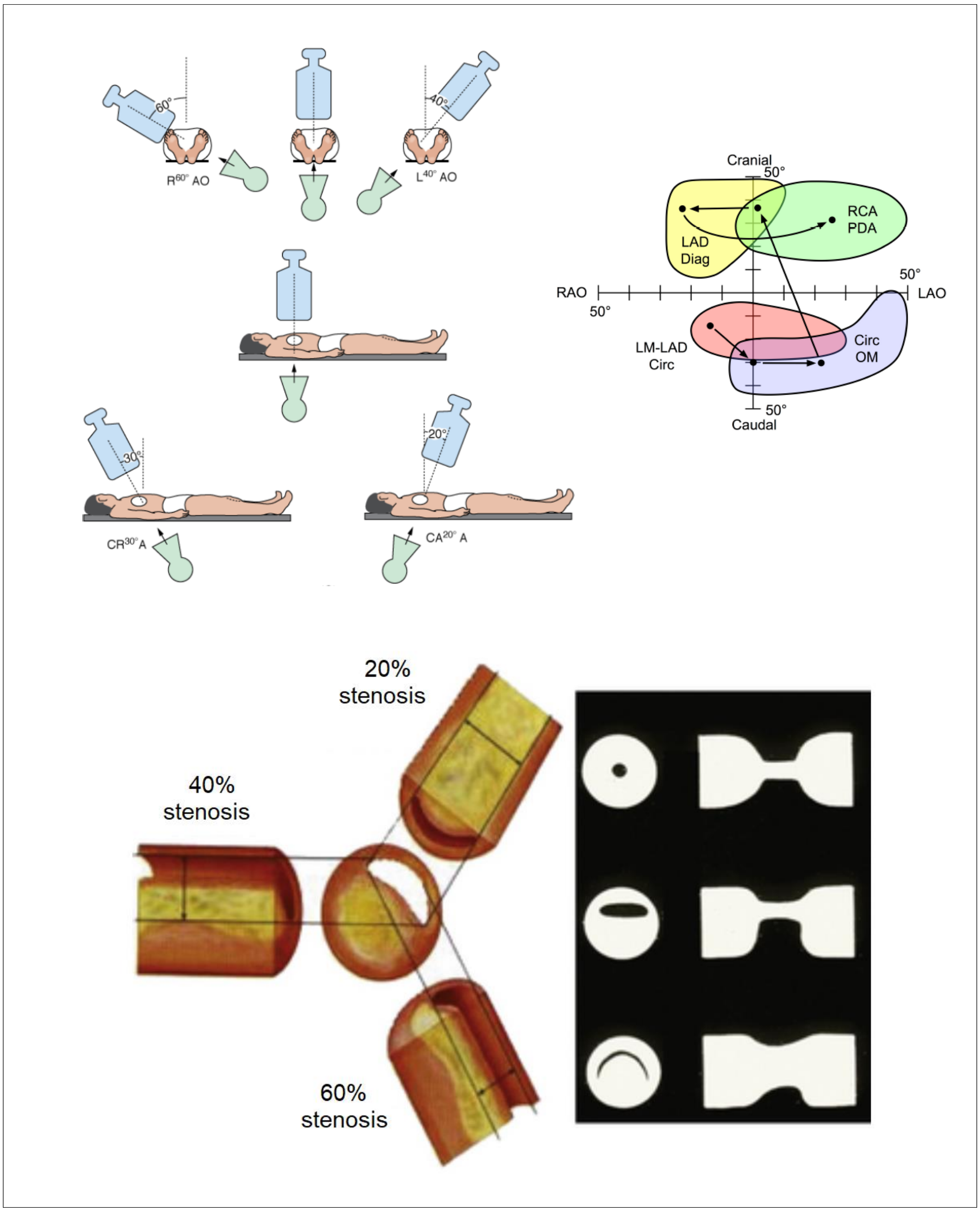

Figure 4.6: Angiographic projections

Ventriculography and aortography are two further interventions which take place in cath lab. The medical rationale for these procedures is different - ventriculography is a medical imaging test used to determine a person's heart function in the right, or left ventricle and aortography is used to diagnose diseases of the aorta (ref). However, from the radiological perspective, the principle is more or less the same as the other procedures discussed thus far. The main difference is that, usually, fewer x-ray images are required, thus doses are likely to be lower.

Very often the coronarography, as it is described here, is immediately followed by another procedure, an angioplasty, which is use of a balloon to stretch open a narrowed or blocked artery. Usually it is not known in advance whether one or both procedures will be required. The coronarography is the diagnostic step, and, if required, the angioplasty is the curative step. If angioplasty is required, it is carried out with a procedure called thromboaspiration, which is done manually or with the aid of a device. Figure 4.7 illustrates how the thrombus is then extracted from the vessel. Angioplasty can also be performed for peripheral departments (e.g. the superficial femoral artery, posterior tibial artery, carotid artery.

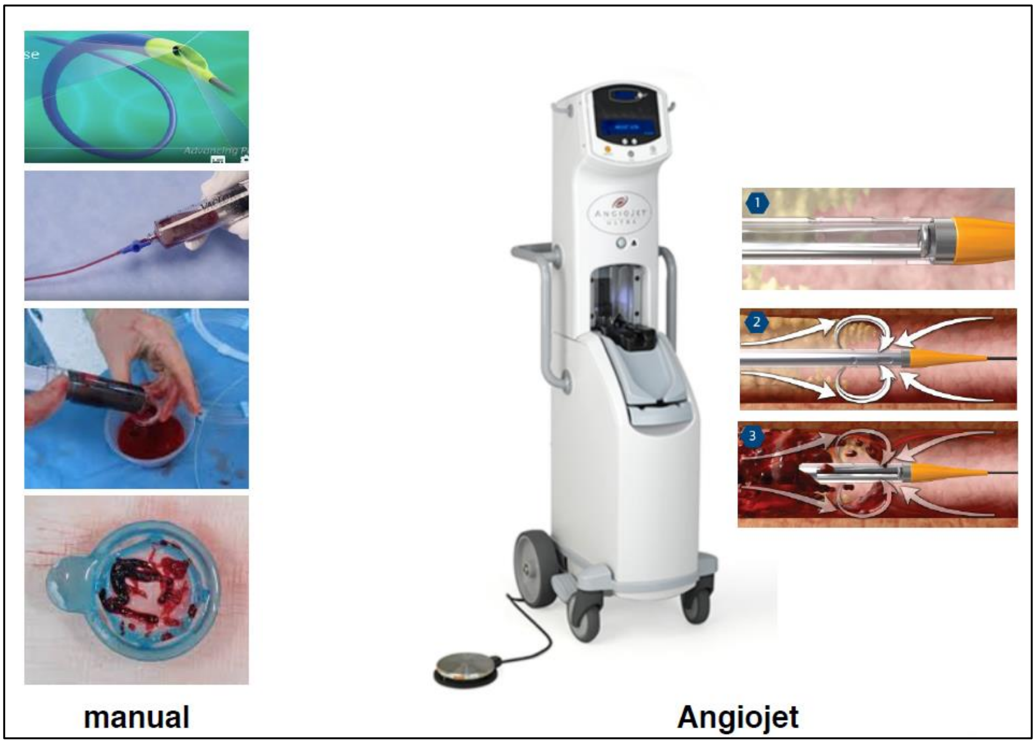

Figure 4.7: Thromboaspiration

4.3 References

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5. Dosimetric units and quantities for eye lens monitoring, standards, type testing, calibration procedures and phantoms

Rolf Behrens, Physikalisch-Technische Bundesanstalt (PTB), Germany.

5.0 Abstract

The International Commission on Radiological Protection (ICRP) have reduced their recommended dose limit for the eye lens from 150 mSv down to 20 mSv per year for occupational exposure (ICRP, 2011). Detailed information is available in ICRP Publication 118 (ICRP, 2012). This recommendation has been adopted in the European directive 2013/59/EURATOM (EU, 2014) and consequently, in national law for all EU member states. As a result of this, several investigations regarding eye lens dosimetry have been carried out. This chapter of the report focuses on dosimetric quantities for eye lens monitoring, type testing, calibration procedures and phantoms and on PTB's activities since then and provides guidance on the published documents which deal with specific issues on eye-lens dosimetry.

5.1 Dosimetric quantities, dosemeters, type test and calibration procedures

First, it is advisable to think about the quantity to be used for the purpose under consideration.

The protection quantity for the lens of the eye is the *Equivalent dose to the lens of the eye*, H_{lens} (ICRP, 2010).

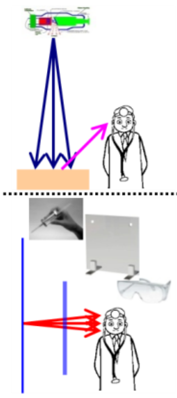
Since 2011, to assist optimization of protection measures to meet the forthcoming reduction of dose limits for the eye lens, investigations were carried out regarding the adequacy of the $H_p(d)$ quantity. Until then, in many countries, dosemeters calibrated in terms of the dose equivalent quantity $H_p(0.07)$ were seen as being adequate for monitoring the dose to the eye lens. However, in the case of reduced dose limits, the use of the dose equivalent quantity $H_p(3)$ becomes necessary. The following papers address the adequate quantity for eye lens dosimetry, and which type of dosemeter is thus suitable to monitor eye lens dose, depending on the type of application:

- R. Behrens and G. Dietze: *Monitoring the eye lens: Which dose quantity is adequate?* Phys. Med. Biol. 55, 4047 (2010) and Phys. Med. Biol. 56, 511 (2011)
- R. Behrens: *Monitoring the Eye Lens*, IRPA13-Beitrag: TS7e.3 (2012)

Figure 5.1 summarises the main results, which are as follows:

In pure photon radiation fields, $H_p(0.07)$ may be used. Then, extremity dosemeters are suitable when worn near the eye and in case they detect radiation scattered back from the head. They can be calibrated on either the ISO water slab phantom or the ISO polymethyl methacrylate (PMMA) rod phantom. Details are available in:

- R. Behrens, J. Engelhardt, M. Figel, O. Hupe, M. Jordan, and R. Seifert: *$H_p(0.07)$ photon dosemeters for eye lens dosimetry: Calibration on a rod vs. a slab phantom*, Rad. Prot. Dosim. 148, 139 (2012)



Radiation field	$H_p(0.07)_{rod}$ / H_{lens}	$H_p(0.07)_{slab}$ / H_{lens}	$H_p(3)_{slab}$ / H_{lens}	$H_p(10)_{slab}$ / H_{lens}
X-ray mean $E < 30$ keV	0.9 – 5	1 – 5	≈ 1	0.01 – 0.9
X-ray mean $E > 30$ keV	0.8 – 0.9	≈ 1	≈ 1	0.9 – 1.2
Beta max. $E < 0.6$ MeV and X-rays	1 – 100	1 – 100	≈ 1	see above
Beta max. $E \approx 1$ MeV and X-rays	1 – 500	1 – 500	≈ 1	$2x10^{-4} – 1$
Beta max. $E > 1.5$ MeV and X-rays	1 – 60	1 – 60	≈ 1	$2x10^{-4} – 1$

$H_p(0.07)_{slab}$ is ONLY adequate for photon radiation.

$H_p(3)$ is NECESSARY for beta radiation.

$H_p(10)$ is NOT adequate for E_{ph}<40keV & ß

R. Behrens and G. Dietze: Phys. Med. Biol. 55 (2010) 4047-4062 and Phys. Med. Biol. 56 (2011) 511

Figure 5.1: Which quantity for the lens of the eye?

In case beta radiation significantly contributes to the dose, $H_p(3)$ is advisable. Details on the use of this quantity and calibration phantom and procedures are available in:

- R. Behrens: *On the operational quantity $H_p(3)$ for eye lens dosimetry*, J. Radiol. Prot. 32 (2012), 455-464

For $H_p(3)$ dosemeters, it is important to mention that both the slab and the cylinder phantoms are suitable for calibration at normal radiation incidence (usually 0°). However, type tests (especially above 30° radiation incidence) should be carried out on a cylinder phantom.

Details regarding the influence of the phantom shape were investigated and results are described in:

- R. Behrens and O. Hupe: Influence of the phantom shape (slab, cylinder or Alderson) on the performance of an $H_p(3)$ eye dosemeter Rad. Prot. Dosim., 168, 441 (2016)

Figure 5.2 summarizes calibration and characterization for eye-lens dosemeters, whilst Figure 5.3 presents calibration, characterization and measurement conditions for whole body, eye-lens and ring dosemeters.

The following papers give conversion coefficients from air kerma to $H_p(3)$ for the slab phantom and cylinder phantom; thus, enabling the performance of photon calibrations and irradiations in terms of $H_p(3)$:

- R. Behrens: *Air kerma to dose equivalent conversion coefficients not included in ISO 4037-3*, Rad. Prot. Dosim. 147, 373 (2011)
- R. Behrens: *Air kerma to $H_p(3)$ conversion coefficients for a new cylinder phantom for photon reference radiation qualities*, Rad. Prot. Dosim. 151, 450 (2012)

Photon area dosemeters can be irradiated or calibrated in terms of $H'(3)$, as conversion coefficients from air kerma to $H'(3)$ for the ICRU sphere are available for both mono-energetic photons as well as for radiation qualities according to ISO 4037:

- R. Behrens *Conversion coefficients for $H'(3;\Omega)$ for photons* J. Radiol. Prot. 37, 354 (2017)

Likewise, beta dosemeters can be irradiated or calibrated in terms of $H_p(3)$ and $H'(3)$, as the Beta Secondary Standard, BSS 2, has been extended:

- R. Behrens and G. Buchholz: *Extensions to the Beta Secondary Standard BSS 2*, Journal of Instrumentation, Vol. 6, P11007 (2011)

Further information on the BSS 2 is available on PTB's website: https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_6/6.3/f_u_e/bss2cons.pdf

Investigations in nuclear medicine yielded dose rate constants of beta-photon nuclides as well as the shielding effect of goggles for beta-photon nuclides are reported in:

- B. Szermerski et al.: *Dose rate constants for the quantity $H_p(3)$ for frequently used radionuclides in nuclear medicine*, Z. Med. Phys. 26 (2016) 304
- I. Bruchmann et al.: Impact of radiation protection means on the dose to the lens of the eye while handling radionuclides in nuclear medicine, Z. Med. Phys. 26 (2016) 298

Conversion coefficients from fluence to the equivalent dose to the lens of the eye, H_{lens}, are given in the following papers:

- R. Behrens, G. Dietze, and M. Zankl: *Dose conversion coefficients for electron exposure of the human eye lens* (just one eye as phantom), Phys. Med. Biol. 54, 4069 (2009) and corrigendum Phys. Med. Biol. 55, 3937 (2010)
- R. Behrens: *Dose conversion coefficients for electron exposure of the human eye lens: Calculations including a full human phantom*, Rad. Prot. Dosim. 155, 224 (2013)
- R. Behrens and G. Dietze: *Dose conversion coefficients for photon exposure of the human eye lens*, Phys. Med. Biol. 56, 415 (2011)
- R. Behrens: *Compilation of conversion coefficients for the dose to the lens of the eye* Rad. Prot. Dosim. 174, 348 (2017)

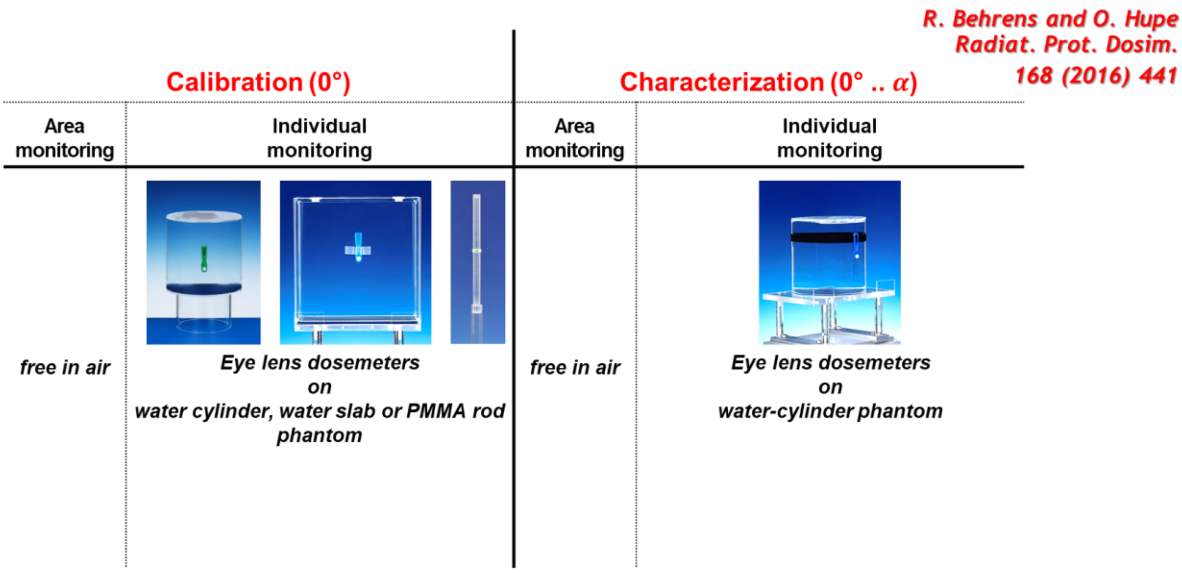


Figure 5.2: $H_p(3)$ eye lens dosemeters: calibration and characterization

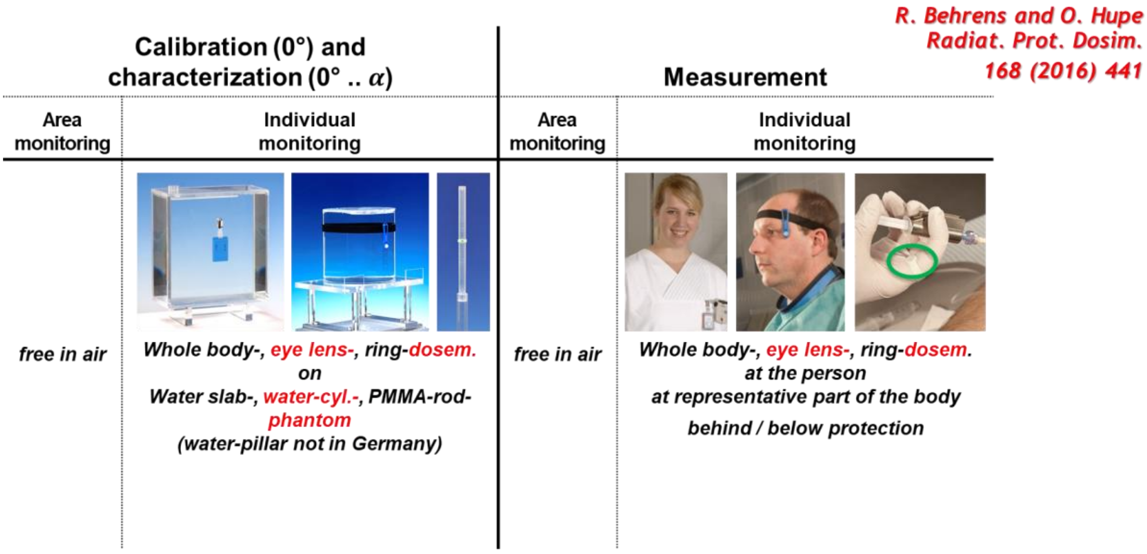


Figure 5.3: Calibration, characterization and measurements

5.2 International documents

Since ICRP recommended the reduced dose limit for the lens of the eye in 2011, and partly even prior to this, on the basis of the increasing weight of evidence for a greater sensitivity of the lens of the eye to ionizing radiation, international organizations began to explore the implications of this.

First of all, the European ORAMED Project was performed within the EC 7th Framework Programme:

- ORAMED Project: Optimization of RAdiation protection for MEDical staff (https://www.oramed-fp7.eu/eu) with a detailed final report published as a EURADOS Report (Vanhavere, 2012) but available also on the ORAMED project website, together with several scientific papers (https:///oramed-fp7.eu/en/papers).

Moreover, IAEA started an action to provide guidance for eye-lens dosimetry in practice, which resulted in the publication of the IAEA TecDoc 1731 (IAEA, 2014). Information is also provided on IAEA's website on both medical staff as well as patient radiation protection:

- https://www.iaea.org/resources/rpop/health-professionals/radiology/cataract/staff
- https://www.iaea.org/resources/rpop/health-professionals/radiology/cataract/patients

Furthermore, several international standards have already been adopted or are currently being revised to implement the operational quantities $H_p(3)$ and $H'(3)$:

- IEC 61331-3: Requirements to medical protective equipment (2014)
- ISO 4037: Photon reference radiation fields (2019)
- ISO 6980: Beta reference radiation fields (2004 – currently in revision)
- ISO 15382: Dosimetry in practice (2015)
- IEC 62387: Requirements to dosemeters (passive) (2020)
- IEC 61526: Requirements to dosemeters (active) (2010 – currently in revision)
- ISO 14146: Routine test for dosemeters (2018)

5.3 Intercomparisons and dosemeter tests

At least three comparisons for eye lens dosemeters in terms of $H_p(3)$ were conducted and a fourth is currently being carried out:

- I. Clairand et al. *First EURADOS intercomparison exercise of eye lens dosemeters for medical applications*. Radiat. Prot. Dosim. 170 (2016), 21-6.
- R. Behrens et al.: *Intercomparison of eye lens dosemeters*, Rad. Prot. Dosim. 174 (2017) 6
- I. Clairand et al.: *EURADOS intercomparison exercise of eye lens dosemeters*, Rad. Prot. Dosim. 182 (2018) 317
- EURADOS Intercomparison 2019 for extremity and eye lens dosemeters (IC2019exteye)

In general, in photon fields, $H_p(0.07)$ and $H_p(3)$ dosemeters perform well, whilst in beta fields $H_p(0.07)$ dosemeters overestimate H_{lens} up to a factor of 5000.

For further information regarding eye lens dosemeter intercomparisons, see also section 11 of this report.

5.4 ICRU proposal for new operational quantities for external radiation

Figure 5.4 shows an overview of the protection quantities and the corresponding operational quantities, used in radiation protection.

However, it is important to note that ICRU Report Committee 26 (https://icru.org/home/uncategorised/report-committee-26) proposed a set of operational quantities for radiation protection for external radiation, directly based on effective dose and for an extended range of particles and energies. It is accompanied by quantities for estimating deterministic effects to the eye lens and the local skin. The proposed operational quantities are designed to overcome the conceptual and technical shortcomings of those presently in use. A summary of the proposed operational quantities, highlightening the improvements with respect to the present, legal monitoring quantities, is presented in:

- T. Otto et al.: *The ICRU proposal for new operational quantities for external radiation,* Rad. Prot. Dosim. 180 (2017) 10

It should be noted that calibration, characterization and measurement procedures remain unchanged and "only" new conversion coefficients are provided, therefore, calibration coefficient and energy dependence change.

The ICRU Publication 95 (ICRU, 2020) has been published in 2020. For direct comparison with Figure 5.4, Figure 5.5 shows the same scenario but with the ICRU Report Committee 26 proposal for new operational quantities.

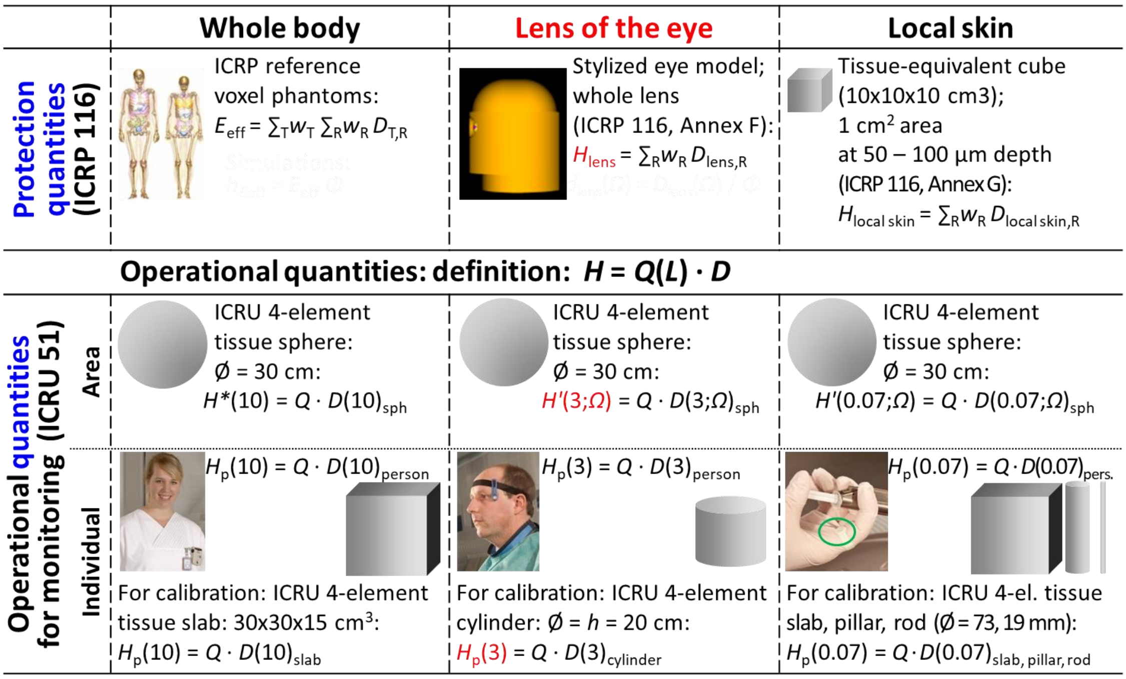


Figure 5.4: Overview of the current protection as well as operational quantities.

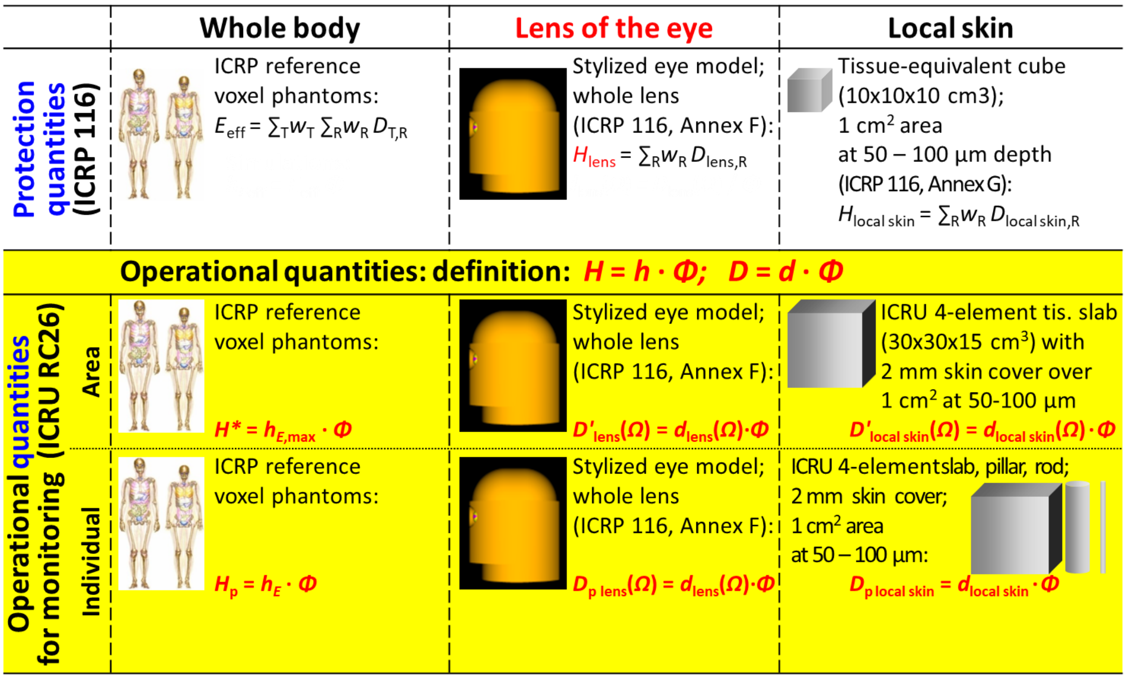


Figure 5.5: Overview of the ICRU proposal for new operational quantities.

5.5 Summary of topics and correspondent relevant publications

The publications listed below are available on PTB's website as well as in the following publications:

- Conversion coefficients for mono-energetic electrons: Φ to H_{lens}: Phys. Med. Biol. 54 (2009) 4069 & Phys. Med. Biol. 55 (2010) 3937 & Rad. Prot. Dosim. 155 (2013) 224

- Conversion coefficients for mono-energetic photons: Φ to H_{lens}: Phys. Med. Biol. 56 (2011) 415
- Compilation of conversion coefficients Φ to H_{lens}: Rad. Prot. Dosim. 174 (2017) 348
- Monitoring the eye lens: Which dose quantity is adequate? Phys. Med. Biol. 55 (2010) 4047 & Phys. Med. Biol. 56 (2011) 511 J. Radiol. Prot. 32 (2012) 455 & IRPA13 contribution TS7e.3
- Conversion coefficients for photon spectra: K_a to $H_p(3)_{slab}$: Rad. Prot. Dosim. 147 (2011) 373
- Conversion coefficients for photon spectra: K_a to $H_p(3)_{cyl}$: Rad. Prot. Dosim. 151 (2012) 450
- Conversion coefficients for photon spectra: K_a to $H'(3)$: J. Radiol. Prot. 37 (2017) 354
- $H_p(0.07)$ photon dosemeters: Calibration on both rod and slab phantom: Rad. Prot. Dosim. 148 (2012) 139
- Type tests only on cylinder phantom: Rad. Prot. Dosim. 168 (2016) 441
- Beta irradiations in $H_p(3)$ and $H'(3)$: Extensions to the Beta Secondary Standard BSS 2: J. Instrum. 6 (2011) P11007 & Erratum & Addendum
- Dosemeter tests: Photon fields: $H_p(0.07)$ and $H_p(3)$ dosemeters perform well Beta fields: $H_p(0.07)$ dosemeters overestimate H_{lens} up to a factor of 5000! Rad. Prot. Dosim. 174 (2017) 6 Rad. Prot. Dosim. 182 (2018) 317
- Nuclear medicine:
  Dose rate constants of beta-photon nuclides: Z. Med. Phys. 26 (2016) 304
  Absorption of googles for beta-photon nuclides: Z. Med. Phys. 26 (2016) 298
- Final report of the ORAMED project (Vanhavere, 2012)
- ICRU proposal for new operational quantities: Rad. Prot. Dosim. 180 (2017) 10

5.6 References

EU, 2014. European Union, 2014. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

IAEA, 2014. INTERNATIONAL ATOMIC ENERGY AGENCY. Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye, IAEA-TECDOC-1731,IAEA, Vienna.

ICRP, 2010. Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures. *ICRP* Publication *116*, Ann. *ICRP* 40(2-5).

ICRP, 2011. Statement on Tissue Reactions – ICRP ref 4825-3093-1464 – April, 21st (2011)

ICRP, 2012. Statement on Tissue Reactions / Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiological Protection Context. *ICRP Publication 118*, Ann. ICRP 41(1/2).

ICRU, 2020. International Commission on Radiation Units and Measurements. *Operational Quantities for External Radiation Exposure* ICRU Report 95, J. ICRU 20(1) (Sage Publishing, Thousand Oaks, CA)

Vanhavere, F., Carinou, E., Gualdrini, G., Clairand, I., Sans Merce, M., Ginjaume, M., Nikodemova, D., Jankowski, J., Bordy, J-M., Rimpler, A., Wach, S., Martin, P., Struelens, L., Krim, S., Koukorava, C., Ferrari, P., Mariotti, F., Fantuzzi, E., Donadille, L., Itié, C., Ruiz, N., Carnicer, A., Fulop, M., Domienik, J., Brodecki, M., Daures, J., Barth, I., Bilski, P., 2012. ORAMED: Optimization of Radiation Protection of Medical Staff. EURADOS Report 2012-02, ISSN 2226-8057, ISBN 978-3-943701-01-2. Braunschweig.

6. Occupational exposure of the eye lens in interventional procedures: how to assess and manage radiation dose

Olivera Ciraj Bjelac, Vinca Institute of Nuclear Science, University of Belgrade, Serbia; **Eleftheria Carinou**, Greek Atomic Energy Commission (EEAE), Greece; **Paolo Ferrari,** Radiation Protection Institute (ENEA), Italy; **Merce Ginjaume**, Universitat Politecnica de Catalunya (UPC), Spain; **Marta Sans Merce,** Institute of Radiation Physics, University Hospital of Lausanne (CHUV) and University Hospital of Geneva (HUG), Switzerland and **Una O'Connor**, St. James's Hospital, Ireland.

6.0 Abstract

Following the results of a number of studies on radiation cataractogenesis, the International Commission on Radiological Protection has re-evaluated the dose limit for lens of the eye and recommended a reduction of the dose limit for the eye lens for workers from 150 mSv to 20 mSv per year. With this, the number of situations requiring specific eye lens monitoring is likely to increase. Occupational exposure from interventional x-ray procedures is one of the areas in which increased eye lens exposure may occur. Contrary to whole body dosimetry, eye lens dosimetry is currently not well established and numerous studies have been carried out to investigate various aspects of eye dosimetry, including the development of new dedicated eye dosimeters and calibration procedures.

Accurate dosimetry is an important element to investigate the correlation of observed radiation effects with radiation dose, to verify the compliance with regulatory dose limits and to optimize radiation protection practice. According to the International Commission on Radiation Units and Measurements (ICRU), the operational quantity $H_p(3)$ is the most appropriate quantity to monitor the eye lens dose. Several important initiatives were undertaken to develop eye lens dosimeters calibrated in terms of $H_p(3)$. The position of the eye lens dosimeter should be as close as possible to the eye, preferably in contact with the skin and the detector should face the radiation source. In particular, in interventional procedures, the dosimeter should be on the side closest to the x-ray tube and when protective lead glasses or face masks are used, the dosimeter should be worn behind these protective tools. Alternatively, the dosimeter could be worn above the protective equipment and an appropriate correction factor can be applied. If a specific dosimeter is not available, $H_p(3)$ can be estimated through dosimeters calibrated in terms of the ICRU quantities $H_p(10)$ and $H_p(0.07)$ by using proper correction factor, which is associated with larger uncertainty. In the absence of any dose measurement, the eye lens dose could be assessed from other indirect parameters, such as patient dose. The accuracy of the assessed dose is affected by the quality of the information provided and by the assumptions made.

The factors influencing eye lens dose can be grouped into a few main categories: beam orientation, access route, fluoroscopy settings and operating mode, use of protective tools (shielding screens, glasses) and factors related to the operator such as workload, skill and training. The use of lead glasses with a good fit to the face, appropriate lateral coverage and/or ceiling suspended screens is recommended in workplaces with potential high eye lens doses. In general, a typical dose reduction factor for a single shielding tool is 5-25 and for combination of tools is 25 or more, even up to a factor of 1000.

Eye lens exposure can be optimized with careful use of geometry, taking into account clinical requirements. Personal protective equipment should be used routinely; lead glasses with a good fit

to the face, good lateral coverage and/or ceiling suspended screens should be used to optimize eye dose. However, the practical implementation of monitoring eye lens doses still remains a challenge.

6.1 Introduction

Radiation-induced cataract was first reported in an experimental study in the early days of use of x-rays in medicine, only a year following the discovery of the x-rays (Chalupecky, 1897). In recent years, following the results of a number of studies on radiation cataractogenesis, the International Commission on Radiological Protection (ICRP) re-evaluated the dose limit for the lens of the eye, based on the new findings that lens opacities may occur at thresholds lower than previously thought. Furthermore, at lower doses and dose rates, similar to those that might be encountered in occupational practice in medicine, visually disabling cataracts may occur over many years (ICRP, 2012a; Rehani et al., 2011; Shore et al., 2010). Consequently, ICRP has set the threshold dose for radiation-induced eye cataracts to be around 0.5 Gy for both acute and fractionated exposures (ICRP, 2012a) and recommended a reduction of the dose limit for the eye lens for workers from 150 mSv to 20 mSv per year (ICRP, 2012a). This reduction has become the subject of intensive scientific debate, including authors who justified (Bouffler et al., 2012; IAEA 2013) and challenged (Martin, 2011a) the proposals. As new evidence on eye lens injuries associated with exposure to ionizing radiation have become available, eye lens dosimetry has also become a very active research area (Thorne, 2012; Ciraj-Bjelac et al.; 2012, Jacob et al., 2013a).

Eye lens dosimetry is important for the investigation of correlation of observed radiation effects with dose; it contributes to better radiation protection and provides tools for verification of compliance with regulatory dose limits. Until recently eye lens dosimetry has not been well established and the International Commission on Radiation Units (ICRU) operational quantity, personal dose equivalent at depth 3 mm, $H_p(3)$, has hardly been used in practice. Furthermore, the accuracy and practicality of eye lens dose assessment still remains a challenge in medical field (ICRU, 1985). Therefore, the objective of this chapter is to (i) review eye lens dose levels in clinical practice that may occur from the use of ionizing radiation in fluoroscopy-guided interventional procedures; and (ii) to review eye lens dose monitoring arrangements and dose assessment methods including impact of potential dose reduction factors.

6.2 Eye lens injuries due to occupational exposure in interventional procedures

Occupational exposure in medicine is one of the areas in which increased eye lens exposure is likely to occur, in particular in fluoroscopy guided procedures in radiology and cardiology (Farah et al., 2013; ICRP 2012b). Other areas include orthopedic surgery, urology, anesthesiology, vascular surgery, CT fluoroscopy and gastroenterology (ICRP, 2012b; Martin, 2009; Jacob et al., 2013b; Antic et al., 2013; Bor et al., 2009; Efstathopoulos et al., 2011; Koukorava et al., 2011; Heusch et al., 2014; Paulson et al., 2001).

One of the first studies performed on interventional radiologists, reported that the prevalence and severity of posterior subcapsular cataract (PSC) was associated with age and years of practice in interventional procedures (Junk et al., 2004). Approximately half of those examined had early lens changes including posterior dots and vacuoles associated with radiation exposure (ICRP, 2012a). Recently, other pilot studies in collaboration with the International Atomic Energy Agency (IAEA) and professional cardiology societies have investigated the relationship between such occupational exposure and subsequent eye lens changes (Rehani et al., 2011; Ciraj-Bjelac et al., 2012; Vano et al., 2010; Ciraj-Bjelac et al., 2010). PSC opacities were found in 38% of examined cardiologists and 21% of paramedical personnel, compared with 12% of controls. Cumulative occupational mean eye lens doses were estimated at 6.0 Sv for cardiologists and 1.5 Sv for associated staff when eye lens protection was not used (Vano et al., 2010; Ciraj-Bjelac et al., 2010). A strong dose–response relationship between occupational x-ray exposure and detectable posterior eye lens changes in interventional cardiologists was reported. Another large study included prospective analysis accompanied by a 20-year follow-up of more than 35,000 radiological technologists and assessed the risk for eye lens opacification and cataract (Chodick et al., 2008). The study provided evidence that exposure to relatively low doses of ionizing radiation (lifetime dose up to 60 mGy) may be harmful to the eye lens and increases the long-term risk of cataract formation. The findings suggested that likelihood of cataract formation increases with increasing exposure to ionizing radiation with no apparent threshold level. These studies highlighted the need for accurate assessment of eye lens dose in clinical practice.

6.3 Approaches in eye lens dose assessment in clinical practice

Numerous studies were carried in the last decade, with an aim to investigate various aspects of eye lens dosimetry, such as the development of new dedicated eye lens dosemeters and calibration procedures (Vano et al., 2010; Jacob et al., 2013a; Carinou et al. 2015; Ferrari et al., 2007; Behrens et al., 2011; Bordy et al., 2011; Bilski et al., 2011). Furthermore, clinical studies have been conducted to discuss the methodology of the assessment of the eye lens dose levels, to investigate the monitoring arrangements using different types of dosemeters, to study correlations of eye lens dose with patient dose indices and to perform retrospective eye lens dose assessment (Jacob et al., 2013b; Antic et al., 2013; Efstathopoulos et al., 2011; Heusch et al., 2014; Carinou et al., 2015). At present, the approaches in eye lens dose assessment are based on the use of passive dosemeters, including double dosimetry, on active dosimetry or retrospective dose assessment.

6.3.1 Eye lens dose assessment using passive and active dosemeters

The operational quantity, personal dose equivalent, $H_p(3)$, is the most appropriate quantity to monitor the eye lens dose (ICRU, 1985). Recently, several important initiatives were undertaken to develop eye lens dosemeters calibrated in terms of $H_p(3)$ (Bilski et al., 2011; Gilvin et al., 2013; Ferrari et al., 2016; Clairand et al., 2016; Behrens et al., 2012). All these new devices should conform to suitable calibration procedures and type tests (Bordy et al., 2011). If a dedicated dosemeter (and appropriate correction factors) is not available, $H_p(3)$ can be estimated through routinely used dosemeters calibrated in terms of $H_p(10)$ and $H_p(0.07)$ if adequate correction factors are used (IAEA, 2013; Behrens and Dietze, 2011; Behrens, 2012). It is important to underline that in this case, the uncertainty of the dose measurements can be significantly higher.

Double dosimetry is based on use of two dosemeters, one at chest level under the apron and another, at collar level above the apron. A dosemeter located at collar level over the apron can be used for eye dose assessment, if suitable correction factor is applied (ICRP, 2018; Vanhavere et al., 2011). If a collar dosemeter is used, the correction factor can vary from 0.4 (Martin, 2011b) to 1.4 (Geber et al., 2011), due to the difference in radiation field characterizing the measuring point where the dosemeter is placed, with respect to the operator's head. Nevertheless, in this case, certain practical issues common for individual monitoring in general, need to be considered, such as unavailable double dosimetry, unknown position of the dosemeters, irregular or erratic use of dosemeters and variability in practice among the countries.

Active personal dosemeters in a form of small detectors clipped onto glasses or otherwise worn on the head enable direct monitoring of eye dose. They provide dose assessment in real time and evaluation of dose per single procedure. Such dosemeters are important part of operational radiation protection and can be an effective tool for reduction of occupational doses (Ciraj-Bjelac et al., 2014; Clairand et al., 2011; Ginjaume et al., 2011), however, they must meet certain requirements to be suitable for the assessment of the occupational exposure in medical applications (Vanhavere et al., 2011; Clairand et al., 2011; Struelens et al., 2011).

Dosimetry in real time is either based on ambient monitors (Omar et al., 2017) or assessment of scatter dose levels in real time (Vano et al., 2011). Real time dosimetry has a significant educational role, can be a backup to personal dosimetry, can be used to gather dose information retrospectively, to assess working habits, for staff comparison, for assessment of correlation of dose rate with cumulative dose to staff, and for assessment of correlation of staff dose to patient dose for different procedures. Furthermore, methods of computational dosimetry can be also used as backup to personal dosimetry, for auditing the regular and proper use of personal dosemeters and for assessing the need for additional protection. Computational technologies are those that do not require physical dosemeters, and these can be combined with position tracking to calculate personnel doses (ICRP, 2018; Ciraj-Bjelac et al., 2016; Podium, 2020).

Appropriate dosimetry arrangements require balance between accuracy and practicality. Ideally, for accurate eye lens dose assessment, dosemeters should be type tested and calibrated in terms of $H_p(3)$ using an appropriate phantom. The best position of dosemeters is on the side of the head nearest to the radiation source, either behind the protective glasses (which is not very convenient) or above the glasses (with suitable correction factor). However, the dosemeters must not interfere with the wearer's vision. In interventional practice the use of 3 or more dosemeters (e.g. chest, collar, eye) brings into focus the issue of practicality, in particular in terms of reliability and consistency of dosimetry. This is the reason why, if the radiation field is well known, $H_p(3)$ can be estimated employing, on apron, whole-body dosemeters calibrated in terms of $H_p(0.07)$ and $H_p(10)$ (ICRP, 2018; Ciraj-Bjelac et al., 2016).

6.3.2 Retrospective eye lens dose assessment

Retrospective dose assessment relies on either correlation of eye lens dose to patient dose or on scatter dose rate and typical exposure parameters for particular procedures.

An approach based on kerma-area product (P_{KA}) has been used to perform, for example, a retrospective dosimetry for the medical staff. The accuracy of the assessed dose is affected by the quality of the provided information and by the assumptions made (Antic et al., 2013; Vanhavere et al., 2011; Ciraj-Bjelac et al., 2016). The difficulties in establishing a good correlation between the P_{KA} and medical staff eye lens dose are due to a number of influencing factors such as tube orientation, beam collimation, access route, working practices and use of protective devices (eye lens lead glasses, lead shielding, etc). Therefore, at present, there is no clear consensus in the literature about the use of correlation factors to convert patient dose to eye lens dose to the staff. However, data regarding normalized eye lens dose per unit P_{KA} , can be found in the literature (Ciraj-Bjelac et al., 2016; Vano et al., 2013b ; Pirchio et al., 2014; Burns et al.; 2013, Kim et al.; 2008, Sanchez et al., 2010; Ubeda et al., 2013; Vano et al., 2008; Kong et al., 2015; O'Connor et al., 2013; Ho et al., 2007; Safak et al., 2009; Bush et al., 1985; Tsalafoutas et al., 2008 ; Krim et al., 2011 ; Vano et al. ; 1998, Pratt et al., 1993; Lie et al., 2008; Dauer et al., 2010; Vano et al., 2013a) and are presented in Table 6.1.

Table 6.1 Typical measured eye lens dose levels and eye lens dose normalized to respective kerma-area product (P_{KA}) in various fluoroscopy guided procedures, adopted from Ciraj-Bjelac et. al. (2016)

Type of procedure	Eye lens dose per procedure (µSv)	Eye lens dose/ P_{KA} (µSv $Gy^{-1}cm^{-2}$)
Interventional cardiology, first operator, various procedures, dose with protective tools	121±84 (4.5-370)	0.94±0.61
	52±77 (4-644)	1.0
	3.3-1040	-
	170 (53-460)	3.3-6.0
	13 (0-61)	1.37
	72 (32-107)	0.86 (0.46-1.25)
	66 (5-439)	1.0
	-	1.0
	15-53	-
	23 (10-230)	0.4 (0.2-2.6)
Interventional cardiology, first operator, various procedures, dose without protective tools	-	10-11
	300-2500	3.2-3.4
Various Interventional radiology, procedures, with protective tools	47 (0-557)	1.19
Hepatic chemoembolization	270-1070/16 -64 (unprotected/protected)	-
Iliac angioplasty	250-1110/15-66 (unprotected/protected)	-
Neuroembolization (head)	1380-5600/83-336 (unprotected/protected)	-
TIPS creation	410-1860/25-112 (unprotected/protected)	-
Anesthethesiology, various procedures	44	0.278-1.305
Gastroeneterology, ERCP	90/10 (unprotected, overcouch/undercouch)	0.98-1.4/14-21 (unprotected, undercouch/overcouch)
Vascular surgery, EVAR	10 (unprotected)	-
Urology, various procedures	26 (unprotected)	-
Urology, percutaneous renal calculus removal	100 (unprotected)	-
Orthopedic surgery, various procedures	50 (unprotected)	-
CT fluoroscopy, various procedures	7-48	-
CT guided interventions	3.5 (0.2–39.9)	-
Various procedures	-	0.47-0.84

Another alternative is to assess eye lens dose from the dose evaluated in a "typical" procedure and multiply it by the number of procedures performed by the worker. Because of the variability of the doses evaluated during different practices (Vanhavere et al., 2011) such methodology should be used carefully. The estimated doses can be corrected, when appropriate, by a dose reduction factor if protective tools are used (Ciraj-Bjelac et al., 2012; Vano et al., 2010). This approach has been used in a number of eye epidemiological studies, as presented in Table 6.2.

Table 6.2 Results of retrospective dose assessment for interventional cardiologist in different studies

Professional group	Cumulative dose	Reference
Cardiologists	(25-1600) mSv	Jacob et al. (2012)
Cardiologists	(0.1-18.9) Sv	Vano et al. (2013a)
Cardiologists and support staff	(0.1 – 21) Sv	Ciraj-Bjelac et al. (2010)
Cardiologists and support staff	(0.1-27) Sv	Vano et al. (2010)

Both approaches are associated with large uncertainty (of order of magnitude) due to the variable position of the operator and other staff members in the room, technical and physical factors, social desirability and memory bias, as well as due to uncertainty related to the efficiency of protective tools and their use. In such cases, validation by means of measurements is needed (Pirchio et al., 2014). Nevertheless, this approach is also used to predict annual eye doses in risk assessment (typical dose per procedure x predicted workload for the year), which is further discussed in the section 1.6.

6.4 Current status of eye lens dose levels

Clinical studies have provided a valuable input to recent knowledge about methods for eye lens dose assessment and assessed dose levels. However, there is a huge variety in both dosimetry approaches and reported results, which makes comparison and overall use of the available dosimetric data very difficult. Eye lens doses were assessed in various clinical set-ups, using both measurements on phantoms, as scattering medium and operator, and measurements on operators during various interventional procedures. Information about routine use of eye lens dosimetry is generally lacking. The dose data is available mainly for the first operator and occasionally for other staff members such as nurses and radiographers. As expected, the reported range of doses is huge, from few µSv to few mSv, as already presented in Figure 6.1.

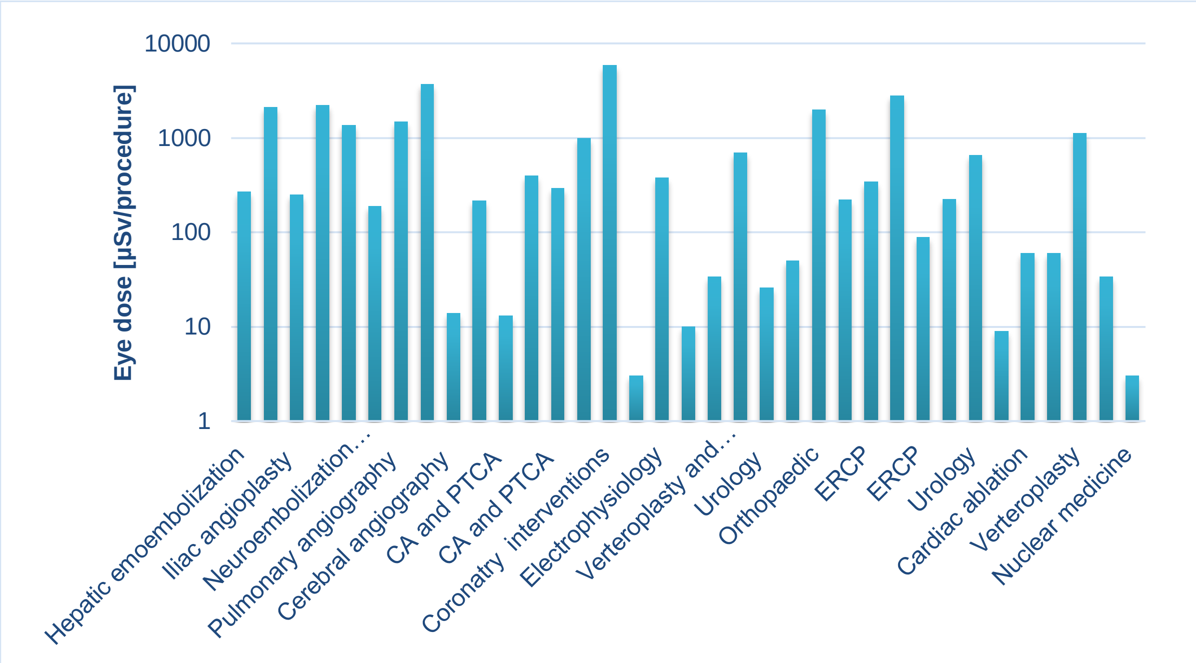


Figure 6.1: Typical eye lens dose levels (per procure) for various fluoroscopy procedures

Unprotected eye lens dose values vary up to 250- fold for different fluoroscopic views (Burns et al., 2013) and reported eye lens dose values per procedure range from less than 0.1 to 1100 µSv (Kim et al., 2008). Multiple acquisition modes are used in clinical conditions (Sanchez et al., 2010; Ubeda et al., 2013) in which dose rate at the level of the operator's eye ranges from 1-22 mSv h^{-1} (fluoroscopy) to 12-235 mSv h^{-1} (DSA- digital subtraction angiography). Eye lens doses for seven interventional radiology systems were measured using phantoms simulating patients 16–28 cm in thickness undergoing low-, medium- and high-mode fluoroscopy, cine cardiac imaging and Digital Subtraction Angiography -DSA (Vano et al., 2008). Mean dose rates to the eye lens during fluoroscopy were between 6 and 35 mSv per min for the low- and high-dose scenarios, respectively. Similar estimations were performed for hepatic chemoembolisation, iliac angioplasty, pelvic embolisation, and transjugular intrahepatic portosystemic shunt creation. Assessed eye lens doses for these procedures ranged from 0.25 to 3.72 mSv per procedure when protection was not used and from 11 to 330 µSv with use of protective tools (Vano et al., 2008; Kong et al., 2015; O'Connor et al., 2013; Ho et al., 2007; Safak et al., 2009; Bush et al., 1985; Tsalafoutas et al., 2008; Krim et al., 2011; Vano et al., 1998; Pratt et al., 1993; Lie et al., 2008; Dauer et al., 2010; Vano et al., 2013a).

6.5 Factors influencing dose to the eye lens

The factors influencing the eye lens dose can be grouped into a few main categories: those which are patient related, equipment related and those procedure or practice related. Patient related factors are connected to the clinical problem and thus, to the fluoroscopy time and number of images and to the size of the patient. The equipment related factors include: geometry of the x-ray tube (undercouch/overcouch), use of biplane systems, performance characteristics of the x-ray system, including the machine settings, the scatter radiation distribution, etc. The practice related factors are: use of protective tools, position of the staff relative to the x-ray tube and patient, projections used, exposure setting, collimation, access route and workload and physician's experience and skills (Vanhavere et al., 2011; Koukorava et al., 2014).

The highest exposure to the operator is associated with left anterior oblique (LAO) and cranial projection (Koukorava et al., 2011; Vanhavere et al., 2011). In particular, due to distribution of the scatter radiation, LAO projection, which is common in clinical practice, delivers 3-7 times higher dose to the eyes compared to right anterior oblique (RAO) projection. Furthermore, the over-couch x-ray tube geometry delivers, on average, 12 (range 2-27) a times higher dose to the operator's eye compared to the undercouch geometry. Moreover, the efficiency of lead glasses as a protective tool strongly depends on their orientation with respect to the scattered radiation and their design; for example, their transmission for oblique projections can be up to 90% (Geber et al., 2011).

The use of lead glasses provides effective protection for the eye lens, but there are issues of comfort and practicality. The glasses are usually heavy and may slip down from the bridge of the nose, which creates a particular problem when performing sterile procedures (Martin, 2009). Published dose reduction factors can vary significantly and range from 1.4 to 10 (Burns et al., 2013; Sturchio et al., 2013). The air gap between the glasses and the eyes was found to be the primary source of scattered radiation reaching the eyes (Geber et al., 2011; Sturchio et al., 2013; Thornton et al., 2010). Therefore, larger glasses with better lateral coverage provide better dose reduction.

Multiple studies, based on Monte Carlo techniques or measurements performed either on phantoms or on operators, have stressed the importance of protective equipment, such as ceiling suspended shields and lead glasses (Carinou et al., 2015; Koukorava et al., 2014; Ferrari et al., 2016; Sturchio et al., 2013; vanRooijen et al., 2014). In general, a typical dose reduction factor for a single shielding tool is 5-25 and for combination of tools is 25 or more, even up to a factor of 1000 (vanRooijen et al., 2014; Thornton et al., 2010).

6.6 Eye lens monitoring arrangements

The 2013 revision of the BSS of the EU (EU, 2014) sets the European framework for the protection of the eye lens against the danger arising from exposure to ionising radiation, including dose limits for members of the public and for exposed workers. Early 2018, the new limit was implemented in the national legislation in all European member states (NCS, 2018). With introduction of the new dose limit for the eye lens, the number of situations requiring specific eye lens monitoring is likely to increase (IAEA, 2013; NCS, 2018). Prior to undertaking routine individual monitoring for the eye lens, the dose levels should be estimated in order to determine which method, if any, should be used as well as the length of monitoring period (IAEA, 2013). These can be deduced from workplace monitoring results, available literature data, from simulations or from results of the individual monitoring for a limited time. Furthermore, according to the BSS a prior risk assessment should be performed for all employees who are exposed to ionising radiation. The risk assessment should result in an estimate of the dose that an individual worker is liable to receive, including the equivalent eye lens dose. When the prior risk assessment results in an eye lens dose of more than 15 mSv per year, the employee must be classified as a category A worker (EU, 2014), which requires a systematic individual monitoring.

According to other international recommendations, routine monitoring of the eye lens dose should be undertaken if the provisional estimation indicates that the annual equivalent dose to the eye lens is likely to exceed a certain dose level, such as 5-6 mSv (i.e. 3/10 of the dose limit) (IAEA, 2013; Martin, 2011b; IRPA, 2017). A pilot individual monitoring assessment is one of the best approaches to identify workers that require eye lens monitoring and to decide on the best dosimetry system; for instance, eye lens monitoring may be necessary in interventional radiology and cardiology departments. Staff involved in fluoroscopy used outside the imaging departments may also be considered as workers to be monitored for eye lens dose monitoring, particularly for high workloads.

For example, eye dose per procedure in interventional neuroradiology procedures is estimated to 248 µSv and 18 µSv without and with glasses, respectively. In this case, the number of procedures that can lead to the cumulative dose of 20 mSv is 600 and 120 per year, with and without glasses respectively. The reported dose of other fluoroscopy guided procedures (in gastroenterology, gynaecology, urology) ranges from 0.1 to 0.5 mSv per procedure, with average of 13 mSv per year (Tavares et al., 2016; Bahruddin et al., 2016). Annual doses to interventional cardiologist are reported to be about 10 to 20 mSv per year (Betti et al., 2019).

The position of a dedicated eye lens dosemeter should be as close as possible to the eye, preferably in contact with the skin and the detector should face the radiation source. In particular, in interventional procedures, the dosemeter should be on the side closest to the x-ray tube and when protective lead glasses or face masks are used, the dosemeter should be worn behind these tools, which is not very convenient in most cases. Alternatively, dosemeter could be worn above the protection and appropriate correction must be applied.

When the use of a dedicated eye lens dosemeter is impractical, the eye lens dose can be alternatively evaluated using a dosemeter at trunk or thyroid level above the protective tools (Farah et al., 2013). An approximate correction factor of 0.75 to estimate the eye lens dose from this unprotected dosemeter is recommended by several authors (Carinou et al., 2015). This method for the estimation of the eye lens doses is associated with large uncertainty and great caution is needed if the measured dose levels are close to the dose limits.

In the absence of any dose measurement, the eye lens dose could be estimated from patient dose, using the conversion from P_{KA} to eye lens dose of 1 µSv $Gy^{-1}cm^{-2}$, when protective tools are used, and 10 µSv $Gy^{-1}cm^{-2}$ for situations without protection. Indeed, the P_{KA} provides an ideal patient dose quantity, since it gives a measure of the total radiation emitted, which is linked to the amount of scatter to which operators are exposed. However, in this case the uncertainty and variability is even larger.

6.7 Conclusions

Accurate dose measurements are a prerequisite for investigation of low dose effects to the lens of the eye. Dedicated and calibrated dosemeters are available nowadays. Whenever direct monitoring of eye lens dose in terms of $H_p(3)$ is not available, the eye lens dose could be estimated using other available methods, as whole-body dosemeters or patient dose indices; however, an extra uncertainty factor should be considered. The question of what dose monitoring is appropriate for an interventional facility is not straightforward. Possible options include active and passive dosimetry and link to the patient dose indices (with larger uncertainty).

The situation with eye protection is rather optimistic. If radiation protection tools, the most importantly protective screens or lead glasses are used, the risk for eye injuries is controlled. The protective tools are advised for staff performing interventional procedures in radiology and cardiology, as well as for personnel using fluoroscopy outside imaging departments. Furthermore, if x-ray equipment of properly maintained and used, one can keep the radiation dose to eye lens at the minimal level.

6.8 References

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7. Eye lens monitoring: how is it implemented in different countries?

Eleftheria Carinou, Greek Atomic Energy Commission (EEAE), Greece.

7.0 Abstract

In the framework of the implementation of the Basic Safety Standards, in European and international level, a lot of concern has been raised about the regulatory and practical implementation of eye lens dose monitoring requirements. One important step towards this direction for the Member States is the revision and review of the respective national legislative framework; and the second is the practical implementation arrangements related to eye lens exposure. Taking these challenges into account, EURADOS WG12 organised a survey at the end of 2017, through a web questionnaire regarding the national dose monitoring regulations. The questions were related, inter alia, to the methodology for the determination of the equivalent dose to the lens of the eye and their registration to the National Dose Registry (NDR).

The results of the questionnaire showed that, in 14 out of 26 countries that answered to the questionnaire, there is a legal requirement to estimate the dose to the lens of the eye. In almost half of the countries the dosemeter above the protection is being used for the estimation of the dose to the lens of the eye. Moreover, all of the responding countries use a kind of national database for keeping the individual monitoring data but the personal dose equivalent at depth 3 mm, $H_p(3)$, which is used as the operational quantity for the eye lens exposure, is stored in the NDR of only 7 out of 26 countries. The results of the survey should not be interpreted as a clear realistic view on the current regulatory status of the eye lens monitoring arrangements due to the time period that the survey has been conducted. Many of the countries that participated in the survey were in the process of drawing their roadmaps for drafting and implementing the new basic safety standard regulations set in the international and European scene per 2018. The results of the survey are in agreement with the results of the review regulatory services performed by IAEA in various Member States.

Since the survey was performed just before the implementation of the European Basic Safety Standards Directive it is seen that the national occupational exposure framework, and more specifically the eye lens requirements, require intensive and immediate work under the coordination of the competent authorities to be in line with the latest Basic Safety Standards and achieve harmonisation within the European countries.

7.1 Provisions for eye lens monitoring in international and European Basic Safety Standards

In 2012 the International Commission on Radiological Protection (ICRP) proposed a reduction of the annual limit on the equivalent dose to the lens of the eye for the exposed workers, from 150 to 20 mSv per year (ICRP, 2012). The limit was subsequently adopted by the International Atomic Energy Agency (IAEA) (IAEA, 2011 and 2014) and the European Council (EC, 2014) and this was included in the respective publications of the international and European basic safety standards, respectively.

More specifically, International Basic Safety Standards were approved by the Board of Governors of the International Atomic Energy Agency in 2011 and the General Safety Requirements Part 3, GSR Part 3 (Interim) was issued in 2011 (IAEA, 2011) that was subsequently superseded by GSR Part 3 in 2014, IAEA BSS (IAEA, 2014). In this final report the new dose limit for the lens of the eye for the occupational exposure is set to 20 mSv per year averaged over five consecutive years (100 mSv in

5 years) and of 50 mSv in any single year. Furthermore, a technical document was issued to provide interim guidance on the implications of the new dose limit applicable for the occupational exposure to planned exposure situations (IAEA, 2013). The technical document was addressed to regulatory bodies, licensees and employers in hospitals, general industry and nuclear installations. Finally, in 2018, IAEA issued a safety guide (IAEA, 2018) about the control of occupational exposure, including the exposure of the lens of the eye.

Meanwhile, the Council Directive 2013/59/EURATOM, EU BSS (EC, 2014) followed the ICRP guidance (ICRP, 2012) on the limit for equivalent dose for the lens of the eye in occupational exposure. In the article 9 of the Directive the limit is set to 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year. This provision of the EU BSS is legally binding for the EU Member States which should thus have brought it into force by early 2018.

In this point it should be mentioned that in order to monitor the equivalent dose to the lens of the eye the most appropriate method is to measure the personal dose equivalent at 3 mm depth, $H_p(3)$, with a dosemeter worn as close as possible to the eye. Since this procedure may not be very practical, other methods may be used such as the measurement of $H_p(10)$ or $H_p(0,07)$ both from dosemeters worn on the trunk and then estimate the $H_p(3)$ by applying a suitable algorithm.

Additional provisions in the two versions of the basic safety standards related to the new dose limit for the lens of the eye include the following:

- The personal dose equivalent at depth 3 mm, $H_p(3)$, shall be used for monitoring exposure of the lens of the eye.

- The limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year for the public exposure. The same value (i.e. 15 mSv) is applied for the classification of the workplaces (controlled and supervised areas) as well as for the categorisation of exposed workers.

- An adequate monitoring system shall be set up in the Member States for workers who are liable to receive significant exposure of the lens of the eye (i.e. more than 15 mSv).

- The data system for individual radiological monitoring shall include, inter alia, the equivalent doses in the different parts of the body in mSv.

The above provisions reflect a consensus of the different Member States on the level of protection in occupational exposure and more specifically to the lens of the eye. Their practical implementation includes the effective involvement of all the relevant stakeholders, organizations and fora to establish a strict process to include the above key elements, not only in the regulatory framework, but also in their everyday routine.

7.2 Status of eye lens monitoring in hospitals

The proposed dose limit for the lens of the eye raised many concerns about how to demonstrate compliance with the respective regulatory requirements. Many studies (Broughton et al., 2013, Jacob et al. 2013, Vanhavere et al. 2011) have shown that there are workplaces where the eyes are close to the radiation sources, the radiation field is non-homogeneous, and the level of exposure can exceed the new limit if radiation protection measures are not taken or if the workload is high.

Following this, many organisations, such as hospitals with interventional suites, have tried to assess the level of exposure to the lens of the eye and set up an appropriate monitoring programme.

In this respect, in 2014, one year after the issuance of the EU BSS (EC, 2014), the members of EURADOS Working Group 12 (Dosimetry in medical imaging) tried to assess the situation related to eye lens monitoring in European countries. One of the primary aims of WG12 of EURADOS was to increase the understanding of eye lens dose issues for medical staff, and to this end, a questionnaire was developed in order to establish an overview of the status of the monitoring programs in hospitals (Carinou et al., 2014). More specifically, the questions of the survey were about the knowledge about the new limit and the monitoring and dosimetry requirements. The questionnaire was sent to medical staff in European hospitals with interventional radiology (IR) and nuclear medicine (NM) departments.

In total, 195 responses were received from 23 European countries. 93% of the responses stated that they were familiar with the change in the eye lens limit for the exposed personnel. From these, about half of them (55%) had already performed some specific monitoring studies for the lens of the eye.

Answers regarding the eye lens monitoring and dosimetry issues were received from 165 hospitals where there are IR and/or NM workplaces. For the rest of the section when a specific workplace is mentioned the percentage is relative to the number of responses per workplace for each answer and not to the total number of responses received (165). The values of maximum eye lens doses in IR provided by the hospitals highlighted the need to increase or optimise the use of radiation protection means (35% indicated maximum doses above 20 mSv) and the need for implementing eye lens dose monitoring in this field (50% indicate maximum doses above 15 mSv).

Regarding the means of measuring or estimating the exposure to the lens of the eye, the majority replied that they use a specific eye lens dosemeter. 27% in IR and 18% in NM replied that they use a whole-body dosemeter and a correction factor was used in order to estimate the dose to the lens of the eye (Figure 7.1). The total number of answers per working place is 157 and 83 for IR and NM respectively.

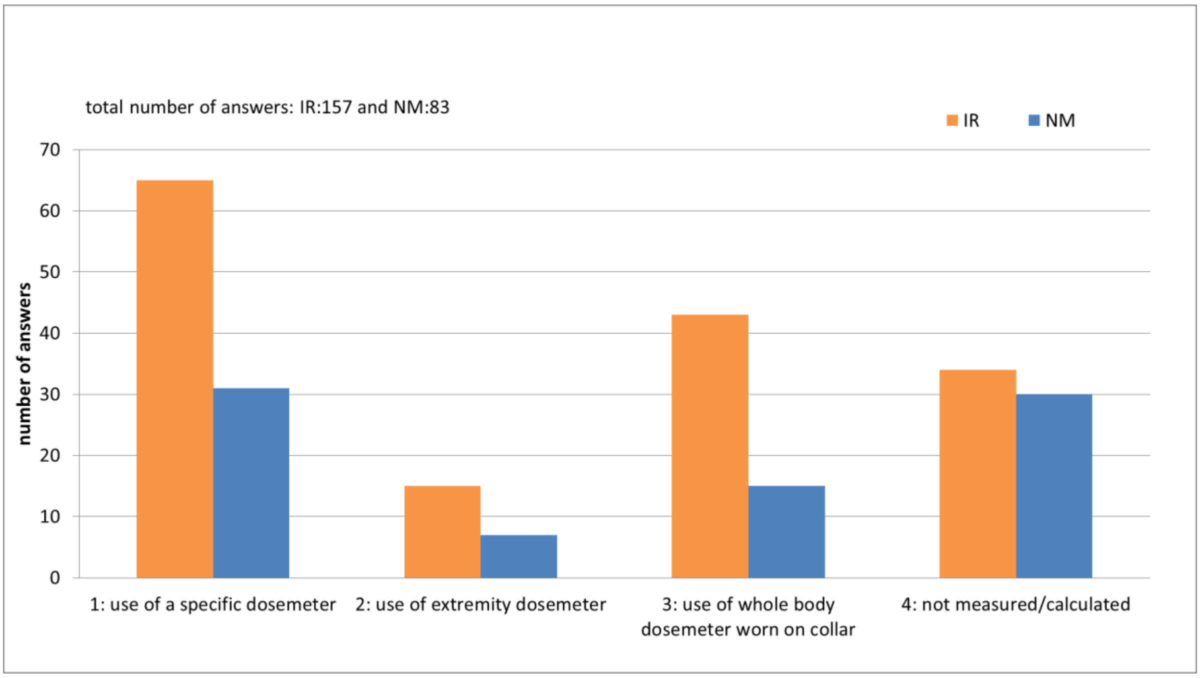

Figure 7.1: Percentage of responses about the way that the doses to the lens of the eye were measured or estimated.

When a specific dosemeter for the lens of the eye was used, the position varies considerably (Figure 7.2). In the majority of the cases the dosemeter was worn in front of the lead glasses. It should be noted that there were cases where the dosemeter was worn on the shoulder.

Regarding the radiation protection means, most of the personnel in IR workplaces used some kind of protection for the eye. The most frequent solution for protection was the ceiling suspended screen.

In conclusion the survey of 2014 in the European hospitals showed that there was good awareness of the reduced eye dose limit. Many specific eye dose studies had already been performed or were in progress. The survey highlighted that the new eye lens dose limit can be exceeded for those working in IR workplaces. However, many different procedures have been developed for the measurement of the dose to the lens of the eye or for its estimations. These different approaches include differences about the use or not of a specific dosemeter for the lens of the eye, the position of the whole-body dosemeter in order to estimate the equivalent dose to the lens of the eye, the correction factors when lead glasses are worn, and so on.

Therefore, guidance is needed in order to harmonise these procedures across Europe during this adjustment period of adopting the new limit taking advantage of the lessons learnt from the situation in the methodologies used for the estimation of the effective dose.

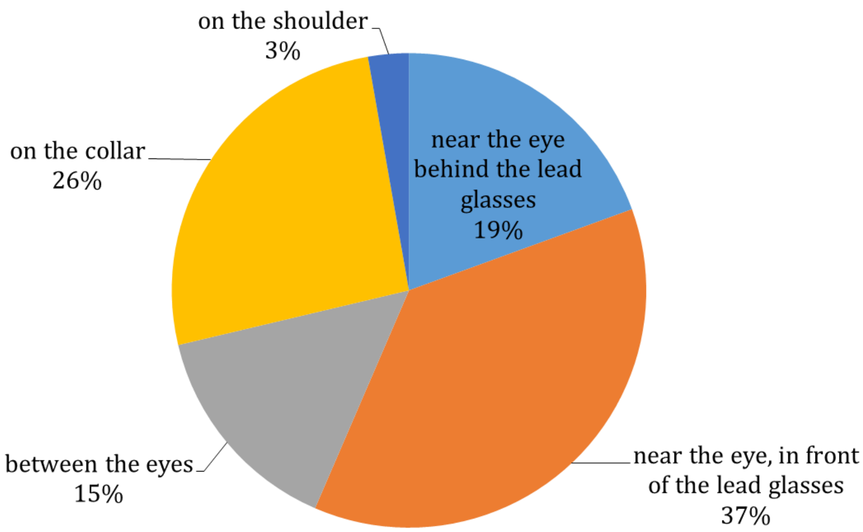

Figure 7.2: Percentage of responses about the position of the eye lens dosemeter.

7.3 Regulatory status of eye lens monitoring

The regulatory implementation of the provisions in the international and European safety standards (EC, 2014; IAEA, 2014) regarding the new limits is a process that involves many stakeholders and tasks. The first important step for the Member States is the revision and review of the respective national legislative framework; and the second is the practical implementation arrangements related to eye lens exposure. It is noted that the new General Data Protection Regulation for the European countries shall also be taken into account (EU, 2016). Considering these challenges, EURADOS WG12 organised another survey at the end of 2017, through a web questionnaire regarding the national dose monitoring regulations, especially when radiation protective garments are used (Carinou et al., 2019). The questions were related, inter alia, to the methodology for the determination of the equivalent dose to the lens of the eye and their registration to the National Dose Registry (NDR).

The results of the questionnaire showed that, in 14 out of 26 countries that answered to the questionnaire, there was a legal requirement to estimate the dose to the lens of the eye. As shown in Figure 7.3, in more than half of the countries (54%) there was a legal requirement in place to estimate the dose to the lens of the eye at the time the questionnaire was distributed. In almost half of the countries, a dosemeter above the protection was being used for estimation of the dose to the lens of the eye. In seven countries, dedicated eye lens dosemeters were being used.

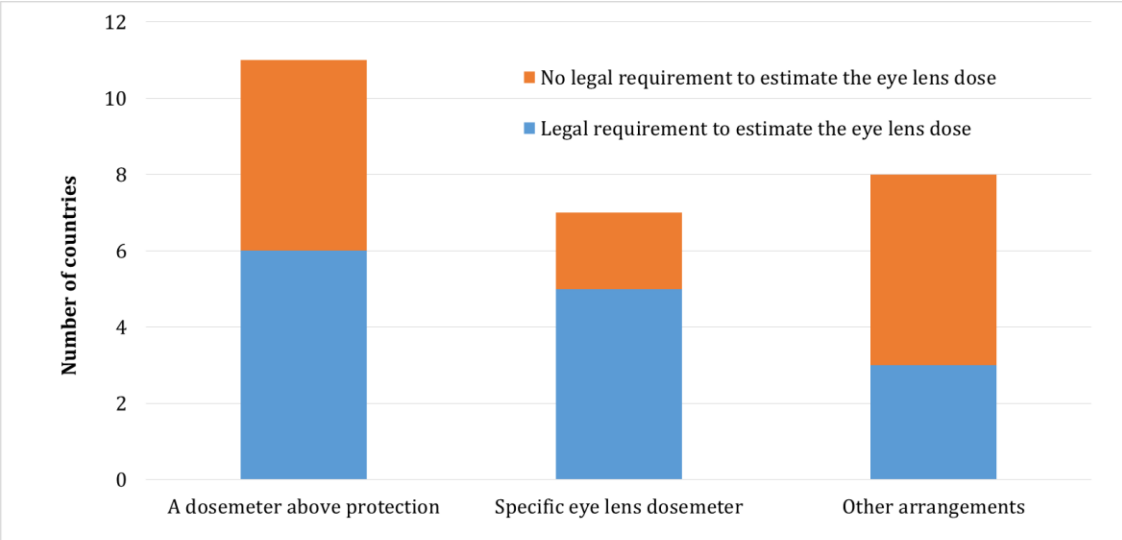

Figure 7.3: Requirements and respective methods for the estimation of the dose to the lens of the eye.

Moreover, all of the responding countries used a kind of national database for keeping the individual monitoring data; but the personal dose equivalent at depth 3 mm, $H_p(3)$, which is used as the operational quantity for the eye lens exposure, is stored in the NDR of only 7 out of 26 countries (Figure 7.4). The results of the survey should not be interpreted as the definitive regulatory status of the eye lens monitoring arrangements since many of the countries that participated in the survey were in the process of facing the challenges of the new regulatory framework set by the EU BSS. The results of the survey are in agreement with the results of the review regulatory services performed by IAEA in various Member States.

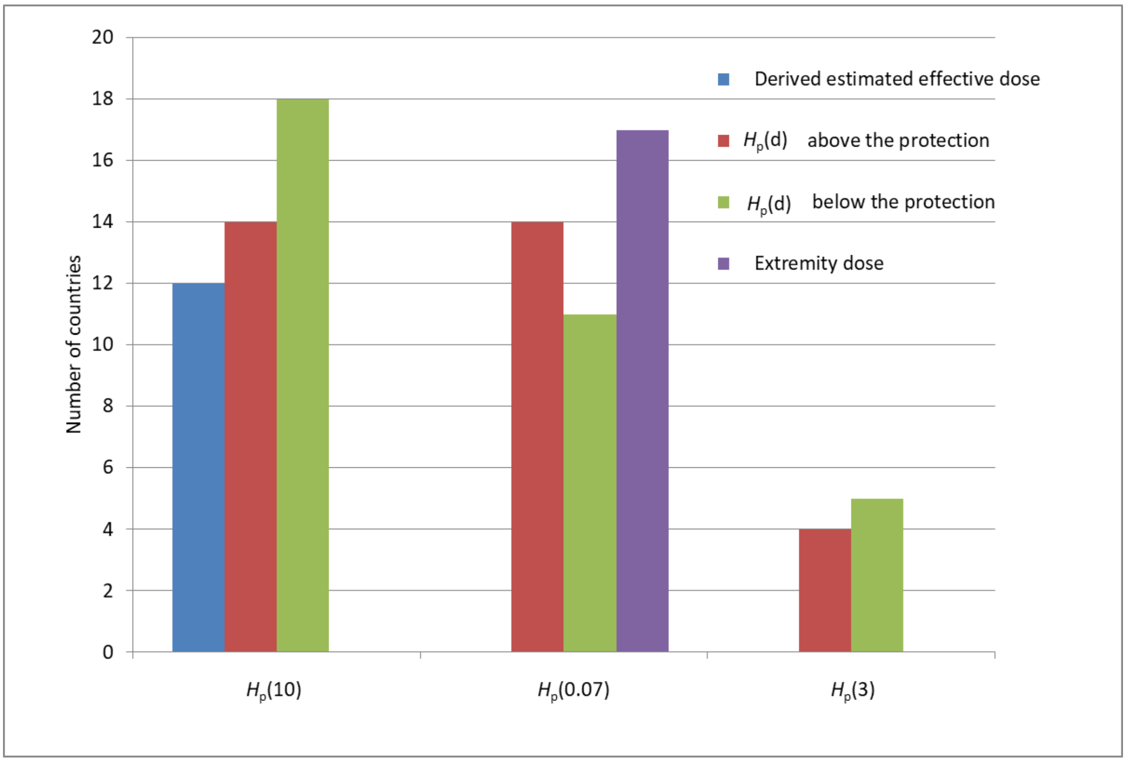

Figure 7.4: Number of responses regarding the parameters included in the NDR.

As the survey was performed just before the implementation of the European Basic Safety Standards Directive, it was seen that the national occupational exposure framework, and more specifically the eye lens requirements, required intensive and immediate work under the coordination of the competent authorities to use the experience gained in the past as well as the lessons learnt from similar issues and achieve the required standards as well as harmonisation within the European countries.

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8. Radiation protection devices of the eye lens in medical staff

Jérémie Dabin, Belgian Nuclear Research Centre (SCK CEN), Belgium.

8.0 Abstract

Since the early 2010s, several studies have reported an elevated incidence of eye lens opacities typically associated with ionising radiations among the interventional staff. These individuals receive the highest doses of ionising radiations in the medical sector, with cumulative eye lens doses ranging from a few mSv up to a few Sv over their entire career.

Many devices are available to protect the staff: from frequently used equipment, such as lead glasses or ceiling-suspended screen, to drapes positioned on the patient or the ceiling- suspended cabins. However, estimating the actual efficiency of those devices remains challenging because it can be strongly affected by their design and by the exposure conditions.

Within its many activities, the MEDIRAD project (Implications of medical low dose radiation exposure) aims to bridge gaps in the knowledge of staff radiation protection. The efficiency of novel equipment to protect the eye lens of cardiologists is investigated. Radioprotective drapes (Radpad, Mavig) covering the patient, masks and a novel ceiling-suspended cabin (Zero Gravity) are thoroughly investigated by means of Monte Carlo simulations validated through clinical measurements on the staff and on phantoms.

The article presents a review and a comparison of the efficiency of common devices to protect the eye, completed with results of the MEDIRAD project for more recent devices. Special attention is dedicated to the different methodologies used for evaluating the equipment efficiency.

The MEDIRAD project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 755523.

8.1 Introduction

Since the early 2010s, several studies have reported an elevated incidence of eye lens opacities typically associated with ionising radiations among hospital interventional staff (Ciraj-Bjelac et al., 2010; Vaño et al., 2013). These individuals receive the highest doses of ionising radiations in the medical sector, with cumulative eye lens doses potentially ranging from a few mSv up to a few Sv over their entire career (Struelens et al., 2018).

Nowadays, many devices exist to protect the eye lens of the staff. The combination of lead glasses and ceiling-suspended screen is surely the most frequently used during interventional procedures (Domienik-Andrzejewska and al., 2018), but other devices, although less frequently used, such as drapes to be positioned on the patient and various types of cabins, also exist. However, estimating the actual efficiency of those devices remains challenging because it can be strongly affected by their design and the exposure conditions.

One of the goals of the MEDIRAD project (Implications of medical low dose radiation exposure) was to bridge gaps in the knowledge of staff radiation protection. The efficiency of novel equipment to protect the eye lens of cardiologists is investigated. Radioprotective drapes covering the patient, masks and a novel ceiling-suspended cabin are thoroughly investigated by means of Monte Carlo (MC) simulations validated through clinical measurements on the staff and on phantoms.

The article presents a non-exhaustive overview of the efficiency of common devices to protect the eye, completed with results of the MEDIRAD project. The main focus is the dose reduction for physicians performing interventional procedures.

8.2 Radioprotective glasses

8.2.1 Radiology and interventional procedures

Lead glasses are among the most frequently studied devices to reduce eye lens exposure in radiology and interventional procedures, on the basis of a long research history. In the 1970s, several studies evaluated the transmission of different eyewear material directly placed in the primary beam. For instance, Richman et al. (1976) reported a reduced transmission by approximately 70% for lead glasses (0.25 mmPb). A few years later, more realistic studies based on measurements on anthropomorphic phantom in scatter fields representative of interventional procedures demonstrated dose reduction between 85% to 90% (Bergström et al., 1977; Marshall et al., 1992). More recently, phantom studies (McVey et al., 2013; Sturchio et al., 2013; van Rooijen et al., 2014) investigated the effect of various combinations of physician position and head orientation during interventional procedures. Influence of different glass designs was also evaluated (Sturchio et al., 2013; van Rooijen et al., 2014). The glass models tested (all but one with a 0.75 mm Pb equivalent thickness) showed dose reduction to the left eye as low as 9% in the least favourable exposure conditions and as high as 89% in the most favourable ones.

Monte Carlo simulations were performed to study more extensively the influence of the exposure conditions. Koukorava et al. (2011; 2014) published an extensive MC study of eye lens exposure to interventional staff, considering independently the contribution of numerous factors such as the x-ray beam projections and qualities, the staff position and head orientation and the design of the glasses. In general, the authors found the key factors having a major influence on the glass efficiency were the projections, the glass design, notably the eye coverage and the air gap between the eyes and the glasses, and the head orientation. As an illustration, combinations of 3 glass models and 7 projections resulted in a wide range of reduction, with average reduction to the left and right eye lens from 44% to 87% and from 24% to 46%, respectively. The authors also found that the beam energy and the lead equivalent thickness of the glasses (if equal or greater than 0.5 mm Pb) had little influence. These results have been completed by other computational studies investigating the effect of additional configurations and phantom models. For instance, one might cite the work of Principi et al. (2016) and Mao et al. (2019).

8.2.2 Nuclear medicine

Aside from interventional procedures, the use of radioprotective glasses can be very effective in nuclear medicine. Owing to the different particles and the wide range of energies encountered, glass efficiency strongly depends on the handled isotopes.

Bruchmann et al. (2016) investigated the efficiency of plastic (2 mm polycarbonate) and lead glasses (0.5 mmPb) to protect the staff when handling various radioisotopes. Only a direct irradiation geometry was considered. The glasses were most efficient to reduce the exposure for ^{90}Y and ^{68}Ga which are high energy beta emitting nuclides. The eye lens dose from ^{68}Ga was reduced by 35% and 50% when using plastic and lead glasses, respectively. Unsurprisingly, plastic glasses offered no protection against ^{18}F and ^{131}I; lead glasses no more than 20% reduction at best. These results were in line with simple photon attenuation calculations. For ^{99m}Tc, the use of lead glasses could reduce the eye lens dose by 70%. The efficiency was remarkable for ^{90}Y, reducing the eye lens dose by 90%

and 99% for plastic and lead glasses, respectively. Based on the electron ranges in matter, Behrens et al. (2009) calculated that glasses with thicknesses equivalent to 13 mm PMMA or 6 mm glass should suffice to completely stop electrons with energy lower than 3.5 MeV.

Those results were in general agreement with the Monte Carlo study of Cho et al. (2017) who studied the effects of various lead glass thicknesses on gamma-emitting radionuclides. The authors confirmed that the eye lens reduction was proportional to the lead equivalent thickness of the glasses and inversely proportional to the emitted gamma-ray energy, with the efficiency decreasing in the order of ^{201}Tl, ^{123}I, ^{99m}Tc, ^{67}Ga, ^{111}In and ^{18}F; the dose reduction being significant for radioisotopes emitting lower energy gammas, namely ^{123}I, ^{201}Tl and ^{99m}Tc.

8.2.3 Veterinary medicine

To the authors' knowledge, no studies were published specifically on the efficiency of radioprotective lead glasses in veterinary medicine. This does not seem to be a concern. The knowledge accumulated in the field of nuclear medicine, radiology and interventional procedures can be applied to the corresponding veterinary fields. Nevertheless, the specificities of veterinary imaging which can affect the exposure conditions should not be overlooked.

8.3 Radioprotective cabins

In a radioprotective cabin Figure 8.1, the physician is surrounded by several leaded walls, including a transparent lead glass section, with a high lead equivalent thickness (from 0.5 to 2 mm Pb). Those cabins have mostly been used for electrophysiological procedures and cardiac device implantations. New cabin models, however, were recently designed for haemodynamic procedures.

Figure 8.1: Pictures of a commercially available radioprotective cabin model: Cathpax® CRM Single, LemerPax (source: left: www.lemerpax.com) and clinical use (right: Ploux et al., 2014).

By its sheer design, the radioprotective cabin appears to be one of the most efficient device to reduce overall operator dose during interventional procedures. To the authors' knowledge, only very few studies investigated the efficiency of radioprotective cabins to reduce the physician eye lens dose: during electrophysiological procedures (Dragusin et al., 2007), during device implantation (Ploux et al., 2010; Ploux et al., 2014) and during interventional radiological procedures (Maleux et al., 2016). All the authors reported radiation dose levels within the cabin close to the background levels. For that reason, the exact dose reduction factor of the cabin could not always be quantified, but this is of limited importance for radiation protection purpose.

8.4 Ceiling-suspended screen

In the frame of the ORAMED project (Vanhavere et al., 2011), nearly 1300 interventional procedures were monitored for eye lens dose, including hundreds of procedures performed with a ceiling-suspended shield. Considerable variation in the ceiling shield effectiveness was observed depending on the type of procedure, with median reduction ranging from 38% to 86% for the left eye and from 55% to 64% for the right eye. The reason for the variation was suspected to be incorrect positioning of the ceiling shield.

Koukorava et al. (2011; 2014) also used MC simulations to investigate the wide variation in dose reduction observed in the ORAMED project. For 25 irradiation conditions, the shield reduced the dose, on average, by 55% for the left eye and 58% for the right eye. Maximal dose reduction of up to 90% to the left eye lens and up to 93% for both eyes was reported. The irradiation conditions had a considerable effect on the dose reduction, with the ceiling screen being more efficient when positioned close to patient and the primary x-ray field.

8.5 Radioprotective drapes on the patient

Since the 2000s, lead or lead-free drapes positioned on the patients (Figure 8.2) have been used to reduce overall operator dose during interventional procedures. More than 20 studies, mostly clinical, were published in the literature. Few studies reported the drape efficiency to reduce eye lens exposure. Nevertheless, considerable variation in the drape efficiency to protect the eye lens was observed in interventional cardiology. Musallam et al. (2015) and Dabin et al. (2018) reported, on average, reduction to the left eye by about 50%; while Politi et al. (Politi et al., 2012) only found 14% reduction and Grabowizc et al. (2017) reported no significant effect. In a recent clinical trial performed in the frame of the MEDIRAD project (McCutcheon et al., 2020), an average of 58% decrease to the left eye dose was measured.

Figure 8.2: Pictures of two commercially available lead-free drape models: RADPAD subclavian shield (left, Worldwide Innovations & Technologies; source: www.radpad.com) and radial X-ray protection drape (right; MAVIG; source: McCutcheon et al., 2020).

The variability in the drape efficiency was also investigated by means of MC simulations considering various projections, staff positions, drape composition and drape placement (Dabin et al. 2020). The main parameter of influence was the x-ray beam projection. In a fixed clinical setting, different projections resulted in dose reduction varying from 3% up to 40%. In addition, the simulated drape position could lead to about 10% variation.

8.6 Radioprotective mask

Within the MEDIRAD project, the efficiency of three different face mask designs (Figure 8.3) with 0.1 mmPb was evaluated by means of MC simulations for several combinations of beam projections and operator positions representative of interventional cardiology conditions (Dabin et al. 2020).

Figure 8.3: Pictures of two commercially-available RP face mask models: VIS400 face mask (left; source: www.varaylaborix.com) and Full face style mask (right; Philips Safety products, source: www.phillips-safety.com). Both models were investigated by MC simulations in the frame of MEDIRAD study.

The key parameter influencing the dose reduction was clearly the design of the mask, notably the length. The shorter mask model, whose lower edges stopped in the nose region, offered no significant dose reduction to the eyes (maximum 8%), irrespective of the beam projection or physician position. The longer mask models, whose lower edges covered the chin of the physician, significantly reduced the doses to the left and right eyes from 43% to 84% and 10% to 81%, respectively.

8.7 Zero-gravity suspended system

The Zero-gravity (Figure 8.4) is a suspended system composed of an apron with increased lead thickness (0.5 to 1 mm Pb depending on the location) equipped with lead flaps over the upper arms and a lead face shield (0.5 mm Pb). As for the radioprotective cabin, only limited evidence is available.

Figure 8.4: Pictures of the Zero Gravity suspended radiation protection system (Worldwide Innovations & Technologies): Floor Unit suspended system (left; source: www.biotronik.com) and clinical use (right; source: Savage et al., 2013).

Haussen et al. (2016) reported about 50% dose decrease to the eye lens during interventional neuroprocedures while Savage et al. (2013) reported 94% reduction during various types of interventional procedures. Monte Carlo simulations performed in the frame of MEDIRAD (Dabin et al. 2020) showed reduction to the eye lens dose from 83% to more than 95% for projections representative of interventional procedures, while validation measurements on an anthropomorphic phantom showed dose reduction from 75% up to 96%.

8.8 Conclusion

Selecting an appropriate radiation protection device for the eye lens is a challenging task. The potential for dose reduction of most devices could strongly depend on their design and the exposure conditions. For those personal devices that are directly aimed at protecting the eye region, such as the lead glasses and the masks, an extended eye coverage and the smallest possible gap between the face and the device are crucial parameters to ensure adequate protection.

By contrast, some devices, such as the ceiling-suspended screen, the radioprotective cabin and the Zero gravity suspended system, can offer significant dose reduction to the eye lens – and other tissues and organs - in most circumstances if they are properly used.

Finally, in addition to the mere dose reduction efficiency, factors not directly related to radiation protection such as ergonomics, frequency of use, expected exposure, price and protection of other organs, should also be considered in the selection process.

8.9 Acknowledgements

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9. Eye lens exposure: risk assessment in different types of workplaces

Robert Kollaard, Nuclear Research and Consultancy Group (NRG), The Netherlands.

9.0 Abstract

For years, the annual dose limit for occupational exposure of the lens of the eye to ionising radiation was not really considered an issue, and the dose to the eye was only monitored occasionally. With the national implementation in 2018 of the European Council Directive 2013/59/Euratom, this dose limit was reduced from 150 to 20 mSv and the Member States are expected to implement an adequate system for the monitoring of category A workers. Where the system for monitoring the whole-body dose is settled in most countries, this is not the situation for the lens of the eye. This paper presents a system for eye lens dose monitoring, based on the particle type, energy, angle of incidence and geometry of the radiation field and the use of protective measures. The system provides recommendations for the adequate operational quantity and dosemeter position for some of the most relevant workplaces.

9.1 Introduction

Various investigations have addressed the sensitivity of the lens of the eye to ionising radiation during the last decade. As a result of these investigations, the International Commission on Radiological Protection (ICRP) recommended in 2011 to reduce the dose limit for the lens of the eye for occupational exposure from 150 mSv to 20 mSv per year (ICRP, 2012). This dose limit was adopted in the European Basic Safety Standards (BSS) in 2013 (EU, 2014), where the limit for public exposure of the lens of the eye was maintained at 15 mSv. Based on the dose to the lens of the eye, only workers with an expected dose above 15 mSv are classified as exposed workers of category A. With the national implementation of the BSS in 2018, the European Member States are expected to implement an adequate system for the monitoring of category A workers who are liable to receive a significant internal exposure or significant exposure of the lens of the eye or extremities (BSS article 41.1). Although this article of the BSS sets a framework for individual monitoring, it does not elaborate on how such an "adequate system for monitoring" is to be established, leaving the freedom to the Member States in the practical implementation. With the reduced dose limit for the lens of the eye, the situation becomes especially demanding for workers with an expected dose close to or more than 15 mSv, as it may be the case for e.g. fluoroscopically-guided interventional procedures or isotope production practices.

Beside the dosemeter design in use, the most important elements of an adequate system for monitoring workers in a specific workplace are: 1) the adequate dose quantity to be used, 2) the position on the body of the dosemeter to be worn and 3) the type of dosemeter. The operational quantity for eye lens dose monitoring is the personal dose equivalent at a depth of 3 mm, $H_p(3)$, the estimator of the equivalent dose to the lens of the eye. Behrens et al. in two publications (Behrens et al., 2010; Behrens, 2012) have shown that in many exposure situations other dose quantities than $H_p(3)$ can adequately estimate the dose to the lens of the eye as well. Based on this work, the International Atomic Energy Agency (IAEA) published a technical document (further referred to as IAEA TECDOC) (IAEA, 2013), where a number of schemes for different particle types are proposed in order to determine the dose quantity and the dosemeter position for eye lens dose monitoring. Although these schemes are definitely a step closer to an "adequate system for monitoring" than the general requirement in the BSS, the IAEA TECDOC does not contain specific examples where the schemes are applied to typical workplaces.

The purpose of this paper is to propose a practical recommendation for establishing an adequate system for eye lens dose monitoring in the most relevant workplaces, depending on the local exposure conditions. Next to the schemes in the IAEA TECDOC, the recommendations by the International Organization of Standardization (ISO, 2015), the Netherlands Commission on Radiation Dosimetry (NCS, 2018), the ICRP (ICRP, 2018) and the International Radiation Protection Association (IRPA, 2017) will be considered.

9.2 Parameters influencing eye lens dose monitoring

The IAEA TECDOC considers three main impact factors that should be taken into account for each type of radiation:

- energy and angle of incident radiation;
- geometry of the radiation field (may change during the monitoring period);
- usage of personal protective equipment or shields and its correct use.

The adequate operational dose quantity depends mainly on the type, energy and angle of the incident radiation. The adequate wearing position of a dosemeter depends mainly on the geometry of the radiation field and the presence of protective equipment. These aspects will be discussed in detail in the following sections.

9.2.1 Choice of operational dose quantities

$H_p(3)$ is the most adequate operational quantity to estimate the equivalent dose to the lens of the eye for the entire photon energy range. For photons with a mean energy higher than 40 keV and entering the lens of the eye mainly from the front, the personal dose equivalent at a depth of 10 mm, $H_p(10)$, is considered to be a suitable quantity. According to the IAEA TECDOC, $H_p(0.07)$ can be used as well to estimate the dose to the lens of the eye at all energies and angles, but it overestimates the dose at lower photon energies.

For beta radiation, the schemes make use of the maximum beta energy. Because low energy electrons do not penetrate the lens of the eye, dedicated monitoring is not considered necessary when the maximum energy is below 0.7 MeV. When the maximum beta energy is higher than 0.7 MeV and no protective equipment is used for shielding of the lens of the eye, the only adequate dose quantity to estimate the dose is $H_p(3)$.

In mixed photon/beta fields where the maximum beta energy is more than 0.7 MeV, $H_p(3)$ is recommended as the only adequate dose quantity. In most of the complex situations, where – next to photons and electrons – neutrons are present in the field, a summation of the $H_p(10)$ dose measured with a neutron dosemeter and the $H_p(3)$ dose measured with a dosemeter suitable for betas and photons is considered adequate (Gualdrini et al., 2013).

9.2.2 Dosemeter wearing position

The IAEA TECDOC scheme determines the adequate wearing position using the geometry of the radiation field and the presence of protective equipment. The influence of both aspects is discussed in the following sections.

When homogeneous fields are present, monitoring on the trunk may be adequate to estimate the dose near the lens of the eye. For photons and neutrons this situation may occur, especially when the radiation source is distant and the worker is exposed to a parallel beam. The IAEA TECDOC suggests that exposure to betas is usually inhomogeneous and monitoring should be performed near the lens of the eye (when monitoring is considered necessary).

An important aspect, to be taken into account with respect to the adequate wearing position, is under which conditions a field is not considered homogeneous. In the presence of strong dose gradients, the dose at different positions of the body may differ significantly. Such dose gradients may not only be found for beta radiation, but also when the distance from the monitoring position to the radiation source is small. In almost all workplaces with an expected dose to the lens of the eye of more than 10 mSv, the distance from the radiation source to the lens of the eye is less than 1 meter. In these workplaces the most accurate measurement position is always near the lens of the eye receiving the highest dose. A measurement of the dose at a different location (such as the chest) might be adequate as well in workplaces where the distance from the radiation source to the dosemeter is consistently smaller than the distance to the lens of the eye. In such cases, the measured dose may serve as a conservative estimator of the dose to the lens of the eye.

Another aspect that may influence the homogeneity of the field is the presence of protective equipment. The measurement may not adequately estimate the dose to the lens of the eye when the shielding of the dosemeter differs from the shielding of the eye. The IAEA TECDOC presents the following scenarios in which this may occur:

- When the shielding protects the trunk but not the head.
- This results in inhomogeneous exposure conditions where a dosemeter at the trunk does not adequately estimate the dose to the lens of the eye.
- When using personal protective equipment for the lens of the eye (such as lead glasses). In this situation a correction factor should be applied to estimate the dose to the lens of the eye.

9.3 An adequate system for eye lens dose monitoring at typical workplaces

Workplaces where workers are liable to receive a significant exposure to the lens of the eye are described in several publications, such as the IAEA TECDOC (IAEA, 2013), the technical information sheets provided by the French Radiological Protection Society (French Radiological Protection Society, 2016), the publication by the IRPA task group (IRPA, 2017) and the report of the Netherlands Commission on Radiation Dosimetry (NCS, 2018).

This NCS study presents an adequate system for eye lens dose monitoring for the following cases:

(1) staff performing fluoroscopically-guided interventional procedures;

(2) staff involved in the preparation and administration of isotopes for nuclear medicine;

(3) veterinary medicine professionals involved in imaging of horses, both by x-ray and by scintigraphy;

(4) staff performing industrial radiography;

(5) staff involved in isotope production or working in the nuclear industry.

It should be noted that the most significant exposures of the lens of the eye are found in interventional radiology and cardiology. For the other groups mentioned here, measured whole-body doses of more than 10 mSv are only found occasionally (NCS, 2018) and systematic doses of more than 15 mSv are not expected. Although the examples presented in this paper may not be exhaustive, it will at least provide a methodology to determine what system may be adequate for eye lens dose monitoring of workers at other workplaces.

9.3.1 Fluoroscopically-guided procedures

Medical specialists may be exposed to high doses during fluoroscopically-guided procedures in disciplines such as interventional cardiology and radiology, vascular surgery and neurosurgery. In most of these procedures the operator is standing next to the table, and the x-rays scattered by the patient contribute mostly to the worker's dose.

Adequate dose quantity - Based on the typical angle of the incident scattered radiation (obliquely from below) and the mean energies from 20-100 keV (Clairand et al., 2011), $H_p(0.07)$ or $H_p(3)$ are the most adequate dose quantities.

Adequate wearing position - Since the distance of the worker to the radiation source is small and the dose gradient is large, the radiation field can be considered inhomogeneous. The use of shielding may result in an even more inhomogeneous exposure of the body. Based on these considerations, the most adequate measurement position is found near the eye. When protective equipment is used for the eye, a correction factor is required to estimate the dose to the lens of the eye, unless the monitoring takes place behind the protective equipment. The use of correction factors will be addressed further in the discussion section of the paper.

Conclusion - A dosemeter near the lens of the eye, calibrated in terms of $H_p(0.07)$ or $H_p(3)$, is adequate for eye lens dose monitoring of these workers. When personal protective equipment is used to protect specifically the eyes, an appropriate correction factor needs to be applied.

9.3.2 Nuclear medicine

It is difficult to make a general statement about an adequate system for eye lens dose monitoring in nuclear medicine, because the different radionuclides that are being used give rise to different exposure conditions. Most of the workers in nuclear medicine are exposed to doses lower than 15 mSv, and eye lens dose monitoring is not mandatory. In case measurements are to be performed in specific working conditions, the following is recommended:

Adequate dose quantity - In planar scintigraphy or Single Photon Emission Computed Tomography (SPECT), radionuclides (such as ^{99m}Tc) are used with photon energies in the range between 100 and 200 keV. Since the workers involved in practices with these radionuclides usually receive a frontal exposure, dosemeters calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$ can be used.

In nuclear medicine departments, where the exposed workers are additionally involved in imaging techniques with Positron Emission Tomography (PET) using for example ^{18}F or ^{68}Ga, as well as in therapeutic procedures (using for example ^{131}I or ^{177}Lu) where the maximum beta energy is below 700 keV, the dose to the lens of the eye is determined by photons of higher energies. As the betas do not contribute to the dose to the lens of the eye, dosemeters calibrated in terms of $H_p(3)$ or $H_p(10)$ are the most appropriate to estimate the dose.

For some of the radioisotopes used in PET and for therapeutic radioisotopes, such as ^{15}O and ^{90}Y, the maximum beta energy is higher than 700 keV and monitoring of the beta contribution might be needed if the shielding used is not sufficient to absorb the beta radiation completely. In this case, only dosemeters calibrated in terms of $H_p(3)$ are appropriate to estimate the dose to the lens of the eye.

Adequate wearing position - When the operators are preparing or injecting radiopharmaceuticals (emitting photons or betas) they are positioned very close to the source. The distance between on one hand the trunk and source, or on the other hand the eyes and the source, varies significantly, and the worker is exposed to an inhomogeneous radiation field. Therefore, the only adequate monitoring position is near the eyes.

Conclusion - A dosemeter calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$ is adequate for eye lens dose monitoring of workers in planar or SPECT imaging. For PET and therapy applications (when betas with an energy up to 700 keV are present), a dosemeter calibrated in terms of $H_p(3)$ or $H_p(10)$ is the most adequate. However, for therapy applications where the unshielded eye lens is exposed to beta energies higher than 0.7 MeV, $H_p(3)$ is the only adequate dose quantity. In all situations, the most adequate wearing position is near the eye.

9.3.3 Veterinary medicine

The highest exposures in veterinary medicine are found during the imaging of horses using x-rays or planar scintigraphy, as in these procedures the worker is standing close to the horse. Once more, it should be noted that whole-body doses higher than 10 mSv are rarely found in this type of workplaces (NCS, 2018). The use of distance tools for x-ray imaging and the use of shielding and strategies to limit the time close to the animal may be helpful to limit the dose to the worker. The exposure conditions for this worker group are similar to those in medical x-ray imaging and nuclear medicine.

Conclusion - A dosemeter near the lens of the eye, calibrated in terms of $H_p(0.07)$ or $H_p(3)$, is adequate for eye lens dose monitoring of workers performing x-ray imaging in veterinary medicine. For workers using personal protective equipment to protect specifically the eyes, an appropriate correction factor then needs to be applied when the dosemeter is placed on the outside of the equipment. A photon dosemeter near the lens of the eye, calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$, is adequate for the monitoring of workers in planar scintigraphy.

9.3.4 Industrial radiography

During industrial radiography, x-ray sources or sealed sources (such as ^{192}Ir) are used for non-destructive testing of different types of objects. As mentioned before, whole-body doses higher than 10 mSv are rarely found in this field. Workers may receive significant doses when accidental exposures occur such as the evacuation of a trapped source.

Adequate dose quantity - Because of the high energies of these sources (> 200 keV), dosemeters calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$ can be used.

Adequate wearing position - In most of the exposure situations occurring in industrial radiography, the worker is exposed to a homogeneous radiation field at large distances from the source. A monitoring position at the chest can be considered suitable to estimate the dose to the lens of the eye. During transport of a sealed source between locations or when accidents occur, the distance from the source to the lens of the eye can be small and the field can be considered inhomogeneous (but usually the radiation source is closer to the trunk than to the lens of the eye).

Conclusion - A dosemeter calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$ is adequate for the monitoring of workers in industrial radiography. For most exposure situations, a wearing position at the chest is adequate to estimate the dose to the lens of the eye. When an accident occurs, the dose to the lens of the eye may need to be estimated afterwards, especially when the distance from the source to the eye lens of the worker was smaller than the distance to the dosemeter.

9.3.5 Isotope production

In most of the activities in isotope production, the source can be shielded sufficiently and the exposure of the lens of the eye is limited. However, significant exposures may occur amongst operators replacing activated target foils at cyclotrons (NCS, 2018; French Radiological Protection Society, 2016). During this replacement, the distance from the foil to the lens of the eye is small. The trunk of the operator may be shielded, but visual guidance of his activities is necessary. Depending on the setup, the lens of the eye can be exposed to a significant dose.

Adequate dose quantity - Although the activated isotopes in the target foil emit mixed beta and gamma radiation, the effect of the beta radiation is limited due to the aluminium flange holder, and workers are mainly exposed to high energy photon radiation. Therefore, the dosemeter may be calibrated in terms of either $H_p(0.07)$, $H_p(3)$ or $H_p(10)$.

Adequate wearing position - As the working distance is small and the body of the operator may also be positioned behind shielding, the radiation field geometry is not considered homogenous. Therefore, monitoring near the eyes is adequate to estimate the dose to the lens of the eye.

Conclusion - A dosemeter near the lens of the eye, calibrated in terms of $H_p(0.07)$, $H_p(3)$ or $H_p(10)$, is adequate for the monitoring of the workers replacing activated target foils at cyclotrons.

9.3.6 Nuclear industry

Significant exposures of the lens of the eye can be found in activities performed in nuclear industry, for instance during inspections performed on steam generators, work on vessel closure thermocouples, and welding on hot spot and dismantling operations (French Radiological Protection Society, 2016). Because of the diversity of these activities, the inspection of steam generators is highlighted herein after as an example. One should be careful to generalise this example to other activities, because the geometry and protection measures may be different, but the same methodology can be applied to define the most appropriate quantity and wearing position.

Adequate dose quantity - The radiation field consists mainly of a mix of beta and gamma radiation, originating from activation products such as ^{58}Co and ^{60}Co. During inspections, the workers are using a respirator mask. Since this mask is shielding the beta component of the radiation, the dose to the lens of the eye is in practice delivered by the gamma radiation, for which $H_p(3)$ or $H_p(10)$ are the most appropriate dose quantities.

Adequate wearing position - The inspectors work in close proximity to the source of radiation, which tends to be closer to the head than the rest of the body (ratio close to 1.5 (French Radiological Protection Society, 2016)). Because of these inhomogeneous exposure conditions, monitoring near the eyes is the most adequate to estimate the dose to the lens of the eye.

A headband eye lens dosemeter may be hard to combine with the use of a respirator mask. When such a headband system is worn under the mask, the hermeticity of the mask may be compromised. Therefore, the preferred approach may be to wear the dosemeter for the lens of the eye outside of the respirator mask, and to determine and apply an appropriate correction factor for the protective effect of the mask.

Conclusion - A dosemeter near the lens of the eye, calibrated in terms of $H_p(3)$ or $H_p(10)$, is adequate for the monitoring of workers inspecting steam generators. When the dosemeter is used outside the respirator mask, an appropriate correction factor needs to be applied.

9.4 Discussion

9.4.1 Interpretation of legal requirements

In general, the European BSS presents two approaches for the monitoring of workers. The requirement for category A workers is to set up an adequate system for their monitoring, whereas for category B workers it is sufficient to prove that they are correctly classified.

With respect to eye lens dose monitoring, this means that category A workers shall be monitored systematically once the expected dose to the lens of the eye is 15 mSv or higher.

The situation for category B workers is less straightforward. Unless there are national requirements in place, in analogy to whole-body monitoring, periodic monitoring of the dose to the lens of the eye may be performed to demonstrate that the equivalent dose to the lens of the eyes is below 15 mSv.

9.4.2 Main challenges

Several recommendations can be found with respect to eye lens dose monitoring. In its publication, IRPA (9) recommends monitoring using a collar or head dosemeter, where the collar dosemeter needs to be positioned on top of the apron (if used). In the same publication, for workers receiving an annual dose to the lens of the eye from 1-6 mSv, it is recommended to perform a pilot prior to initiation of the work in order to establish dose levels. For workers receiving a dose higher than 6 mSv, regular monitoring is recommended. The IRPA publication provides a general recommendation for the wearing position of the dosemeter for the lens of the eye, irrespective of the dose level or exposure conditions.

In contrast, the ICRP 139 publication (ICRP, 2018) does differentiate among specific dose levels for workers involved in interventional procedures. It is stated that for lower doses, the collar dosemeter worn above the apron on the side adjacent to the x-ray tube should give a good indication of the level of radiation to which the eye is exposed when no eye protection is used. The collar dosemeter is considered only an indicator of the eye dose, rather than an accurate measurement. The ICRP 139 publication suggests that when the cumulated reading of the collar dosemeter is expected to exceed a certain value (e.g. 10 mSv) and no protective eyewear is worn, it may be advisable to improve the accuracy of the assessment by wearing a dosemeter adjacent to the most exposed eye.

The approach in this paper is to provide a practical recommendation for an adequate system for eye lens dose monitoring, depending on the working environment and exposure conditions, but irrespective of the dose level. We focused on worker groups for which the level of 15 mSv might be reached and concluded that for most groups, the adequate monitoring position is close to the (most exposed) eye. The main reason for this conclusion is the inhomogeneous exposure of the worker, who is often working in close proximity to the source of radiation. Because of the suggested monitoring position near the eye, the monitoring should be done with a dedicated eye lens dosemeter. The availability of such dosemeters has improved since the ORAMED project developed the Eye-D™ system (Vanhavere et al., 2012), as it was demonstrated in the eye lens dosimetry intercomparisons in 2014 and 2016 by EURADOS (The European Radiation Dosimetry Group) (Clairand et al., 2016 and 2018).

9.4.3 Approaches to estimate the eye lens dose

In order to verify that the eye lens dose of workers is systematically below 15 mSv, and demonstrate that their categorisation is correct, different approaches can be used. For many workplaces, whole-body dosimetry results are available and can be used to estimate the dose to the lens of the eye. Alternatively, a dedicated survey with dosemeters for the lens of the eye can be performed over a limited period in order to estimate the annual dose to the lens of the eye. The ISO provides recommendations for such a survey in its publication 15382 (ISO, 2015). The survey should be performed under representative conditions during a period of at least three consecutive months.

Typical examples for which the whole-body dose can be used to estimate the dose to the lens of the eye are: 1) when the expected dose to the lens of the eye is consistently lower than the whole-body dose, due to the larger distance of the lens of the eye to the source, or 2) when the ratio of the dose to the lens of the eye to the whole-body dose is constant. Although such an approach may be useful for certain workplaces, one should be careful. Different publications in the field of interventional radiology and cardiology compare the measured whole-body and dose to the lens of the eye, where for most workers the measured whole-body dose is higher than the dose to the lens of the eye, but for some workers the dose to the lens of the eye is (considerably) higher. In general, a large variation is observed in the ratio of the dose to the lens of the eye to the whole-body dose indicated by a dosemeter worn either on thyroid collar or on the chest level. This ratio depends a lot on the practice and the position of the dosemeters. Values of this ratio of 0.38 to 1.86 have been recorded in literature for vertebroplasty and electrophysiology procedures (Carinou et al., 2015). Similar data is available from an European study in the field of interventional cardiology, demonstrating an average ratio of 0.73 with maxima up to 9.6 from measurements on more than 200 interventional cardiologists (Struelens et al., 2018). This variation increases the uncertainty of the dose assessment. Therefore, care should be taken if the dose calculated using this method reaches the investigation level or even the dose limit. If this is the case, more accurate evaluations should be performed.

9.4.4 Corrections for the use of personal protective equipment

The dose to the lens of the eye cannot be estimated accurately under all circumstances. When personal protective equipment is in use, the question is raised where to position the dosemeter. According to IAEA and ISO publications (IAEA, 2013; ISO, 2015), the dosemeter should be worn under the protection or behind an equivalent layer of material. Otherwise, appropriate correction factors to take the shielding into account should be applied. In practice, except when large protective eyewear such as face masks are used, it is often difficult to position the dosemeter under the protection without interfering with the wearer's vision (ICRP, 2018) and ensuring a complete shielding. In literature, high dose reduction factors (DRF) can be found for protective glasses (DRFs up to 7 are reported, (Martin, 2016)). The publications of Martin and ICRP suggest using a DRF of 2 and not greater than 4 within the field of fluoroscopically-guided interventional procedures. Very recently some new developments are being proposed to integrate the eye dosemeter into the radiation protection glasses (Hoedlmoser et al., 2018). This could be a method for more reproducible positioning of the dosemeter.

The use of a DRF should only be considered when (NCS, 2018):

- a quality assurance system is present to verify the actual use of the protective equipment;
- the glasses and frame contain a minimum lead equivalent of 0.5 mm;
- the monitor is positioned such that the worker's head is not tilted during imaging.

In such a case, the protection of the glasses is expected to be much lower.

9.4.5 Adequate systems for other situations

The question what system is adequate for eye lens dose monitoring for applications different than described above, should be considered carefully. In this consideration, the energy and angle of the incident radiation, geometry of the radiation field and the use of personal protective equipment should be taken into account. Obviously, monitoring the dose to the lens of the eye with a dedicated $H_p(3)$ dosemeter near the eye will – in general – prove to be adequate. For those workers with an expected dose to the lens of the eye of close to or more than 15 mSv, it is usually clear which activities give rise to a significant exposure of the lens of the eye. Based on the conditions of these activities, the judgement needs to be made what dose quantity and measurement position is adequate.

9.5 Conclusion

Based on legal requirements for dose monitoring (EU, 2014), an adequate system should be implemented in specific workplaces with a significant dose to the lens of the eye. With the methodology proposed by the IAEA (IAEA, 2013), for most category A workers (when based on their expected dose to the lens of the eye), the use of a dedicated dosemeter for the lens of the eye is recommended, mainly due to the small distance of the worker to the radiation source. This can be of great importance for medical specialists performing fluoroscopically-guided procedures. For workers with a significant dose to the lens of the eye, but below 15 mSv, the "adequate system" is used mainly for the demonstration of the fact that the worker is correctly classified. In these cases, it can be acceptable to estimate the dose to the lens of the eye using the results of whole-body dosimetry or using the results from pilot studies with dedicated eye lens dosemeters.

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10. Eye lens dosimetry: a dosimetry service perspective

Tom W.M. Grimbergen, Mirion Dosimetry Services, Arnhem, The Netherlands

10.0 Abstract

About ten years ago most Individual Monitoring Services (IMSs) did not offer specific services for monitoring the exposure of the lens of the eye. ICRP Publication 103 (ICRP, 2007) stated: "personal dose equivalent $H_p(3)$, has rarely been used in practice and very few instruments exist for measuring this quantity. It is suggested that its use is discontinued because the monitoring of the exposure to the eye lens is also sufficiently achieved if the dose to the eye lens is assessed in terms of the other operational quantities".

However, in early 2018 the new dose limit for the equivalent eye lens dose, 20 mSv in a single year (or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year) for occupational exposure, as stated by the Basic Safety Standards (BSS) Directive 2013/59/EURATOM (EU, 2014) has been implemented in national legislation in many EU-member states. Also, BSS states that "especially category A workers should be systematically monitored based on individual measurements performed by a dosimetry service. In cases where workers are liable to receive significant exposure of the lens of the eye, an adequate system for monitoring must be in place."

Consequently, there has been an increasing demand for personal dosemeters designed specifically for monitoring the exposure of the lens of the eye. Such a dosemeter is able to measure the operational quantity $H_p(3)$ when worn close enough to the eye. IMSs might choose to either design and manufacture the dosemeter themselves or purchase an off-the-shelve product. In either case, the IMS will have to be able to provide evidence of the suitability of the dosemeter. Other aspects of running an IMS which might be affected include calibration, the issuing process including labelling, the read-out process, quality assurance procedures, the IT-system, reporting, logistics, training of personnel, accreditation and/or the approval by the competent authority. In addition, there might be specific requirements for reporting eye lens doses to the national dose registry or other national entities.

This paper describes some examples of the practical approach for offering services for monitoring the exposure of the eye lens. From the practical point of view, it is also important to consider the expected number of eye lens dosemeter subscriptions. Although this number might be influenced by local legislation, it is expected that in general the number will be low. As an example, two years after the implementation of the new dose limit into the national legislation in the Netherlands, the number of eye lens dosemeter subscriptions at Mirion Dosimetry Services in Arnhem amount to less than 0.5% of the total amount of subscriptions.

10.1 Introduction

Like all organisations, IMSs need to have the ability to adapt to changing situations to remain relevant to all their stakeholders. This chapter describes the impact of the new limit for the eye lens dose from an IMS perspective and the different drives influencing choices to be made by IMSs to adapt to the changing situation.

Because of the diversity of IMSs currently in operation, it is only possible to give a "birds-eye" overview of some possible consequences and solutions. In particular, the scope of this chapter will be limited to the situation in the European Union (EU) and will give examples taken from a small number of IMSs in the EU. The examples only serve as illustration and do not necessarily indicate "good practice" nor imply any endorsement by the author of this chapter or by EURADOS.

10.2 Jumping-off Point

10.2.1 IMSs in the EU

In the EU the definition of a dosimetry service is laid down in Council Directive 2013/59/EURATOM (EU, 2013): "*"dosimetry service" means a body or an individual competent to calibrate, read or interpret individual monitoring devices (…) or to assess doses, whose capacity to act in this respect is recognised by the competent authority*". Member states have their own competent authority for the formal recognition (also called "approval") and may also set specific legal rules for recognition of IMSs. Some guidance for authorities can be found in RP-160 "Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation" (EC, 2009). While requirements and procedures for recognition vary between the 27 Member States, similarities can be found as well, such as: the dose results produced by approved IMSs have a legal status, and the services should incorporate a certain level of Quality Assurance (QA). Participation in (inter)national intercomparisons and accreditation according to ISO-17025 (ISO, 2007) are regarded as good practice and in some Member States are requirements for recognition.

In practice, IMSs show a wide variety of organizations: from scientific institutes to in-house services at hospitals or universities, to commercial service providers. The size of IMSs in terms of number of individuals monitored varies from smaller than 100 to larger than 100 000 (Gilvin et al., 2015).

10.2.2 Eye lens dosimetry before 2013

Before 2013, there was not much interest in monitoring the dose to the eye lens. With maybe a few specific exceptions, it was assumed that compliance with the limit for effective dose (20 mSv per year) would be sufficient to also comply with the limit of 150 mSv per year for the dose to the eye lens. In 2007, ICRP suggested that a specific operational quantity for monitoring dose to the eye lens had become obsolete: "*personal dose equivalent $H_p(3)$, has rarely been used in practice and very few instruments exist for measuring this quantity. It is suggested that its use is discontinued because the monitoring of the exposure to the eye lens is also sufficiently achieved if the dose to the eye lens is assessed in terms of the other operational quantities*" (ICRP, 2007).

From a EURADOS survey held in 2012, it was concluded that from the 78 responding IMSs, 40% were evaluating the eye lens dose (Gilvin et al., 2015). About 50% from those (or 20% of all respondents) used the specific operational quantity $H_p(3)$, and only 16% (or 6% of all respondents) offered a dosemeter to be worn at a position near the eye. Only 7% of all respondents said they report $H_p(3)$.

Overall, before 2013, the measurement infrastructure for monitoring dose to the eye was quite poor, because there was little or no demand: very few types of dosemeters to measure $H_p(3)$ at a position near the eye, lack of standards giving guidance for type testing and calibration, no suitable phantoms and associated air kerma to $H_p(3)$ conversion factors, and no (inter)national intercomparisons.

10.3 What influences changes for IMSs?

Like all other organizations, an IMS has to take into account and react to changing circumstances in order to stay relevant for all its stakeholders. The process of identifying and analysing information relevant for the IMS and developing, adjusting and implementing plans can be regarded as elements for developing and implementing a strategy. Figure 10.1 shows a model loosely inspired by the 5-forces model of Porter (Porter, 1979). The model identifies five “forces” influencing the IMSs: legislation, the users (or customers), suppliers, other IMSs, and alternatives.

The next five paragraphs describe for each of the “five forces” how they may impact the topic “eye lens dosimetry” for IMSs.

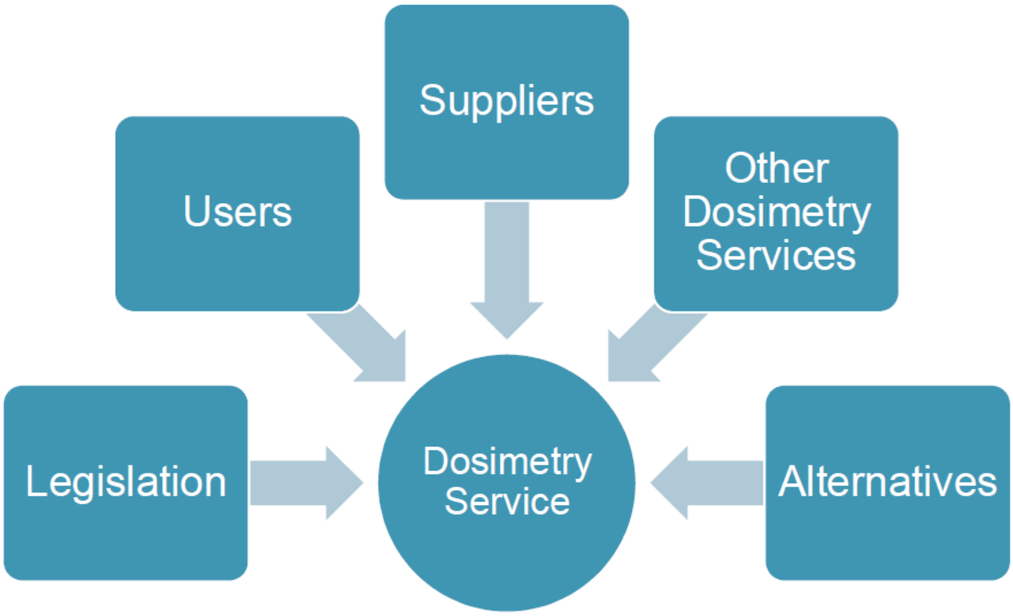

Figure 10.1: "Five forces" influencing an IMS (after Porter, 1979)

10.3.1 Legislation

Because of the legal status of the results produced by approved IMSs, it goes without saying that changes in legislation can have an essential impact on IMSs. In Council Directive 2013/59/EURATOM (EU, 2014) the annual dose limit of 20 mSv for the eye lens was adopted. Furthermore, the Directive stated “*especially category A workers should be systematically monitored based on individual measurements performed by a dosimetry service. In cases where workers are liable to receive significant exposure of the lens of the eye, an adequate system for monitoring must be in place*”.

Member States were to implement the Council Directive into their national legislation by February 2018. Whereas the Council Directive leaves quite some room for interpretation, Member States might choose to be more specific in their legal requirements. However, Member States may follow different policies with respect to the degree of detail, resulting in varying legal requirements in the different Member States.

Specifically, for requirements aimed at IMSs, differences in legal requirements exist regarding:

- Level of technical detail
- The need to offer a specific $H_p(3)$ dosemeter
- The need to offer a dosemeter suitable for positioning close to the eye
- The need to include eye lens dosimetry in the scope of the approval
- How to take into account the effect of protective eye wear

Additionally, the Member States may have legal requirements aimed at the users (radiation workers and their employers), stating for which workers specific eye lens dosimetry would be applicable.

Finally, Member States might introduce requirements for adding results of eye lens dosimetry to legal dose records, radiation passbooks and reporting eye lens doses to the national dose registry. Depending on the local arrangements, this might also impact the work of the IMS.

In the Netherlands, the legislator followed a policy to take over the Council Directive 2013/59/EURATOM in the national legislation as literally as possible, minimising country specific additions. The yearly limit of eye lens dose of 20 mSv has been adapted. With respect to monitoring, only very generally stated requirements have been included in legislation, such as the requirement for employers to provide a "suitable system of monitoring" to their employees. More specific guidelines were published by the Netherlands Commission on Radiation Dosimetry (NCS, 2018). Such guidelines do not have an official legal status but are being regarded as examples of "good practices". At the moment, there are no provisions to record eye lens doses in the national dose registry.

In contrast, in the UK the practice of recording the eye lens dose in the national dose registry has been in place for many years. McWhan and Dobrzynska (McWhan et al., 2018) describe the impact of lowering the dose limit for eye lens in the UK nuclear industry. Legal dosimetry is made with whole body active dosemeters (APDs) and (whenever needed) a passive eye lens dosemeter. Before 2018, as a conservative approach, H_{eye} was set equal to the sum of $H_p(0.07)$ from the APD and $H_p(3)$ from the eye dosemeter (whenever used). With the new limit set to 20 mSv per year, this conservative algorithm would lead to a significant number of apparent dose limit violations in the UK nuclear sector. To prevent this, a new algorithm for determining the legal eye lens dose was proposed and implemented. This new algorithm sets H_{eye} is set equal to $H_p(0.07)$ from the APD or $H_p(3)$ from the eye dosemeter, whichever is the higher value.

10.3.2 Users, customers

From the IMS perspective, the radiation workers and their employers, who use the dosimetry systems, are the customers. Obviously, it is of crucial importance for IMSs to be able to understand and fulfil the needs of the customers.

The main goal of the radiation protection policies of employers is to protect their employees from the harmful effects of ionizing radiation. In order to do this, employees need to ensure that their organisations comply with legal requirements. When it comes to radiation monitoring of their employees, employers will rely on the approved IMSs. With some exaggeration one could say that employers expect the approved IMS to provide them with the only "one true value" for the legal eye lens dose.

From the economic standpoint, employers will have interest in limiting the resources spent on the dosimetry program to an acceptable level. Examples of costs for the employer are the attention and time from own staff needed to manage the dosimetry program, costs for dosemeter subscriptions, and costs for lost dosemeters.

Finally, employers have interest in ensuring the welfare of their employees, which includes limiting the possible annoyance of employees due to having to wear (multiple) dosemeters. Apart from limiting specific eye lens dosemeter assignments to those employees who really need it, the wearing comfort of the dosemeter is very important.

The wearing comfort of a dosemeter can be improved by reducing the size and weight of the dosemeter, and by offering different options for attachment methods. Figure 10.2 shows the result of a questionnaire held in Germany for 500 dosimetry users (Hoedlmoser, 2019a). This figure shows that some attachment methods are more popular than others, but that there is not one single method which will be preferred by the majority of the customers.

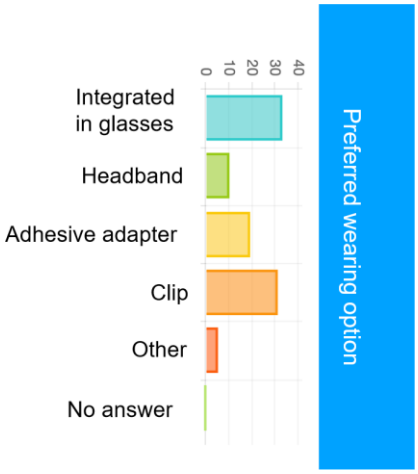

Figure 10.2: Results of a questionnaire about preferred lens dosimeter attachment options. Y axis numbers show percentages of replies for a given option, from 100 total replies (Hoedlmoser, 2019a)

To provide the best possible service for their customers, IMSs should offer high quality dosemeters at low costs, which can be easily used in the dosimetry program, which don't get lost easily, and which offer multiple options for attachment (or at least the most preferred ones).

10.3.3 Suppliers

IMSs depend on suppliers. Typically, suppliers will provide the IMS with the necessary hardware including (parts of) dosemeters, reader equipment, attachment accessories, etc. In addition, IMSs may need suppliers for IT-support services, calibration services and intercomparisons.

For all supplies, IMSs need to make a "make or buy" decision. As explained above, before 2013, there were almost no suppliers available for either specific eye lens dosemeters or calibration services. Therefore, IMSs needed to develop and manufacture their supplies themselves. Obviously, larger IMSs are in a better position to start this kind of in-house development than smaller ones. In addition, IMSs based in research institutes might be better equipped for early stage development projects. In the case of eye lens dosimetry, research projects funded by the EU, such as ORAMED (Vanhavere et al., 2012), played an important role in these early stage developments.

More recently the evolution of products supporting eye lens dosimetry has moved from research to more commercially based developments. Figure 10.3 shows an interesting recent result of collaboration of an IMS with industry, integrating an eye lens dosemeter into radiation protection glasses (Hoedlmoser et al., 2019b).

Figure 10.3: Eye lens dosemeters integrated into radiation protection glasses (Hoedlmoser et al., 2019b)

Following the developments in dosimetry hardware, intercomparisons for eye lens dosemeters have been developed by EURADOS (Clairand et al., 2016; Clairand et al., 2018). This has been followed by inclusion of eye lens dosemeter intercomparisons in the scheme of regular intercomparisons for approved IMSs organized by EURADOS.

After a decade of developments, the infrastructure for offering routine eye lens dosimetry seems to be reasonably complete. As an illustration of the diversity of available solutions, Figure 10.4 shows the first section of search results following a Google search for “eye lens dosemeter” (December 2020).

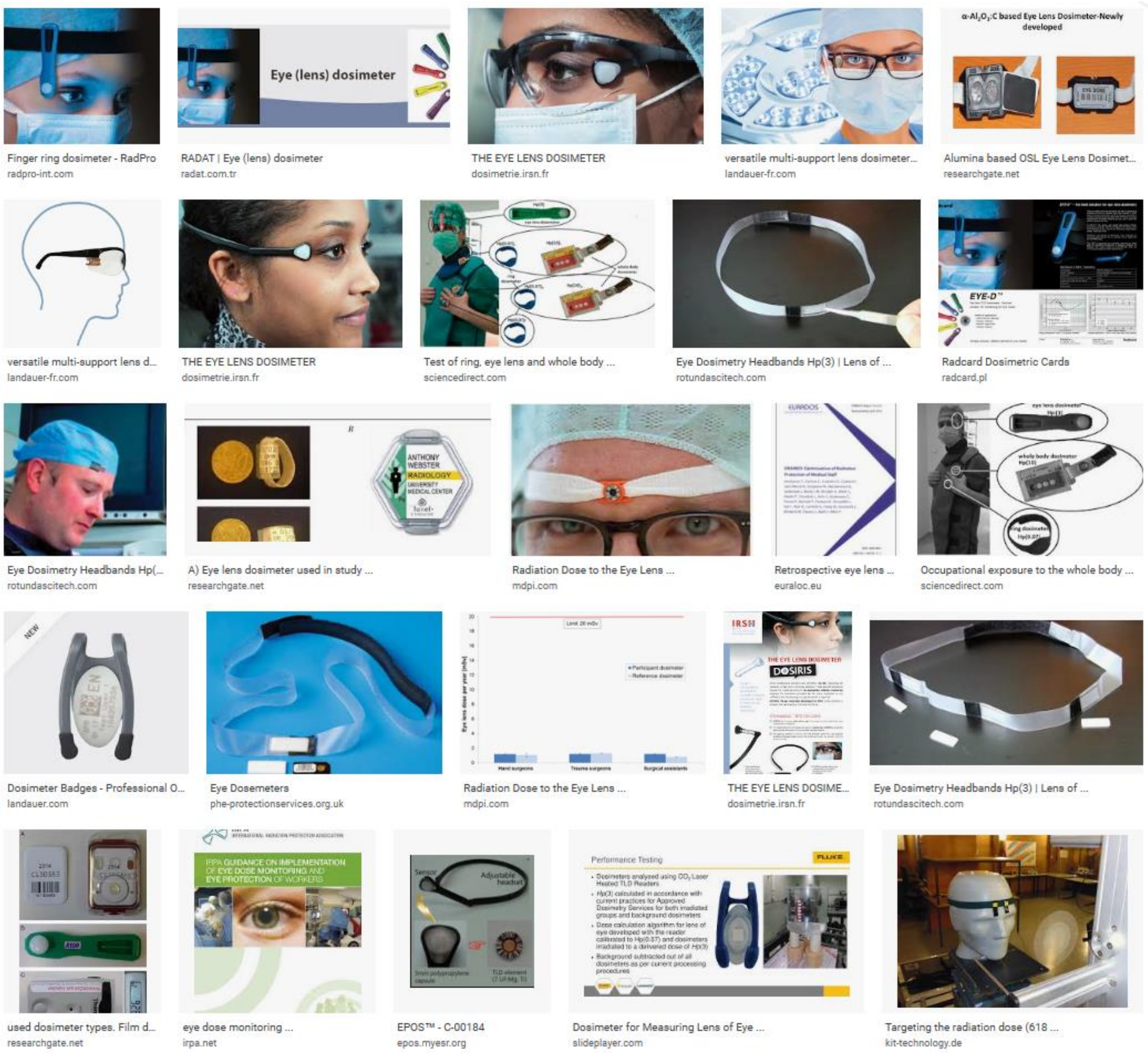

Figure 10.4: Google search results for "Eye lens dosemeter", December 2020.

10.3.4 Other IMSs

From a specific IMS perspective, other IMSs might be regarded as competitors, partners and/or suppliers. Obviously, this will depend on the mutual positions of the IMSs: yes/no to whether they are commercially active in the same market, different stage of completeness of portfolio, etc.

IMSs having mutual interests cooperate on bilateral base or in larger communities such as EURADOS, to share developmental costs and to prevent "re-inventing the wheel". Some IMSs might choose to buy eye lens dosemeters from another IMS, or even outsource the evaluation of the dosemeters to another IMS (provided this is compliant with local regulations).

In contrast, IMSs which face competition will need to carefully investigate the offer of the competing IMS, and then must decide if and how the competition can be successfully challenged. Success in competition can be supported by ensuring unique selling points which are hard to copy by the competition (for example, special attachment option for optimal wearing comfort), by offering the service for a better price and/or by offering other advantages for the customer.

10.3.5 Alternatives

An IMS offering eye dosimetry services should also keep an eye on possible alternative solutions for protecting the eye of the worker against harmful effects of radiation. Alternative approaches which were commonly accepted before the recent developments around eye lens dosimetry started might still be acceptable in many situations.

As an alternative for a specific eye lens dosemeter designed to measure $H_p(3)$ close to the eye, "traditional" dosemeters designed to measure $H_p(10)$ and/or $H_p(0.07)$ might give acceptable results, depending on dose levels and radiation qualities. Also, measurement at a position near the eye might not be critical when the radiation field can be considered to be homogeneous, for example when the radiation source is at larger distances and there is no partial shielding of the radiation field. In those cases, a reasonable estimate of the dose to the eye may be deduced from a whole body dosemeter worn either on the collar or another position of the body. For some situations it might be feasible to apply a "conversion factor" to convert a reading of a whole body dosemeter to an acceptable estimate of the eye lens dose, thus abandoning the need for wearing multiple dosemeters (see for example IRPA, 2017; NCS, 2018).

When it is possible to reduce the uncertainty in the results of computational models or risk assessments to a sufficiently low level, these calculations might provide an alternative form of insurance for compliance with eye lens dose limits, reducing or even abandoning the need for routine eye lens dose monitoring. Obviously, this will be easier to achieve in simple exposure situations compared to more complex situations (strong spatial gradients, movement of sources and/or workers). Even for those complex exposure situations attempts are being made to develop computational models as an alternative for individual monitoring, like in the "Podium" project (Abdelrahman et al., 2020). Although these attempts are not yet at a maturity level sufficient to completely abandon physical dosemeters for individual monitoring, perhaps in future this work might at least reduce the need to wear more than one dosemeter at the same time.

10.4 Implementation example: Mirion Dosimetry Services (Arnhem)

As an illustration of the actual implementation of eye lens dosimetry at an IMS, this paragraph shows the approach chosen by Mirion Dosimetry Services, Arnhem (formerly known as NRG), a midsize IMS serving about 2000 customers in the Netherlands. As already stated in the introduction, this information is only given as an implementation example and does not imply any endorsement. Any IMS will have to choose its appropriate approach which fits to local circumstances and requirements.

10.4.1 Approach chosen

Because the Dutch legislator chose to implement Council Directive 2013/59/EURATOM as literally as possible, no specific legal requirement exists in the Netherlands regarding how to measure eye lens dose. There is not a clear legal requirement that eye lens dosimetry should be included in the system for approved IMSs. Also, no provision has been made to include eye lens dose in the national dose registry (NDRIS).

Because of the anticipated low number of eye lens dosemeter subscriptions, the choice was made to outsource eye lens dosimetry to another IMS, which already offered a well-established headband type eye lens dosimetry service. The other IMS, which does not operate directly in the Netherlands, supplies the unirradiated dosemeters, reads them after use and reports to Mirion Dosimetry Services, Arnhem the measured dose per dosemeter number. Mirion Dosimetry Services, Arnhem has the responsibility of assigning the dosemeters to end-users and reporting the dose results to the end-users.

As almost no technical requirements can be found in Dutch legislation, the guidelines published by the Netherlands Commission on Radiation Dosimetry (NCS, 2018) were followed, such as the use of the quantity $H_p(3)$.

10.4.2 Implementation steps

Even when the measurements itself are outsourced, the IMS still has to deal with a number of implementation steps. In this example, several changes had to be made to the IT systems managing the dosimetry systems, to allow for the new type of dosemeters to be managed by the IMS and ordered by the customers, and to implement a specific reporting template for eye lens dosimetry subscriptions.

Because Mirion Dosimetry Services, Arnhem is responsible to its customers for the quality of the reported results, procedures were set up to monitor the quality assurance (QA) of the system. As with all other dosimetry systems at Mirion Dosimetry Services, a dummy customer was set up for eye lens dosimetry. Every measuring period, the dosemeters of this dummy customer receive a well-established dose from the calibrated irradiation system. The reported doses can then be compared with the expected value. In addition, Mirion Dosimetry Services participated in the international intercomparison organized by EURADOS, $IC2019_{ext,eye}$.

Finally, staff had to be trained to work with a number of new procedures for logistics and QA procedures, and to be able to assist customers with questions around eye lens dosimetry.

10.4.3 Experience up to now

Since the start of the new service, requests were received from about 2% of all customers. From these customers, about 50% stopped their subscriptions after a trial period of a few months. This corresponds to the survey period as recommended in the guidelines published by the Netherlands Commission on Radiation Dosimetry (NCS, 2018). It is important to note that in the Netherlands, for workers wearing protective garments, the whole body dosemeter is always worn outside the protective garment, high on the chest (NCS, 2008). While this practice leads to over-estimation of effective dose, which may imply the need for applying a correction factor, in many situations the reading of the unshielded whole body dosemeter might give a reasonable estimate of the dose of the (unshielded) eye, thus reducing the need for a specific eye lens dosemeter.

Up to now, the annual eye lens dose did not exceed 10 mSv for any of the monitored workers.

Figure 10.5 shows the relative number of subscriptions for eye lens dosemeters. The graph shows a modest peak about one year after introduction. Meanwhile the number of subscriptions seems to have stabilized at the relatively low number of about 0.2% of the total number of dosimetry subscriptions.

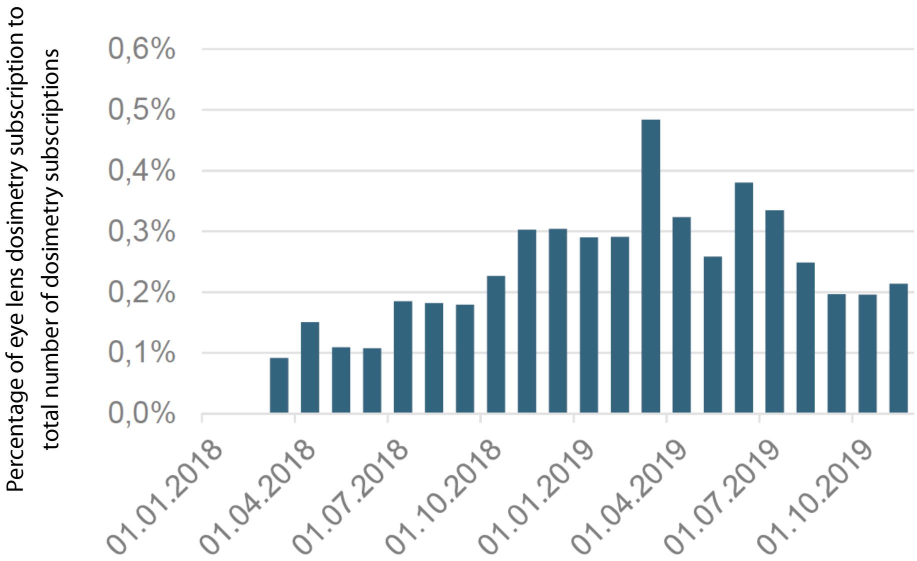

Figure 10.5: Relative number of eye lens dosimetry subscriptions at Mirion Dosimetry Services (Arnhem).

10.5 Summary

When developing and implementing a system for eye lens dosimetry, the IMS has to take into account the influence of local legislation, the users (or customers), suppliers, other IMSs, and alternatives. During the last decade the metrological infrastructure for measurement of $H_p(3)$ has been increasing, enabling IMSs to set up well-established services for eye lens dosimetry. The efforts needed to setup such a system are similar as for any other (new) dosimetry system. However, depending on local requirements and state of radiation protection practices, the number of actual eye lens dosimetry subscriptions may be limited to a relatively low number.

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11. EURADOS intercomparisons on eye-lens dosemeters

Isabelle Clairand, Institute of Radiological Protection and Nuclear Safety (IRSN), France.

11.0 Abstract

For many years, the European Radiation Dosimetry Group (EURADOS) has been organising intercomparison exercises (for whole-body, extremity and environment dosemeters) dedicated to individual monitoring services (IMS). These exercises give IMS the opportunity to compare their results with other participants and develop plans for improving their dosimetry systems. In the context of the new eye lens dose limit for occupational exposure equal to 20 mSv per year stated by the revision of the European Basic Safety Standards Directive 2013/59/EURATOM, EURADOS organized two intercomparisons dedicated to eye lens dosemeters, a first one in 2014 only for photon fields, and a second one in 2016 including tests with photon and beta radiations.

Each intercomparison brought together about twenty participants from more than a dozen countries that provided dosemeters all composed of thermoluminescent detectors of various types and designs. The dosemeters were irradiated with several photon and beta fields defined in relevant standards. Participants were asked to report the doses in terms of $H_p(3)$ using their routine protocol. The results provided by each participant were compared to the reference delivered doses and anonymously analysed.

Results are globally satisfactory for photon qualities, for both intercomparison exercices, since 90% of the results are in accordance to the ISO 14146 standard requirements. For a minority of participants, some discrepancies between results and reference doses are observed for irradiation setups characterized by low energies and/or large angles.

Results are less satisfactory for betas. The main observed difficulty is an over-estimate of $H_p(3)$ for low beta energy. This study demonstrates that dosemeters designed for $H_p(0.07)$ are not suitable to monitor the dose to the eye lens in case of betas because the filter placed in front of the detector is not thick enough. Dosemeters designed for $H_p(0.07)$ are suitable for monitoring the eye lens dose only in pure photon radiation workplaces but not in workplaces with significant contributions of beta radiation. Only dosemeters properly designed for $H_p(3)$, i.e. optimized for both photon and beta fields simultaneously, are able to perform eye lens dose monitoring at all workplaces in a satisfactory way.

11.1 Introduction

For many years, EURADOS has been organising intercomparison (IC) exercises dedicated to Individual Monitoring Services (IMS), for whole-body, extremity and environmental dosemeters (Grimbergen et al., 2011; Romero et al., 2016). These exercises give IMS the opportunity to compare their results with other participants and develop plans for improving their dosimetry systems. In the context of the decrease of the eye lens dose limit for occupational exposure to 20 mSv year^{-1} (EU, 2014), EURADOS organized two intercomparisons dedicated to eye lens dosemeters: a first one in 2014, considering photon radiation fields, so called IC2014$_{eye}$ (Clairand et al., 2016) and a second one in 2016, so called IC2016$_{eye}$ (Clairand et al., 2018), with photon and beta radiation fields.

11.2 Material and methods

11.2.1 Organisation and scope of IC exercises

Each exercise was managed and coordinated on behalf of EURADOS by an Organisation Group composed of members of EURADOS. Both $IC2014_{eye}$ and $IC2016_{eye}$ were designed to be a blind test for all participants who reported their results without knowing the reference dose values. For both IC, for photon radiation fields, the only information given to participants was that the irradiations would be performed with a ^{137}Cs reference field (S-Cs) and in photon fields representative of medical workplaces, without knowing the exact beam qualities. Regarding the beta radiation fields, participants were informed that the beam qualities chosen were ^{85}Kr, ^{90}Sr+^{90}Y and ^{106}Ru+^{106}Rh. The participants did not know which dosemeter would be irradiated to which type of radiation.

All participants were requested to prepare their dosemeters according to their usual procedures and to report the doses in terms of $H_p(3)$ using their routine protocol. All the data were treated confidentially using an identification code assigned to each participant.

11.2.2 Participants

In the case of $IC2014_{eye}$, the participants came from 20 IMS from 15 different countries (Austria, Belgium, Czech Rep., France, Greece, Italy, Lithuania, Poland, Rumania, Serbia, Slovakia, Spain, Switzerland, UK and Ukraine). For $IC2016_{eye}$, the participants were from 22 IMS from 12 different countries, even outside of Europe (Bulgaria, Czech Republic, France, Germany, Israel, Italy, Slovakia, Spain, Switzerland, Turkey, United Kingdom and USA).

All the provided dosemeters were composed of thermoluminescent detectors (Figures 11.1 and 11.2). For $IC2014_{eye}$, nine participants provided an Eye-D™ system (developed during the ORAMED European project (Vanhavere et al., 2012)), three participants provided dosemeters with a specific holder to be worn at the level of the eyes and eight participants provided dosemeters placed in a plastic bag. For $IC2016_{eye}$, a majority of participants provided dosemeters placed in a plastic bag, six provided an Eye-D™ system, three provided dosemeters with a specific holder and two provided whole-body dosemeters.

In addition, most of the participants indicated, via a questionnaire, some technical information such as the type of the included detector, the filter used if any, as well as the phantom and energy quality used for calibration. Regarding the energy quality used for calibration, in both cases, the majority of participants use pure S-Cs or pure S-Co or both, some participants used various x-ray spectra, and a minority of participants used mixed S-Cs and x-ray.

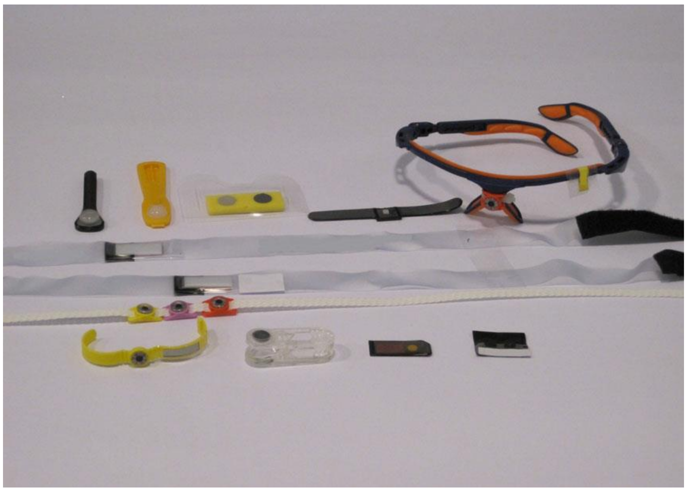

Figure 11.1: Dosemeters provided by the participants for $IC2014_{eye}$ (photo credit IRSN)

Figure 11.2: Dosemeters provided by the participants for $IC2016_{eye}$ (photo credit PTB).

11.2.3 Irradiation conditions

Reference qualities are named according to their short name defined in the standards (ISO, 2019a) and (IEC, 2005).

Tables 11.1, 11.2a and 11.2b indicate the irradiation conditions in terms of radiation beam quality, angle and dose range for each setup. For photons, S-Cs and narrow radiation field series defined in ISO 4037–part 1 standard (ISO, 2019a) were used. In addition, several reference fields representative of those encountered in medical workplaces, defined as "RQR" in IEC 61267 standard (IEC, 2005) and a so-called "realistic field" representative of the scattered field encountered in interventional radiology at the level of the operator (Bordy et al., 2007) were used. For betas, beta radiation field series defined in ISO 6980-1 standard (ISO, 2006) were used.

The irradiations were performed on a cylindrical head phantom (20 cm × 20 cm) (Gualdrini et al., 2011; Vanhavere et al., 2012; ISO, 2019b).

Conversion coefficients to relate air kerma to $H_p(3)$ were taken from Behrens (Behrens, 2012) for ISO 4037 qualities, from Principi et al. (Principi et al., 2016) for IEC 61267 qualities and from Behrens et al. (Behrens et al., 2012; Behrens, 2015) for beta radiation qualities. For the "realistic field", the conversion coefficient was calculated with PENELOPE Monte Carlo code (Salvat et al., 2009) as described in EURADOS Report 2012-02 (Vanhavere et al., 2012).

Two dosemeters of each participant were irradiated for each setup.

Table 11.1 Irradiation plan for photon qualities ($IC2014_{eye}$).

Radiation quality and angle of incidence	Mean energy (keV)	Dose range $H_p(3)$ (mSv)
S-Cs; 0°	667	0.4 – 0.5
S-Cs; 0°	667	2.0 – 2.2
S-Cs; 60°	667	2.0 – 2.1
N-40; 0°	33	3.0 – 3.1
N-60; 0°	48	3.0 – 3.1
N-80; 0°	65	3.0 – 3.1
RQR6; 0°	44	2.6 – 2.7
RQR6; 45°	44	2.5 – 2.6
RQR6; 75°	44	2.1 - 2.2
Realistic field	45	0.9 - 1.0

Table 11.2a Irradiation plan for photon qualities ($IC2016_{eye}$).

Radiation quality and angle of incidence	Mean energy (keV)	Dose range $H_p(3)$ (mSv)
RQR6; 0°	44	2.0 – 3.0
RQR6; 45°	44	2.0 – 3.0
RQR6; 75°	44	2.0 – 3.0
N-100; 0°	85	2.0 – 3.0
S-Cs; 0°	662	2.0 – 3.0
S-Cs; 60°	662	2.0 – 3.0

Table 11.2b Irradiation plan for beta qualities ($IC2016_{eye}$).

Radiation quality and angle of incidence	Mean energy (MeV)	Dose range $H_p(3)$ (mSv)
^{85}Kr; 0°	0.24	0.03 – 0.04
$^{90}Sr+^{90}Y$; 0°	0.8	2.0 – 3.0
$^{90}Sr+^{90}Y$; 60°	0.8	2.0 – 3.0
$^{106}Ru+^{106}Rh$; 0°	1.2	1.0 – 1.5

11.2.4 Results evaluation

The numerical results are reported as the dosemeter response R, where R is defined as the value of the dose reported by the participant and corrected for transit dose, H_s, divided by the reference value, $H_p(3)_c$, given by the irradiation laboratory.

The performance limits according to the ISO 14146 standard (ISO, 2018), commonly known as “trumpet curves”, were adopted to analyze the results:

$$\frac{1}{F}\left(1-\frac{2H_0}{H_0+H_C}\right) \le R \le F\left(1+\frac{H_0}{2H_0+H_C}\right) \quad (1)$$

where H_c is the conventional quantity value, R is the response, F = 1.5 according to the recommendations of ICRP 75 report (ICRP, 1997).

For IC2014$_{eye}$, H_0 was chosen equal to 0.085 mSv for all participants, assuming a “lower limit of the dose range for which the system has been approved” of 1 mSv in a year, and an issuing frequency of 12 per year, consistent with the EURADOS report “EURADOS Intercomparison 2008 for Whole Body Dosemeters in Photon Fields” (Grimbergen et al., 2012).

For IC2016$_{eye}$, H_0, was chosen equal to 0.3 mSv, according the current version of the ISO 14146 standard (ISO, 2018).

11.3 Results and discussion

11.3.1 Photon qualities

Figures 11.3 and 11.4 give a general overview of the response values R as a function of the reference doses H_C for photon qualities for each IC.

Globally, 90% of the results were within the trumpet curves (see the definition of this term in the paragraph dealing with results evaluation) for photon qualities. This percentage is almost equal to 100% for S-Cs, N-100 and N-80. This is consistent with the fact that these qualities are very often used for calibration purposes by the participants. This percentage decreases for lower energy setups: 89% for RQR6; 0°, 84% for RQR6; 45° and 77% for RQR6; 75°. The worst result corresponds to low energy and large angle irradiation setups.

Figures 11.5 and 11.6 give a representation of the results with box plots for each participant. A relatively large variability was observed among participants, the median of responses ranges from 0.7 to 1.6.

The difficulties noticed for large angle irradiation setups were more frequently observed for dosemeters placed in plastic bags, but this was not systematic, and the difficulties also occurred for other types of dosemeters. In addition, these results do not show any obvious link with the beam quality used by participants for the calibration. A deeper analysis cannot be carried out due the relatively low number of participants and dosemeter types considering the organizers’ commitment to maintain the anonymity of results.

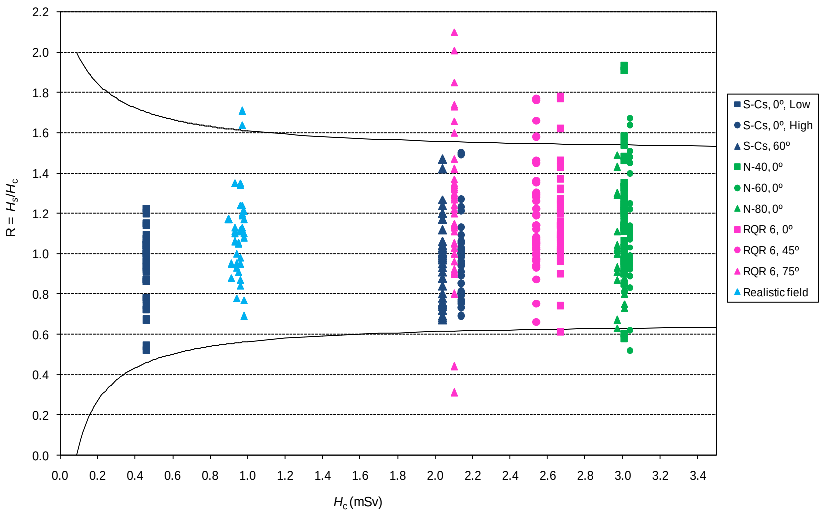

Figure 11.3: Summary of all reported response values *R* as a function of reference dose for all the participants for photon qualities for $IC2014_{eye}$. The short names used for the radiation qualities indicated in the legend are those indicated in the standards ((ISO, 2019a) and (IEC, 2005)).

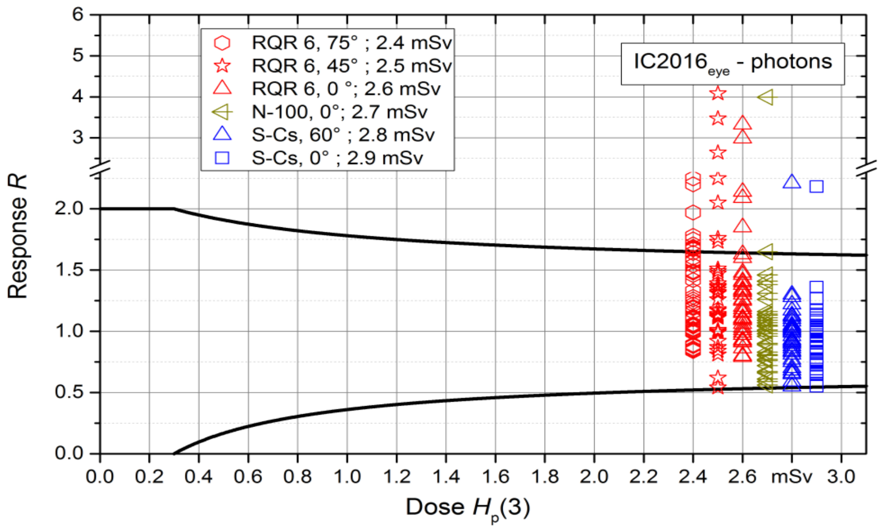

Figure 11.4: Summary of all reported response values *R* as a function of reference dose for all the participants for photon qualities for $IC2016_{eye}$. The short names used for the radiation qualities indicated in the legend are those indicated in the standards ((ISO, 2019a) and (IEC, 2005)).

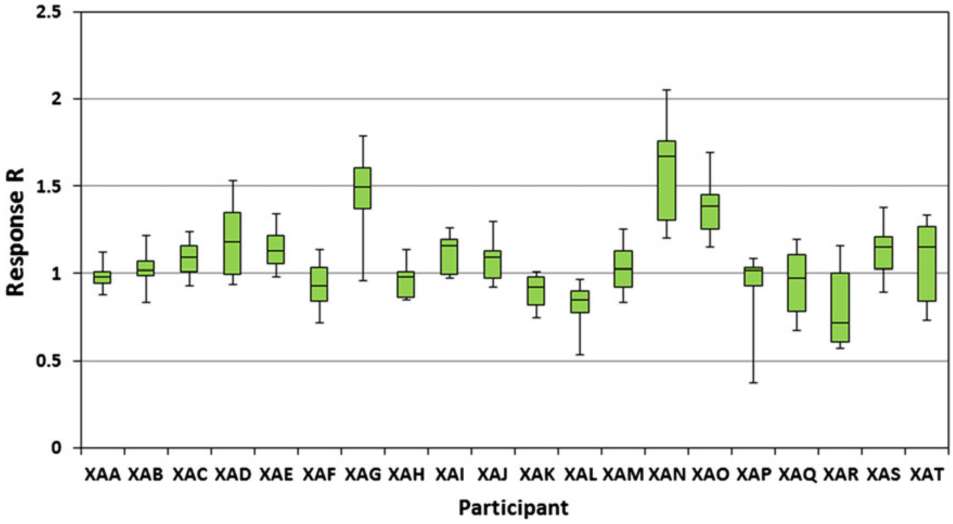

Figure 11.5: Box plots showing the minimum, 1st quartile, median, 3rd quartile and maximum responses for each participant for photon qualities for $IC2014_{eye}$. "XXX" are the participants' identifiers.

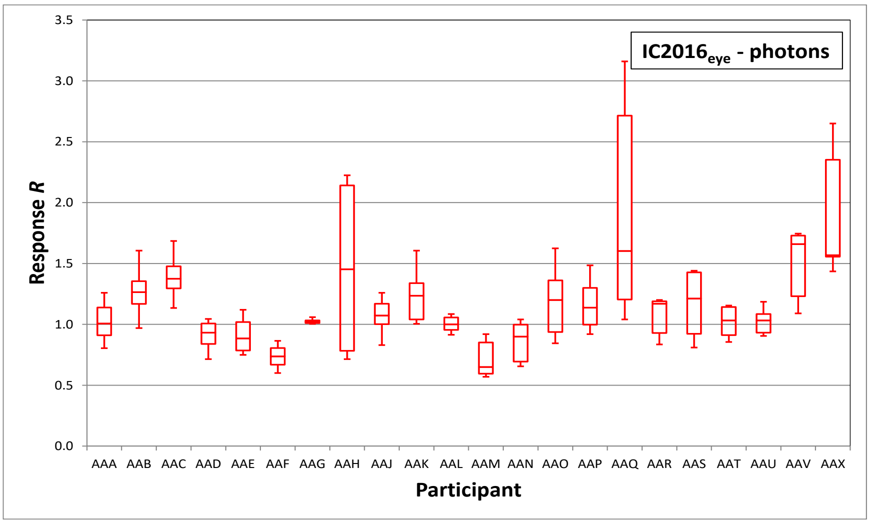

Figure 11.6: Box plots showing the minimum, 1st quartile, median, 3rd quartile and maximum responses for each participant for photon qualities for $IC2016_{eye}$. "AXX" are the participants' identifiers.

11.3.2 Beta qualities

Figure 11.7 gives a general overview of the response values *R* as a function of the reference doses H_C for beta qualities. Only 51% of the results were within the trumpet curves. This percentage differs very significantly with irradiations setups. For ^{106}Ru+^{106}Rh setups, characterised by high energy betas, 84% of results were within the trumpet curves. However, for lower energy betas, the percentages decreased dramatically, 45% for ^{90}Sr+^{90}Y and 41% for ^{85}Kr.

For technical reasons (mainly linked to extremely long irradiation times), the conventional quantity value for ^{85}Kr was low (0.031 mSv). This value is below the usual reporting level and below the lower detection limit of most IMS. Consequently, it is considered that the participants, for whom H_s were not stated for ^{85}Kr for this reason, gave a correct answer. This was the case for five participants.

Figure 11.8 gives the distribution of the response value for each irradiation setup using a box plot representation. The median of responses ranges from 0.96 to 1.9 for all betas setups except for ^{85}K for which large overresponses were observed with a median equal to 154.

Among the 22 participants, only 1 had results that were 100% within the limits set by the ISO 14146 standard (ISO, 2018) for all setups with beta qualities. For ^{106}Ru+^{106}Rh, 18 were within the trumpet curves, while this number drops to 10 and 8 for ^{90}Sr+^{90}Y 0° and 60°, respectively and to only 4 for ^{85}Kr. A relatively large variability was observed among participants, the median of responses ranges from 0.6 to 13.5. Figure 11.9 presents results using a box plot representation, excluding results for ^{85}Kr; in this case, the median ranges from 0.6 to 9.8. In total, 3 participants were out of the limits for all the beta qualities, and 5 participants were out of the limits for low energy beta qualities (^{90}Sr+^{90}Y and ^{85}Kr).

Large overresponses to ^{85}K radiation were observed for some dosemeters designed for the measurement of $H_p(0.07)$ because there is an insufficient filter in front of the detector. Indeed, ^{85}K has a beta maximum energy of about 0.69 MeV, which does not contribute to the delivered $H_p(3)$ dose, with the exception of the respective small photon contribution (514 keV). For ^{90}Sr+^{90}Y and ^{106}Ru+^{106}Rh, the overresponses were lower, because betas contributed significantly to $H_p(3)$ compared to ^{85}Kr.

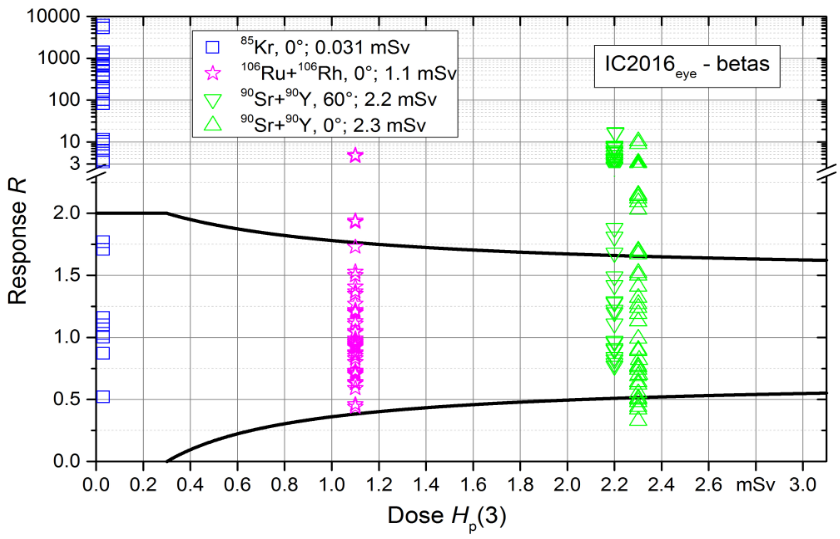

Figure 11.7: Summary of all reported response values R as a function of reference dose for all the participants for beta qualities.

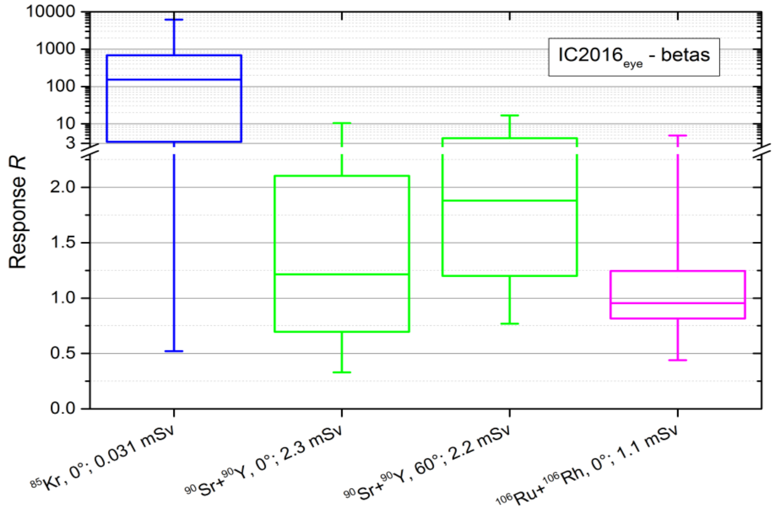

Figure 11.8: Box plots showing the minimum, 1st quartile, median, 3rd quartile and maximum responses per irradiation setup for beta qualities.

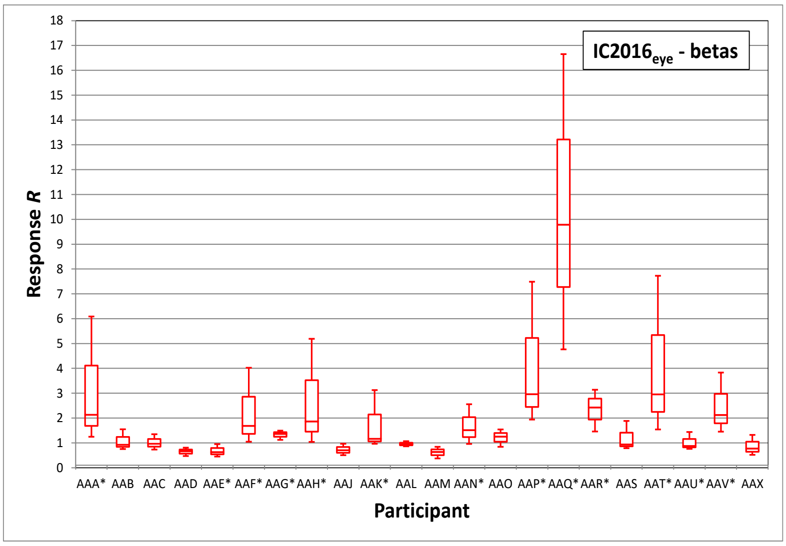

Figure 11.9: Box plots showing the minimum, 1st quartile, median, 3rd quartile and maximum responses for each participant for beta qualities excluding results for ^{85}Kr. Participants marked with * gave results outside of the trumpet curves for ^{85}Kr.

11.4 Conclusion

These two intercomparisons give an overview of the different dosimetry systems currently available for eye lens dose monitoring.

Results are globally satisfactory for photon qualities, whatever the type of dosemeter, since 90% of the results were in accordance to the ISO 14146 standard requirements. For a minority of participants, some discrepancies between the results and reference doses were observed in the case of the irradiation setups characterized by large angles and/or low energies.

Results for betas were less satisfactory and illustrate the difficulties in measuring beta radiation. The main observed problem was an over-estimate of $H_p(3)$ for low beta energy. The intercomparison demonstrates that dosemeters designed for $H_p(0.07)$ are, in general, not suitable to monitor the dose to the eye lens in case of betas because the filter placed in front of the detector is too thin.

This type of intercomparison exercise is intended to be carried out on a regular basis by EURADOS.

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