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GREEK ATOMIC ENERGY COMMISSION

Eye lens monitoring: How is it implemented in different countries?

Eleftheria Carinou, Robert Kollaard and Merce Ginjaume

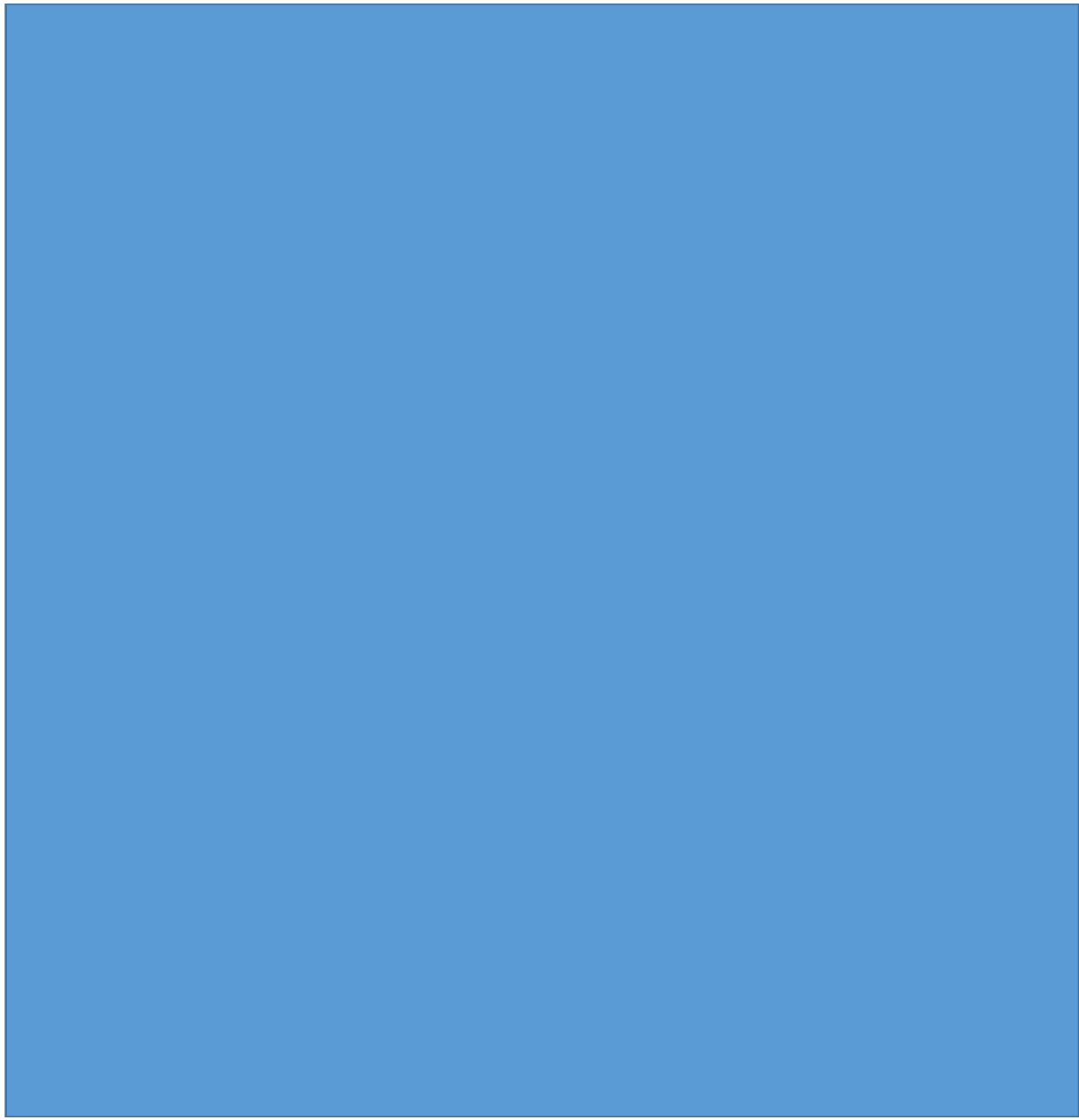
WG12 Dosimetry in medical imaging

Winter School, Eurados, Florence 2020

contents

- Framework
- Provisions in EU Directive 59/2013
- Status of eye lens monitoring in hospitals (2014)
- Regulatory status of eye lens monitoring (2018)
- Implementation in practice
- Conclusions

The framework



INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

ICRP ref 4825-3093-1464

Statement on Tissue Reactions

Approved by the Commission on April 21, 2011

(1) The Commission issued new recommendations on radiological protection in 2007 (ICRP, 2007), which formally replaced the Commission's 1990 Recommendations (ICRP, 1991a). The revised recommendations included consideration of the detriment arising from non-cancer effects of radiation on health. These effects, previously called deterministic effects, are now referred to as tissue reactions because it is increasingly recognised that some of these effects are not determined solely at the time of irradiation but can be modified after radiation exposure. Previously, the Commission had reviewed various aspects of non-cancer health effects of low linear-energy-transfer (LET) ionising radiation in *Publication 41* (ICRP, 1984), high LET radiation in *Publication 58* (ICRP, 1990), the skin in *Publication 59* (ICRP, 1991b), and the skin and the eye in *Publication 85* (ICRP, 2000).

(2) The Commission has now reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose is now considered to be 0.5 Gy.

(3) For occupational exposure in planned exposure situations the Commission now recommends an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv.

2011

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IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Jointly sponsored by
EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO

General Safety Requirements Part 3

No. GSR Part 3

IAEA
International Atomic Energy Agency

2011/4

2013

II

(Non-legislative acts)

DIRECTIVES

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (1). The Directives have been revised several times, most recently by Council Directive 96/29/Euratom (2) which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom (3), Council Directive 89/618/Euratom (4), Council Directive 90/641/Euratom (5) and Council Directive 2003/122/Euratom (6) cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety

(1) OJ L 11, 20.2.1959, p. 221.
(2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.6.1996, p. 1).
(3) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).
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(6) Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJ L 346, 31.12.2003, p. 57).

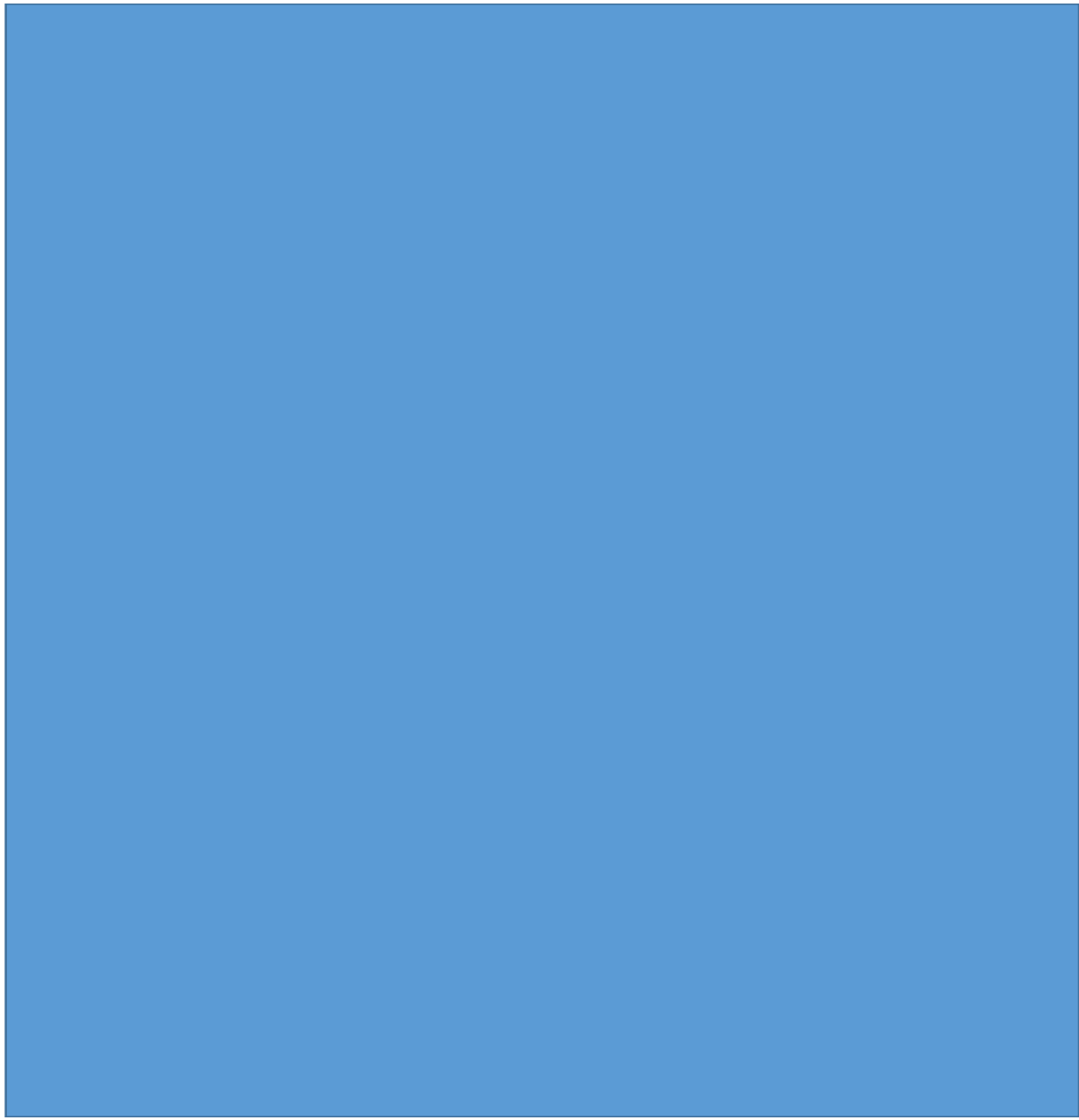
Framework

- Reduction of the annual limit on the equivalent dose to the lens of the eye for exposed workers (international and European basic safety standards)
- Regulatory bodies, scientific committees, professional societies
- RPOs and RPEs
- WORKERS!

- To be implemented by … **February 2018**

- practical implementation of the reduced limit ???

Meanwhile…

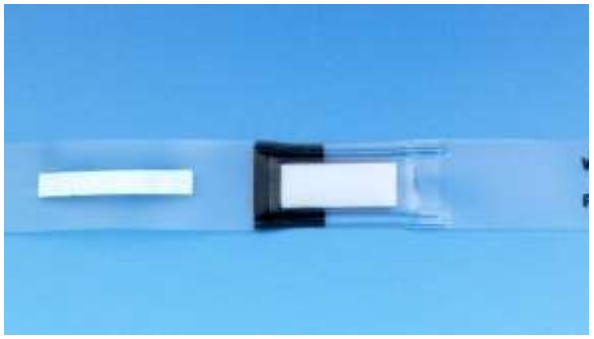


Meanwhile …

- Research projects (ORAMED, EURALOC…)

- Many publications involving measurements, simulations, regulatory issues, quantities to be used, calibration issues etc …

Types of eye lens dosemeters



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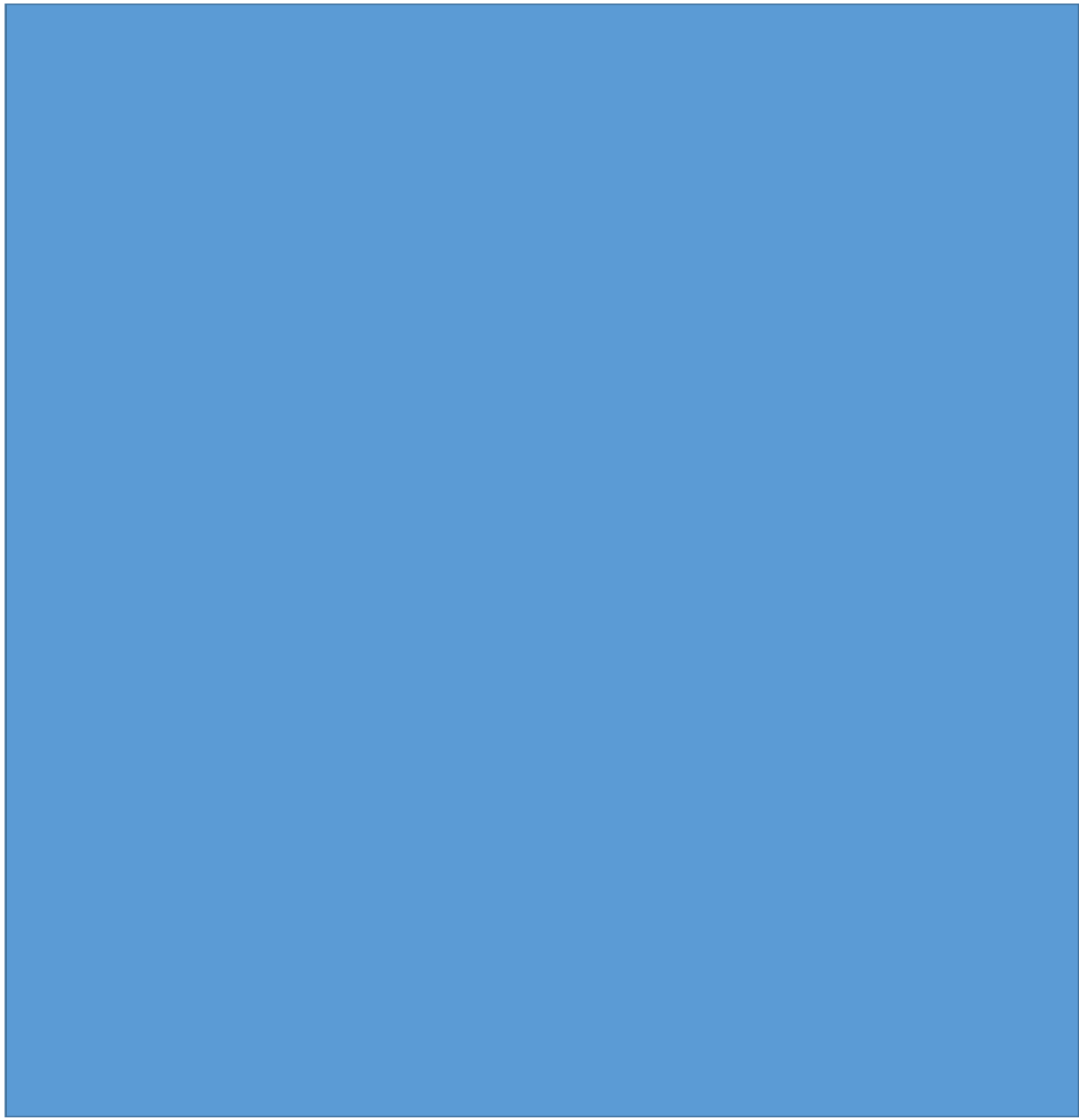
European Directive



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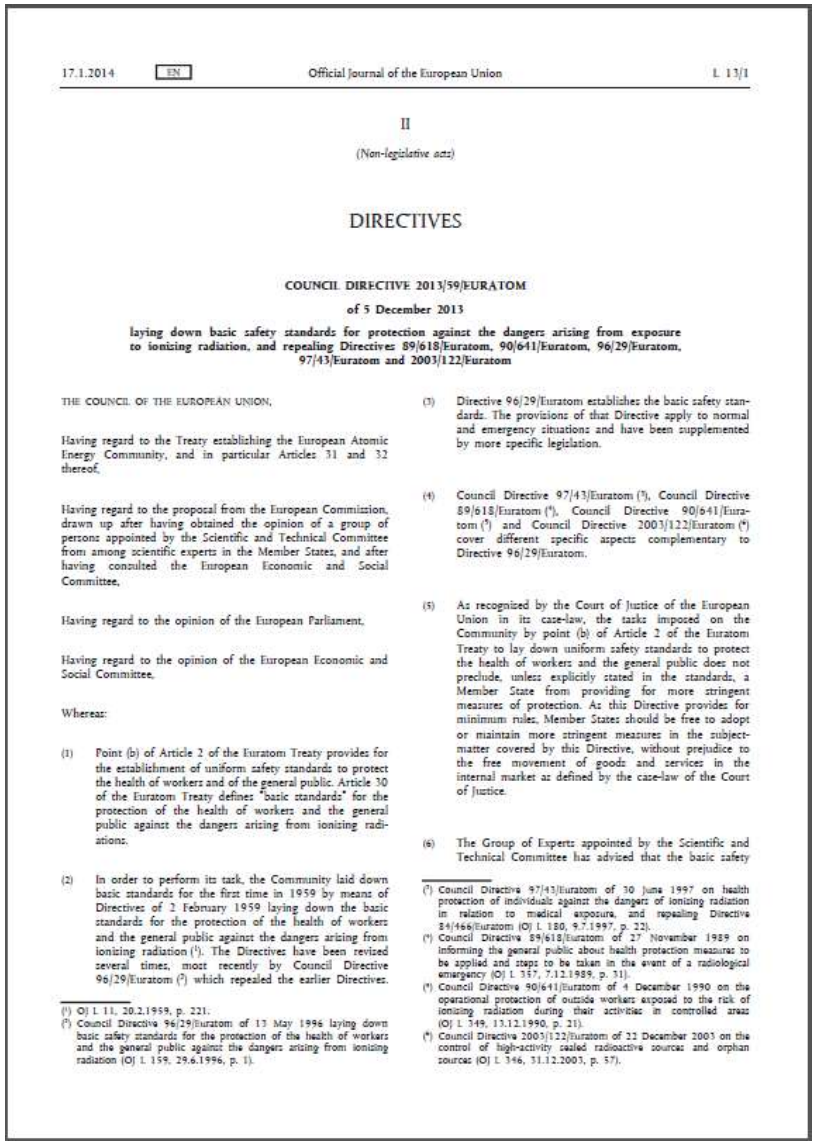
What is foreseen in the EU BSS?

73 pages, 109 articles, and 18 annexes



17.1.2014 EN Official Journal of the European Union L 13/1

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European BSS

- Recital no 14 "*This Directive should also follow new ICRP guidance on the limit for equivalent dose for the lens of the eye in occupational exposure*."
- Article 9 Dose limits for occupational exposure "*a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, as specified in national legislation*"
- Article 11 Dose limits for apprentices and students "*(a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year*;"

European BSS

- Article 12 Dose limits for public exposure *"(a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;"*
- Article 35 Arrangements in workplaces "…*for the purposes of radiation protection, arrangements are made as regards all workplaces where workers are liable to receive an exposure greater than …an equivalent dose of 15 mSv per year for the lens of the eye…"*

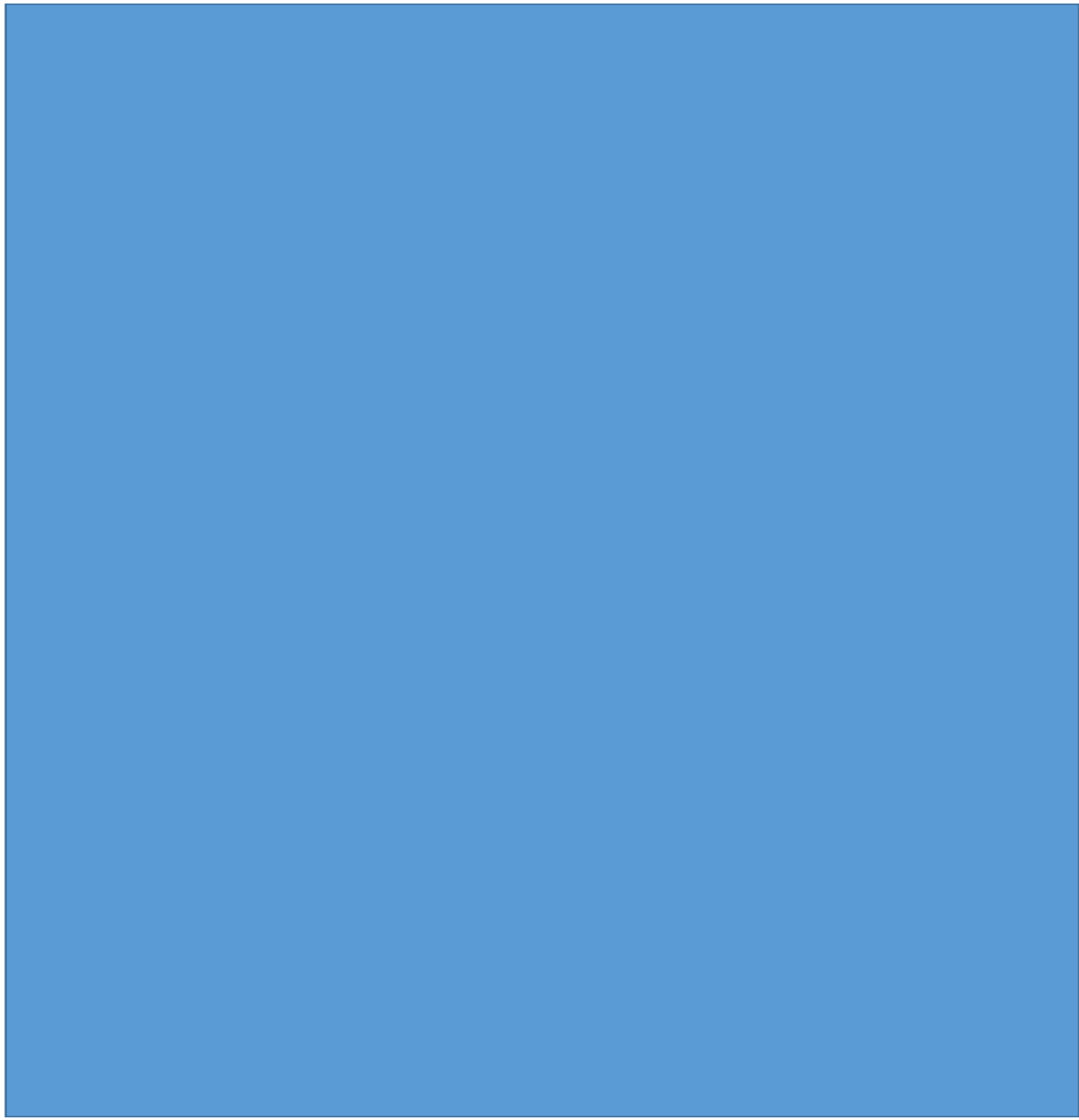
European BSS

- Article 40 Categorization of exposed workers "(*a) category A: those exposed workers who are liable to receive …or an equivalent dose greater than 15 mSv per year for the lens of the eye …;*
- *(b) category B: those exposed workers who are not classified as category A workers*."
- Article 41 Individual monitoring "*In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up*"

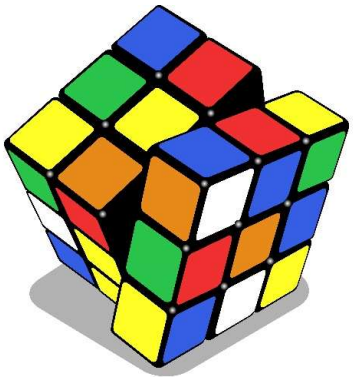
European BSS

- Article 82 Radiation protection expert ….the advice of the RPE shall cover … *"(d) classification of workers;"*
- Annex 10 Data system for individual radiological monitoring "*The results of the individual monitoring of the exposed worker shall include the official dose record (year; …. equivalent doses in the different parts of the body in mSv; …);*"

Implementation by the end users



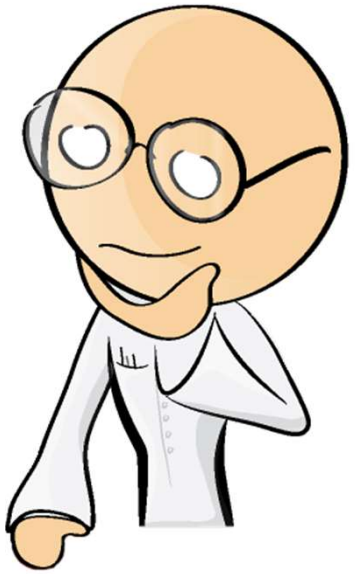
Implementation means …



- ✓How to measure the exposure to the lens of the eye
- ✓How to estimate the eye lens
- ✓Who should be monitored?
- ✓Who is responsible to do the categorization of workers?

To get some answers for the practical implementation …

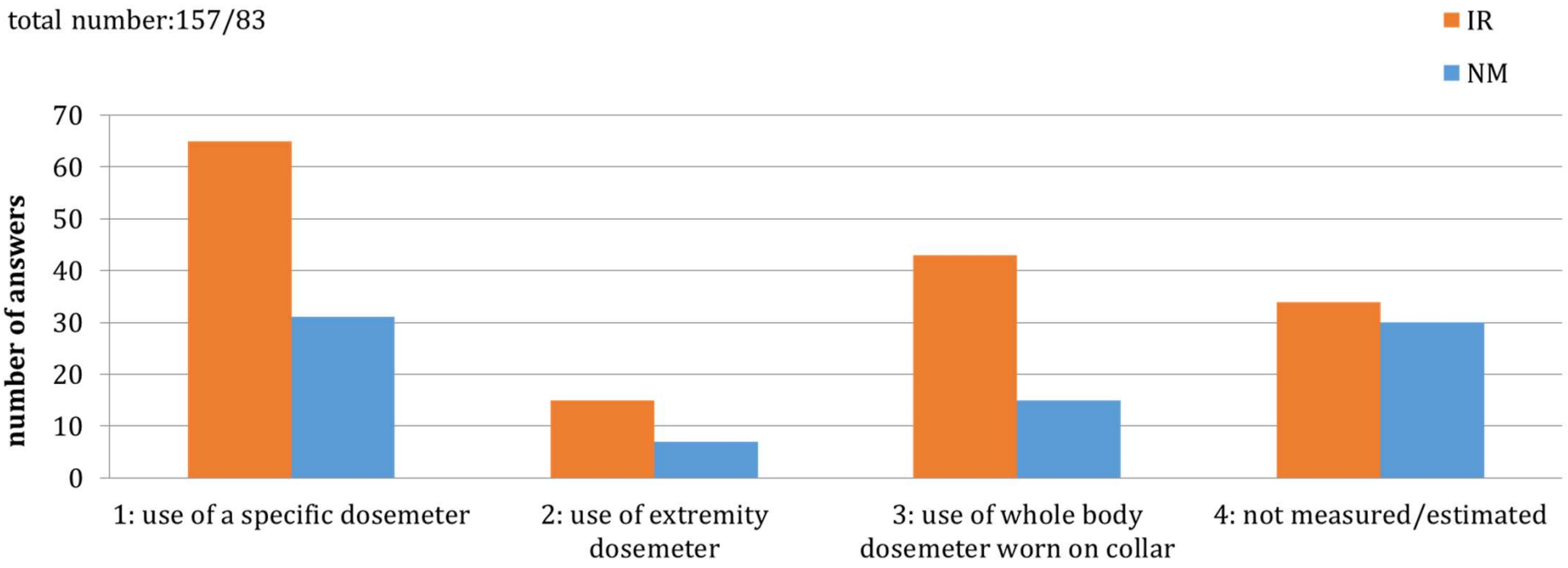
- A questionnaire was developed by the members of WG12 of EURADOS in order to establish an overview of the status of eye lens radiation dose monitoring in hospitals (2014)
- The questions about:
  - knowledge of the proposed eye lens dose limit;
  - monitoring and dosimetry issues;
  - training and radiation protection measures.



Status of eye lens monitoring in European hospitals

- 195 responses from 23 European countries
- 93% of the responses stated that they are familiar with the change in the eye lens limit
- 55% have already performed some specific eye dose monitoring pilot studies

How do you measure/estimate eye lens doses?



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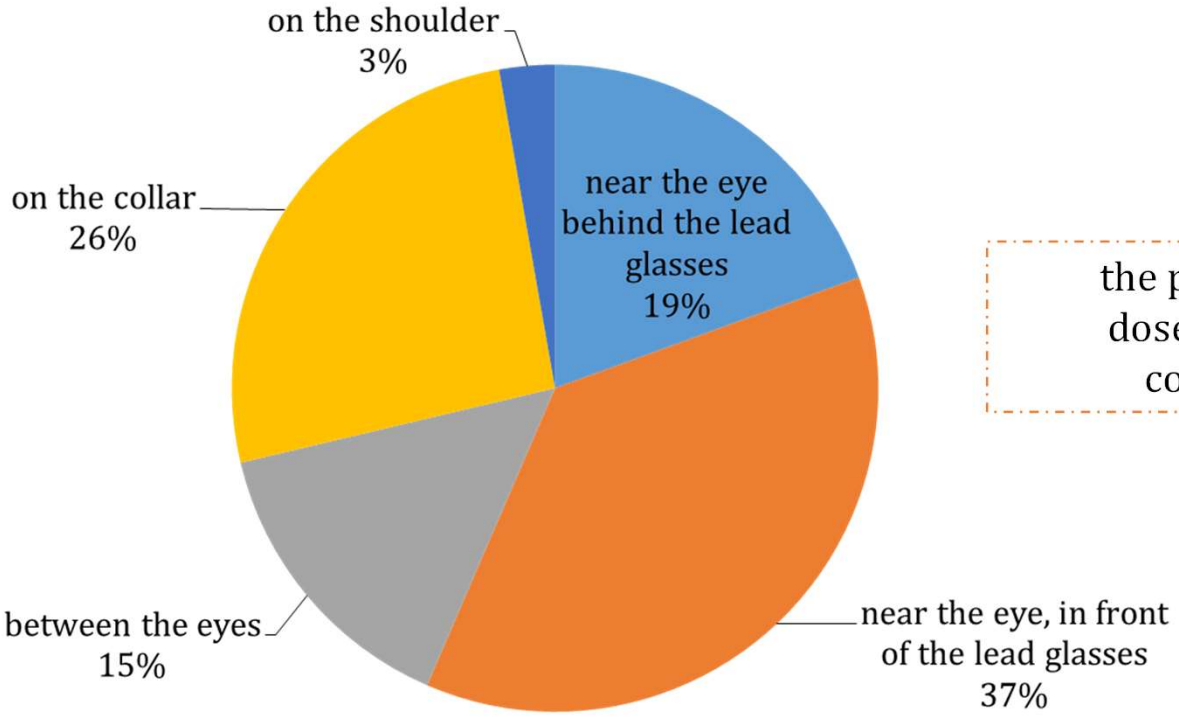
in many cases eye lens monitoring was not performed or, it is done within a framework of specific studies.

Position of the eye lens dosemeter

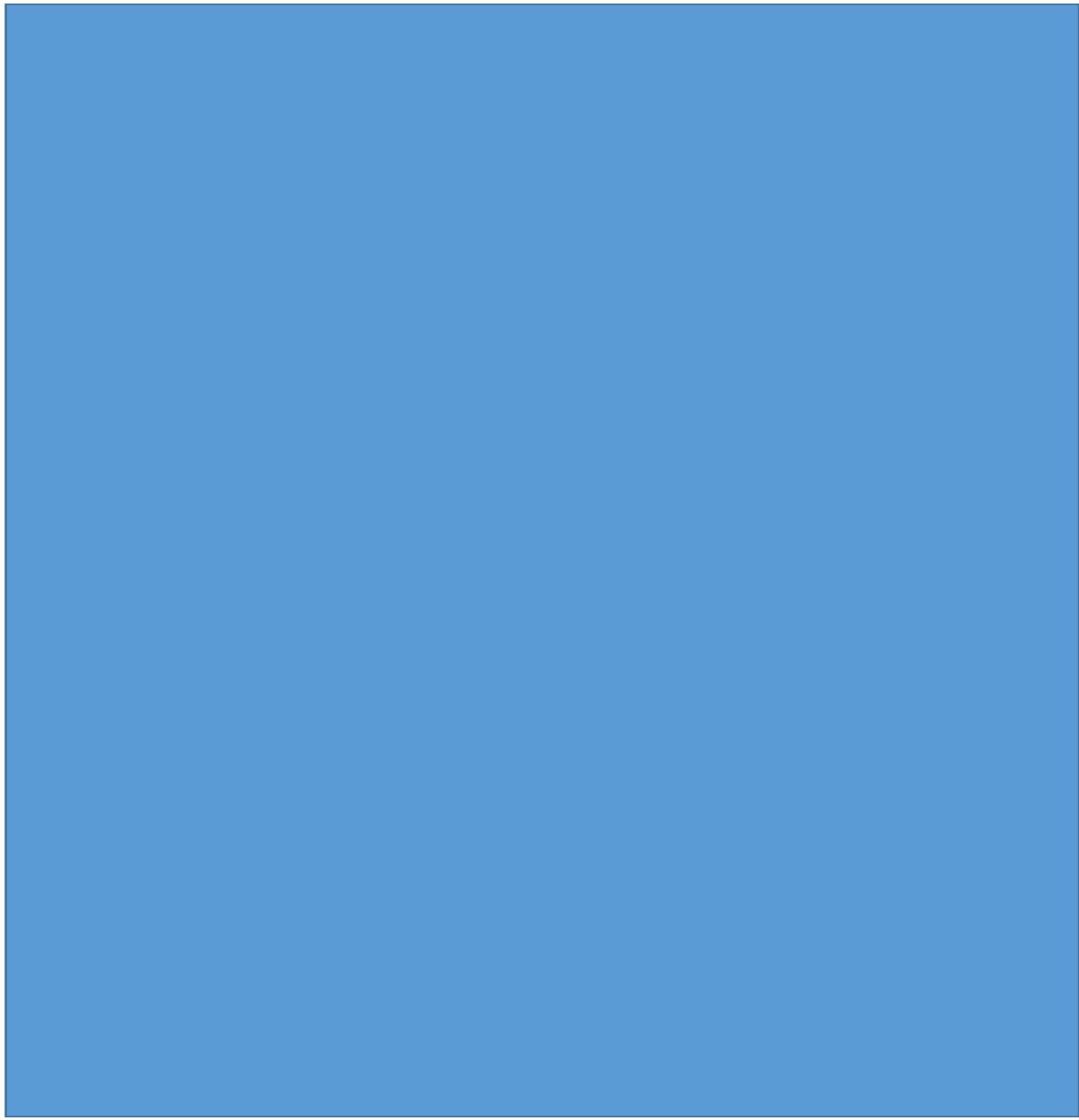


the position of the dosemeter varies considerably.

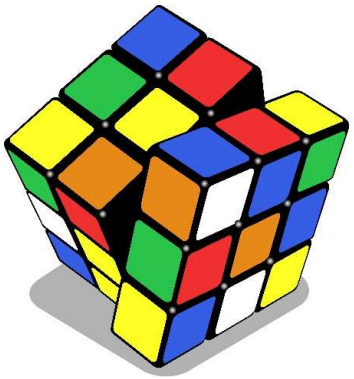
Status of eye lens monitoring in European hospitals - 2014

- There was good awareness of the reduced eye dose limit
- Many specific eye dose studies had already been performed or were in progress
- The new eye lens dose limit could be exceeded for those working with IR
- Harmonisation about the position and method of estimation of the eye lens dose was suggested

Regulatory status



Implementation means …



- ✓Modification of the national regulations
- ✓Registration to the NDR
- ✓In line with GDPR (May 2018)

Also..

- ✓Guidance on appropriate quantity, algorithm, correction factor, position of dosemeter

Overview of the regulatory status of eye lens monitoring

Eurados WG12 organized a survey through a questionnaire addressed to regulatory authorities

- to investigate how the various countries are dealing with the:
  - ✓ estimation of the effective dose, E, and
  - ✓ equivalent dose to the lens of the eyes, H_{lens},

when protective garments such as thyroid collars, lead aprons or lead glasses are worn.

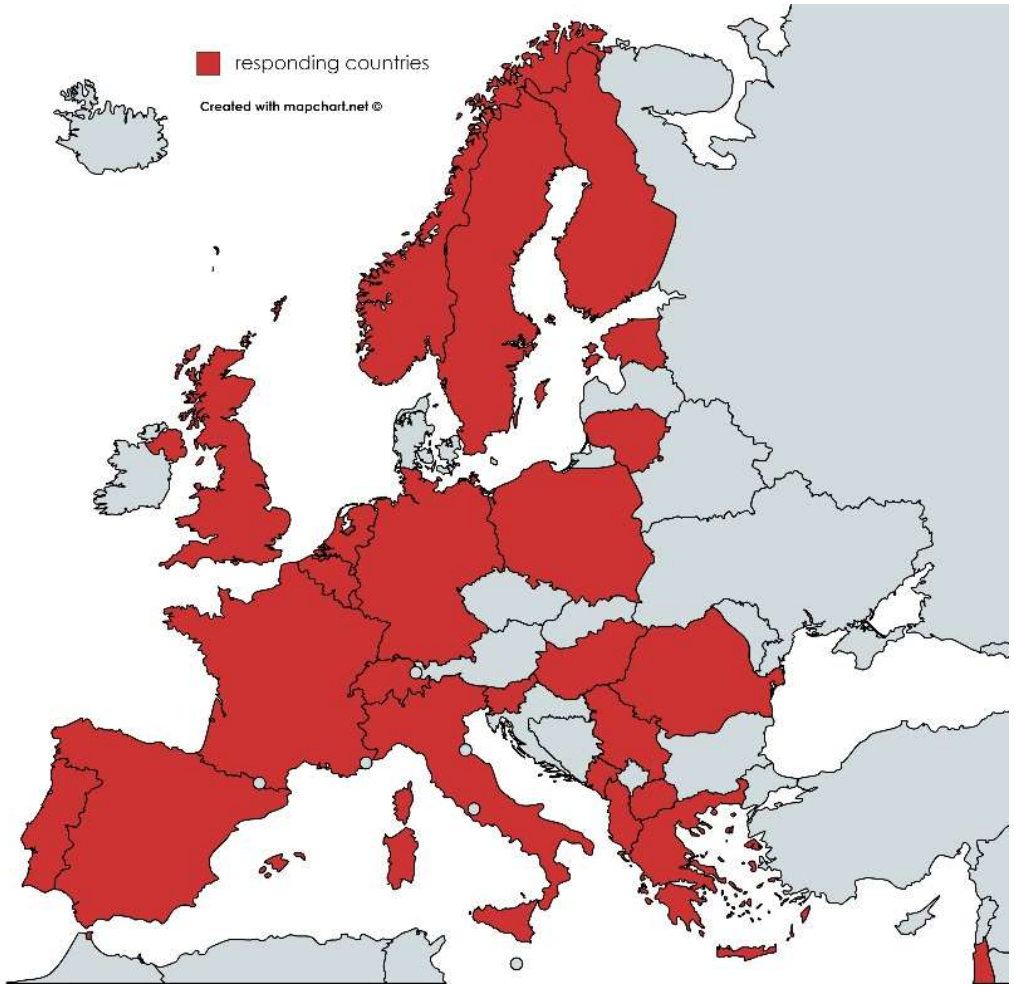
Design of questionnaire

- country's regulations
- double dosimetry
- monitoring of the dose to the lens of the eye
- methodology for the estimation of the effective dose and the dose to the lens of the eye
- national dose register

- few months before the February 2018 deadline for the implementation of the reduction in annual limit European Union member states
- information gathered need to be interpreted in light of foreseen modifications

Answers from

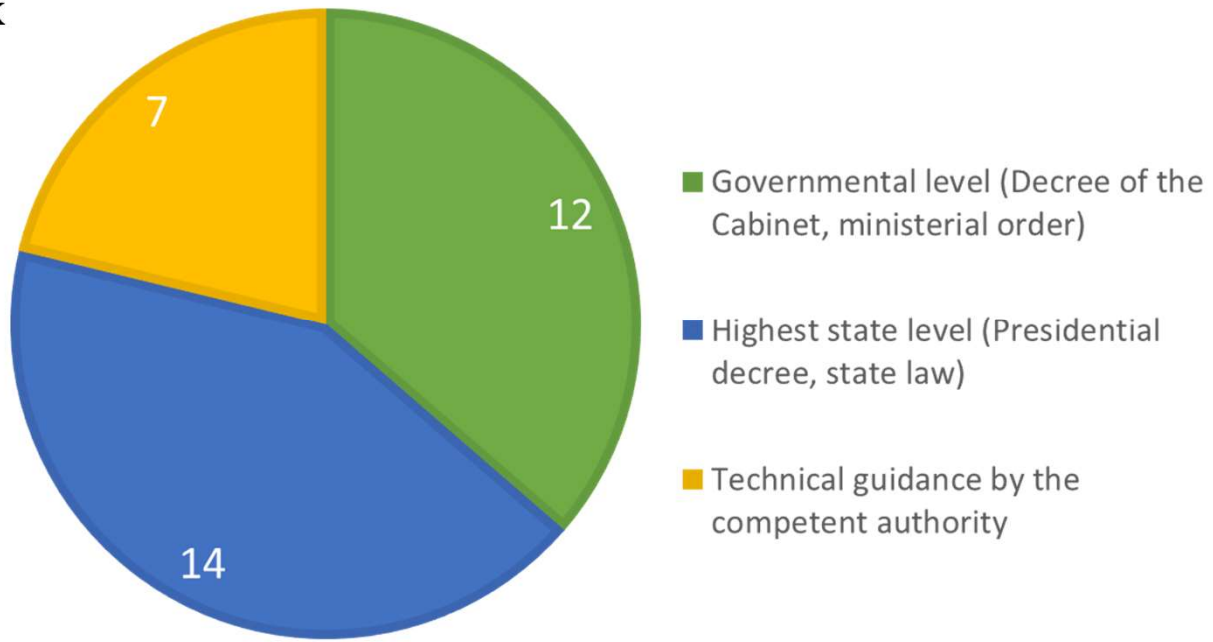
26 countries responded to the questionnaire



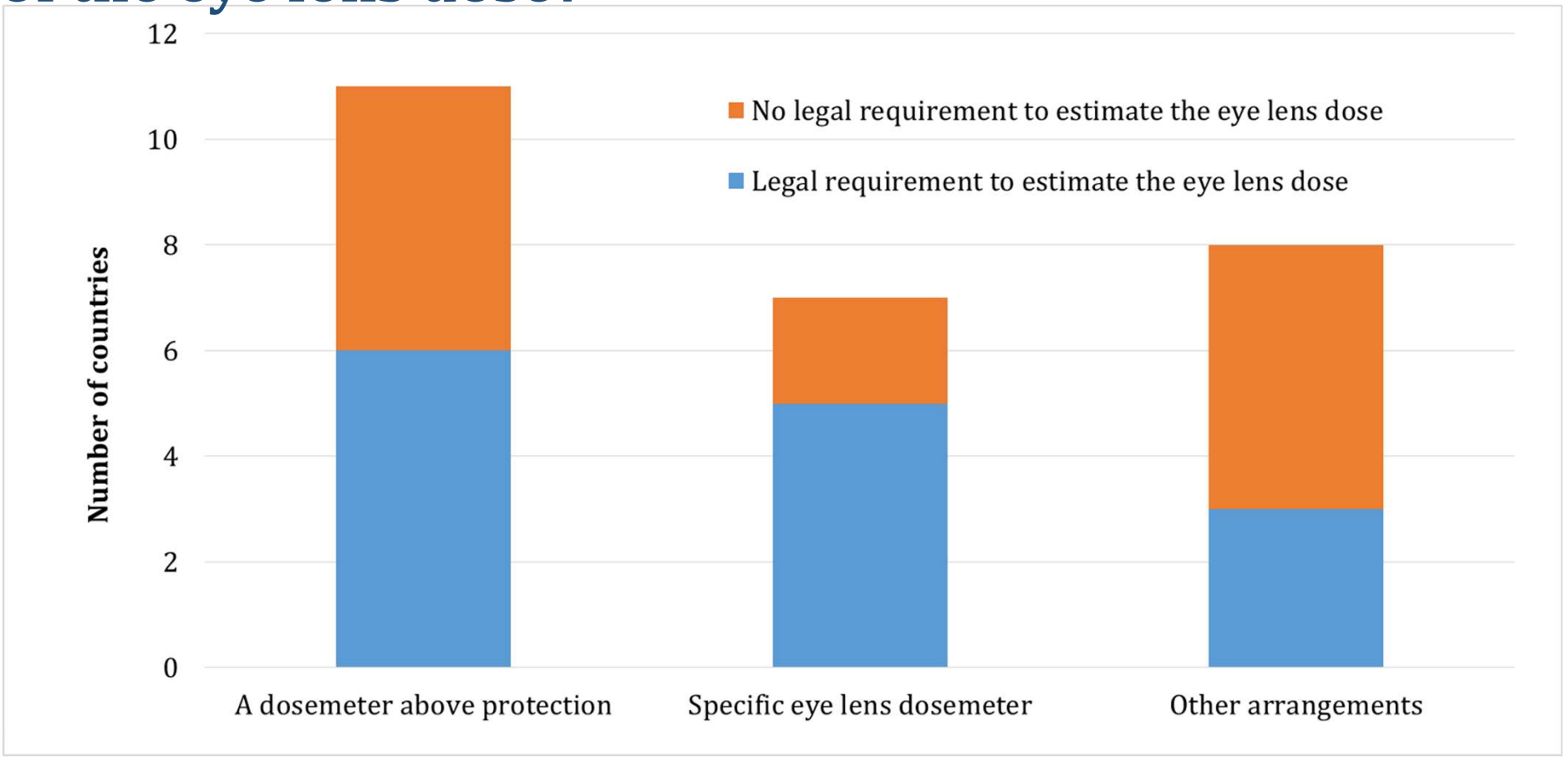
Level of regulatory provisions for determination of the effective dose and/or the operational quantities for individual monitoring

All of the 26 countries have certain provisions in their regulatory framework

However, 12 out of 26 have no legal requirement for the estimation of the dose to the lens of the eye!



What type of dosemeter is required for the estimation of the eye lens dose?



Is there an algorithms in place for the estimation of the eye lens dose H_{lens}?

no! 23/26

Yes! 3/26

- $H_{lens}=f\,H_p(3)$,
- $H_{lens}=f'\,H_p(0{,}07)$,

when eye lens dosemeter is used above the radiation glasses

Yes! 5/26 for the effective dose

Approved by the competent authority

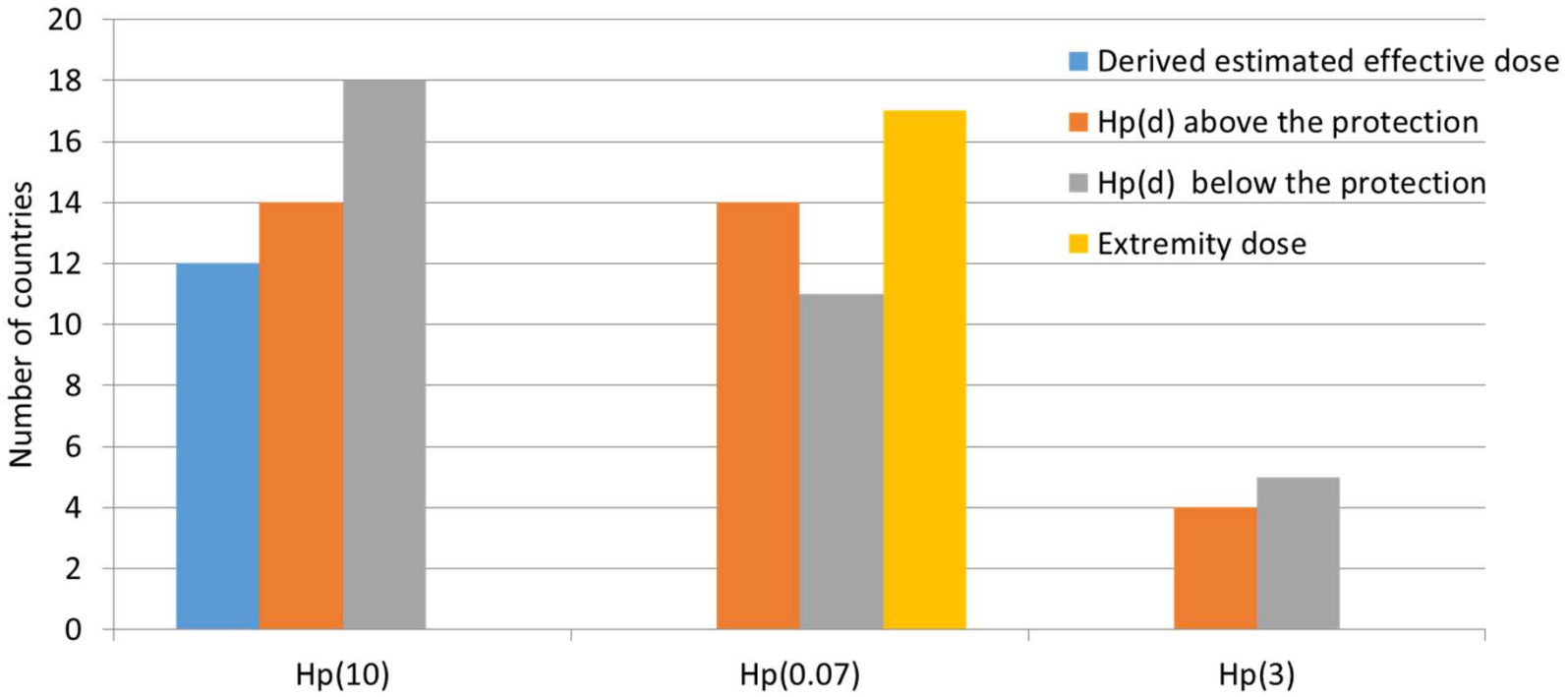
Parameters to be included in the NDR

All of the responding countries use some kind of national database for keeping individual monitoring data.

the operational quantity $H_p(3)$ is stored in the NDR of only 7 out of 26 countries

$H_p(10)$ below	18
$H_p(0.07)$ below	14
$H_p(10)$ above	14
$H_p(0.07)$ above	11
E (estimated from the operational quantities)	12
Extremity doses	17
$H_p(3)$ below	**6**
$H_p(3)$ above	**3**

Parameters to be included in the NDR



Changes foreseen

- 15 out of 26 are considering changing their NDR to be able to record additional parameters, such as
  - the results of double dosimetry,
  - the measured values of $H_p(3)$,
  - the correction factor for the applied protective measures …
- To be in line with the new GDPR

Changes foreseen

A. **Data to be included in the data system for individual radiological monitoring**

3. Data on the worker's identity shall include the worker's:

   (a) surname;

   (b) first name;

   (c) sex;

   (d) date of birth;

   (e) nationality; and

   (f) unique identification number.

4. Data on the undertaking shall include the name, address and unique identification number of the undertaking.

5. Data on the employment of the worker shall include:

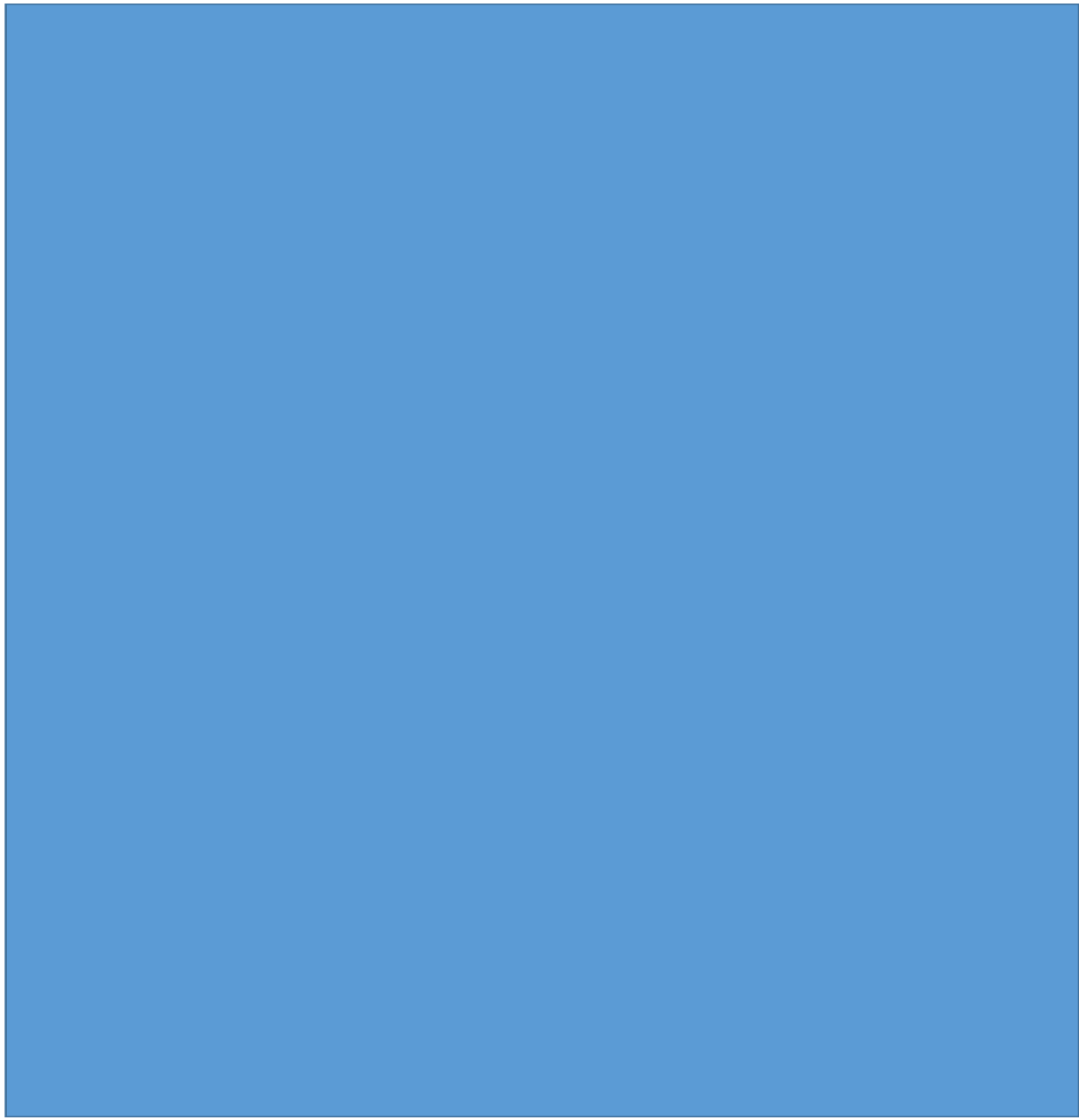
   (a) the name, address and unique identification number of the employer;

   (b) the starting date of individual monitoring; and where available, the end date;

   (c) the categorisation of the worker in accordance with Article 40.

6. The results of the individual monitoring of the exposed worker shall include the official dose record (year; effective dose in mSv; in the event of non-uniform exposure, equivalent doses in the different parts of the body in mSv; and in the event of an intake of radionuclides, the committed effective dose in mSv);

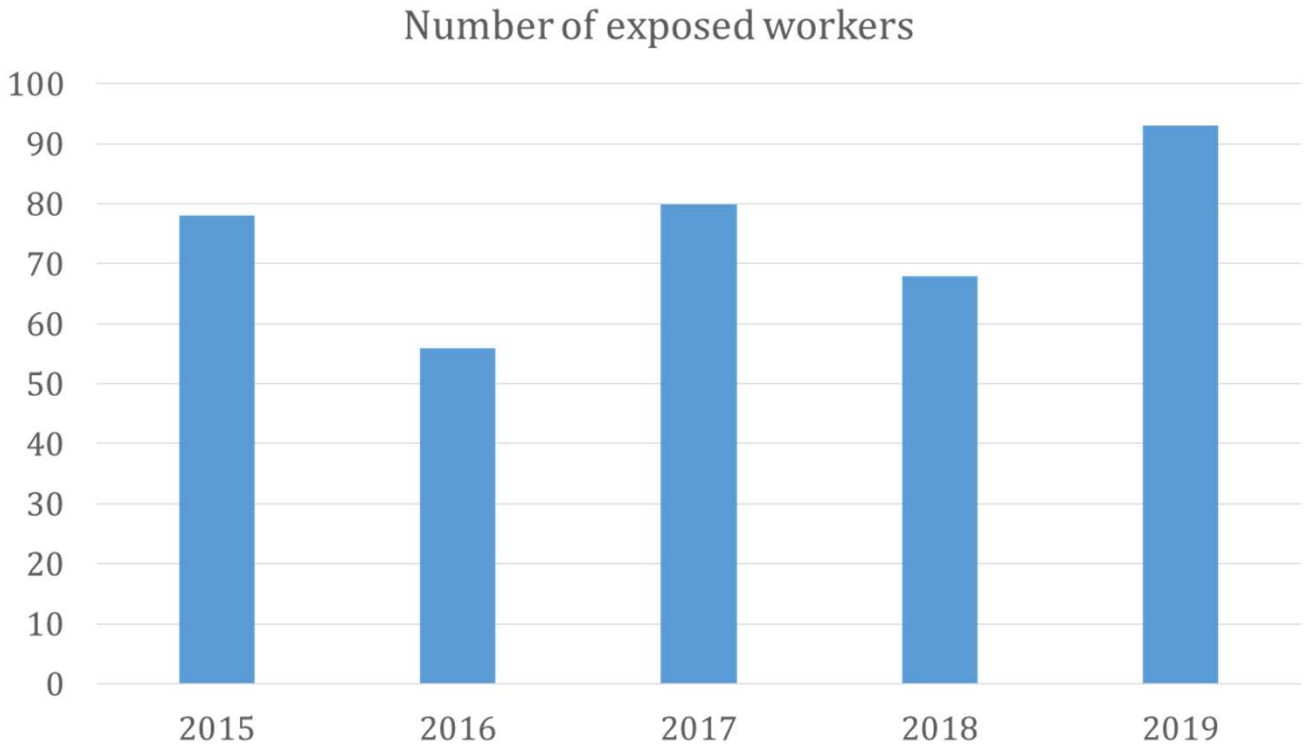
An example



Greek implementation

- ORAMED and EURALOC
- pilot study <2013
- November 2014
- Around 50 interventional cardiologists
- Average monthly dose 0,22 mSv
- Maximum monthly dose 2,5 mSv

Greek implementation



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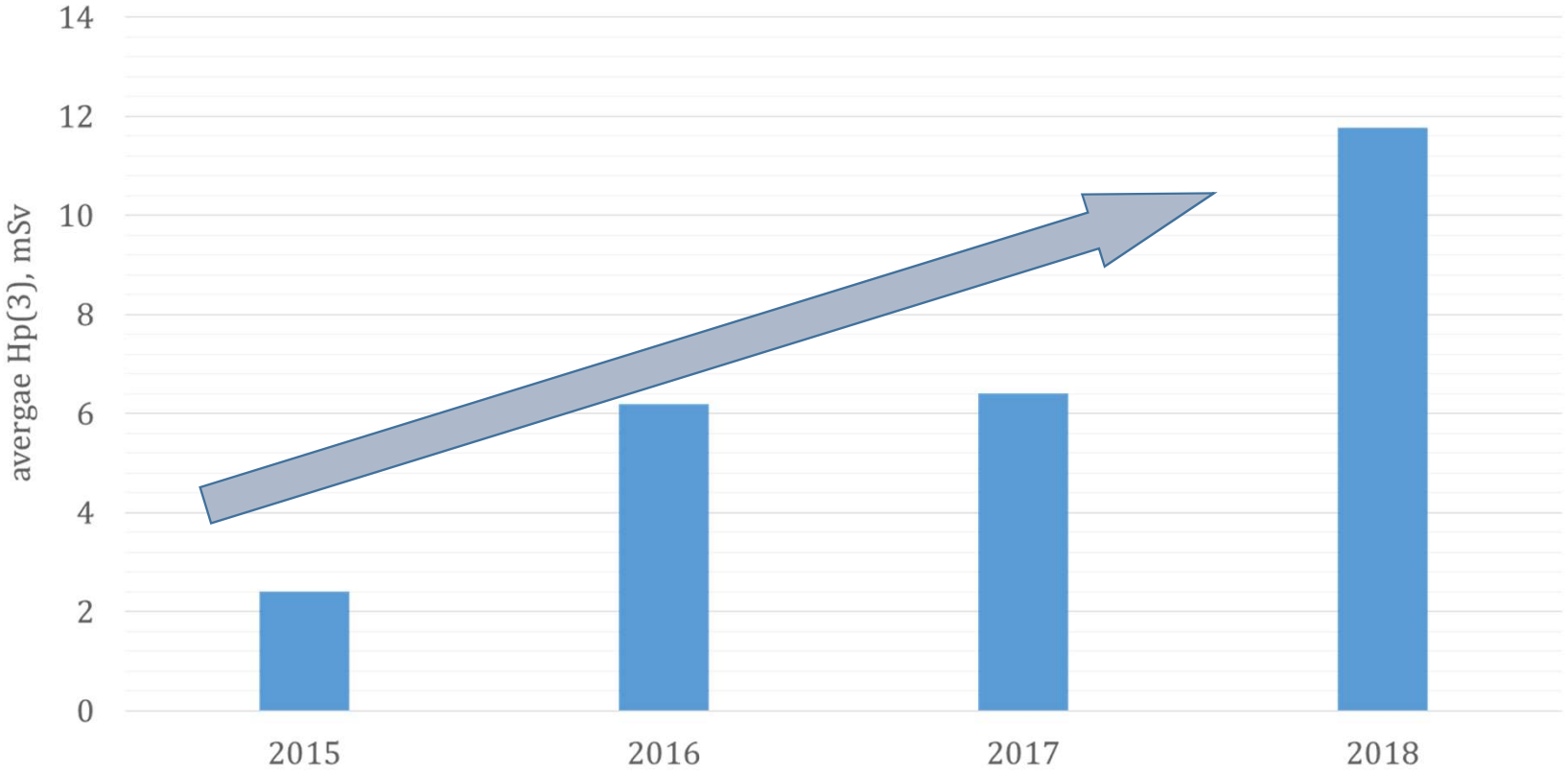

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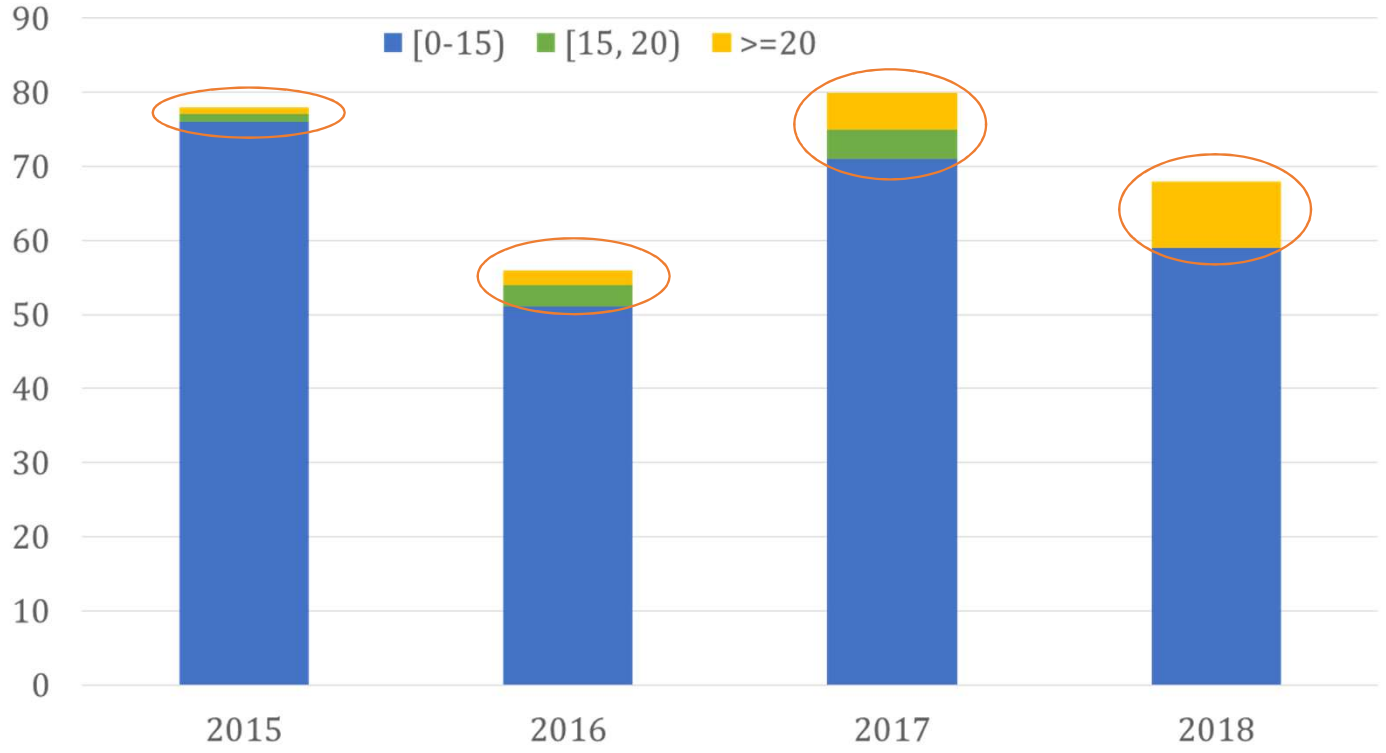
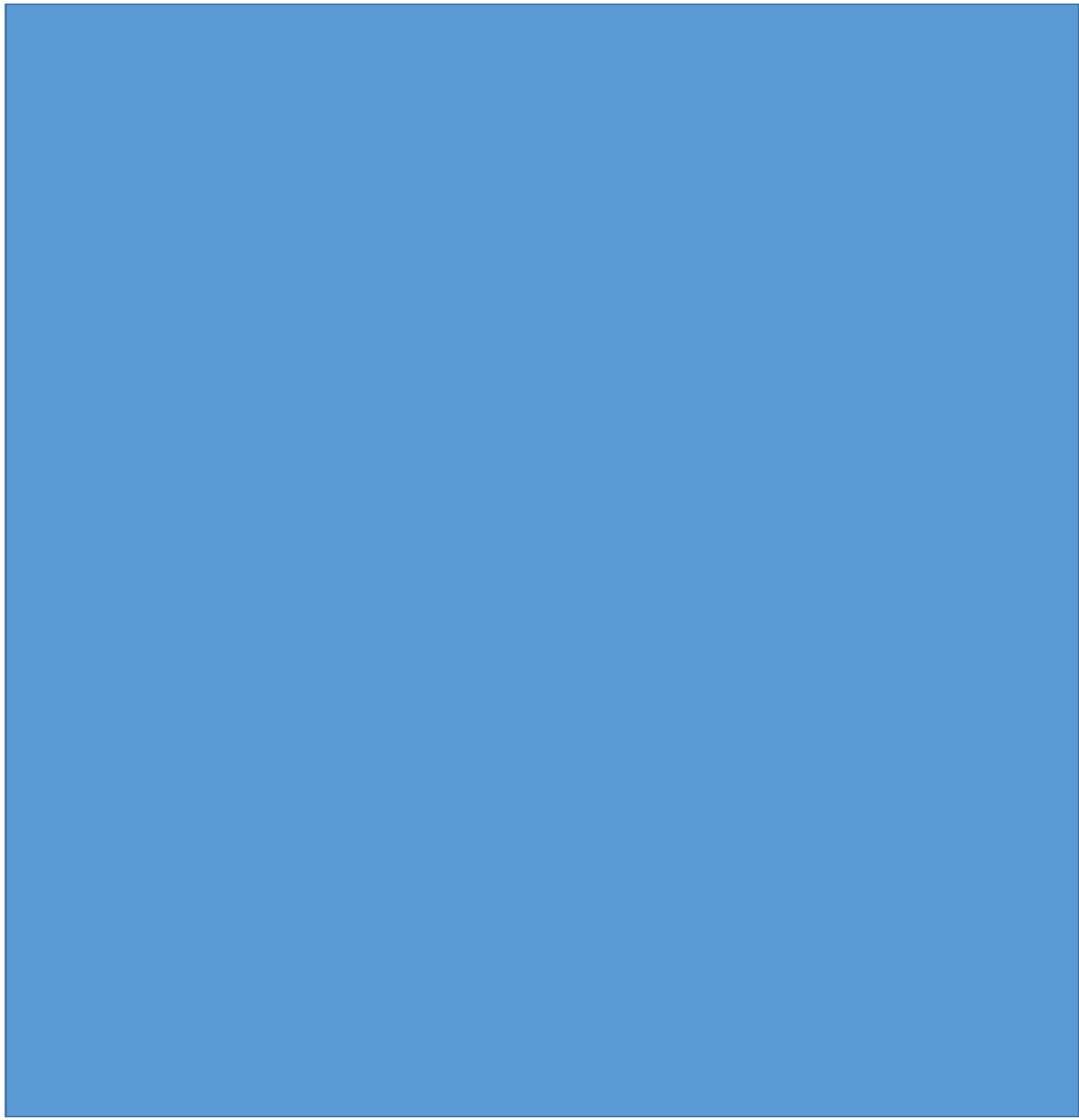


Actions taken



Actions taken

IAEA TECDOC SERIES

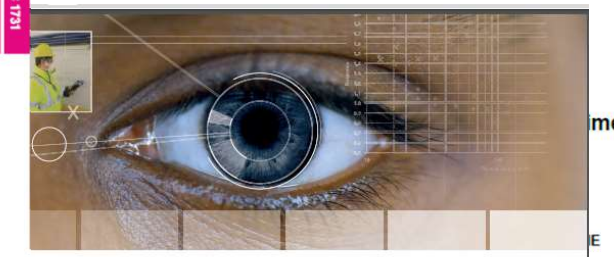
TECDOC No. 1731

Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye

IAEA International Atomic Energy Agency

www.eeae.gr

IAEA TECDOC 1731



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Occupational radiation protection for the lens of the eye

To reduce the risk for cataracts in the lens of the eye, the IAEA General Safety Requirement Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (No. GSR Part 3) states that occupational exposure of the lens of the eye should be limited to an equivalent dose limit of 20 mSv per year, averaged over five years, with no annual dose in a single year exceeding 50 mSv. This dose limit is in line with the recommendation in the International Commission on Radiological Protection (ICRP) Publication 103.

Optimizing protection

Appropriate protective actions need to be taken to ensure that doses to the lens of the eye do not exceed the dose limit. Workers potentially at risk include medical specialists operating image guided equipment in interventional cardiology and interventional radiology, medical specialists performing some tasks in nuclear medicine, workers involved in some tasks in the decommissioning of nuclear facilities, workers in nuclear facilities using glove boxes, workers that carry out some tasks in fuel cycle facilities, emergency response workers and industrial radiographers.

As outlined in the General Safety Guide on Occupational Radiation Protection (No. GSG-7), optimizing protection of workers against high doses to the lens of the eye involve:

- Engineered controls such as shielding to reduce exposure of the eyes.
- Administrative controls such as written rules to control exposure in normal operations.
- The use of personal protective equipment such as protective glasses. Glasses made of Perspex or equivalent materials may be sufficient in cases involving beta radiation. Protective glasses containing lead can be used to protect against scattered low energy X rays.
- Information, instruction and training for workers on any changes to the radiation protection program to reduce doses.

When considered necessary, employers should provide workers with dosimeters to measure the dose to the lens of the eye to verify compliance with the dose limit.

Netherlands Commission on Radiation Dosimetry
Subcommittee 'Protection and Dosimetry of the Eye Lens'
May 2018 DOI: 10.25030/ncs-031

IRPA

IRPA guideline protocol for eye dose monitoring and eye protection of workers

INTRODUCTION

In April 2011, the International Commission on Radiological Protection revised its eye

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JUNE 2016

TECHNICAL INFORMATION SHEETS: SFRP

EYE LENS:
REGULATORY LIMITS, MEASUREMENT, DOSIMETRY AND MEDICAL SURVEILLANCE

The lens of the eye is radiosensitive tissue that can be affected by ionising radiation. It develops opacities, which can go on to become cataracts. As a result of various epidemiological studies[1,2,3] the International Commission on Radiological Protection (ICRP) has proposed a revised exposure limit for the eye lens[4], which in some work situations may lead to a significant change in radiological protection practices around monitoring the risk of eye lens exposures.

In this sheet, we begin by explaining the official limits and the measurement quantities. We then describe various exposure situations and the operating principles and performance of several dosemeters, together with their wearing conditions, before going on to describe the possibilities for indirect monitoring of the dose delivered to the lens and procedures for dosimetric and medical surveillance.

1 - REGULATORY LIMITS AND MEASUREMENT QUANTITIES.

In 2010, ICRP recommended that the occupational exposure limit be reduced for the lens of the eye to 20 mSv per year on average over a five-year period, with a maximum of 50 mSv in any one year[4] (as opposed to the previous 150 mSv over 12 consecutive months). European Directive 2013/59/Euratom gives the same recommendation, though formulated slightly differently: 100mSv over a 5-year period, with a maximum of 50 mSv in any given year [Article 9[3]]. At the time of publication of this information sheet, this recommendation has not yet been transposed into French law.
The limit is expressed in terms of equivalent dose to the lens – H_{lens}[4]. As this quantity cannot be measured, it is estimated via two operational quantities[7,8,9], the first being directional dose equivalent at 3 mm depth – $H'(3)$ – for area monitoring, and the second being individual dose equivalent at 3 mm depth – $H_p(3)$. The depth of 3 mm was selected as it corresponds to the depth at which the part of the lens considered to be sensitive to ionising radiation is located. In order to study the energy deposited in the tissue without using an anthropomorphic phantom, the operational quantities are set using simplified phantom shapes. For example, for $H_p(3)$, a 20 cm diameter right circular cylinder made of ICRU (soft) tissue material is used and for $H'(3)$ the ICRU 30 cm diameter sphere[10,11,12,13].

2 - SITUATIONS ENTAILING LENS EXPOSURE HAZARDS.

The table below gives some examples of lens exposure situations by occupational sector (industry, medical). The exposure risk situations and the sources mentioned for these sectors can also be found in research facilities. This is not intended to be an exhaustive list, but is designed to draw attention to situations we might not necessarily think about and to stimulate an examination of exposure risk according to the work place. The table illustrates the fact that all types of ionising radiations – neutrons, photons and electrons – can entail exposure of the lens. In some circumstances, these exposure situations can lead to dose equivalents close to or even in excess of the exposure limit laid down by Directive 2013/59/Euratom.

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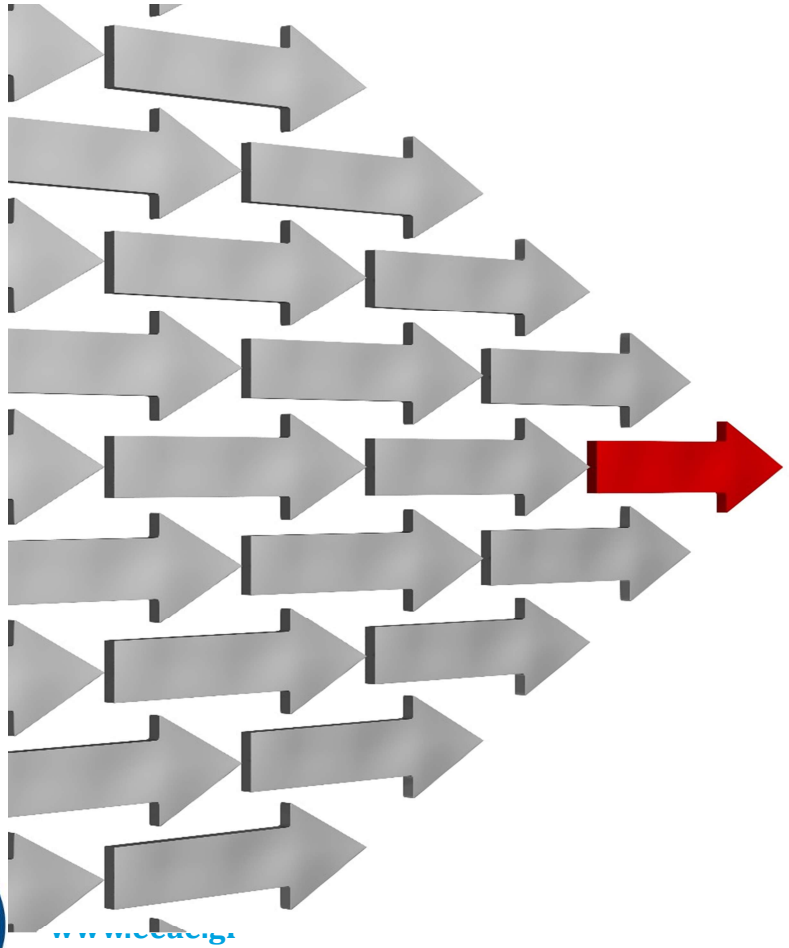
Guidance is given about

- The energy and angle of radiation
- The geometry of the field

- The quantity to be used
- Dosemeters to be used

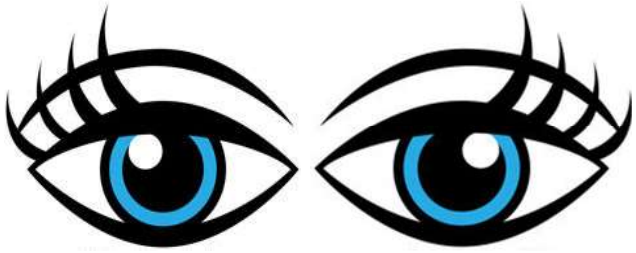
- Protective measures
- Where to wear the dosemeters

Harmonisation …



- The procedures for the estimation of the dose to the lens of the eye
- Type and position of the eye lens dosemeter
- Algorithms to be used
- Clear definition of the parameters to be registered in in national radiation protection database

Thank you very much
for your attention!



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