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> Regulatory Implementation of the Equivalent Dose Limit for the Lens of the Eye for Occupational Exposure

> > Successes and Challenges to the Approaches Identified Through a Survey of Regulators







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NUCLEAR ENERGY AGENCY COMMITTEE ON RADIOLOGICAL PROTECTION AND PUBLIC HEALTH

Regulatory Implementation of the Equivalent Dose Limit for the Lens of the Eye for Occupational Exposure

Successes and challenges to the approaches identified through a survey of regulators

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- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally sound and economical use of nuclear energy for peaceful purposes;
- to provide authoritative assessments and to forge common understandings on key issues as input to government decisions on nuclear energy policy and to broader OECD analyses in areas such as energy and the sustainable development of low-carbon economies.

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The objective of the Committee on Radiological Protection and Public Health (CRPPH) is to assist NEA member countries in the implementation and enhancement of the system of radiological protection. This objective will be met by identifying and effectively addressing those conceptual, scientific, policy, regulatory, operational and societal issues that either favourably or adversely affect the system of radiological protection, thereby promoting national and international good practices and identifying potential weaknesses and vulnerabilities.

To accomplish this, the Committee will contribute to the adoption and the maintenance of high standards of protection for the public, workers and the environment in all activities involving the use of ionising radiations, and particularly, but not limited to the field of nuclear energy.

In this context, the Committee on Radiological Protection and Public Health (CRPPH) shall:

- Provide a forum for the exchange of information and the transfer of experience between national radiological protection authorities on policies, regulatory issues and approaches, and their implementation in the context of realistic radiation exposure conditions, and as appropriate, the risks and regulatory arrangements for other common hazards.
- Seek international understanding and guidance, in support of national authorities, on questions of common concern regarding the interpretation and implementation of the ICRP recommendations and international standards in various fields of application of radiological protection, to contribute to the development of co-ordinated approaches among member countries, and to support the development of new international standards.
- Advance concepts and policies which make the system of radiological protection clear, transparent and adaptable to the broader social dimensions of decision making in complex situations, and further facilitate effective engagement with relevant stakeholders, including their involvement in decision making as appropriate.
- Promote international collaboration on specific radiological protection and radiation-related public health topics of interest to the NEA member countries in the framework of the NEA Strategic Plan.
- Keep under review, contribute to the advancement of, and identify needs for the state of the art in the field of radiological protection at the social-scientific, natural-scientific and technical levels, and promote the preparation of authoritative advice and reference documents, for use by national authorities, policy makers and practitioners, on emerging policy, regulatory and operational issues, and in those areas where international consensus on radiological protection concepts, regulatory issues and practices is sought.
- Help ensure the management of radiological protection knowledge and experience between generations of radiological protection experts.
- Actively interact with the International Commission on Radiological Protection (ICRP) to help link national policy and regulatory needs to the development of international recommendations.

In the fulfilment of its mandate, the CRPPH will work in close co-operation with other NEA Committees as appropriate, particularly the Committee on Nuclear Regulatory Activities (CNRA), the Radioactive Waste Management Committee (RWMC), and the Nuclear Law Committee (NLC), as well as with NEA divisions, and competent bodies within relevant OECD directorates and other international organisations active in the field.

Foreword

The goal of the Nuclear Energy Agency (NEA) Committee on Radiological Protection and Public Health (CRPPH) is to assist member countries in identifying critical and emerging issues in radiological protection, analysing their possible implications for practices and regulation, and contributing to the development of approaches for their resolution.

The NEA Expert Group on the Dose Limit for the Lens of the Eye (EGDLE) was created by the CRPPH with the objective of providing an opportunity for regulators and stakeholders to share lessons learnt in the practical implementation of the International Commission on Radiological Protection's (ICRP's) recommended equivalent dose limit for the lens of the eye for occupational exposures. To this end, the EGDLE supports the CRPPH mandate, in promoting international collaboration on specific radiological protection and radiation-related public health topics of interest to the NEA member countries.

This report summarises the practical experiences of regulators and stakeholders worldwide in implementing equivalent dose limit for the lens of the eye for occupational exposure, including successes and challenges to the approaches. The EGDLE also intends to set up a dedicated network to maintain dialogue and information exchange.

To facilitate the development of the report and help establish a network for continued dialogue and information exchange, a survey was sent to NEA member countries targeting regulators of nuclear, medical and non-nuclear applications. The survey covered: the current status of regulatory dose limits for the lens of the eye, successes in stakeholder engagement, including approaches taken by regulators to ensure positive interactions with stakeholders, accreditation and approval processes for eye dosimetry, and challenges in the practical implementation of new lens of the eye dose limits and actions taken to address these challenges.

This report summarises the analysis of the anonymised EGDLE survey responses and provides insights into opportunities for future work and collaboration.

Acknowledgements

This report was prepared by the Nuclear Energy Agency (NEA) Expert Group on the Dose Limit for the Lens of the Eye (EGDLE) held under the Committee on Radiological Protection and Public Health (CRPPH). The NEA would like to express its appreciation to the members of the EGDLE for their involvement and contributions to ensure the successful fulfilment of the EGDLE mandate. In particular, it would like to recognise the efforts of Christina Dodkin (Canada), Chair, and Marie-Claire Cantone (Italy), Vice-Chair, in addition to the expert members of the EGDLE: Andres Rossini (Argentina), Marie-Anne Chevallier (France), Uwe Oeh (Germany), David Pollard (Ireland), Sumi Yokoyama (Japan), Maria Dolorès Rueda Guerrero (Spain), Giuseppe Testa (Switzerland), Luana Hafner (Switzerland), Vaughan Rees (United Kingdom) and James Dillard (United States).

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In addition to these individuals, many thanks are due to the representatives from the following countries who completed the EGDLE questionnaire: Argentina, Canada, the Czech Republic, Finland, France, Germany, Greece, Iceland, Japan, Norway, Russia, Spain, Switzerland, the United Kingdom and the United States.

Table of contents

List of abbreviations and acronyms7
Executive summary
1. Introduction10
2. Legislative changes to lens of the eye dose limits
3. Regulatory requirements and guidance related to the conduct of risk assessments for the lens of the eye
4. Availability of eye lens dosimeters
5. Challenges associated with recording doses to the lens of the eye
6. Opportunities for future work and collaborations
7. Conclusions
References
Annex A. List of respondent countries to the EGDLE survey
Annex B. Country resources and guidance
Annex C. Dosimeter accreditation and technical specifications
Annex D. Examples of eye lens dosimeters
Annex E. Individual monitoring services – inter-comparisons41
Annex F. Select research publications and studies provided by respondent countries42
Annex G. EGDLE survey44

List of abbreviations and acronyms

CRPPHCommittee on Radiological Protection and Public Health (NEA)DTOTritiated heavy waterEGDLEExpert Group on the Dose Limit to the Lens of the Eye (NEA)EURADOSEuropean Radiation Dosimetry GroupFMBAFederal Medical-Biological Agency (Russia)ICRPInternational Commission on Radiological ProtectionIAEAInternational Atomic Energy AgencyIECInternational Radiation Protection AssociationIRPAInternational Radiation Protection AssociationIRSNInstitut de Radioprotection et de Sûreté Nucléaire (Institute for Radiological Protection and Nuclear Safety, France)ISOInternational Organization for StandardizationNEANuclear Energy AgencyNORMNaturally Occurring Radioactive MaterialOSLOptically stimulated luminescenceOSLDOptically stimulated luminescence dosimeterPTBPhysikalisch-Technisches Bundesanstal (the national metrology institute of Germany)RELIDRetrospective Evaluation of Lens Injuries and DoseTENORMTechnically Enhanced Naturally Occurring Radioactive MaterialTSOTechnical and Scientific Support OrganisationUNSCEARUnited Nations Scientific Committee on the Effects of Atomic RadiationUS NRCUnited States Nuclear Regulatory Commission	BSS	Basic Safety Standards	
EGDLEExpert Group on the Dose Limit to the Lens of the Eye (NEA)EURADOSEuropean Radiation Dosimetry GroupFMBAFederal Medical-Biological Agency (Russia)ICRPInternational Commission on Radiological ProtectionIAEAInternational Atomic Energy AgencyIECInternational Electrotechnical CommissionIRPAInternational Radiation Protection AssociationIRSNInstitut de Radioprotection et de Sûreté Nucléaire (Institute for Radiological Protection and Nuclear Safety, France)ISOInternational Organization for StandardizationNEANuclear Energy AgencyNORMNaturally Occurring Radioactive MaterialOSLOptically stimulated luminescenceOSLDOptically stimulated luminescence dosimeterPTBPhysikalisch-Technisches Bundesanstal (the national metrology institute of Germany)RELIDRetrospective Evaluation of Lens Injuries and DoseTENORMTechnicall and Scientific Support OrganisationUNSCEARUnited Nations Scientific Committee on the Effects of Atomic Radiation	CRPPH	Committee on Radiological Protection and Public Health (NEA)	
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FMBAFederal Medical-Biological Agency (Russia)ICRPInternational Commission on Radiological ProtectionIAEAInternational Atomic Energy AgencyIECInternational Electrotechnical CommissionIRPAInternational Radiation Protection AssociationIRSNInstitut de Radioprotection et de Sûreté Nucléaire (Institute for Radiological Protection and Nuclear Safety, France)ISOInternational Organization for StandardizationNEANuclear Energy AgencyNORMNaturally Occurring Radioactive MaterialOSLOptically stimulated luminescenceOSLDOptically stimulated luminescence dosimeterPTBPhysikalisch-Technisches Bundesanstal (the national metrology institute of Germany)RELIDRetrospective Evaluation of Lens Injuries and DoseTENORMTechnically Enhanced Naturally Occurring Radioactive MaterialTSOTechnical and Scientific Support OrganisationUNSCEARUnited Nations Scientific Committee on the Effects of Atomic Radiation	EGDLE	Expert Group on the Dose Limit to the Lens of the Eye (NEA)	
ICRPInternational Commission on Radiological ProtectionIAEAInternational Atomic Energy AgencyIECInternational Electrotechnical CommissionIRPAInternational Radiation Protection AssociationIRSNInstitut de Radioprotection et de Sûreté Nucléaire (Institute for Radiological Protection and Nuclear Safety, France)ISOInternational Organization for StandardizationNEANuclear Energy AgencyNORMNaturally Occurring Radioactive MaterialOSLOptically stimulated luminescenceOSLDOptically stimulated luminescence dosimeterPTBPhysikalisch-Technisches Bundesanstal (the national metrology institute of Germany)RELIDRetrospective Evaluation of Lens Injuries and DoseTENORMTechnically Enhanced Naturally Occurring Radioactive MaterialTSOTechnical and Scientific Support OrganisationUNSCEARUnited Nations Scientific Committee on the Effects of Atomic Radiation	EURADOS	European Radiation Dosimetry Group	
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 TENORM Technically Enhanced Naturally Occurring Radioactive Material TSO Technical and Scientific Support Organisation UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation 	РТВ		
TSOTechnical and Scientific Support OrganisationUNSCEARUnited Nations Scientific Committee on the Effects of Atomic Radiation	RELID	Retrospective Evaluation of Lens Injuries and Dose	
UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation	TENORM	Technically Enhanced Naturally Occurring Radioactive Material	
	TSO	Technical and Scientific Support Organisation	
US NRC United States Nuclear Regulatory Commission			
	UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation	

Executive summary

The lens of the eye is one of the body's most radiosensitive tissues. Opacification of the lens, known as a cataract in advanced stages, may be radiation-induced or related to other factors such as age, smoking, or obesity, and can lead to vision impairment and even blindness. To prevent the occurrence of ionising radiation-induced cataracts, regulatory bodies worldwide set equivalent dose limits for the lens of the eye for workers and members of the public.

Several studies have suggested that the development of cataracts may occur following exposure to significantly lower doses of ionising radiation than previously considered. Given this evidence, on 21 April 2011, the International Commission on Radiological Protection (ICRP) issued a formal statement indicating that tissue reactions for the lens of the eye have dose thresholds that are, or might be, lower than previously considered. Related recommendations were issued one year later in Publication 118 (ICRP, 2012).

The Nuclear Energy Agency (NEA) Expert Group on the Dose Limit for the Lens of the Eye (EGDLE) was created by the Committee on Radiological Protection and Public Health (CRPPH) with the objective of providing an opportunity for regulators and stakeholders to share lessons learnt, both successes and challenges, in the practical implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures.

The deliverables of the EGDLE include:

- a report which summarises the practical experiences of regulators and stakeholders worldwide in implementing the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposure, including successes and challenges to the approaches;
- a network to maintain dialogue and information exchange.

To help fulfil its mandate, the EDGLE developed a survey to gather information from NEA member countries' regulatory bodies and Technical and Scientific Support Organisations (TSO) on the implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures. A total of 24 organisations from 15 countries (50% of the NEA CRPPH country membership) provided responses to the survey. The responding organisations represented 18 regulatory bodies and 3 TSOs. In addition, 3 nuclear fuel cycle facilities in one country proactively provided responses, complementing those of the regulatory body.

It is clear that the countries that responded to the survey have been active in various initiatives in responding to the latest scientific information regarding tissue reactions for the lens of the eye, and to the need for revising their respective dose limits for the lens of the eye. Regulators recognised the importance of early engagement with stakeholders while considering revisions to legislation. In this context, stakeholders include: regulated entities and licensees, advisory bodies, unions, professional organisations, and professional societies and associations. Countries also recognised the importance of continued stakeholder engagement in order to advance and promote the resolution of issues and continuous improvements in monitoring and ascertaining doses to the lens of the eyes.

Some practical challenges remain, though most countries are making progress in addressing them in consultation with stakeholders. There is a consensus among responding regulatory organisations on the value of guidance provided by international entities such as the International Atomic Energy Agency (IAEA) and the International Radiation Protection Association (IRPA).

Responding countries identified areas where they could benefit from sharing experiences and from a possible harmonisation in approach. They include:

- Requirements for individual monitoring, and consensus on the use of eye lens dosimeters measuring personal dose equivalent $H_p(3)$.
- Eye lens dosimetry, with the use of ISO and IEC standards to define accreditation and technical/performance specifications for $H_p(3)$ eye lens dosimeters. Issues such as beta and neutron radiations, and mixed radiation fields (beta/photons), and intercomparisons, need to be addressed.
- Dosimeter placement and taking account of personal protective equipment.
- Acceptability of the use of surrogate dosimeters and correction factors.

All the respondent countries identified opportunities for continued dialogue and information exchanges in international fora, especially in the above-mentioned areas, where international harmonisation would be beneficial. They also identified areas of research that could contribute to advances in radiological protection aspects for the eye, in addition to improvements in eye lens dosimetry.

1. Introduction

Background information

The lens of the eye is one of the body's most radiosensitive tissues. Opacification of the lens, known as a cataract in advanced stages, may be radiation-induced or related to other factors such as age, smoking or obesity, and can lead to vision impairment and even blindness. To prevent the occurrence of ionising radiation-induced cataracts, regulatory bodies worldwide set equivalent dose limits for the lens of the eye for workers and members of the public, with due consideration of the recommendations from the International Commission on Radiological Protection (ICRP).

On the basis of the review of recent epidemiological evidence regarding the induction of tissue reactions, the International Commission on Radiological Protection (ICRP) concluded that tissue reactions for the lens of the eye have dose thresholds that are, or might be, lower than previously considered (ICRP, 2011). The Commission stated in Publication 118 (ICRP, 2012) that the threshold for absorbed dose that could cause a radiation-induced opacification of the lens was now considered to be 0.5 gray (Gy). To protect workers, the ICRP recommended reducing the equivalent dose limit for the lens of the eye to 20 millisieverts (mSv) in a year, averaged over defined five-year periods (100 mSv/5 years), with no single year exceeding 50 mSv. The ICRP did not recommend changes to the equivalent dose limit for the lens of the public, as the existing limits were deemed to be sufficiently protective.

The International Atomic Energy Agency (IAEA) incorporated these recommendations into Schedule III of its revised Basic Safety Standards (BSS), GSR Part 3 (IAEA, 2014) in 2014. In 2013, the European Council incorporated the new ICRP recommended dose limits for the lens of the eye into the Basic Safety Standards Directive, 2013/59/EURATOM, *Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation* (EURATOM BSS) (European Commission, 2012). Noting the incorporation of the ICRP recommendations into both IAEA GSR Part 3 and the EURATOM BSS, a large number of countries worldwide have implemented the new recommendations in their national regulatory frameworks.

In order to facilitate stakeholders' understanding of these changes and the underlying science, the Inter-Agency Committee on Radiation Protection published in 2015 a short summary of the situation, which provides simple explanations on: i) the causes of lens opacities, including radiation exposure; ii) cataract prevalence data worldwide and their treatment; iii) recent results of epidemiological studies and their implication for radiation protection policy. This information update also lists the categories of workers that could potentially be impacted by the new dose limit and the actions that could be taken by employers and national regulatory bodies (IACRS, 2015).

Convening the Expert Group on the Dose limit for the Lens of the Eye

The main objective of the Nuclear Energy Agency (NEA) Committee on Radiological Protection and Public Health (CRPPH) is to support member countries in identifying emerging issues, analysing their implications for radiological protection practices and regulation, and contributing to their resolution.

In this context, the CRPPH decided to convene the Expert Group on the Dose limit for the Lens of the Eye (EGDLE). The EGDLE commenced its programme of work in July 2019. Its main objective is to provide an opportunity for regulators and stakeholders to share lessons learnt in the practical implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures.

The deliverables of the EGDLE include:

- a report that summarises the practical experiences of regulators and stakeholders worldwide in implementing the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposure, including successes and challenges to the approaches;
- a network established to maintain dialogue and information exchange.

Overview of the working methods of the EGDLE

To assist the EGDLE in fulfilling its mandate, a survey was developed to facilitate the gathering of information from NEA member countries' regulatory bodies and Technical and Scientific Support Organisations (TSO) on the implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures. The EGDLE survey is included in Annex G of this report.

The EGDLE survey was disseminated to members of the CRPPH on 3 March 2020, and the deadline for responses was extended to 31 July 2020 due to the COVID-19 pandemic.

Profiles of respondents to the EGDLE survey

A total of 24 organisations from 15 countries (50% of the NEA CRPPH country membership) provided responses to the EGDLE survey. The responding organisations represented 18 regulatory bodies and 3 TSOs. Three nuclear fuel cycle facilities also provided responses proactively, complementing the responses of the regulatory body of a country. Annex A of this report provides a list of the respondents.

For the purposes of profiling the respondent countries, the EGDLE survey asked respondents to identify the nature of the regulated activities in the country using the following broad definitions:

- nuclear energy applications, which include nuclear power reactors and nuclear installations associated with the nuclear fuel cycle (e.g. nuclear fuel processing, nuclear waste management);
- medical applications, which include nuclear medicine and any diagnostic facilities (e.g. using radionuclides and x-rays, electrons, protons or ions);
- other non-nuclear applications, which include all operations and activities not associated with the production of nuclear energy (e.g. research reactors, radiation source processing), and other activities involving x-rays and/or radiation sources in research/education and industrial applications; as well as applications related to the use of natural resources containing naturally occurring radionuclides, i.e. Naturally Occurring Radioactive Materials (NORM) or Technically Enhanced (TENORM).

Thirteen respondent countries are involved in all regulated activities (nuclear, medical and non-nuclear applications). In seven of these countries, the regulation of nuclear, medical and non-nuclear applications is a responsibility shared by more than one regulatory body.

12 | NEA/CRPPH/R(2021)1

Two respondent countries are involved in medical and various non-nuclear applications, and one regulator in each country regulates these activities.

REGULATORY IMPLEMENTATION OF THE EQUIVALENT DOSE LIMIT FOR THE LENS OF THE EYE FOR OCCUPATIONAL EXPOSURE

2. Legislative changes to lens of the eye dose limits

Respondent countries have revised, are in the process of revising, or are considering revising their legislation to incorporate the new equivalent dose limits for the lens of the eye for occupational exposures.

Thirteen of the respondent countries have revised, or are in the process of revising, their legislation to incorporate new lens of the eye dose limits. Ten countries have adopted the ICRP recommended dose limits verbatim, applicable to nuclear, medical and non-nuclear applications, with two of these countries implementing a single lens of the eye dose limit of 20 mSv/year for occupational exposures. Seven of these thirteen countries indicated that the revisions to the lens of the eye dose limits occurred, or are occurring, as part of the transposition of the EURATOM BSS into their regulatory frameworks.

In one country, the regulation of nuclear, medical and non-nuclear applications is a shared responsibility between fourteen regulators, depending on the jurisdiction. One regulator of medical and non-nuclear (e.g. industrial use of x-rays and NORM) applications has implemented the ICRP recommended dose limits, while the other twelve regulators for these similar applications continue to implement a dose limit of 150 mSv/year. The regulator responsible for nuclear and all other non-nuclear applications has implemented a dose limit of 50 mSv/year as of 1 January 2021, and postponed consideration of adopting a five-year dose limit. This country currently has no approved dosimeters that have been type-tested or calibrated for $H_p(3)$, and is currently developing requirements for accreditation and technical/performance specifications for such dosimeters.

Two countries have not revised their legislation and are still examining the issue. The reasons include the need for more scientific information with respect to: the types of operations that can exceed the limit, performance testing capabilities (for example, consensus standards and eye models), the relationship between $H_p(10)$ and $H_p(0.07)$ estimation variability, and the need for more data on dosimeters for $H_p(3)$.

Practicalities of the implementation of new lens of the eye dose limits

It is clear that all respondent countries' regulators engaged in stakeholder consultations prior to enacting new legislation with revised equivalent dose limits for the lens of the eye for occupational exposures. It should be noted that stakeholders in this context include: regulated entities and licensees, advisory bodies, unions, professional organisations, and professional societies and associations. Such consultations were viewed as crucial activities to ensure that stakeholders were well-informed of the basis and reasoning for introducing new dose limits, and to provide guidance and address questions and concerns on the practicalities of implementing revised dose limits. The level of engagement varied, and a number of strategies were highlighted by respondent countries, including the following:

• webinars to discuss the science behind the ICRP's recommended dose limits for the lens of the eye, implementation aspects, and eye lens dosimetry;

- dosimetry studies in affected disciplines;
- training, workshops and conferences with societies, associations and professionals, experts and the radiological protection community;
- publication of technical instructions and guidelines;
- interviews and direct contact with affected individual specialists and professionals;
- public consultations and notices.

Examples of the engagement tools, provided by respondent countries, are included in Annex B of this report.

Challenges remain to the practical implementation of revised dose limits, and they are similar across respondent countries' stakeholders. They mainly arise from stakeholders within medical applications, particularly from those in the field of interventional cardiology, although nuclear regulators expressed similar concerns for nuclear power and nuclear fuel cycle facilities. The challenges raised by stakeholders include:

- the cost of demonstrating compliance with reduced lens of the eye dose limits, including costs associated with: enhancements to radiological protection programmes and procedures, dosimetry, personal protective equipment, instrumentation, training and education;
- difficulties and concerns over accurate measurement of lens of eye doses;
- increased requirements for the categorisation of radiation workers;
- the availability of dosimetry (including lack of approved dosimeters, and no defined accreditation and technical requirements for eye lens dosimetry in particular);
- ergonomic issues and concerns, leading to reluctance of personnel to wear eye lens dosimeters or protective glasses (for example, where personal protective equipment is cumbersome and not comfortable);
- issues with dosimeter placement and use of personal protective equipment;
- compliance issues, including reluctance of workers to wear dosimeters close to the eye, inconsistent use of personal protective equipment, difficulties in verifying that dosimeters have been worn correctly, training and education;
- a lack of consistent guidance, including from a regulatory perspective (for example, standardising dosimeter placement, the use of surrogate dosimeters, or the use of correction factors).

Similarly to the challenges raised by stakeholders, one nuclear regulator expressed concern regarding the lack of availability of dosimetry, particularly eye lens dosimetry $H_p(3)$, due to a lack of accreditation and approval processes, and defined technical requirements and specifications in the country. The availability of eye lens dosimeters and technical requirements appear to be well established in most European countries for dosimeters suitable for use in medical applications. These aspects seem to be more of an issue in North America, as well as for dosimeters suitable for radiation fields encountered in nuclear applications. Among nuclear regulators, concerns were expressed regarding the lack of eye lens dosimetry for mixed fields (beta/photons) and neutrons. One nuclear operator also expressed a lack of information on tritiated heavy water (DTO) and its possible contribution

to lens of the eye dose. Since the survey was carried out by the Nuclear Energy Agency (NEA) Expert Group on the Dose Limit for the Lens of the Eye (EGDLE), this issue has been examined in Canada by the CANDU Owners Group through a project initiated in 2021 entitled *Study of the health effects and dosimetric implications of Tritium exposure for the lens of the eye.*

Resolution of stakeholder concerns

Helping to address and resolve stakeholder concerns, respondent countries provided examples, and in some instances references, to resources to illustrate the examples which are provided in Annex B of this report. Some examples include the following:

- In France, the Institut de Radioprotection et de Sûreté Nucléaire (IRSN) designed explanatory information sheets to assist regulators in providing guidance on the placement of dosimeters that would be representative of exposure to the lens of the eye.
- In Japan, guidelines for radiological protection and monitoring of the lens of the eye in the medical field were prepared by the related academic societies, supported by the Radiation Safety Research Promotion Fund of the Nuclear Regulatory Authority (NRA).
- In Switzerland, the regulator of medical applications convened a working group with medical physicists to develop recommendations for topics such as radiological protection and monitoring of the lens of the eyes.
- In the United Kingdom, regulators provided updated approvals for eye lens dosimetry to include a conversion factor to account for the use of personal protective equipment when using dosimetry positioned on the forehead.

In countries pursuing revisions to the dose limit for the lens of the eye for occupational exposures, technical and informative meetings with stakeholders, particularly those involved in medical applications, are expected to help manage concerns. Stakeholder feedback will be solicited and public comments sought to address any concerns and specific issues prior to finalising revisions to legislation.

3. Regulatory requirements and guidance related to the conduct of risk assessments for the lens of the eye

The country responses to the survey by the Nuclear Energy Agency (NEA) Expert Group on the Dose Limit for the Lens of the Eye (EGDLE) do not show a clear consensus regarding demonstration of compliance with lens of the eye dose limits. This is highlighted in the sections of the report discussing individual and workplace monitoring for ascertaining lens of the eye dose. The majority of the responding countries (13) have regulatory guidance and/or general guidelines for conducting risk assessments that encompass eye exposures. Decisions on individual monitoring for ascertaining lens of the eye dose are linked to the outcome of the risk assessment. Where guidance on conducting risk assessments includes guidance on exposure to the eye, respondent countries indicated that the guidance is modelled after and/or informed by the following resources:

- IAEA TECDOC 1731, "Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye" (2013);
- IRPA, "Guidance on Implementation of Eye Dose Monitoring and Eye Protection of Workers" (2017);
- ISO 15382:2015, "Radiological protection Procedures for monitoring the dose to the lens of the eye, the skin and the extremities" (2015);
- IAEA No. GSG-7, "Occupational Radiation Protection" (2018);
- ICRP, "General Principles for the Radiation Protection of Workers" (1997).

Individual monitoring of the lens of the eye

Decisions on individual monitoring of the lens of the eye are made as a result of a risk assessment, and when individual monitoring is prescribed by the regulator. However, not all regulators have stipulated when individual monitoring of the eye is required. Six of the fifteen respondent countries have specified in legislation that individual monitoring is required when lens of the eye doses are projected to be at or greater than 15 mSv/year. The establishment of this level in legislation would seem to correspond to the transposition of the EURATOM BSS by these countries.

One respondent country requires individual monitoring of doses to the eye by measuring the personal dose equivalent at 3 mm depth, $H_p(3)$, with a dosimeter, and will not allow for surrogate dosimetry to be used. To note, one other country currently allows for the use of $H_p(0.07)$ until 31 December 2021, at which time individual monitoring will be required using $H_p(3)$ eye lens dosimeters exclusively.

The other thirteen respondent countries do allow for use of personal dose equivalent $H_p(3)$, or measurement of $H_p(0.07)$ and/or $H_p(10)$ for individual monitoring of doses to the eye. The allowance for the use of surrogate dosimetry (for example, $H_p(0.07)$ and/or $H_p(10)$) for individual monitoring of the lens of the eye includes reasons such as having no approved dosimeters for $H_p(3)$ available in the country, and, in some instances, where a requirement for individual monitoring of the eye has not been established. In nuclear and non-nuclear applications, it appears that there is more flexibility in the use of surrogate dosimetry

 $(H_p(0.07) \text{ and } H_p(10))$, and use of $H_p(3)$ for specific work activities and in certain exposure situations as necessary and as available.

Regarding neutron exposures, and when exposure to neutron fields is non-uniform and the eyes are preferentially exposed, three country responses align with the guidance provided by the IAEA (IAEA, 2013). In particular, dosimeters that measure $H_p(10)$ from neutron radiation may be worn near the eyes to provide a conservative estimate for dose to the lens of the eye. All other countries indicated that neutrons have not been considered because of the nature of the regulated activities (e.g. where neutrons are not encountered) or due to the fact that no neutron dosimetry is available.

Dosimeter placement and accounting for the use of personal protective equipment

There is no consensus on how protective equipment is taken into account when monitoring doses, and how the dosimeter is worn with protective equipment such as eyewear (the location of the dosimeter and whether worn under or over protective equipment) also varied for each respondent country.

Regulators agree that dosimeters should be placed "near the most exposed eye". However, there is no consensus on what "near" constitutes. If protective eyewear is worn (or not worn), guidance also varies or is lacking on the optimal placement of the dosimeter. For example, one regulator of medical applications requires that if individual monitoring of the lens of the eye is required, the dosimeter be placed outside the lead apron on the shoulder closest to the x-ray tube. This country also does not have dosimeters for $H_p(3)$ available, and dosimeters that measure $H_p(10)$ must be used for individual monitoring of the eye.

Seven respondent countries require dosimeters to be worn above protective equipment, and in some instances, a correction factor must be used to estimate dose to the eye. The other countries require dosimeters to be worn under protective equipment, and two countries have not yet defined the preferred practice. Some examples provided by respondent countries are as follows:

- A regulator of nuclear and non-nuclear applications requires that if eye shielding is used, the dosimeter should be located between any shielding material and the lens of the eye. If this is not practicable, a filter that mimics the shielding may be used with the dosimeter or correction factors may be applied.
- A regulator of nuclear, non-nuclear and medical applications requires the dosimeter to be positioned behind protective eyewear and between the eyes if it is not expected that one eye will be more exposed than the other. Otherwise, the dosimeter should be positioned on the side of the most exposed eye.
- In nuclear, non-nuclear and medical applications, one country allows for measurements to be made with eye lens dosimeters $(H_p(3))$ that can be fixed to different protective supports such as lead glasses, visors, caps, etc. Dosimeters can be positioned behind protective glasses as close as possible to the eye without obstructing the view. If eye lens dosimeters are used, they are worn adjacent to the most exposed eye and under shielding. In other cases (for example, a dosimeter worn on the trunk or other locations), the reliability of the method to properly assess the dose to the eye must be validated.

- In medical applications in yet another country, if eye dose is monitored with surrogate dosimetry, a dosimeter that measures $H_p(0.07)$ must be used and worn on the chest. If a second dosimeter is worn over the apron, a dosimeter that measures $H_p(0.07)$ must also be used, and the total dose ascertained using the dosimeters determines the eye dose. A specific eye lens dosimeter may also be used and may measure $H_p(3)$ or $H_p(0.07)$.
- One regulator requires interventional cardiologists to position their $H_p(10)$ dosimeter on the left shoulder, since the left shoulder in most cases is the closest part to the primary field. The dosimeter reading will give a rough estimate for the left eye lens, which is considered the most exposed eye.

Surrogate dosimeters for ascertaining eye doses

Based on the information provided by respondent countries, it is generally recognised that when individual monitoring is required, the personal dose equivalent $H_p(3)$ should be measured, and use of surrogate dosimeters (for example, those that measure $H_p(0.07)$ and $H_p(10)$) is not acceptable. This is particularly true for medical applications.

There is one nuclear regulator that will allow the use of surrogate dosimeters when specific eye lens dosimetry or working conditions do not allow for the wearing of a dosimeter suitable for measuring the dose to the eyes, or when the effective dose is representative of the equivalent dose received to the lens of the eye. Dosimeters that measure $H_p(0.07)$ or $H_p(10)$ can be used as a surrogate, if demonstrated that the dosimeter and method chosen has the same reliability as that based on the measurement of the dose to the lens. For the estimation of the dose to the lens of the eye in interventional radiology facilities, one other regulator has considered the measurement obtained by a surrogate dosimeter placed either on the lead apron or on the thyroid collar to be acceptable. The following formula would be applied to estimate lens of eye dose: $H_{lens}=H_p(0.07)_{apron \text{ or collar}}$. It is noted that this country is revising its legislation to incorporate new dose limits for the lens of the eye, and this practice is acceptable in the interim.

There is also no consensus among respondent countries regarding the use of surrogate dosimeters and correction factors (for example, providing a correction factor that is applied to surrogate dosimetry result(s) in order to ascertain dose to the eye), and in some instances, this method is not allowed. Most countries have not developed any protocols or regulatory guidance as well, with only seven countries having some information available for when such a method could be considered and used.

For situations where the regulator has accepted the use of surrogate dosimeters and correction factors, the correction factors must be proposed/justified by the stakeholder and approved by the regulator, typically on a case-by-case basis. In other instances, accepted correction factors cited from research/literature have been accepted by the regulator. For example:

• One country's medical sector uses dosimeters that measure $H_p(10)$, worn on the collar and above shielding/personal protective equipment, and applies a correction factor of 50% for standard protective eye wear, and a 75% correction factor for wrap-around lead glasses, based on literature (Magee et al., 2014; Sturchio et al., 2013).

- In medical applications within another country, the regulator allows for dosimeters to be worn above the shielding glasses, and a correction factor of 0.48 can be used to estimate the dose for the lens of the eye from the $H_p(10)$ value.
- Another regulator of medical applications requires that an individual correction factor be determined when using a whole body dosimeter $(H_p(10))$ on the chest to monitor the eye lens dose. The factor must take into account the personal protective equipment (glasses, helmet or lead glass wall) and the distance to the eye. If a specific eye lens dosimeter is used, it is recommended to wear it underneath the protective equipment. Otherwise, a correction factor must also be applied. This country has convened a working group, which is developing recommendations on how to determine such a correction factor, and a directive on this was expected in 2020.

Workplace monitoring to estimate dose to the lens of the eye

Based on the information provided by respondent countries, it is generally recognised that workplace monitoring is not acceptable to demonstrate compliance with lens of the eye dose limits. Workplace monitoring can typically only be used to identify/confirm when individual monitoring of the lens of the eyes is required.

One country's regulator of nuclear and non-nuclear applications has accepted that when radiation fields are predictable over long periods of time, it is possible to estimate doses using workplace monitoring at relevant locations representative of the conditions under which individuals will be exposed. If ambient monitoring is being considered, instruments that measure ambient dose equivalent and directional dose equivalent may be used. If ambient monitoring is being considered, $H_p(10)$ and $H_p(0.07)$ may be replaced with H*(10) and H'(0.07) respectively. This country also has no approved eye lens dosimeters and has not legislated when individual monitoring would be required.

4. Availability of eye lens dosimeters

The EGDLE survey explored the availability of eye lens dosimeters in respondent countries, including dosimeter types, technical requirements, accreditation and approval processes,¹ as well as requirements for participation in national/international inter-comparisons. Respondent countries also outlined, where available, notable practices and strategies, including resources and references for technical specifications and approvals, and inter-comparisons.

As noted in the responses from two countries, $H_p(3)$ eye lens dosimeters can be used in all regulated activities (for example, nuclear, non-nuclear and medical applications), if the appropriateness of the dosimeter is confirmed for the radiation fields (including neutrons, if applicable), based on a risk assessment for all exposure situations, and supported by suitable performance testing programmes.

 $H_p(3)$ eye lens dosimeters are not approved and/or available across the majority of the respondent countries. In a number of cases, eye lens dosimeters are approved only for photons, and not for beta and neutron radiations, since there is no legal requirement for beta and/or neutron radiations, no demand for eye lens dosimeters for neutron fields, or because this issue has not yet been considered. This is a particular concern and challenge expressed mainly by nuclear regulators.

In other cases, approved eye lens dosimeters are available for mixed radiation fields. Moreover, it is reported that for beta and neutron radiations, the use of the dosimeters for photon and neutron measurements is acceptable if there is adequate inter-comparison to ensure they fulfil the related requirements.

Approval of eye lens dosimeters

The approval processes implemented by the majority of countries for eye lens dosimeters include type-testing and/or type-approval according to national requirements, and/or accreditation and/or a formal approval procedure. These aspects are discussed further in the section "Technical requirements and specification for eye lens dosimeters" below. One country is currently developing licensing requirements (which would include accreditation, technical and performance specifications) while another country subcontracts eye lens dosimetry from a nuclear fuel fabrication company that has an accreditation for an eye lens

Accreditation consists in third-party attestation (section 7.3) related to a conformity assessment body (section 4.6), conveying formal demonstration of its competence, impartiality (section 5.3) and consistent operation in performing specific conformity assessment activities.

Approval is a permission for a product, service or process to be marketed or used for stated purposes or under stated conditions. Approval can be based on fulfilment of specified requirements or completion of specified procedures. Approval can be given in the context of a conformity assessment scheme (section 4.9).

The conditions for the approval for an individual monitoring service are very different from one country to another. In some countries, accreditation is not required for approval. In others, accreditation is the (or one of the) mandatory requirement(s) for the approval.

^{1.} The definitions of accreditation and approval can be found in "ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles" in the sections indicated below.

dosimetry system. Half of the respondent countries currently do not have an accreditation process for approval of dosimeters for $H_p(3)$.

The majority of European countries and one in South America (note only one country of this region is a member of the NEA) have eye lens dosimeters for $H_p(3)$ available, and the majority have established accreditation processes to ISO/IEC 17025 (ISO, 2017) for individual monitoring services.

In four countries, there are currently no dosimeters for $H_p(3)$ that are approved or available. In one country, headband dosimeters employing $H_p(0.07)$ are available and approved, and optically stimulated luminescence (OSL) $H_p(3)$ dosimeters integrated into protection glasses are available but not yet approved. Examples of eye lens dosimeters, provided by respondent countries, are provided in Annex D of this report.

Technical requirements and specifications for eye lens dosimeters

The technical requirements for eye lens dosimeters are more or less defined depending on the availability of eyes lens dosimeters in the respondent country. Countries' technical standard(s) for the performance criteria for the measurement of $H_p(3)$ with eye lens dosimeters are aligned with or follow IEC 62387 (2020), IEC 61526 (2010), and ISO 15382 (2015). Several countries define their own technical requirements and specifications or use a mix of the international standards, in addition to some specific national requirements. In situations where some dosimeters are available and when an accreditation is needed, compliance with IEC 62387 (2020) is usually required. However, five countries have defined their own national technical requirements, which are detailed in their regulatory documents. These may be based on international standards, but not systematically.

If the requirements are based on international type testing standards, countries refer to IEC 61526 (2010) or IEC 62387 (2020). References to technical requirements and specifications provided by respondent countries are provided in Annex B: Country Resources and Guidance of this report.

When the fulfilment of international standards is required, most countries refer to IEC 62387 (2020), which gives specific type-tests and performance criteria for passive dosimetry (eye lens dosimeters included). This standard was revised recently (latest publication in January 2020), so the version (year of publication) of the document that is referred to in the legislation of most countries varies (for example, versions 2012, 2016 or 2020 of IEC, 2020). Most of the countries referring to IEC 62387 (2020) refer also to ISO 15382 (version 2015 or 2017) (ISO, 2015) which is the standard providing procedures for monitoring the dose to the lens of the eye, the skin and the extremities. One country bases its technical requirements on IEC 62387 (2020) but also on the IEC 61526 standard (2010). The latter deals with the measurement of personal dose equivalents $H_p(10)$ and $H_p(0.07)$ for photons, gamma, neutron and beta radiations for direct reading personal dose equivalent meters, even if the currently available eye lens dosimeters in this country are all based on a passive technique.

Concerning the specifications, in one country's regulatory requirements, it is clearly stated that: "Absorbed dose to the lens of the eye may be assessed in terms of the quantity $H_p(3)$ ". Moreover, countries take a variety of approaches, depending on both the existence/availability of eye lens dosimeters proposed by the individual monitoring service and the way individual monitoring is implemented in practice in a more general way.

Two countries' responses provided only the specifications from the technical sheet from the dosimetry service supplier. It is therefore unclear if other specifications may be legislated in the countries.

Three countries provide general recommendations for individual monitoring services without explicit and/or detailed specifications. As an example, one country requires that "...the IMS [individual monitoring service] shall ensure that any type of dosimeter or other device used has a consistent and adequate level of performance in the radiation fields and ambient conditions likely to be encountered in the environments in which it will be used for estimating the quantities". In addition, one example provided by a regulator included the following, without specifying the eye lens dosimeter: "In general, an appropriate dose range for a dosimeter used in the assessment of E would be ~0.1mSv to ~1 Sv for gamma radiation and ~0.2 mSv to at least 50 mSv for neutrons, for example".

Other countries have precise specifications for eye lens dosimeters. For example, one country has defined that the smallest measured dose should be no greater than 0.10 mSv and with a measurement step no greater than 0.05 mSv. In addition to the minimal recording value and the need to be accredited to certain standards, there are also general specifications for all types of monitoring: whole body, extremity and eye lens dosimetry. This country also requires that the individual monitoring service prove that the dosimeters used meet the needs of the professional sectors.

When the accreditation is a requirement established by the regulatory body, the technical specifications are easiest to define because the eye lens dosimeter in that case should be compliant with national or international standards.

Individual monitoring services offering eye lens dosimeters in national and/or international inter-comparisons

There is no consistent approach in individual monitoring services' participation in national and/or international inter-comparisons. A number of countries have not decided, while others have yet to implement procedures or have not yet published regulatory guidance. The majority of countries are conducting national inter-comparison tests for $H_p(3)$ or have no such national exercise but plan to organise it. If the requirements are not yet mandatory for participation in inter-comparison tests, there is an expectation regarding the participation of approved services, even if there is currently no accreditation or performance testing programme for eye lens dosimeters.

For a number of countries, the participation of individual monitoring services in national inter-comparison is mandatory, and the authorisations related to dosimetry services require the periodic participation in national and/or international inter-comparisons. This participation in the evaluation of the performance of dosimeters provided by individual monitoring services, over the full range of their dosimeters, could be on an annual, triennial or five-year basis.

Moreover, it is interesting to note that one country has taken into account the fact that there could be one available eye lens dosimeter from one unique individual monitoring service in that country. In this case, an inter-comparison exercise cannot be organised. The regulation of this country states the following: "When the inter-comparison cannot be organised because the measurement method used by that laboratory is unique, it is indicated to organise, by the national institute, an evaluation of this method, according to its defined procedure, and this in order to replace the inter-comparison test procedure". In general, international inter-comparison is encouraged, but participation is voluntary and not mandatory. Few countries are considering defining how often to require participation in an international inter-comparison measurement for eye lens dosimeters.

5. Challenges associated with recording doses to the lens of the eye

Five of the fifteen respondent countries could not answer the question regarding challenges associated with recording doses to the lens of the eye since no information was available or the question was not applicable. This is mainly due to the fact that new lens of the eye dose limits have only recently been introduced or have not yet been introduced.

Four respondent countries noted that they have either no issues or only minor problems associated with recording doses to the lens of the eye. Most of these countries are already collecting data on doses to the lens of the eye and thus the change in the dose limit only caused a formal change, if at all, in the dose recording procedure within their National Dose Registries. From the monitored workers' point of view (especially those from medical applications), only minor barriers to collecting eye dose information have been observed thus far.

Respondent countries provide practical challenges from the point of view of the stakeholders, as discussed in the section of this report called "Practicalities of the implementation of new lens of the eye dose limits". Particularly in interventional radiology and cardiology, the wearing of eye lens dosimeters or protective equipment such as lead glasses is in some instances regarded negatively, since it could hinder complex work during surgery. The eye lens dosimeter itself was also identified to be a problem, either due to ergonomic issues or availability.

In general, all countries' responses indicate that the challenges associated with recording doses to the lens of the eye are not fully known, outside of those identified in this report. Five countries indicated that a main issue in recording doses to the lens of the eye is ensuring the application of correct methods for the determination of the dose when a surrogate dosimeter is used. As mentioned previously in this report, four countries have indicated a lack of availability of eye lens dosimeters for personal dose equivalent $H_p(3)$. Respondent countries found it challenging to determine how to record the lens of the eye dose with surrogate dosimeters or other techniques, and how to distinguish this from the dose recorded using $H_p(3)$ eye lens dosimetry. To address this, one nuclear regulator considers an approved surrogate technique would need to be equivalent to $H_p(3)$.

Respondent countries also listed some challenges faced by regulators regarding recording doses to the lens of the eye. For example, one respondent country mentioned that modifications have to be performed in the National Dose Registry to accept $H_p(3)$ values.

Challenges and issues related to recording and tracking doses are related to the stakeholder concerns discussed previously in this report and regard compliance, costs, availability of dosimetry and methods of protection. In particular, challenges with recording include accounting for personal protective equipment and use of correction factors, dosimeter placement, use of surrogate dosimetry, and/or accounting for workplace monitoring methods. The quality of the data is directly related to how to properly record doses in National Dose Registries. Four countries collecting/recording doses to the lens of the eye from dosimetry mounted near the eyes (for example, on the forehead) or on the protective glasses, reported having challenges related to calibration and the correct positioning of the dosimeters. Also, one respondent country highlighted the importance of having proper correction factors that allow realistic doses to be obtained when forehead dosimeters are used.

Overall, it appears that there may be limited information on nuclear workers and an abundance of dose information from medical applications. This is discussed further in the report and is a research need brought forward by respondent countries.

6. Opportunities for future work and collaboration

Based on the information provided by respondent countries, it is clear that there remains a need to improve how the revised lens of the eye dose limits are implemented in practice, particularly around the availability of eye lens dosimeters for all possible exposure situations, and in making them ergonomically convenient. Harmonisation of eye lens dosimetry use and dosimeter placement (positioning and use with shielding/personal protective equipment, including any required correction factors) would also benefit all countries, especially regarding transient workers and ensuring their lens of the eye doses can be properly managed and optimised. Similarly, harmonisation of the acceptability of the use of surrogate dosimetry and corresponding correction factors would be beneficial.

The country responses indicate that work to address these issues is advancing, and helpful resources and references are provided in this report for countries seeking solutions. Continued exchange of information and experiences on these aspects would benefit all countries.

A summary of country feedback follows. Additional information was added as appropriate to complement advances since the closing of the Nuclear Energy Agency (NEA) Expert Group on the Dose Limit for the Lens of the Eye (EGDLE) survey in July 2020.

Implementation aspects

Respondent countries providing feedback agree that standardised and/or harmonised procedures, guidance and requirements would be beneficial around the following themes:

- Eyewear protection and/or other protective devices, including suitability for exposure situations. One country also suggested that an eyewear protection standard would be helpful. Another country suggested that eyewear protection should be mandatory in all instances.
- Harmonisation of accreditation and technical specifications for $H_p(3)$ eye lens dosimeters, to assist in improving the availability of eye lens dosimeters worldwide.
- Internationally accepted eye lens dosimeters and clear instructions for their use.
- Education and training.
- Use of personal protective equipment.
- Non-uniform exposure situations.
- Use of correction factors.
- Standardising dosimeter placement, especially in medical applications.

A respondent country also stated that standardised procedures and accessible guidelines are especially important for small regulatory bodies.

As discussed in Section 5 of this report, challenges associated with recording doses to the lens of the eye include accounting for personal protective equipment and use of correction factors, dosimeter placement, use of surrogate dosimetry, and/or accounting for workplace monitoring methods. The quality of the data is directly related to the methods of recording doses in National Dose Registries. Indeed, feedback from the NEA consultation of the

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) on this issue cited a need for collection of data on doses to the lens of the eye. During the 68th session of UNSCEAR in June 2021, the Committee noted that reported data on the equivalent doses for the lens of the eye (as well as for the hands [skin dose]) were limited. For the Committee's next evaluation of occupational exposures, the Committee expects more countries to be in a position to provide reliable data on this topic.

Exchange of information and experiences

In support of the EGDLE mandate to identify means for continued dialogue and information exchange, respondent countries are open to exchanging information and experiences. A regulatory body indicated that it would be beneficial to convene a group or forum for interested parties to advance questions and concerns and to share practical experiences.

One country said that more data is needed regarding projected lens of eye doses to workers in nuclear applications. Another country suggested exchanging experiences on approving methods of calculating $H_p(3)$ values using correction factors (when surrogate dosimetry is used). Yet another country would like to see a consistent definition of non-uniform exposures and consistency in the interpretation of "near the lens of the eye". Another country would like to share pass/fail criteria for $H_p(3)$ eye lens dosimeters.

European countries noted that they are actively involved in the European Radiation Dosimetry Group (EURADOS), and this platform may facilitate the continued exchange of information and best practices regarding the practicalities of monitoring dose to the lens of the eye. Since the EGDLE survey was carried out, EURADOS published a compendium of papers (2021) based on the presentations delivered during the EURADOS Winter School 2020 on eye lens dosimetry, held in Florence, Italy on 30 January 2020.

Additionally, in November 2020, the IRPA task group published a new report on issues and actions taken in response to the change in the lens of the eye dose limit (Cantone et al., 2020).

Research needs

It is evident that research is the top priority. One country noted there are many different ongoing research projects throughout the world, some of high quality and others of far lower quality (due to, for example, low sample size or variables that are not accounted for). It was suggested that it would be beneficial for groups to be able to identify what quality research is available with respect to eye lens dosimetry types, performance testing, lens of eye phantoms, scatter/buildup, etc.

Another country expressed interest in more science underpinning the ICRP recommendations and cited some research projects underway. Other countries expressed a need for research into placement of eye lens dosimetry or other ways of individual monitoring. Another country noted that there is a need for research on dosimetry for radiation workers following legislative changes to the lens of the eye dose limits, including radiation effects and biology, and epidemiology for radiation workers. Another country suggested an international inter-comparison test on the range of eye lens dosimeters available.

It was suggested that guidance would be beneficial on the wearing of the eye lens dosimeter, especially when wearing personal protective equipment, and to determine the effect in the real world work environment.

A regulatory body identified several fields of interest, especially regarding the issue of lens opacities. From the epidemiological point of view, statistical analysis involving cohorts/populations with representative data are urgently needed. In medical applications, the monitoring of lens opacities and the effects on the lens of the eye among occupationally exposed workers and medical staff should be a priority during congresses and meetings in order to unify all internationally available data (and it was noted that the international study, Retrospective Evaluation of Lens Injuries and Dose [RELID], initiated by the IAEA in 2008, would be a useful initiative in this respect). Finally, in biology, the aetiology of the opacities and the dose response at low doses was suggested as another area that should be urgently addressed. For future consideration, it was expressed that it would be important to conduct both dose assessments in various technologies, and epidemiological studies of radiation effects (in the context of examining whether visually disabling cataract formation is a stochastic response to radiation).

One country identified that Canada's Federal Nuclear Science and Technology network is currently conducting research in the areas of: biological effects and mechanisms of low dose radiation on cataracts; and, determining the needs of the Canadian industry involved in handling radioactive materials and radiation devices, with regard to eye dose monitoring. The CANDU Owners Group also initiated a project in 2021 entitled *Study of the health effects and dosimetric implications of Tritium exposure for the lens of the eye*.

UNSCEAR consultation on this topic included the consideration of the UNSCEAR (2020) report, "Levels and effects of radiation exposure due to the accident at the Fukushima Daiichi Nuclear Power Station: implications of information published since the UNSCEAR 2013 report". In this report, UNSCEAR suggests a possible approach to the assessment of the doses to the lens of the eye for the most exposed workers. Doses to the lens of the eye may be estimated (using $H_p(3)$, if feasible) from immersion in airborne ¹³¹I and associated shorter-lived radionuclides at concentrations that would give rise to the measured thyroid ¹³¹I contents of these workers. Such an assessment would require information on material-specific factors including the physico-chemical form of the airborne material and individual-specific parameters, including breathing rate, which ideally would be derived from information on exposure conditions in the workplace at the time.

Annex F provides selected examples of research publications and studies, cited by respondent countries.

7. Conclusions

It is clear that respondent countries have been active in various initiatives since the International Commission on Radiological Protection (ICRP) statement on tissue reactions for the lens of the eye and the recommendations for revised equivalent dose limits for the lens of the eye. Due to the importance of the ICRP statement, and with new risk information at hand, all countries recognised the importance of early engagement with stakeholders as revisions to legislation are considered. The importance of continued stakeholder engagement is also recognised to advance and promote the resolution of issues and continuously improve the monitoring and measurement of doses to the lens of the eyes.

As discussed in this report, some practical challenges remain, and most countries are advancing in their efforts to address them, in consult with stakeholders. The respondent countries have a consensus on the value in guidance provided by the International Atomic Energy Agency (IAEA, 2013) and the International Radiation Protection Association (IRPA, 2017), for example.

Areas where countries could benefit from sharing experiences and possible harmonisation include:

- The requirement for individual monitoring, and consensus on use of eye lens dosimeters measuring personal dose equivalent $H_p(3)$.
- Eye lens dosimetry, with use of ISO and IEC standards to define accreditation and technical/performance specifications for $H_p(3)$ eye lens dosimeters. Issues such as beta and neutron radiations, mixed radiation fields (beta/photons), and intercomparisons need to be addressed.
- Dosimeter placement, taking into account personal protective equipment.
- Acceptability of the use of surrogate dosimeters and correction factors.

Dialogue and information exchange in international for should continue, especially where international harmonisation would be beneficial.

Research projects to address the needs identified in this report could also significantly contribute to advances in radiological protection aspects for the eye, in addition to improvements in eye lens dosimetry.

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Annex A. List of respondent countries to the EGDLE survey

ArgentinaAutoridad Regulatoria Nuclear Embalse Nuclear Power Plant CONUAR S.A. (Combustibles Nucleares Argentinos S.A.) Atucha Nuclear Power PlantCanadaCanadian Nuclear Safety CommissionCzech RepublicState Office for Nuclear Safety AuthorityFinlandRadiation and Nuclear Safety AuthorityFranceMinistry of Labour: General Directorate for Labour (DGT) French Nuclear Safety Authority (ASN) Institute of Radioprotection and Nuclear Safety (IRSN)GermanyFederal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)GreeceGreek Atomic Energy Commission (EEAE)IcelandIcelandic Radiation Safety Authority (DSA)JapanFujita Health UniversityNorwayNorwegian Radiation and Nuclear Safety Authority (DSA)RussiaState Research Center-Burnasyan Federal Medical Biophysical Center of Federal Medical Biological Agency (SRC-FMBC)Department of Radiation Hygiene, Federal State Budgetary Educational Institution of Further Professional Education "Russian Medical Academy of Continuous Professional Education" under Ministry of Healthcare of the Russian Federation (FSBEI FPE RMACPE MON Russia)SpainNuclear Safety Council (CSN)SwitzerlandFederal Office of Public Health (FOPH)United KingdomHealth and Safety Executive Office for Nuclear RegulationUnited StatesDepartment of Energy	Country	Organisation(s)
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Annex B. Country resources and guidance

The following is a list of select resources and guidance provided by respondent countries.

Argentina

- ARN informa sobre un nuevo límite de dosis equivalente en cristalino para trabajadores ocupacionalmente expuestos, 25 de julio de 2016: <u>www.argentina.gob.ar/noticias/la-arn-informa-sobre-un-nuevo-limite-de-dosis-</u>equivalente-en-cristalino-para-trabajadores
- ARN establece nuevo límite de dosis equivalente en cristalino para trabajadores 23 de Ago de 2016: <u>http://u-238.com.ar/arn-establece-nuevo-limite-dosis-equivalente-cristalino-trabajadores/</u>
- ARN informa nuevo límite de dosis equivalente en cristalino para trabajadores ocupacionalmente expuestos, julio 27, 2016: <u>http://enula.org/2016/07/la-arninforma-nuevo-limite-de-dosis-equivalente-en-cristalino-para-trabajadoresocupacionalmente-expuestos/</u>
- Norma básica de seguridad radiológica AR 10.1.1 : www.argentina.gob.ar/sites/default/files/10 1 1 r3 impresion 2016a norma bas ica_1.pdf

Canada

- Technical Note: Proposed Changes to the Equivalent Dose Limit for Lens of the Eye: www.nuclearsafety.gc.ca/eng/pdfs/Discussion-Papers/16-02/technical-note-lens-of-the-eye-eng.pdf
- CNSC, REGDOC-2.7.2, Dosimetry, Volume 1, Ascertaining Occupational Dose: <u>http://nuclearsafety.gc.ca/eng/acts-and-regulations/regulatory-</u> <u>documents/history/regdoc2-7-2-vol-I.cfm</u>
- CNSC, Webinars on lens of the eye: <u>https://nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history/dis-13-01-webinar.cfm</u>

Czech Republic

- Seminář pro lektory vyučující RO na fakultách lékařských, fakultě Biomedicínského inženýrství, Zdravotně sociální JU, Univerzitě Pardubice (SÚJB, 26.11.2018): www.sujb.cz/radiacni-ochrana/odborne-seminare/
- DOPORUČENÍ SÚJB, bezpečné využívání jaderné energie a ionizujícího záření, Osobní monitorování, Část I. – zevní ozáření, DR-RO-6D.1 REV. 0.0: <u>www.sujb.cz/fileadmin/sujb/docs/dokumenty/publikace/DR-RO-6D.1 REV. 0.0 Doporuceni Osobni Monitorovani cast I.pdf</u>

France

- IRSN, Recommandations sur les bonnes pratiques en matière de radioprotection des travailleurs dans la perspective de l'abaissement de la limite réglementaire de dose équivalente pour le cristallin, Rapport PRP-HOM/2013-00010; https://www.sfrp.asso.fr/medias/sfrp/documents/Divers/SPT/Fiche_SFRP_-_Cristallin_-_FR__06-2016_V2.pdf
- SFRP, crisTallin : Limites réglementaires, mesure, dosimétrie et suivi médical (juin 2016). <u>https://www.sfrp.asso.fr/medias/sfrp/documents/Divers/SPT/Fiche_SFRP_-</u> Cristallin - FR 06-2016 V2.pdf

Japan

- NRA HP, <u>www.nsr.go.jp/data/000238374.pdf</u> and www.nsr.go.jp/data/000226076.pdf;
- MHLW HP, <u>www.mhlw.go.jp/stf/newpage_06824.html</u>, www.mhlw.go.jp/stf/newpage_02959.html, www.mhlw.go.jp/content/000563255.pd;
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- Radiation Council, Japan, The meeting discussion materials of the 147th Radiation Council, Japan (2019), www.nsr.go.jp/disclosure/committee/houshasen/210000045.html.

Norway

- DSA guidelines for the use of diagnostic X-rays and MR (Veileder 5) <u>https://dsa.no/publikasjoner/veileder-5-veileder-om-medisinsk-bruk-av-rontgen-og-mr-apparatur/Veileder_5_Røntgen-MR_2017.pdf</u>
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- StrålevernRapport 2016:12. Østerås: Norwegian Radiation Protection Authority, 2016: <u>www.dsa.no/publikasjon/straalevernrapport-2016-12-tilsyn-med-medisinsk-straalebruk-ved-kardiologiske-intervensjonsavdelinger-2013-2014.pdf</u>
- Radiation Protection INFO: <u>www.dsa.no/publikasjon/straaleverninfo-5-2012-kartlegging-av-straaledoser-til-oeyelinsen-for-radiologer-og-kardiologer.pdf</u>

REGULATORY IMPLEMENTATION OF THE EQUIVALENT DOSE LIMIT FOR THE LENS OF THE EYE FOR OCCUPATIONAL EXPOSURE

Russia

• Methodical Guidelines MU 2.6.5.037-2016 "Monitoring of photon and beta equivalent dose in the skin and in the lens of the eye". Approved by the FMBA of Russia, 27 May 2016

Методические рекомендации МУ 2.6.5.037-2016 «Мониторинг фотонной и бета-эквивалентной дозы в коже и в хрусталике глаза». Утвержден ФМБА России 27 мая 2016 г. <u>MU-2.6.5.037-2016-Kozha-i-hrustalik-080716.pdf</u> - <u>Яндекс.Документы (yandex.ru)</u>

• Methodical Guidelines MU 2.6.5.02-2016 "Determination of individual effective and equivalent doses and arrangement of occupational dose monitoring under conditions of planned exposure. General requirements". Approved by the FMBA of Russia, 18 May 2016

Методические указания МУ 2.6.5.028-2016 «Определение индивидуальных эффективных и эквивалентных доз и организация профессионального дозирования в условиях планируемого воздействия. Общие требования». Утвержден О ФМБА России 18 мая 2016 г. <u>4293748104.pdf</u> - Яндекс.Документы (yandex.ru)

• Methodical Guidelines MU 2.6.1. 3015-12 "Arrangement and performance of individual dose monitoring. The staff of medical organizations". Approved by Rospotrebnadzor.

Методические указания МУ 2.6.1. 3015-12 «Организация и проведение индивидуального дозиметрического контроля. Персонал медицинских организаций Утверждено Роспотребнадзором <u>4293793384.pdf</u> - <u>Яндекс.Документы (yandex.ru)</u>

Switzerland

- B09 Ermittlung und Aufzeichnung der Dosen strahlenexponierter Personen: <u>www.ensi.ch/de/dokumente/richtlinie-ensi-b09-deutsch/;</u>
- List of all information sheets for the new ordinance for the medical sector (only in German, French and Italian): <u>www.bag.admin.ch/bag/de/home/gesund-leben/umwelt-und-gesundheit/strahlung-radioaktivitaet-schall/totalrevision-der-verordnungen-im-strahlenschutz.html</u>

United States

- "New International Commission on Radiological Protection Recommendations on the Annual Dose Limit to the Lens of the Eye," in the Federal Register (76 FR 53847): www.govinfo.gov/app/details/FR-2011-08-30/2011-21900;
- "Assessment of Technical Issues and Feedback," of SECY-12-0064 -Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance (available at www.nrc.gov/docs/ML1210/ML121020128.pdf);

- A summary of stakeholder views on this issue is provided in SECY-12-0064, Enclosure 3, "Assessment of Technical Issues and Feedback," pages 13 through 17 (ADAMS Accession No. ML121020108 (www.nrc.gov/docs/ML1210/ML121020128.pdf));
- On 25 July 2014 (79 FR 43284), available at <u>www.govinfo.gov/app/details/FR-2014-07-25/2014-17252</u>, the US NRC published for comment an advance notice of proposed rulemaking to obtain input from stakeholders on the development of a draft regulatory basis. This rule making was discontinued as part of the rebaselining activities per SRM-SECY-16-0009 (www.nrc.gov/docs/ML1610/ML16104A158.pdf), dated 13 April 2016;
- NCRP Commentary No. 26, Commentary No. 26 Guidance on Radiation Dose Limits for the Lens of the Eye (2016). https://ncrponline.org/shop/commentaries/commentary-no-26-guidance-onradiation-dose-limits-for-the-lens-of-the-eye-2016/.

Annex C. Dosimeter accreditation and technical specifications

The following is a list of select resources for accreditation and technical specifications, provided by respondent countries.

France

- Arrêté du 26 juin 2019 relatif à la surveillance individuelle de l'exposition des travailleurs aux rayonnements ionisants NOR: MTRT1901273A ELI: www.legifrance.gouv.fr/eli/arrete/2019/6/26/MTRT1901273A/jo/texte;
- COFRAC, Exigences spécifiques pour l'accréditation des laboratoires chargés de procéder à la surveillance individuelle de l'exposition des travailleurs aux rayonnements ionisants, LAB REF 37 - Révision 00: <u>https://tools.cofrac.fr/documentation/LAB-REF-37.</u>

Germany

 German Measurement and Verification Act ("Mess- und Eichgesetz"), Physikalisch-Technisches Bundesanstal (PTB), PTB-A 23.2 for personal dosimeters and PTB-A 23.3 for area dosimeters: www.ptb.de/cms/en/ptb/fachabteilungen/abt6/fb-63/information/conformityassessmentaccording-to-module-b-type-examination-of-area-and-individualdosemeters-for-photonradiation-in-compliance-with-the-measures-andverification-act.html.

Russia

- GOST 8.326-89: The State System for Ensuring Uniformity of Measurements. Metrological Certification of Tools;
- Federal Law "On Ensuring the Uniformity of Measurements" dated 6 June 2008 N 102-FZ;
- Federal Law dated 27 December 2019 N 496-FZ "On amendments to the Federal Law "On Ensuring the Uniformity of Measurements";
- Methodical Guidelines MU 2.6.5.037-2016 "Monitoring of photon and beta equivalent dose in the skin and in the lens of the eye". Approved by the FMBA of Russia, 27 May 2016;
- Methodical Guidelines MU 2.6.5.02-2016 "Determination of individual effective and equivalent doses and arrangement of occupational dose monitoring under conditions of planned exposure. General requirements". Approved by the FMBA of Russia, 18 May 2016;
- Methodical Guidelines MU 2.6.1. 3015-12 "Arrangement and performance of individual dose monitoring. The staff of medical organizations". Approved by the Rospotrebnadzor.

Switzerland

- Radiation Protection Ordinance, Art. 66-68: <u>www.admin.ch/opc/en/classified-compilation/20163016/index.html;</u>
- Annex 8 and 9 of Dosimetry Ordinance for lens of eye dosimetry technical requirements: <u>www.admin.ch/opc/de/classified-compilation/20163018/</u> index.html.

United Kingdom

- www.hse.gov.uk/radiation/ionising/dosimetry/index.htm;
- www.hse.gov.uk/radiation/ionising/dosimetry/requirements-pt1.pdf;
- www.hse.gov.uk/radiation/ionising/dosimetry/dosimetry-state.pdf.

Verification process at the Czech Metrology Institute

• <u>www.cmi.cz/</u>.

Annex D. Examples of eye lens dosimeters

The following are examples of eye lens dosimeters, provided by respondent countries.

The dosimeters listed in the table have different dose ranges, from a minimum dose of 0.01 mSv to a maximum dose of 50 Sv for photons and from 0.05 mSv to 50 Sv for betas. In addition, the photon energy response of the dosimeters varies from one to another and covers a specific energy range between 5 keV and 6 MeV. The different the beta energy responses vary between 24 keV and 3.5 MeV.

Table D.1: Examples of available eye lens dosimeters in respondent countries

* A: Available, AA: Available and approved, N: No information regarding availability and approving, S: Not approved, but used in studies.

Model	Manufacturer	Dosimeter type	Reference for additional dosimeter details	Number of countries where available*
NUVIA Dosimetry eye lens film dosimetry system (film FOMA Bohemia)	NUVIA Dosimetry	Film $H_p(3)$ eye dosimeter	http://nuviadosimetry.com/dozimetri e-ocni-cocky/	<u>A: 1</u>
EYE-D	RADCARD	Thermo- luminescent $H_p(3)$ eye dosimeter (TLD $H_p(3)$	www.radcard.pl/det/eye_d.html	<u>A:2</u> <u>AA:1</u> S: 1
Landauer Vision	Landauer	TLD $H_p(3)$	www.landauer.com/sites/default/files /product-specification- file/LANDAUER%20Vision.pdf	<u>AA:1</u> <u>N:2</u> <u>A:1</u>
Landauer Luxel +	Landauer	Pulsed Optically Stimulated Luminescence Dosimeter (POSLD)	www.landauer.co.uk/	<u>N:1</u>
DOSIRIS	IRSN dosimetry laboratory	TLD $H_p(3)$	http://dosimetrie.irsn.fr/en- us/Documents/Product%20files/DOS IRIS%20EN%20WEB.pdf	<u>N:1</u> <u>A:1</u>
MKD (type A)	Dose	TLD MKD (type A) $H_p(3)$	-	<u>N:1</u>
Complex AKIDK- 401 with DVDS-1 dosimeters (in the skin of the face and in the lens of the	Certified by the FATRiM RF (the certificate number 48862) and registered in the	DVDS-1 and DVDS-2	-	<u>N:1</u>

		1		
eye), with DVDS-2 dosimeters (in the skin of the handbreadth)	State register of Measuring Instruments under number 51882-12			
Panasonic UD-807	Panasonic	TLD		<u>A:1</u>
Headband dosimeter, Thermo- Electron Harshaw Ext-Rad XD-707H	Harshaw TLD	Harshaw EXTRAD type	www.phe- protectionservices.org.uk/cms/assets/ gfx/content/resource_2974cs6788076 842.pdf	<u>N:1</u>
Lens dosimeters developed by Japan Atomic Energy Agency and universities	-	Optically stimulated luminescence dosimeter (OSLD)	Yoshitomi H., Hagiwara M., Kowatari M., Nishino S., Sanami T. and Iwase H. Assessment of equivalent dose of the lens of the eyes and the extremities to workers under nonhomogeneous exposure situation in nuclear and accelerator facilities by means of measurements using a phantom coupled with Monte Carlo simulation. Proceedings of 14 th International Congress of the International Radiation Protection Association (IRPA-14), Vol.3 1188-1195 (2017)	<u>N:1</u>
dosiEYE	DOSILAB	-	-	<u>N:1</u>
ORANO	-	TLD dosimeter used as an eye lens dosimeter	-	<u>N:1</u>
AWST-OSL-AD 01	Mirion Technologies (AWST) GmbH	OSLD	https://awst.mirion.com/	<u>AA:1</u>
LPS-TLD-TD 09	LPS Berlin	TLD	www.lps-berlin.de/	<u>AA:1</u>

* A: Available, AA: Available and approved, N: No information regarding availability and approving, S: Not approved, but used in studies

Annex E. Individual monitoring services – inter-comparisons

The following is a list of select resources for individual monitoring services and intercomparisons, provided by respondent countries.

Argentina

 Resolution 180/13: www.argentina.gob.ar/sites/default/files/resolucion_directorio_180-13.pdf

Germany

- PTB inter-comparison: <u>www.ssk.de/SharedDocs/Beratungsergebnisse/2011/Anforderungen_an_Personen</u> <u>dosimeter.html</u>
- Physikalisch-Technisches Bundesanstal (PTB) for all dosimeter types (not only eye dosimeters) issued for legally relevant measurements; for photon dosimetry requirements:
 www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_6/6.3/vergl/reg_ph_oton.pdf
- German Commission on Radiological Protection: <u>www.ssk.de/SharedDocs/Beratungsergebnisse/2011/Anforderungen_an_Personen</u> <u>dosimeter.html</u>

Greece

• EEAE, Recognition of services and experts - Governament Gazzete 3271/B/2019: https://eeae.gr/en/services/recognition-of-services-and-experts

United Kingdom

- Criterion 18 of <u>www.hse.gov.uk/radiation/ionising/dosimetry/requirements-</u> <u>pt1.pdf</u>
- Requirements for the approval of dosimetry services (updated 2020): www.hse.gov.uk/radiation/ionising/dosimetry/requirements-pt1.pdf

Annex F. Select research publications and studies provided by respondent countries

The following is a list of select research publications and studies provided by respondent countries. This list is by no means exhaustive.

Atanackovic J. (2018), "Evaluation of eye lens dosimetry at CANDU power plants", CNSC Webinar, 27 September 2018, <u>www.nuclearsafety.gc.ca/eng/pdfs/Presentations/other/lens-of-the-eye-presentation-atanackovic.pdf</u>.

Behrens, R. and G. Dietze (2010), "Monitoring the eye lens: which dose quantity is adequate?", *Phys. Med. Biol.*, 2010, 55(14):(4047-4062), DOI: 10.1088/0031-9155/55/14/007.

Behrens, R. (2016), "Compilation of conversion coefficients for the dose to the lens of the eye", *Radiat. Prot. Dosim.*, 174(3), 348-370, DOI:10.1093/rpd/ncw194.

Behrens, R., J. Engelhardt, M. Figel, O. Hupe, M. Jordan and R. Seifert (2012), " $H_p(0.07)$ Photon dosemeters for eye lens dosimetry: calibration on a rod vs. a slab phantom", *Radiation Protection Dosimetry* (2012), 148, 139–142

Behrens, R., O. Hupe, F. Busch, J. Denk, J. Engelhardt, K. Günther, H. Hödlmoser, M. Jordan and J. Strohmaier (2017), "Intercomparison of eye lens dosimeters", *Radiation Protection Dosimetry*, 174, 6–12, https://doi.org/10.1093/rpd/ncw051.

EPRI (2017), "Lens of Eye Dose Guidance and Good Practices: Recommended Readiness for Lens Dose Limit Changes at Nuclear Power Plants", www.epri.com/research/products/3002010626.

Gudjonsdottir, J. and H.M. Thorisson (2017), "Operator Eye Lens Doses in CT Fluoroscopy-guided Procedures", Proceedings of the IAEA International Conference on Radiation Protection in Medicine: Achieving Change in Practice (2017), 11–15 December 2017, Austria, p.96, https://www.iaea.org/sites/default/files/18/02/rpop-Vienna, session2.pdf (accessed on 26 January 2022).Hanu A. (2018), "Assessment of radiological hazard and occupational dose to the lens of the eve at the Bruce Power Nuclear Generating Station", CNSC Webinar. September 2018. www.nuclearsafety.gc.ca/eng/pdfs/Presentations/other/lens-of-the-eye-presentationhanu.pdf.

Hoshi K., H. Yoshitomi, K. Aoki, Y. Tanimura, S. Yokoyama and N. Tsujimura (2020), "Eye lens dosimetry for workers at Fukushima Daiichi Nuclear Power Plant-1: Laboratory study on the dosemeter position and the shielding effect of full face mask respirators", *Radiation Measurements*, Volume 134, June 2020, article 106304.

Lie ØØ, G.U. Paulsen and T. Wøhni (2008), "Assessment of effective dose and dose to the lens of the eye for the interventional cardiologist", *Radiat Prot Dosimetry*, 2008, 132(3):313-318, doi:10.1093/rpd/ncn296.

Papp, C., M. Romano-Miller, A. Descalzo, S. Michelin, A. Molinari, A. Rossini, C. Plotkin, G. Bodino, G. Esperanza, M. Di Giorgio and R. Touzet (2017), "Results of RELID study 2014-Buenos Aires, Argentina retrospective evaluation of lens injuries and dose", *Radiation Protection Dosimetry*, 2017, Apr;173(1-3):212-217, DOI: 10.1093/rpd/ncw339.

Sanchez, R.M., E. Vano, J.M. Fernandez, F. Rosales, J. Sotil, F. Carrera, M.A. Garcia, M.M. Soler, J. Hernández-Armas, L.C. Martinez and F. Carrera (2012), "Staff Doses in Interventional Radiology: A National Survey", *Journal of Vascular and Interventional Radiology*, Volume 23, Issue 11, <u>https://doi.org/10.1016/j.jvir.2012.05.056</u>.

Sanchez, R., E. Vano, J.M. Fernandez and J.J. Gallego (2010), "Staff radiation doses in a real-time display inside the angiography room", *Cardiovascular Interventional Radiology*, 2010, Dec; 33(6): 1210-4, DOI: 10.1007/s00270-010-9945-4.

Sociedad Argentina de Radioprotección (2015), Evaluación Retrospectiva de Lesiones en el Cristalino y Dosis - Estudio RELID 2014 en Buenos Aires – Argentina, X Congreso Regional Latinoamericano IRPA de Protección y Seguridad Radiológica (2015), "Radioprotección: Nuevos Desafíos para un Mundo en Evolución. Buenos Aires, 12-17 April 2015.

Strohmaier J. and C. Naber (2017), Untersuchungen zur Strahlenexposition der Augenlinse von beruflich strahlenexponiertem Personal - BfS Research Project 3613S40011; BfS-RESFOR-129/17, <u>http://nbn-resolving.de/urn:nbn:de:0221-2017112214449</u>

Tsujimura N., K. Hoshi, K. Aoki, H. Yoshitomi, Y. Tanimura and S. Yokoyama (2020), "Eye Lens Dosimetry for Workers at Fukushima Daiichi Nuclear Power Plant—2: Field study using humanoid phantoms", *Radiation Measurements*, Volume 134, Article 106305, 2020, DOI:10.1016/j.radmeas.2020.106305.

Vano, E., L. Gonzalez, J.M. Fernandez and Z.J. Haskal (2008), "Eye lens exposure to radiation in interventional suites: caution is warranted", *Radiology*, 248(3):945–953, DOI: 10.1148/radiol.2482071800.

Vano, E., R.M. Sanchez and J.M. Fernandez (2015), "Estimation of staff lens doses during interventional procedures. Comparing cardiology, neuroradiology and interventional radiology", *Radiation Protection Dosimetry*, 165(1-4): 279-83, DOI: 10.1093/rpd/ncv049.

Yokoyama, S., I. Ezaki, H. Tatsuzaki, S. Tachiki, S. Hirao, K. Aoki, Y. Tanimura, K. Hoshi, H. Yoshitomi and N. Tsujimura (2020), "Measurements of the doses of eye lens for the workers of Fukushima Daiichi Nuclear Power Plant", *Radiation Measurements*, 138(3), Article 106399.

Yoshitomi, H., M. Hagiwara, M. Kowatari, S. Nishino, T. Sanami and H. Iwase (2017), "Assessment of equivalent dose of the lens of the eyes and the extremities to workers under nonhomogeneous exposure situation in nuclear and accelerator facilities by means of measurements using a phantom coupled with Monte Carlo simulation", Proceedings of 14th International Congress of the International Radiation Protection Association (IRPA-14), Vol.3 1188-1195, International Radiation Protection Association.

Annex G. EGDLE survey

Background Information

The main objective of the OECD Nuclear Energy Agency (NEA)'s Committee on Radiological Protection and Public Health (CRPPH) is to support member countries in identifying emerging issues, analysing their implications for radiological protection practices and regulation, and contributing to their resolution.

In 2012, the International Commission on Radiological Protection (ICRP) recommended a reduction to the equivalent dose limit for the lens of the eye for occupational exposures in planned situations from 150 mSv per year to 20 mSv in a year, averaged over defined five-year periods (i.e. 100 mSv/5 years), with no single year exceeding 50 mSv (ICRP, 2012). At present, this recommendation has been, is currently being, or is under consideration to be implemented by countries worldwide, affecting the radiological protection community, especially with its incorporation into the international BSS (IAEA, 2014) and the Euratom BSS (EC, 2013).

In this context, the CRPPH decided to convene an **Expert Group on the Dose limit for the Lens of the Eye** (EGDLE). The EGDLE commenced its program of work in July 2019. Its main objective is to provide an opportunity for regulators and stakeholders, e.g. nuclear and non-nuclear stakeholders, to share lessons learned (both successes and challenges) in the practical implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures. The EGDLE mandate was approved for a two-year term, to March 29, 2021. The deliverables of the EGDLE include:

- A report which summarises the practical experiences of regulators and stakeholders worldwide for implementing the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposure, including successes and challenges to the approaches; and
- A network established to maintain dialogue and information exchange.

To assist the EGDLE to fulfill its mandate, more information is needed on the views of nuclear and nonnuclear regulatory bodies, and technical support organisations (TSOs) where applicable. Therefore, a survey has been developed to facilitate the gathering of information from regulatory bodies and TSOs on the implementation of the ICRP's recommended equivalent dose limit for the lens of the eye for occupational exposures.

References

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

IAEA, 2014. Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. General Safety Requirements Part 3. No. GSR Part 3.

European Commission 2013 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.

Survey Questions – This survey will take approximately one hour. For each question where relevant, please provide references and/or links to documents that will be useful to illustrate the answer and share with the EGDLE.

Note that the individual completed surveys will not be made publicly available. The analysis of information will refer to the organisation type(s) and/or the countries rather than to a specific organisation.

Responder's profile:

• Please specify the details of the responding organisation for the purpose of the responders list:

Organisation name:	
Address:	
Country:	

- Please specify the nature of the organisation:
 - \Box Regulatory body

Technical Support Organisation (TSO); please, specify:

□ Other organisation involved in regulation; please specify: _____

• Please specify which occupational category(ies)/field(s) your organisation is responsible for or engaged in:

Note that in case your organisation is responsible for several fields (i.e. nuclear and non-nuclear), please provide answers for each field where appropriate.

Nuclear
Medical
Other:

Provide the number of licensees and workers for each category, if possible:

Nuclear
Medical
Out and

□ Other: _____

• Are you responding on behalf of:

Your organisation?	\Box Yes	
Your country?	\Box Yes	□ No
Other?	\Box Yes	□ No If yes, please specify:

• Please provide the details of a contact person in the event that further clarification of the survey responses is required:

Name:	
Function:	 _
Organisation:	
Country:	 _
E-mail:	_
Phone number:	

1. If legislative changes have been made in your country regarding the equivalent dose limit for the lens of the eye in response to ICRP Recommendations: what was the change, when did the change occur, and through what type of legal instrument was the change made? *Please provide references and/or links to documents that will be useful to illustrate the answer.*

Please provide answers for each field (nuclear, medical, other) as appropriate.

If no legislative changes have been made in response to ICRP Recommendations: are there changes currently underway or under consideration to the dose limit(s) for the lens of the eye? What is the main reason/rationale for not having proceeded to revising legislation up to now? *Please provide answers for each field (nuclear, medical, other) as appropriate.*

2. What has been (or is planned to be) the level of engagement/consultation with stakeholders with respect to communicating the consideration of, or the implementation of, changes to the dose limit for the lens of the eye? What communication strategies have been (or are planned to be) used? For example, what was (or will be) your approach to inform/consult with stakeholders? Have stakeholder-specific communication tools been developed, e.g. adapted to each occupation type? Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

3. Are there any strategies or good practices related to the implementation of a new dose limit for the lens of the eye that would be useful for the EGDLE and other regulatory bodies to be aware? For example, were topical workshops organised to discuss and disseminate approaches? Are guidance documents being elaborated or currently available? If yes, did the process involve stakeholders? Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

4. If your country has implemented changes to the dose limit for the lens of the eye, what concerns or experiences, in terms of compliance, costs, dosimetry, and methods of protection, and stakeholder engagement, have been encountered by the regulator? How have these concerns been managed by the regulator? *Please identify which field (i.e. nuclear, medical, other) the response pertains to.*

If your country has not implemented changes to the dose limit for the lens of the eye, how will concerns or experiences in terms of compliance, costs, dosimetry, methods of protection, and stakeholder engagement, be managed by the regulator? *Please identify which field (i.e. nuclear, medical, other) the response pertains to.*

- 5. Demonstration of compliance with the dose limit for the lens of the eye (please answer each sub-question):
 - a) Is there regulatory guidance on how projected dose is to be addressed in the risk assessment, including the determination of whether individual monitoring is required? Is the decision on direct or indirect monitoring linked to the outcome of the risk assessment? Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

b) Are there any required specifications for individual monitoring of the lens of the eye? If yes, what is the level of exposure to the lens of the eye for a worker that requires individual monitoring adjacent to the most exposed eye? *Please provide answers for each field (nuclear, medical, other) as appropriate.*

c) What type of dosimeter is accepted for individual monitoring?

For example, is only $H_p(3)$ allowed, or can $H_p(0.07)$ or $H_p(10)$ be used as a surrogate? If available, are there any protocols or regulatory guidance that can be shared on this issue? Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

d) How is the use of protective equipment accounted for?

For example, how does the use of protective equipment affect the placement of eye dosimeter(s): adjacent to the most exposed eye, under or above shielding, dosimeters worn on the collar, etc.? Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

e) Are correction factors allowed to be used for demonstrating compliance with equivalent dose limits for the lens of the eye? If available, are there any protocols or regulatory guidance that can be shared? *Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.*

f) What indirect monitoring methods have been accepted by the regulatory body (e.g. use of surrogate methods or estimates, including calculations and/or area monitoring)? Is this covered in regulatory guidelines? *Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.*

g) In what situations would workplace monitoring be acceptable to demonstrate compliance with the dose limit? Is there regulatory guidelines on acceptable methods? *Please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.*

- 6. $H_p(3)$ eye dosimeters issues: Please answer each sub-question for each field (nuclear, medical, other) as appropriate.
 - a) What type of $H_p(3)$ eye dosimeters are approved and available in your country (manufacturer name, model)? Please provide references and/or links to documents that will be useful to illustrate the answer.

b) Is there an accreditation process for approval of $H_p(3)$ eye dosimeters in your country? If yes, please provide details on what are they and, if publicly available, a reference(s) to the accreditation process.

c) Are approved $H_p(3)$ eye dosimeters available that are suitable for nuclear and nonnuclear occupational exposures, and/or for mixed radiation types/fields (such as beta/photons)? Have neutron fields been considered?

d) What are the technical requirements and specifications for eye dosimeters (including: minimum measurable dose equivalent $H_p(3)$, overall specifications for accuracy and precision, type testing, performance testing, reference standards, independent testing, accepted correction factors and special performance tests)? Are there publicly available documents that can be provided or referenced?

e) Is there a mandatory participation of Individual Monitoring Services offering $H_p(3)$ eye dosimeters to national and/or international inter-comparison? If publicly available, please provide a reference(s) to the process.

7. Have there been any challenges associated with recording doses to the lens of the eye?

For instance, have there been any particular issues such as: recording and tracking doses for itinerant worker; recording doses when surrogate methods and/or indirect monitoring methods are used; recording doses when protective equipment(s) is/are used; etc.?

If yes, and if your country has implemented changes to the dose limit for the lens of the eye, for each challenge identified, explain how it was handled and whether the approach was successful. If not, please describe the major barriers. *Please provide answers for each field (nuclear, medical, other) as appropriate.*

If yes, and if your country has not implemented changes to the dose limit for the lens of the eye, what are the foreseen challenges associated with recording doses to the lens of the eye? Are any actions planned to address these challenges? *Please provide answers for each field (nuclear, medical, other) as appropriate.*

8. Is there a summary of lens of eye dose data from routine monitoring, and/or data from relevant studies or research that can (could) be shared with the EGDLE?

If possible, please provide either raw data or aggregated data (e.g., range of recorded doses, average dose, and percentile of a distribution) with a brief summary of the monitoring procedure implemented, or please provide references and/or links to documents that will be useful to illustrate the answer. Please provide answers for each field (nuclear, medical, other) as appropriate.

9. Are there any instances where the dose limit(s) for the lens of the eye was/were exceeded? If yes, describe the circumstances and type(s) of practice(s) (interventional radiology, other medical practices, nuclear operations, nuclear decommissioning, etc.).

- 10. Are there any matters you wish to bring to the attention of the EGDLE? Express your expectations and prioritise them by giving the justification of your ranking regarding:
 - implementation aspects

• exchange of information and experiences

research needs