Report of Task Group on the impact of the Eye Lens Dose Limits

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IRPA

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Summary

In January 2015, IRPA launched a Task Group aiming to contribute in creating a positive and complete awareness about radiation protection in the work place, with particular attention to exposure of the lens of the eye. This Report presents the results of a survey on the view of the IRPA professionals on the new limit to the lens of the eye and on the wider issue of tissue reactions. Recommendations derived from the survey are presented.

1. Introduction

The International Commission on Radiological Protection, after reviewing epidemiological evidence on tissue reactions, in its statement on tissue reactions, April 2011, and ICRP Publication 118 (2012), suggested a reduced nominal threshold of 0.5 Gy in absorbed dose for effects in the eye lens. At the same time the Commission recommended a reduction in the eye lens dose limit for occupational exposure in planned exposure situations from 150 mSv/y to 20 mSv/y, averaged over defined periods of 5 years, with no single year exceeding 50 mSv.

This recommendation has been incorporated into the new International Basic Safety Standards IAEA, 2012, and in the current European Basic Safety Standards, 2013.

The European Member States are required to implement the new BSS by February 2018 and accordingly, for the purpose of monitoring and surveillance, workers with lens exposure likely to exceed 15 mSv/y will be classified as category A workers.

1.1 IRPA TG, Phase 1

The International Radiation Protection Association, IRPA, established a Task Group (TG) in December 2012, chaired by John Broughton, SRP, to provide an international view on the impact of implementation of the ICRP reduced dose limit for the eye lens for occupational exposure. IRPA Associate Societies (ASs) were asked to complete a questionnaire addressing three topics: implications for dosimetry; implications for methods of protection; and wider implications of implementing the revised limit.

Answers were received from 12 ASs (Argentina, Belgium, France, Hungary, Italy, Japan, Nordic Societies, Spain, Romania, Slovakia, UK and USA), covering 16 countries from regions including Europe, North and South America and Asia. A comprehensive report, with general and specific conclusions, was produced by the TG and topic experts, chosen from volunteers nominated by the ASs, (Broughton et al 2013). The results of the survey were presented at the ICRP 2nd International Symposium on the System of Radiological Protection, ICRP 2013, and at other different events (Broughton et al. 2015).

IRPA agreed to continue this work to ensure that the findings and concerns highlighted in the work done by this initial TG would be integrated into the ongoing international discussion on implementation of the revised dose limit to the lens of the eye.

1.2 IRPA TG, Phase 2

On January 9th, 2015, the terms of reference was approved by the IRPA President defining a TG phase 2, to contribute in creating a positive and full awareness about radiation protection at the working places, with attention to exposure of the lens of the eye and the revised dose limit for workers. The initial structure of the TG was:

Chair *Marie Claire Cantone* (President AIRP, Italy),
Vice-Chair *Mercè Ginjaume* (Vice President SEPR, Spain)
Saveta Miljanic (CRPA, Croatia)

and on March 21st, 2015, the group has been completed by including the members directly nominated by the ASs:

Colin Martin (SRP, UK)
Keiichi Akahane (JHPS, Japan)
Louisa Mpete (SARPA, South Africa)
Severino C. Michelin (SAR, Argentina)
Cynthia M. Flannery (HPS, US)
Lawrence T. Dauer (HPS, US)
Stephen Balter (HPS, US)

The aim of the TG is to report the evaluations and positions of the radiation protection community, after the first TG report presented and approved, nearly three years ago, on July 2013 by the IRPA E.C., with reference to: i) the best applied methods for monitoring dose to the lens and possible critical issues in relation to the dose limits, with attention also to the methods used to reduce dose to the eye; ii) the ongoing path towards the implementation at legislative level in the different countries. At the same time, this second phase TG provide an opportunity to obtain the views of professionals of the IRPA ASs on considerations related to the wider generic issue of tissue reactions.

2. The questionnaire, its distribution and the obtained responses

The TG developed a questionnaire to promote awareness and feedback mechanisms regarding practitioner experiences on eye lens dose and to collate key practical experiences on monitoring eye lens dose, on methods of protection, and related practical implementation issues.

The questionnaire as a tool to structure the responses, is based on 22 questions addressing, within the different areas of practice, four topics:

1) Implications for Dosimetry. This topic concerns the implications for monitoring and assessing dose to the lens of the eye and the interpretation of the results;

2) Implications for Methods of Protection. This topic concerns the implications for methods of protection used to reduce dose to the eye, in the context of optimization of protection.

Likewise for topic 1, most contributions refer to methods of protection in medical applications, and more specifically in interventional radiology and cardiology.
3) Wider Implications of Implementing the Revised Limits. This topic aims to identify any direct or indirect impact on current practice, which would result from implementation of the revised dose limit.
4) Legislative and other general aspects. This topic aims to highlight, at national level, the activities in preparing guidelines addressing eye monitoring and the progress along the path of legislative processes in consideration of the new limit. Moreover, this topic addresses the wider issue of tissue reactions with attention to circulatory diseases.

On April 23rd, 2015, IRPA ASs were asked to provide responses, views and any additional comments on the basis of the questionnaire.

A total of twenty two IRPA ASs, covering 40 countries from Africa, North and South America, Asia, Australia and Europe, actively contributed by collecting, with their own internal procedures, views and comments from their professionals, on the impacts related to the implementation of the new limit for the lens of the eye, and by filling in the questionnaire. The TG Phase 2 has received the completed questionnaire from the associations of: Argentina, Australia and New Zealand, Austria, Belgium, Canada, Croatia, Eastern Africa, France, German-Swiss, Hungary, Israel, Italy, Japan, Korea, Netherlands, Nordic societies, Romania, Russia, Southern Africa, Spain, United Kingdom, USA.

3. The structure of the survey Report

The TG members have analyzed the collected answers to discuss and define not only the common points and issues which have attracted the attention of the majority of the ASs, but as well, where present, the peculiarities and specific issues from the topics concerned.
As a result of this activity, the responses received for each of the 22 questions, under the four topics, have been collated and summarized to obtain an effective and complete picture.

This analysis is reported in section 2.
In order to give a presentation of the key themes that have emerged, section 3 presents the conclusions that can be drawn from the survey, with attention to the following points: - Direct implication in dosimetry and protection; Pilot studies; Implications related to dose recording and itinerant workers; Exposure for the eye lens of patients and public; Health surveillance; The status of legislative processes with regard to the new limits for the lens; The wider issue of tissue reactions; Costs; and Training.
A series of specific recommendations derived from the received responses, are presented, in section 4, with reference to the following main subjects: Scientific and regulatory aspects; Dosimetry and Protection aspects; Cost implications; Awareness, culture and training; and Consideration of tissue effects other than eye lens effects.

In addition, the TG has taken the opportunity to look at possible changes and trends in the ASs views from first survey to this second one, after nearly three years (see section 5).

4. Presentation of answers

4.1 Topic 1 Implications for Dosimetry:

Q1. Since there is already a requirement to assess doses to the eye, what is/are the current best method(s) in use for the measurement of Hp(3)? Consider and specify in terms of the location, the types of dosimeters and the use of correction factors.

The principle area in which special attention is thought to be required by all ASs relates to measurement of the dose to the lens of the eye in medical applications, specifically interventional radiology and cardiology. The use of x-ray imaging in medical interventions is a special case because personnel are required to work in close proximity to x-ray sources and the exposures received are non-uniform as staff wear lead aprons to shield the body while the head may not be protected. Currently half of the ASs reported that a dosimeter worn outside the collar of the lead apron is used to give an indication of eye dose, but no factor was applied to correct the dose to provide a better assessment of the dose received by the eye. However, the majority of countries do not have results that are sufficiently comprehensive to relate to eye dose levels at the present time.

A dosimeter measuring Hp(3) placed close to the eye is seen as the ideal method for measuring the dose to the lens and several ASs reported that this was done at some centres for interventional clinicians. However, a number of ASs considered that direct measurements adjacent to the eyes may not be practicable or sufficiently robust for routine use and that measurements at the collar provided an acceptable alternative. Most ASs that favoured a dosimeter worn close to the eye stated that this should be on a head band without giving details of the exact position, but a few suggest that the dosimeter should be worn either on the forehead, or on the eyebrow ridge or side of the head adjacent to the x-ray source. A fifth of the ASs suggested attaching the dosimeter to or incorporating it into protective glasses as an alternative option.

The issue of how to take account of personnel wearing protective eyewear was raised by many ASs, with several suggesting application of an agreed correction factor, and one preferring measurements made under lead glasses.

For the nuclear industry and other non-medical sectors the use of a whole body dosimeter is considered likely to be sufficient for the majority of workers.

Q2. What systems under consideration or further development are you aware of or are you using for improved measurement of Hp(3)? Please consider and specify the different dosimetry methods: from the use of double dosimetry (over-apron at neck and under-apron at chest) to the use of a single collar dosimeter, outside apron, to obtain an indication of both eye lens and body doses, to the use of a supplementary dosimeter placed in a position adjacent to the eye. Consider both passive and active dosimeters. Provide cost implications where possible.

All ASs reported that their countries are planning to use passive dosimeters such as thermoluminescent (TLDs) or optically stimulated luminescent dosimeters (OSLDs) to measure the dose to the lens of the eye, but a quarter said that suitable dosimeters were not available currently in their countries. Special dosimeters worn close to the eye have only been used in specific pilot studies in most countries. Several ASs reported that active dosimeters are being considered, especially during initial dose assessments and during optimization of protection. Where eye monitoring is performed currently, either at the collar or the head, the use of Hp(3) is limited because suitable dosimeters are not yet widely available, and so both Hp(0.07) and Hp(10) are used. Most countries propose to use Hp(3) in the future provided methods are available, but Hp(0.07) may remain in use for photon fields in a few countries, if this is regarded as adequate. The production of suitable dosimeters, establishment of

calibration facilities for Hp(3), and the associated arrangements for regulatory approval are perceived as important needs in a number of countries.

Difficulties are foreseen in achieving good compliance in wearing dosimeters by interventional radiologists and cardiologists who are the ones more likely to receive eye doses approaching the new dose limit. Therefore, arrangements that are put in place need to make compliance as straight forward and practical as possible, but in addition to this, there is a need for improvement in radiation protection culture through raising the awareness of staff about effects on the eye, methods of reducing exposure and the importance of wearing dosimeters. In order to achieve this radiation protection professionals, with support from their management need to engage staff in programmes of education and continuous improvement (Cole et al 2014).With regard to facilitating compliance, it is considered that dedicated eye dosimeters will only be appropriate for more highly exposed workers. A collar dosimeter is seen as having the potential to provide a satisfactory method of checking the dose levels to which most personnel are exposed by countries that have experience in dose monitoring. A number of ASs reported that in their countries a collar dosimeter would be worn as the first dosimeter by staff working with x-rays, with Hp(3) giving a measure of eye dose, while about a quarter reported they would use dosimeters both under and over the lead apron. The majority of countries are now starting to use a dosimeter worn at the collar outside the lead apron to provide indicative values for the dose to the eye lens. Most ASs indicated that the proposed neck dosimeter should be worn at the collar on the side nearest to the x-ray tube, with a few suggesting at the shoulder, and one simply a chest dosimeter. Two ASs proposed that interventional staff wear a dedicated dosimeter adjacent to the eye and one under the lead apron to provide a measure of effective dose, and another two are comparing this approach with the collar and under apron double dosimeter option.

An issue raised with regard to the wearing of collar dosimeters, was the need for agreement on a suitable category under which the doses could be recorded in the national dose register. Some ASs reported that the reading of the collar dosimeter was recorded as the eye dose. Although the readings will only give an indication of eye dose, the application of correction factors is not looked upon favourably by regulators and would have large uncertainties.

For the nuclear and other industries studies are being undertaken to establish ratios between direct measurements of eye dose and body dosimeter results. Special dosimeters will be required to measure Hp(3) for neutrons where workers are exposed to more than one type of radiation, for example, in well logging with mixed radiation fields (gamma and neutrons), or workers in nuclear facilities.

From the varied responses it is clear that there is uncertainty around the cost implications. ASs estimated that the cost would be high, not only because of the extra dosimeter, but due to the radiation protection officer time to evaluate whether corrections to the measurements are required, and additional accounting and management. One AS stated that without proper preventive risk assessment and stratification of workers, the increased costs for dosimetry could be unacceptable. Another AS estimated that the nominal cost of a dosimeter would be about 7 Euro, including the delivery, evaluation and reporting, together with the additional dosimetry service requirements (e.g. verification, calibration, accreditation, and licensing).

Q3. Are these measurement methods dependent (or likely to be dependent) on the level of the dose being measured on the type of work or on any other conditions?

Almost all ASs in countries that had experience in eye dose monitoring stated that dedicated eye dosimeters would only be required for a smaller number of highly exposed individuals

who were likely to approach the eye dose limit. Dose levels for the collar dosimeter could be set to trigger wearing of additional eye dosimeters.

Q4. What methods will be used to assess potential doses to the eye lens and to identify staff members who are likely to require monitoring for eye dose?

Identification of personnel who could receive high doses to the eye lens would in the majority of countries be undertaken through risk assessment. Potential dose levels for different staff would be based on personal job description, and type of work and sources used. For interventional clinicians, the workload, types and numbers of procedures, and positions with respect to the radiation sources, as well as dosimetry data in the literature would be applied. This would be supplemented with workplace measurements, analysis of dosimetry data, and the results of pilot studies undertaken to determine dose levels, including the use of active dosimeters in assessment of potential eye doses. A primary two stage practice is foreseen by the majority of countries for interventional radiology and cardiology staff: 1) the use of a collar dosimeter as the first option, and 2) an additional dosimeter would be worn adjacent to the eye, by those recording a dose with the collar dosimeter above an agreed level.

Q5. Are you aware of any pilot study in progress or already finished ? Please specify details or references and highlight the changes since the last 2 years.

Three quarters of the ASs reported that some pilot studies related to doses to the lens of the eye are being conducted in their countries. The general aims are to identify staff groups who could potentially receive high doses to the lens of the eye in different work places and investigate the most appropriate monitoring arrangements. The studies focus primarily on interventional radiology and cardiology procedures, quantifying doses and collecting data that could be useful for future dosimetry applications for the lens of the eye. The potential dose reduction from the wearing of lead glasses and the resulting optimization of doses to the lens of the eye have been studied. There are also some studies that involve initiatives to monitor patients who could receive significant doses to the eye lens.

In several countries national organizations such as institutes of radiation protection, professional societies, national dosimetry services and other research laboratories are collaborating with hospitals and other users in pilot studies, and in one country the regulator is funding two such projects. One collaborative study quantifying doses to the lens of the eye of interventional cardiologists involves a national workers' compensation board. Since it is conceivable that current and previous exposures to the lens of the eye could impact on worker compensation matters/claims. The majority of the pilot study programmes reported have been carried out in the last few years and most are focused on medical applications, but some could be expanded to address issues relating to exposures of the lens of the eye in the nuclear industry in the future.

The European Radiation Dosimetry Group (EURADOS) has undertaken studies of optimization of radiation protection of medical staff (ORAMED) that includes personal dosimetry. This has involved collation of large amounts of dosimetry data from nine European countries with a wide range of practices and the results have been published in an extensive report [Vanhavere et al 2012]. A number of countries around the world that had not undertaken any studies of their own were aware of this publication and the report from the IAEA on the subject [IAEA 2014]. Other publications quoted by responders were NCRP [2010] and Vano et al [2013].

Several ASs referred to an International Conference on Individual Monitoring that was held in Belgium in 2015, in which results on different aspects relating to eye dosimetry were reported for all sectors by many different countries. Proceedings are to be published as a

special issue of the journal Radiation Protection Dosimetry [IM2015]. Investigations of a number of methods for estimating eye dose based on ratios such as Hp(3)/Hp(10) for both the nuclear and medical sectors have been proposed at the meeting. Much of the work reported relates to the nuclear industry and ASs supported follow-up of the potential of the methodologies described. The application of a specific Hp(3) dosimeter close to the eye could be a more feasible method for monitoring the lens dose in the nuclear Industry.

ASs also mentioned projects to assess the prevalence of pre-cataract lesions and expand the knowledge and awareness of effects among cardiologists. Congresses of the Latin America Society of Interventional Cardiology have initiated a project entitled Retrospective Evaluation of Lens Injuries and Dose (RELID) in which eye examinations to detect opacities have been performed on delegates. Similar projects based around international conferences are being undertaken for interventional radiologists in other parts of the world.

Q6. Are there any implications for dose recording, including possible considerations for itinerant workers ("outside workers" - i.e. people who work at more than one location)?

The majority of ASs consider that there are significant implications relating to dose recording for itinerant workers. Many countries already use a National Dose Register, in which dosimetry data associated with each person are summed continually, especially for nuclear applications. However, a number do not at the present time include eye lens doses, which are only recorded by the approved dosimetry services and the employing organisations. Thus there are likely to be significant issues in extending the dose records kept currently, and recording results from the additional dosimeters will add to the administrative burden. Many ASs did not mention their National Dose Register in their responses.

The issue of itinerant workers is thought to present a significant problem for the medical sector, especially where clinicians work in both public and private hospitals. Clinicians working in several departments and hospitals are likely to receive low doses from a number of different locations, and tracking and recording of these doses is a major challenge. ASs reported a variety of practices with regard to maintaining monitoring records. In some countries dosimeters are provided by employers just for work undertaken in their hospitals, which then have to be collated, whereas in others employees have the option of having two dosimeters – one which is carried from one workplace to another, and the other is workplace based. Responsibility for collation of doses is also variable and may lie with the primary employer or the dosimetry service where there is a single national laboratory providing the service. The use of multiple dose monitoring service providers in some countries could increase the administrative burden of cross checking and collating results. There is a need for greater cooperation between respective management teams with regard to dosimeter positioning and ensuring the correct dosimeters are worn, as well as for the sharing of dose information.

Within the nuclear sector procedures for tracking itinerant workers are thought usually to be in place. However, a study in the United States reported that there are significant numbers of itinerant workers who are badged at more than one location in a year, especially nuclear power facility workers (Boice et al 2006). This study found that nearly 32% of workers are being monitored for radiation at more than one facility. This study demonstrated that movement of workers between plants occurs widely, and good measures need to be in place to make sure dose recording is done efficiently to avoid under-recording of doses.

National Dose Registers only record data for workers in single countries and do not take account of international workers. The Nordic countries indicated that International dose passports are becoming increasingly important for international consultants and workers in addition to the National Dose Registers.

Q7. Are there any problems foreseen in achieving compliance by wearing eye dosimeters and if so, is there any information about strategies that might be used to overcome these problems?

Significant problems are foreseen in ensuring staff wear dosimeters correctly and consistently, because of the comparatively poor appreciation of the risk in the medical sector. ASs reported that the current level of compliance in wearing dosimeters was unsatisfactory in most countries with users frequently forgetting to wear dosimeters, not returning them at the end of the monitoring period, and leaving them on clothing in locations where they receive additional exposure. The additional effort required for the management of an extra dosimeter for the eye will only compound these problems. This is an important reason given by ASs in support of the plan to measure the eye lens dose with the whole body collar dosimeter. Substantive programmes of education and motivational training, emphasizing the benefits of a strong radiation protection culture are seen as the best ways to tackle the problem of persuading staff to wear the additional dosimeters required consistently. These can only be implemented through the engagement of radiation protection professionals and staff with proactive support and encouragement from management (Cole et al 2014). The education programmes need to be coupled with audits of compliance overseen by radiation protection professionals, and reviews to identify any 'disconnects' which create poor communication and address relevant issue.

Another issue that a third of ASs highlighted as being likely to affect compliance is the potential discomfort involved in use of an eye dosimeter, especially by medical staff wearing spectacles. Eye dosimeters will require some device to keep them in the proper position, and compliance will be reduced if they are uncomfortable or obscure vision. Further improvement in the design of suitable dosimeter holders by the manufacturers to minimise any discomfort and to improve ease of use would be welcomed. The need to maintain the sterility of the dosimeter and the holder that are used on a daily basis is also a concern. The option of attaching dosimeters to spectacles was proposed by several countries.

Harmonisation of the approach to monitoring and agreement on the optimum location for head dosimeters are issues that still need to be addressed. Agreement about suitable methods for taking account of protection provided by lead glasses when dosimeters are worn outside the protection is important. The lack of suitable dosimeters to measure Hp(3) was seen as an issue in some countries. The cost of implementing arrangements that require an extra dosimeter and protective measures requiring purchase of protective eyewear may be a further obstacle to implementation.

Q8. Are there experiences in the evaluation of dose to the lens of the eye, in relation to possible contamination ?

Experience of contamination of the lens of the eye is very limited. Doses to the lens of the eye in relation to possible contamination may be due to contamination of the individual or the work place. In the case of work place contamination, the particle flux (surface activity), rather than the dose, should be monitored. The medical sector is unlikely to need to evaluate doses to the eye lens from personal contamination.

One AS reported that the possibility of contamination of dosimeters could be assessed using a surface contamination meter before they were returned to the dosimetry service from centres where contamination was a risk, and work procedures could be put in place at the dosimetry service for dealing with dosimeters reported to be contaminated.

4.2 Topic 2 Implications for Methods of Protection

Q9. What procedures and currently available protective equipment are used for reduction of the dose to the eye? Indicate also any problem experienced and provide cost implications if possible.

In the medical field eye lens dose is often reduced by protective shielding systems such as, leaded glasses, ceiling suspended shielding and table curtains. However, such protections are not always available and their use is quite different from hospital to hospital, even within the same country. Because of the dose limit reduction, the use of these protection means shall be more frequent and personnel would require additional training on their proper use as well as on general radiation protection methods (to increase distance from the source, to reduce time of exposure). Several ASs insist on the importance of the correct use of the protection means: the lower the dose limit, the more crucial is the position of the protections, which is often more important than the lead thickness equivalence.

In nuclear installations such as NPP's and reprocessing facilities, shielding masks and glove-box, as well as remote systems, were already in use before the introduction of the new dose limit. No major changes are foreseen except for one association, which pointed out the possibility of requiring special attention in non-uniform external exposure in the case of renovation and maintenance of hot cells in reprocessing facilities.

One of the problems more frequently identified is related to the discomfort associated with the use of lead glasses because they are heavy and very often are not suitably individually fitted. In addition, for some countries their use is also an economic issue. Generally speaking, the need to implement any additional protection means is foreseen as an increase in cost of procedures for the employer. Another issue raised by several ASs is the difficulty to correctly assess the eye lens dose when using lead glasses.

Q10. What procedures and equipment might be used in the future for reduction of the dose to the eye? Are you aware of any study in progress to evaluate the effectiveness of the protection?

For the future, the majority of ASs foresee to continue with the use of the protection means presented in the previous paragraph, increasing and improving their use, as well as their design and specifications. The need to increase awareness of workers potentially exposed is highlighted. Two ASs propose the use of active real-time dosimeters for such purpose.

Some manufacturers have developed special equipment, such as Cathpax CRT, Lemer Pax Innovative and Carquefou, but their use will probably be limited to the more wealthy countries and a few specialized departments.

In the nuclear sector, potential CCTV operations, different analysis techniques, or anything to place the operator at a remote position may be employed.

Q11. What methods are used to ensure that the use of protective equipment is optimized?

Safety culture implementation, training and awareness of risk are presented as the main relevant methods to ensure an optimized use of protective equipment. Some responders also pointed out the usefulness of audits, enforcement of law, engagement of responsible or experts, dosimetry analysis, risk assessment studies or dissemination of research results.

Q12. What specific training needs are already implemented or are foreseen in the near future related to the new limits and what are the direct implications?

Specific training is already available in about half of the countries, however most countries believe there will be need of further training once the new limit is enforced. Some other countries state that specific training curricula will be decided once the new legislation is in place. The training needs are likely to be variable depending on the previous experience and safety culture implementation.

The "Belcolore project" a part of the European EURALOC project was cited as a good example of an initiative in which awareness of a particular professional group, interventional cardiologists in this case, was stimulated through a combination of education/training and eye lens examination on the volunteers among them.

The use of electronic dosimeters is also presented as a useful tool for training and optimization of procedures.

4.3 Topic3 Wider Implications of Implementing the Revised Limit

Q13. Are there any short-term implications before the satisfactory implementation of revised dosimetry and methods of protection (as in those topics described above)?

Suitable monitoring routines need to be widely available by the time specific regulations come into force and it seems, as indicated in one answer, impossible to implement in a short time for all the countries. As reported by one of the ASs, a review of occupational doses in high volume hospitals (Dauer, 2014), to evaluate the medical workers who, if unprotected, could be near or exceeding the lens dose of 20 mSv/y, will provide a very useful information. It is also important to consider appropriate lens dosimetric monitoring as new uses of radiation in medicine are implemented.

Indications given by different ASs are oriented towards the determination of what is appropriate as far as dosimetry, equipment and procedures, is concerned:

- the urgency to agree on methods for eye lens dose estimation;
- the organization of surveys, the development of new dosimeters and their characterization for the different applications;
- the need to proceed for high level risk assessments by considering all workers categories and for radiation safety program review with the development of new procedures and working instruction and to establish the level of introduction of individual monitoring of dose to the lens of the eye for the workers.

Moreover it is indicated the assessment and confirmation of the appropriateness of PPE and the improvement in its use together with protective shields for interventional specialists as

well as the development of nominal shielding protection factors and the design of the attachment to fix the dosimeter for lens eye dose in relation to face PPE. It has been mentioned that an initial application period up to 5 years could give time for improved practices to be introduced.

A better education and training of workers exposed as well as further support from specialists, such as radiation protection services, will be required.

Q14. Are there any potential long term issues which may have an impact on working activities on a more permanent basis?

It is well recognized by a number of ASs that there will be economic issues for the institution, with greater costs associated with methods of protection, additional training, and implementing the additional dosimetry (Thronton et al, 2010).

There is a need for a survey of the exposure dose level of interventional radiologists and cardiologists and in general there is a need for a greater administrative attention to prevent exceeding the limit, while possible legal ramifications are also foreseen. Moreover, the permissible time at work in specific fields of radiation, might need to be reduced, and as a consequence, for example, some interventional staff may have to reduce the number of sessions they can do per year in order to keep within the new dose limit. This will lead to additional costs as more staff may have to be trained to perform interventional procedures. It is also mentioned that an over-emphasis on the associated risks may induce the possibility of a reduction in the number of physicians entering interventional radiological and cardiological professions, with possible consequences on patients' accessibility to the more advanced medical procedures. However, it is likely that both the additional costs and the risk of a reduced number of interventional physicians will drive the institution (and the industry) towards the development of better means of protection and a more effective use of them, to prevent a critical shortage of trained and capable physicians.

A concern expressed by the European countries is the possibility that classification of radiation workers from category B to A would be based on eye dose, with an increase in administrative activities and costs, due to the management of a surveillance system. It is suggested by some ASs, that uncertainties in or lack of data on exposures of the lens of the eye, prior to implementation of novel routine monitoring procedures, may cause concern for employees and employers in relation to future lens opacities and cataracts, and that if any worker in the radiation field develops a cataract there could be legal cases related to the protection and its effectiveness, with particular attention on dosimetry surveillance.

Q15. Are there any implemented or foreseen changes in the Health surveillance of the workers? Specify costs estimates, if possible.

Half of the answering ASs foresee changes while the other half do not foresee changes in the health surveillance of the workers.

It is argued that, where relevant, the lens dose should be the object of explicit attention in the health surveillance of professionally exposed persons and that the eyes, as well as skin, should be included in health evaluations for radiation workers under the related regulations. Moreover one AS reported that national regulations for eye surveillance in radiation workers, are issued every 5 years and another AS reported that national legislation indicates an

ophthalmological examination every two years for workers in radiology and interventional radiology, and for persons working with neutron sources and heavy particles. A different AS commented that a large fraction of the radiation workers receives already routine eye care. It is also mentioned that a routine (e.g. yearly) examination of the eye lens may be difficult to organize, because of the need to involve a trained specialist and because it requires pupil dilation, which is uncomfortable, may include some risk, and may make a worker not available for work later that day. Some ASs suggested an eye examination for people who have high potential exposures or have symptoms of cataract formation and moreover in one country it is foreseen that there will be a mandatory baseline occupational health examination, before an interventional radiologist / cardiologist starts to work.

In European countries health surveillance is in general carried out for workers classified as Category A, that is, following the new EU Directives, for workers who are liable to receive an effective dose greater than 6 mSv/y or an equivalent dose greater than 150 mSv/y for the skin and extremities, or greater than 15 mSv/y for eye lens. On the contrary, following the previous EU Directives, a dose greater than 45 mSv/y was considered for the eye lens in the Category A. With the new limits for the lens of the eye, there will probably be an increase in classified workers and this will be likely to lead to an increased number of workers covered by health surveillance, and the licensed physicians would indicate the need for further specialist ophthalmologic examinations.

It was emphasized by one AS, that there is still a need for a recognized standard methodology for investigation of lens opacities that will also require organizing specific training for the ophthalmologists aiming towards a uniform methods for identification, categorization, documentation, and diagnosis, as well as the evaluation of occupational assessments.

Only about one quarter of the answers refer explicitly to costs related to the changes. Different views are expressed, from no cost up to significant costs implication, and an estimation of approximately 50 euro per worker per year is also given. One AS addressed the case of a worker who develops a cataract and subsequently needs cataract surgery, noting that the current cost for the operation in their country is estimated to be about 720 USD while 580 USD is currently covered by public health insurance.

Q16. Are there any circumstances in which you foresee that the introduction of new limits for the workers might lead to more claims for compensation?

The large majority of the ASs agree in a likely increased number of claims for compensation in relation to new limits on eye lens dose for workers. The idea that once limits are restricted, a door for concern is open on the basis of previous dose reports and in the vision of unprotected exposure in the past years, is explicitly expressed by two ASs, while another AS mentioned that the experience, with previous examples of reduction in dose limits, did not result in an increase of compensation claims. When thinking about an increased number of claims for compensation, the attention, within the different ASs, is focused: on the evaluation of the eye lens dose, by implementing appropriate dosimeter and by creating a solid safety culture; the need for effective dose register that can correctly capture the eye lens dose; and the need for good medical surveillance to attempt to distinguish radiological cataract from naturally occurring ones.

Some ASs focus the attention on the fact that cataract formation is multi-factorial, as several causes, besides radiation, are known contributing to its development and on the difficulty in proving causality.

One AS considers that the development of a specific expertise, by a licensed physician, will be necessary to recognize and judge the disease, with regard to the causal link with previous exposures to ionizing radiation or with other causes. Moreover one AS suggests that the difficulty in proving causality for cataract will give little chance in a traditional legal setting, while the situation might change dramatically if cataract (or its posterior sub capsular variant) is added to the list of professional diseases, since in that case the burden of proof would be reversed: if professional exposure to ionizing radiation can be demonstrated as a cause, a cataract could be considered as radiation-induced, unless proven otherwise.

Q17. What is the issue to be considered on the exposures for the lens of the eye for the patients in medicine and for the public ?

The attention of the ASs, while answering this question, is addressed more on issues referring to patients than to public. Dose limits do not apply in the case of patients, and protection is obtained by a systematic application of the justification and optimization principles. Physicians and medical staff are expected to rely on their judgment and the importance of the increasing emphasis given on education and awareness on radiation doses is claimed by the ASs and moreover a specific focus towards eye dose is also expected. Interventional radiology requires an explicit attention to the eye lens dose restriction and consequently to specific training.

In addition to interventional radiology and fluoroscopically guided procedures, the critical medical diagnostic procedure cited by the ASs is CT, and specifically head CT, with specific emphasis given in optimization through procedures such as organ dose modulation and avoidance of direct exposure to the eye. Shielding can be envisaged although its usefulness is controversial, since it may or may be not feasible depending on the procedures or it may generate more problems than the expected dose saving, as some ASs have expressed in detail. In any case, the detriment associated with eye lens dose is not expected to introduce a negative weight in the justification process for x-ray examinations in general, while a critical group could be children requiring repeated procedures. For patients in radiotherapy, as considered by two ASs, eye lens exposure could be high and should be considered in the treatment and follow up planning.

As far as the public is concerned, in general, the ASs agree on the fact that it is difficult to have, in reality, a scenario whereby a member of the public would receive a significant dose to the lens of the eye, taking also into consideration the limit for the public of 15 mSv/year, for equivalent dose to the lens and moreover that it is possible to consider the current limit for effective dose of 1 mSv as most probably the limiting quantity. The public could be exposed due to accidental conditions, but protracted public exposures of the lens of the eye are not specifically foreseen. Additional concern is not expected while considering exposure of the lens of the eye for the public and also a lowering of the public dose limit is not expected in the light of the reduction of the lens of the eye dose limit for workers.

Q18. Are there any additional matters regarding the change of dose limit that you wish to bring to the attention of the Task Group?

Nearly half of the ASs give their contribution to this question, while the remaining ones did not have anything to bring to attention. About half of the contributions refer to the need for clear guidelines, guidance or practice recommendations, and the remaining half of the answers refer to the bases that led to the recommendation of the new limits for lens of the eye.

The ASs highlighted to the TG the need of and their appreciation toward the identification of specific guidelines : for CT and x-ray examinations (including x-ray examination in health screening) for the calculations and methods in operational experience for eye lens dose; for practical estimations based on the actual exposure compared with the new limits as well as the consideration that the measurement by a dedicated dosimeter may not always be necessary; for the introduction of a proper guideline concerning the need to apply a preventive risk assessment and stratification of workers in high and low risk groups, as regard to exposure of the eye lenses.

The need for good practice recommendations clearly emerges.

There is a suggestion, by one of the ASs, that the RP community should explicitly take into consideration, in application of the precautionary principle, the uncertainties which accompany the scientific evidence, underlying the numerical choices about the dose and even about the reality of a threshold dose for cataractogenesis (in particular for those exposed as children). Although it is known that the new limits for the lens refer to the workers, one wonders if there is any scientific basis with reference for instance to the public. It is also expressed, by another AS, the opinion that there is not a really convincing epidemiological justification for the introduction of the new limits of the average annual equivalent dose to the lens at the level of 20 mSv/y, and it is suggested that, for instance, a limit of 30 mSv/y is going to reduce adverse effects on the practice of radiation monitoring and it requires less additional costs while hiring workers. It is also noted that so drastic a reduction in dose limit needs due time to be implemented and applied, since it will deeply change some previously consolidated operating procedures.

It is hoped to organize a special discussion on the topic of limits for the lens of the eye within IRPA, for example on the occasion of the IRPA 14, and the ASs also suggest that the TG will share the findings, to have also more arguments and subjects for bringing up the issues to the stakeholders.

4.4 Topic 4 Legislative and other general aspects

Q19. Are there in your country, guidelines or documents under preparation, addressing eye lens monitoring related to the new dose limit for workers?

For the large majority of the ASs, guidelines addressing eye lens monitoring related to the reduced dose limits for workers, were either completed or under development or planned for future development.

In some countries, the process of including the new dose limits in the regulations is already well advanced e.g. :

- papers are released for public consultation and stakeholder engagement opportunities are made available to address the new dose limits;

- draft regulatory standards have incorporated the new eye dose limits with subsequent guidance planned at a later stage;
- radiation protection ordinances are under revision and are planned to become effective in 2017;
- the new limits and guidance are expected to be published in national codes of practice and safety guides, which are under development;
- a national radiation protection standard that implements the new dose limit is expected to become effective in 2016 and the specific ordinance on the aspects of lens of the eye dosimetry is in preparation;
- a document on radiation protection procedures in Interventional Radiology, with specific attention to dose estimates to the lens of the eye and related best practice guidelines on dosimetry and protection equipment, is in the final stages of preparation.

As mentioned in the introduction, the Euratom Directives 2013/59 will include the new occupational dose limits for the lens of the eye, and the European Member States must comply with the Directives by February 2018. The promulgation of the new Directives, including the new dose limit to the lens of the eye, is in progress and is in an advanced stage in the European member states. Among all the answering ASs: two indicate that there is no intention to change the dose limit; while three did not indicate plans for regulatory changes or guidance development to address the reduced dose limit, since still in evaluation mode.

Q20. Does your Association have an involvement with governmental or regulatory advisory bodies regarding consultation for legislation, at national level, about radiation protection?
Answers to this question were mainly positive, but the level of involvement varied significantly.

A number of provide consultation to governmental and regulatory bodies, some with an advisory role, in revisions to the standards, and some others submit comments on draft regulatory documents during the public consultation period. Representatives and members of some ASs serve on regulatory working groups**.** Four ASs include members which are also part of the regulatory body.

Four ASs indicated either no involvement or no direct involvement with governmental or regulatory advisory bodies.

Q21. What is the progress on the ongoing path of legislative process with regard to the new limits for the lens of the eye in your country?

For eight ASs in European countries the legislative processes are well advanced or just started in view of the implementation of the Directives 2013/59 EURATOM by 2018, which includes the new limits for the lens of the eye. Information is either not available or not specified in the answers by the other ASs referring European countries. The process of considering the new limits for the lens of the eye has also been initiated in the majority of the ASs in non-European countries. In general, through consultations, engagements, and stakeholder feedback (e.g., interventional cardiologists), the draft regulations addressing a reduction in the lens of the eye dose limit, are under consultation for comments and, in most cases, will be approved for the implementation of the new requirement. In one country the

new regulations are currently in revision and are expected to become effective in 2017. One country is considering introducing the new dose limit in two stages: the first stage (lasting at least 5 years) would set the limit for the equivalent dose to the lens of the eye at 50 mSv/year in any single year; the second stage, after analyzing the results of the first stage, would apply the recommended limit of 20 mSv per year, averaged over five consecutive years (100 mSv in 5 years), but not exceeding the 50 mSv/year. Another AS has indicated that the national regulatory body updated the standards with the new recommendations, but that the new limits only applied to commission employees, and that there are no plans to update national regulations for occupational exposures. Two ASs have indicated that that they have not yet started any discussion on a legislative process with regards to new limits for the lens of the eye. One country that was in the process of reviewing stakeholder input during the time of the survey, has since decided to discontinue development of revisions to the regulatory standards that would include a reduction in the dose limit to the lens of the eye.

Q22. Are you analyzing and taking into consideration the wider issue of tissue reactions and particular the case of circulatory disease because of recent evidence of higher incidences of injury occurring at lower doses than previously reported?

The wider issue of tissue reactions and the case of circulatory diseases are recognised, but very few activities have been carried out in this field at the level of the professional societies, and for the majority of the societies, this issue has not yet been taken into consideration. No actions are planned in practice, at this stage, at the level of ASs by the large majority.

Various points of view and argumentations are expressed by the different ASs, e.g.:

- after monitoring the international developments on this issue, the ASs realized they do not have sufficient resources or means to conduct independent analyses or researches;
- even if members of different ASs are considering the wider issue of tissue reactions, this point has not been identified as an issue, requiring the attention of the AS at this time;
- the data available are still considered uncertain and the need to continue the epidemiological and experimental investigations has been expressed;
- it has been also indicated that many factors, other than radiation dose, can contribute to the tissues reactions, like psycho-emotional-stress, non-ionizing radiation, chemical substances, etc.

Other comments have expressed a need for adequate international guidance and that, when all the aspects of the dose of the lens of the eye will be more settled, the attention on other tissue reactions such as circulatory diseases should be considered. One AS is raising awareness through actions such as awareness campaigns and continual educations specifically targeted at the medical sector. Another AS cited specific national guidelines, prepared with the contribution of the national associations, in the field of interventional radiology, coronary and circulation, aimed at reducing circulatory disease in patients.

5. Conclusions

5.1 Direct implication in dosimetry and protection

5.1.1 The area of medical applications, has emerged in general as being more demanding in the ASs answers, with more attention being required on measurement of the dose to the eye lens, specially in interventional radiology and cardiology where the staff exposure is non-uniform. Attention is given to the implications in dosimetry and protection, addressing the following specific issues:

- A dosimeter measuring Hp(3) placed close to the eye is considered the ideal method, but although it appears to be used in some centers for interventional clinicians, this is primarily in the conduction of pilot studies for specific dosimeters;
- Where eye monitoring is currently performed, either at the collar or the head, Hp(0.07) and Hp(10) are used predominantly, because of the limited availability of Hp(3) dosimeters, which are not yet widely available;
- Most countries propose to use Hp(3) for the future, provided methods become available, although Hp(0.07) may remain in use for photon fields in a few countries, if this is regarded as adequate;
- When a dosimeter, worn close to the eye is the choice, there is general agreement that this should be on a head band, and a few suggestions are given about the position: the side of the head, the eyebrow ridge, on the forehead, or attached into the protective glasses;
- Half of the ASs report the use of a dosimeter, worn at the collar outside the lead apron for providing indicative eye dose values, but no correction factor is applied to obtain a better assessment of eye dose;
- More than sixty per cent of the answers received, indicate that eye dosimeters will only be considered for more highly exposed workers, approaching the limit, while collar dosimeters are seen as having the potential to provide a satisfactory method to check the dose level to which the majority of personnel is exposed;
- For the identification of personnel, who could receive high doses, it is suggested that the use of a collar dosimeter is the first option, and then an additional dosimeter to be worn adjacent to the eye, by those workers recording, with the collar dosimeter, a dose above an agreed level;
- Protective shielding systems to reduce eye dose are indicated as not always being available and with different possible uses, hospital by hospital, even within the same country. It has been mentioned that models of mobile radiation protection cabins, designed for interventional procedures, have been developed, but most probably their use will be limited to a few specialized departments.

5.1.2 In the area of nuclear or other non-medical sectors, the use of a whole body dosimeter worn on the trunk is considered to be sufficient, while special dosimeters will be required to measure Hp(3) for neutrons, where the workers are exposed to mixed radiation fields. It is also recognized that in this area protective measures are already in use and no major changes are foreseen, except attention to possible non uniform external exposure as in the case of hot cells.

5.1.3 Regardless of the area of use, important issues emerge, beside the economic ones, about the use of lead glasses and they are the discomfort of wearing them, the feeling of being heavy and not being suitably fitted for individuals, and the difficulty in correctly assessing the eye dose.

5.2 Pilot studies

The majority of the pilot study programs reported, are focused on medical applications, but some also could be expanded to address issues related to exposures of the lens of the eye, in the future, for the nuclear industry.

Three quarters of the ASs reported that some eye lens dose related pilot studies are being conducted, in their countries, aimed at potential reduction of the dose through wearing lead glasses and the resulting optimization of doses, and also some studies involving initiatives to monitor patients who could receive significant doses to the eye lens.

5.3 Implications related to dose recording and itinerant workers.

In relation to this point, specific and new issues are emerging:

- where a form of National Dose Register is already in use, with a continuous summation of doses especially in the nuclear field, if the eye lens dose is not specifically included in the register, but recorded by the dosimetry services, recording results from additional dosimeters used to monitor the eye dose, will increase the administrative burden;
- dose recording for itinerant workers in the medical sector, such as clinicians working in several hospitals, both public and private, is a major challenge, since different practices are likely to be used as regards the provision of dosimeters by employers; and the responsibility for collation of doses.

5.4 Exposure for the eye lens of patients and public

5.4.1 For patients.

- Specific emphasis is given to optimization, considering exposure to the lens of the eye in radiology procedures, particularly interventional neuro-radiology and head CT;
- In general the detriment associated with eye lens dose is not expected to introduce a negative weight in the justification process for x-ray examinations, but children requiring repeated procedures are considered a critical group.

5.4.2 Public.

- ASs agree that it is difficult to predict real scenarios for members of the public, receiving significant doses to the eye lens, taking into consideration the limit of 15 mSv/y for members of the public. They could be exposed from unforeseen accidents, but protracted exposures of the eye lens in the public sector are not foreseen.

5.5 Health surveillance

- Health surveillance of workers, who are likely to receive high exposures to the eye lens, should include observation of the lens of the eye;
- The difficulty in carrying out yearly routine examinations of the lens was mentioned, because of the need to refer to an ophthalmologist and the need also to consider workers availability;

- It is considered that such examinations should be restricted to workers with high potential exposure, or symptoms of possible cataract formation, and specifically a mandatory examination has been considered before a radiologist or cardiologist starts interventional work;
- European countries are probably facing an increased number of workers undergoing health surveillance, due to the likely increase in the number of workers classified as Category A, in view of the changed eye dose limit, and the need for specific ophthalmologic visits will be in general indicated by licensed physicians.

5.6 Legislative processes status with regard to the new limits for the lens

The legislative processes of considering the new limits for the lens of the eye have been initiated in the majority of the countries represented by the answering ASs:

- Many ASs are directly involved in the consultation process regarding the national legislation on RP with different types and levels of involvement: from an advisory role to direct involvement of ASs members in consulting or regulatory groups or with members working directly in regulatory bodies;
- The introduction of a reduction of equivalent dose to the lens in two stages is one example of the approaches towards a new regulation: 5 y to implement the reduction to 50 mSv/y, followed by considering a further reduction to the new limit, based on the results of the analysis;
- In EU Member States, the legislative processes are in general well advanced, since the implementation of the Directives 2013/59 EURATOM, which includes the new limits for the lens of the eye, is expected by February 2018;
- National guidelines for improved monitoring and protection of workers, addressing monitoring aspects in relation to the new dose limits are defined, planned, or in the completion phase in the large majority of the countries.

5.7 The wider issue of tissue reactions

Almost all professional societies are informed about the wider issue of tissue reactions, such as, in particular, about the question of the association between low- moderate-dose exposure to ionizing radiation and late occurring circulatory diseases, and the related nominal threshold dose (0.5 Gy), lower than previously estimated.

The large majority of the ASs have not yet taken into consideration or routinely considered this issue. In this sense, different views /reasons were expressed :

- the uncertainties in the available data and studies supporting the question;
- the lack of resources for pursuing independent research on the subject;
- the existence of many potential factors, other than radiation, which can contribute to tissue reactions;
- the opportunity to settle, first, all the aspects relating to the lens of the eye dose before focusing attention on the wider issues.

5.8 Costs

It is commonly understood that the application of the new limit will generate additional costs, but there is uncertainty about the size of the increase and the types of costs, which will be increased:

- Any additional protection measure to reduce eye dose is foreseen as an increase in costs;
- Economic issues are associated with methods of protection, additional training, and implementing the additional dosimetry. In general any cost of implementing arrangements that requires an extra dosimeter and protective measures requiring the purchase of protective eyewear may be a further obstacle to implementation;
- The costs would be high, besides considering the extra dosimeters, due to the additional time required by radiation protection officers to evaluate whether corrections to the measurements are needed;
- To prevent exceeding the eye lens dose limit, the time at work, in specific fields of radiation, might need to be reduced. For example, if some interventional staff may have to reduce the number of sessions in order to keep within the new dose limit, additional cost for more staff has to be considered;
- In European countries, the possible workers reclassification for radiation workers from B to A on the basis of eye dose, will increase administrative activities and surveillance costs.

5.9 Training

Substantive programs of education and motivational training, combined with compliance audits are seen as the best way to tackle the problem of persuading staff to consistently wear the required additional dosimeters.

Significant problems are expected in ensuring that the staff will wear dosimeters, correctly and consistently, because of the comparatively poor appreciation of the risk in the medical sector.

Other relevant approaches, in addition to the proper training, to contribute towards an optimized use of protective equipment, are:

- safety culture implementation;
- risk assessment studies and awareness of risk;
- audit procedures and engagement of experts.

ASs have also expressed that additional specific training, in relation to the new limit for eye lens dose, is foreseen only once the new limits will be enforced.

The changes required to deal with the new dose limit provide a challenge and ASs should take charge and strongly promote developments, in line with ‘IRPA Guiding Principles for Establishing a Radiation Protection Culture’. This encompasses development of a pattern of knowledge and behaviors as a combination of science, values and ethics, and includes not only the well-established justification, optimization and dose limitation principles, but also the sharing of competence by training and education. This is the most effective way for reducing doses to the level at which they are as low as reasonably practicable.

6. Recommendations

A series of specific recommendations can be obtained from the responses received by the IRPA ASs and they are presented hereafter under a number of headings.

6.1 Scientific and regulatory aspects

- There is a need to survey the exposure dose level for some specific medical procedures and in general there is a need for a greater administrative attention to prevent staff doses exceeding the limit, which may have possible legal implications;
- An important unmet need for a number of countries is the availability of suitable dosimeters, the presence of calibration facilities for Hp(3), and the associated arrangements for regulatory approval;
- There is a need to define a suitable category under which the eye doses could be recorded in the National Dose Register. At present in some countries the readings of the collar dosimeter are recorded as the eye dose and the use of correlation factors has large uncertainties;
- A guideline is needed on how to measure the eye dose of personnel wearing protective eyewear, since now some countries are suggesting the application of a correction factor while others are suggesting measurements under the lead glasses;
- There is a need to establish proper procedures to ensure that itinerant workers will have, first, good and effective measures taken in cooperation among respective management teams with regard to the choice of the dosimeter and its positioning, and, second, efficient dose information sharing and recording procedures thus avoiding under-recording doses;
- The need of an International Dose Passport is becoming more and more relevant for international workers and consultants, in addition to their National Dose Registers.

6.2 Dosimetry and Protection aspects

- Harmonization of the approach to monitoring and agreement on the optimum location for head dosimeters are issues that still need to be addressed;
- There is a need to reach a consensus about suitable methods for taking into account the protection provided by lead glasses when dosimeters are worn outside the protection.

6.3 Costs implications

- A proper preventive risk assessment and an adequate stratification of workers are indeed recommended to reduce the cost of dosimetry to an acceptable level;
- The importance of limiting the dose to the eye lens has to be recognized with the support of activities to improve significantly the Radiation Protection Culture, specifically in the medical sector.
- In order to achieve the necessary reduction of dose to the eye, there is a need to make protective methods, which are wearable and comfortable, available in all medical facilities, where this relevant.

6.4 Awareness, Culture and Training

- It is well recognized, in particular in the medical field, that there is a need to improve awareness of workers who may be exposed, their education and training, and further support from specialists, such as radiation protection services, is recommended;
- There is a need to establish awareness programs and additional training for medical staff on the proper use of protective equipment, as well as radiation protection approaches to reduce eye dose. In addition their awareness about patient eye lens dose needs to be emphasized;
- There is still the need to agree on a standard system for the investigations of lens opacity. This will also require the organization of specific training for ophthalmologists in view of a uniform identification, categorization, as well as an agreed standard evaluation of occupational assessments.
- The importance of establishing and reinforcing a sound Radiation Protection Culture in the workplace is recognized, as an effective approach to move the behaviors of both the individuals and the organizations towards the highest standards. Education and training are essential elements for a positive behavior at the working place and moreover proper communication among all practitioners has a definite impact on improving protection of workers and patients. IRPA developed Guiding Principles for establishing a Radiation Protection Culture (IRPA, 2014) and more recently, in 2015 IRPA launched a new initiative in conjunction with the World Health Organization (WHO) and the International Organization of Medical Physics (IOMP) for establishing and promoting Radiation Protection Culture in Medicine (2015 Buenos Aires meeting and 2015 Geneva meeting, www.irpa.net/)

6.5 Consideration of tissue effects more than eye lens effects

- Addressing the aspects emerging on the wider issue of tissue reactions, a need was expressed for adequate international guidance, specifically on the implication of circulatory disease risk for radiation protection and by addressing the different areas of practice;
- By considering that uncertainty tends to inhibit direct impact on guidelines, there is a need to continue research:
    - On better understanding about the mechanism of a possible change in circulatory diseases, following the exposure of low- moderate-dose of radiation;
    - On examining the impact of possible confounding factors, e.g. smoking and other lifestyle factors;
    - On considering and characterizing uncertainties, e.g. associated with epidemiological studies, and how they may be incorporated into the risk evaluation.
- There is a lot of uncertainty, more research is inevitable (and ongoing): there are issues that could become very important, but the ASs are having difficulty in following the debate and the possible implications. There is definitely here a role to be played by IRPA, to do more to follow this issue more closely, and to identify and address, at the earliest opportunity, possible future implications for the profession.

6.6 Additional matters of attention

A large group of the ASs has expressed to this TG, the need for clear and specific guidelines with reference to:

- the calculations and methods to be used in operational practice for eye lens dose determination;
- the practical estimations based on the actual exposure, the new limits and the consideration that measurements with a dedicated dosimeter shall not always be necessary;
- the application of a preventive risk assessment and stratification of workers in high and low risk groups, with regard to exposure of the eye lenses.

Moreover, suggestions were expressed that the community should take into consideration and pay attention to:

- the uncertainties accompanying the scientific evidence e.g. in threshold dose for cataractogenesis;
- the possible scientific basis for new limits for the lens to the public;
- the option of applying a higher average annual dose limit to the lens (e.g. 30-50 mSv), instead of 20 mSv, in consideration of the less than convincing epidemiological justification for the new limit. This would have lower additional costs for implementing.

7. About the trend in the ASs views from first to second TG phase

It has been five years from the ICRP Statement on tissue reactions containing the recommendations for an equivalent dose limit for the lens of the eye of 20 mSv in a year for workers, and has been 3 years since the first survey carried out by IRPA on the implications concerning this topic.

If we look at how the ASs community has reacted to the survey, some aspects come to our attention:

- A greater involvement and a larger number of answers on the subject;
- Despite the number of questions in this survey being doubled (from 11 to 22), the participating ASs have increased by almost 90% (from 12 to 22);
- The process of taking into account changes to monitoring the lens of the eye and protection is now clearly being addressed and no longer being postponed.

By referring to the Report and publications of the first phase IRPA TG [J. Broughton et al., 2013, a2015, b2015] some aspects of the trend can be summarized as follows:

- The need for '*harmonisation of radiological protection criteria to monitor the eye lens for workers'* as indicated in 2013 is still a challenge, but now three quarters of the ASs reported that some pilot studies related to doses to the lens of the eye are being conducted in their countries, with the general aim to identify staff groups who could potentially receive high doses to the lens of the eye, in different work places and to investigate the most appropriate monitoring arrangements;
- The attention to a '*confusion among radiation practitioners about the rational for the change in the dose limit'* indicated in 2013 is now less evident in the answers. This is likely to be a result of meetings, events and documents on the subject, through which practitioners have become involved and engaged, but we also think that this is the

result of a shift in attention now towards a greater concern about the implementation of the new dose limit. However, there is still a residual concern that the new dose limit is not thoroughly scientifically underpinned;

- From this second survey, it emerges that the ASs are no longer focused on the motivations of the significant reduction of the dose limit (*'The relationship between dose and cataract formation is not well understood and the causality should be clarified' in 2013*), but more focused on the implication in dosimetry and protection even though at the international scientific research level, the matter of whether radiation cataracts are deterministic effects, stochastic effects or both is still open to question, and the need for further epidemiological and mechanistic studies is acknowledged. The attention to these aspects, in ASs seems to have shifted to the field of the wider issue of tissue reactions, with the case of circulatory disease and the uncertainties in the available data and studies supporting the question;
- Great differences were present in the ASs answers, in the first survey, about cost implications for the reduction of the eye dose, and the perception of future compensations caused by the new limit. Now, great differences still remain about cost implications: for instance, in the health surveillance of the workers the answers span from no cost to significant costs, while on future compensations, a large majority of ASs agree that there are likely to be an increased number of claims for compensation in the future;
- Now, more attention appears to be dedicated to implications related to dose recording compared to the first survey, e.g. from additional dosimeters to monitor the eye dose, to dose recording for itinerant workers, from possible differences in provision of dosimeters, and to the responsibility for collation of doses. This attention could also be the result of the ASs community naturally focusing on practical aspects aimed at reduction of the eye dose;
- European countries are paying more attention now than in 2013, to the aspect of classification of radiation workers with the increase in administrative activities and to the cost for dosimeters and surveillance systems. This is doubtless related to the implementation of the new Euratom Directive, to be completed by 2018 by the European Member States.

What is certain is that a number of questions remain: the passage of 3 years since the first IRPA survey is insufficient to create a profoundly different picture with every aspect resolved. Even though it is 5 years since the recommendation for a new eye lens limit, a complete resolution of all the practical issues has not been achieved. We conclude, as evidence from the responses received, that 'such a drastic reduction in the dose limit needs due time to be implemented and applied, since it will deeply change some previously consolidated operating procedures', but nevertheless we are gradually progressing along the path of considering the implementation.

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