

EN

# Radiation Exposure of the Lens of the Eye



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MAVIG

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## Radiation Exposure of the Lens of the Eye

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## Introduction

With this information brochure, MAVIG would like to provide an overview of the current status (September 2023) of radiation exposure of the lens of the eye.

It contains **information** on ...

- ▶ ***dose limits for the lens of the eye in accordance with German legislation and EU law,***
- ▶ ***the effect of radiation,***

as well as a **guide** ...

- ▶ ***regarding the application of the threshold model,***

and **provides you with** ...

- ▶ ***the facts about measurements to monitor the dose to the lens of the eye***
- ▶ ***the existing options for effectively reducing radiation exposure of the lens of the eye.***

**NOTE:** The information contained in this flyer is based on German legislation and EU directives. Other international laws and regulations may differ.

## About us.

MAVIG GmbH is an independent research and manufacturing company that has been operating successfully across the globe for over 100 years.

MAVIG products stand for quality and reliability, made in Germany. Our product range includes X-ray equipment-oriented and structural radiation protection, personal protective equipment and ceiling-mounted suspension systems.

All MAVIG products are designed and manufactured in strict compliance with the applicable laws, regulations and standards – sometimes even with higher specifications than required.

Our product portfolio covers all technical radiation protection measures (personal protective equipment as well as technical on-site protective devices) to optimize scatter radiation exposure of the examiner and the patient. Everything is available from a single source and our products are optimally matched to the application and to each other.




| Organ equivalent dose limits for the lens of the eye of occupationally exposed persons  |        |
|---|--------|
| Limits per calendar year for occupationally exposed persons   |        |
| <br>ICRP "Statement on Tissue Reactions" dated April 21 <sup>st</sup> , 2011   | 20 mSv |
| <br>EU Directive 2013/59/EURATOM of December 05 <sup>th</sup> , 2013   | 20 mSv |
| <br>The German Radiation Protection Act (StrSchG) of June 27 <sup>th</sup> , 2017, in force since December 31 <sup>st</sup> , 2018 | 20 mSv |

Fig. 1: Equivalent dose limits for the lens of the eye

| Limits for occupationally exposed persons in accordance with the German Radiation Protection Act (StrSchG), in force since December 31 <sup>st</sup> , 2018 |                |
|---|----------------|
| Limits for occupationally exposed persons aged 18 and over  |                |
| <b>Effective dose</b>   | <b>20 mSv</b>  |
| <b>Organ equivalent dose</b><br><i>for the lens of the eye</i>  | <b>20 mSv</b>  |
| <b>Organ equivalent dose</b><br><i>for the skin</i>   | <b>500 mSv</b> |
| <b>Organ equivalent dose</b><br><i>for hands, lower arms, feet and ankles</i>   | <b>500 mSv</b> |

Fig. 2: Additional limits according to the Radiation Protection Act

**NOTE:** The information contained in this flyer is based on German legislation and EU directives. Other international laws and regulations may differ.

- ▶ **Dose limits do not represent a clear cut-off value between "risk-free" and "risky" radiation exposure.** <sup>6</sup>
- ▶ **Hence, compliance with the limits does not mean that a health risk can be fully excluded.** <sup>6</sup>
- ▶ **According to the Radiation Protection Act, any exposure to radiation must therefore be kept as low as possible, even below the specified limits (principle of optimization).** <sup>7</sup>

## Dose Limits

The lens of the eye is considered an organ which is particularly sensitive to radiation <sup>1</sup>. As a result of exposure to radiation, the lens of the eye may become cloudy. This in turn leads to reduced vision and even blindness. Radiogenic lens opacities are referred to as radiation-induced cataracts. Although posterior subcapsular cataracts are predominant, cortical changes all the way to total opacification of the lens are also known. These result in the surgical removal of the opacified lens and insertion of an artificial lens.

National and international radiation protection bodies have recognized the lens of the eye's high degree of sensitivity to radiation and have set organ dose limits for occupational radiation exposure of the lens of the eye. Over the decades, these have been successively lowered in line with the current state of research.

In Europe, the limits for occupational radiation exposure are defined by the Euratom committee and adopted by the European institutions. The member states of the European Union then turn those limits into national law.

The limits are therefore legally defined maximum values that are not allowed to be exceeded. The committees use the recommendations of the ICRP (International Commission on Radiation Protection) as a scientific reference in the field of radiation protection. This international organization is responsible for summarizing the state of scientific knowledge on the effects of ionizing radiation and for publishing key principles on radiation protection.

Already in April 2011, the ICRP issued recommendations <sup>2</sup> to reduce the previous dose limit of 150 mSv (millisieverts) per year to 20 mSv per year for occupationally exposed persons. This recommendation was based on updated research results and epidemiological studies, which suggest that the radiation sensitivity of the lens of the eye is far higher than previously assumed.

Based on this recommendation, the Euratom working group formulated an EU Directive 2013/59/Euratom establishing basic safety standards for protection against the dangers arising from exposure to ionizing radiation, which came into force in December 2013. The ICRP recommendation was implemented and 20 mSv per year was set as the new organ equivalent dose limit for the lens of the eye <sup>3, 4, Note 1, Note 2</sup>.

EU Directive 2013/59/Euratom was nationally implemented in Germany with the Radiation Protection Act on December 31<sup>st</sup>, 2018. This means that a legally binding limit for the lens of the eye of 20 mSv per calendar year now applies to persons occupationally exposed to radiation <sup>5, Note 3</sup>.

Note 1: Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionizing radiation of December 5<sup>th</sup>, 2013 (OJ L 13/1), Article 9: "The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv."

Note 2: In addition, Article 11 of EU Directive 2013/59/Euratom specifies 15 mSv per year as the equivalent dose limit for the lens of the eye for trainees and students between the ages of 16 and 18.

Note 3: The German Radiation Protection Act (StrSchG) of June 27<sup>th</sup>, 2017 also specifies that the respective authority may allow an equivalent dose of 50 mSv for a single year in individual cases, whereby a total of 100 mSv may not be exceeded in five consecutive years. For occupationally exposed persons under the age of 18, the equivalent dose limit for the lens of the eye is 15 mSv per calendar year.

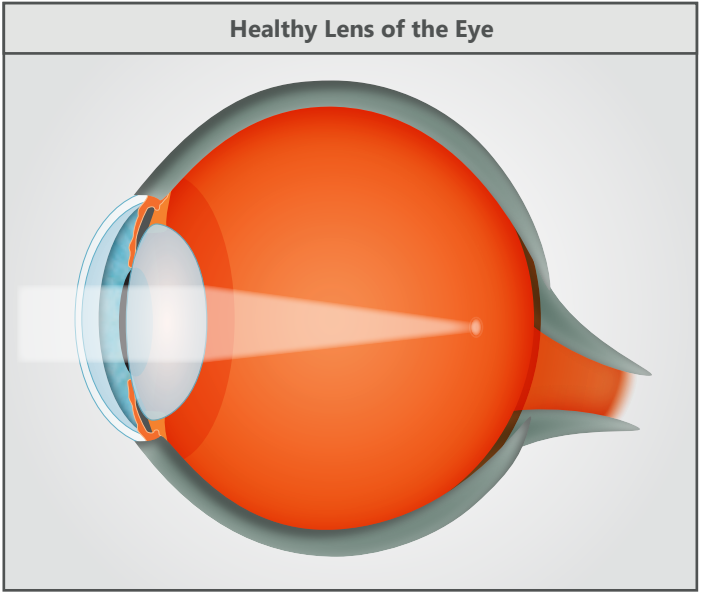


Fig. 3a: Healthy lens of the eye

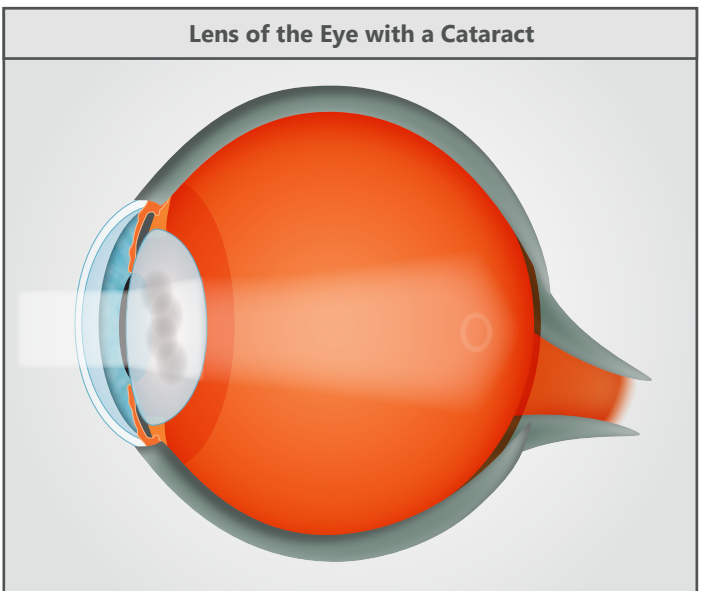


Fig. 3b: Lens of the eye with a cataract

- ▶ **The applicability of a threshold model for the lens of the eye remains uncertain.**
- ▶ **The consensus in radiation protection is to always minimize radiation exposure. Thus, all uncertainties of a nominal threshold value are taken into account.**
- ▶ **If a threshold for radiation-induced cataract formation exists, it is estimated to be very low at around 100 mGy (milligray).**

## Threshold Levels

Typically, the biological effect caused by ionizing radiation is divided into two types: deterministic and stochastic radiation effects.

Deterministic radiation effects cause an acute reaction, e.g. reddening of the skin due to exposure of the body to ionizing radiation. This is characterized by the fact that a certain threshold dose or threshold value must be exceeded. In contrast, there is no threshold value for stochastic radiation effects. Thus, the probability of radiation-induced long-term effects cannot be neglected even at very low radiation doses greater than zero.

For a long time it was assumed that radiogenic lens opacities (radiation cataracts) were exclusively a deterministic effect. The ICRP assumes a threshold value of 500 mGy (equivalent to 500 mSv) for acute or prolonged exposure <sup>2</sup>. However, the ICRP explicitly recommends that exposure is to be kept well below the threshold value. This is explained by uncertainties in the application of a threshold level and its specific numerical value. In one of his scientific papers, Hamada et al. <sup>8</sup> provides a detailed insight into the scientific rationale behind the ICRP recommendation of 2011 and considers the mechanisms that lead to radiation-induced cataracts.

The Commission on Radiological Protection (SSK) also states that current epidemiological studies and experimental data raise the question of whether a threshold dose for causing cataracts of the lens of the eye exists <sup>9</sup>. For example, this is reflected in a statement by Chodick et al. <sup>10</sup>: "Our findings and the results of recent studies suggest that the likelihood of cataract formation increases with increasing exposure to ionizing radiation with no apparent threshold value, [...]"

Further studies indicate that even exposure to relatively low doses of ionizing radiation increases the long-term risk of developing cataracts. Neriishi et al. <sup>11</sup> establishes an estimated value of 100 - 800 mGy as the threshold dose for the prevalence of surgical cataracts.

Apart from the development of cataracts, there is little research on the effect of ionizing radiation on the eye with regard to low doses of radiation. For this reason, the NCRP (National Council of Radiation Protection) recommended a comprehensive assessment of the overall impact of ionizing radiation on the eye as early as 2016 <sup>12</sup>.

It is still unclear how ocular pathologies, e.g. glaucoma or macular degeneration, are influenced or even induced by ionizing radiation. Due to the very limited data available, a threshold level of > 5 Gy is assumed for the occurrence of radiogenic glaucoma <sup>13,14</sup>, which is considerably higher than for cataract formation.

## Radiation Exposure of the Lens of the Eye Monitoring the Dose to the Lens of the Eye

### Eye Lens-Dosimeter Measured Parameter $H_p(3)$

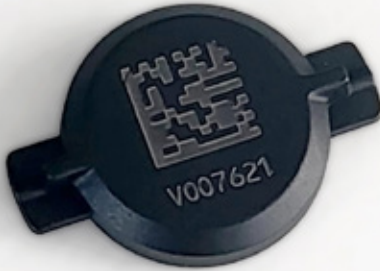


Fig. 4: Eye Lens-Dosimeter

### X-Ray Protective Glasses with Dosimeter Connection



Fig. 5: X-ray protective glasses with integrated adapter for a dosimeter

- ▶ **If an equivalent dose of 15 mSv or more per calendar year is expected, you are obligated to officially monitor the dose to the lens of the eye.**
- ▶ **According to the IRPA (International Radiation Protection Association), the dose to the lens of the eye should be officially monitored from an equivalent dose of 6 mSv per year.**
- ▶ **The determination of the organ equivalent dose of the lens of the eye in the measured parameter  $H_p(3)$  is mandatory starting January 1<sup>st</sup>, 2022 at the latest.**



## Monitoring the Dose to the Lens of the Eye

Official personal dosimetry on a regular base is required by law for measurement-related monitoring of the dose to the lens of the eye if a higher equivalent dose than 15 mSv per calendar year is to be expected. This is specified in the German Radiation Protection Ordinance (StrSchV) of November 29<sup>th</sup>, 2018 for persons occupationally exposed to radiation <sup>15</sup>. As is mandatory for whole-body dosimetry, eye lens dosimetry is evaluated by an officially approved personal dosimetry service.

For this purpose, the independent parameter  $H_p(3)$  was introduced in addition to the parameters  $H_p(10)$  and  $H_p(0.07)$  already known in radiation protection.  $H_p(3)$  dosimeters were developed for a representative measurement of the eye lens dose at a tissue depth of 3 mm, which is indicated by the number 3 in brackets respectively, ( $H_p(10)$  is the measurement at a tissue depth of 10 mm,  $H_p(0.07)$  at a tissue depth of 0.07 mm). The need for the new parameter is therefore a result of the anatomy of the eye. The lens of the eye is located at a depth of 2 - 4 mm, which reduces or completely invalidates the informative value of previous personal dosimeters for the equivalent dose to the lens of the eye. The StrSchV therefore specifies that the organ equivalent dose to the lens of the eye must be determined from January 1<sup>st</sup>, 2022 at the latest in the new parameter  $H_p(3)$  using dosimeters that comply with the Measurement and Verification Act <sup>16</sup>.

However, as already explained in the previous discussion on thresholds, each regulatory threshold must be considered. The IRPA sees the need for regular eye lens dose monitoring starting at a dose threshold of 6 mSv per calendar year. For annual equivalent doses of between 1 and 6 mSv regular monitoring is recommended <sup>17</sup>.

The measurement for determining the eye lens dose is technically challenging with regard to defining a suitable position of the dosimeter. It is important to ensure that the measurement takes place at a representative measurement site where ideally the highest exposure is to be expected <sup>18</sup>. "Ideal conditions" were defined to enable practicability in everyday clinical routine. These state that the  $H_p(3)$  dosimeter should be placed as close as possible to the eye facing the radiation source and behind all existing protective devices. As changing positions of the dosimeter would influence the measurement to such an extent that the measured values cannot be used, maintaining a fixed position is essential for meaningful and reproducible dose measurement <sup>19</sup>. X-ray protective glasses with integrated dosimeter connections are therefore predestined to meet the requirement for a firmly defined position for the eye lens dosimeter <sup>20</sup>.

For evaluating measurements, on the other hand, which are intended to determine the expected eye lens dose for a certain procedure or workplace or as a basis for deciding on suitable radiation protection measures, it makes sense to measure the dose in front of and behind the radiation protection equipment. This means that not only the actual radiation field is assessed, but also the effectiveness of the existing protective equipment, such as X-ray protective glasses. X-ray protective glasses with an integrated dosimeter connection are a useful tool here, as measurements can be carried out with a defined measuring position without the need to assign a person. For this case, the use of an  $H_p(3)$  dosimeter is recommended, even if this is not an official personal dose measurement.

**Ceiling-Suspended Radiation Shield  
with Protective Curtain**

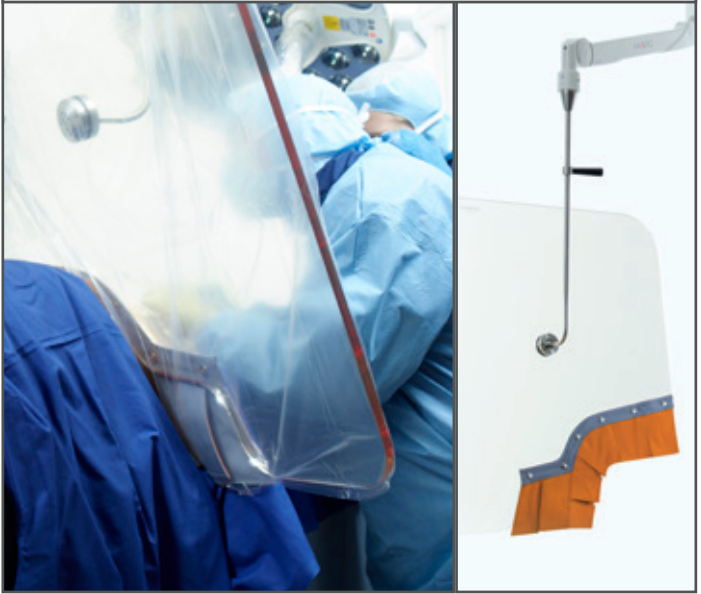


Fig. 6: Radiation shield with protective curtain as ceiling-mounted protection

**Radiation Protective Drapes in Addition  
to the Radiation Protective Shield with Curtain**

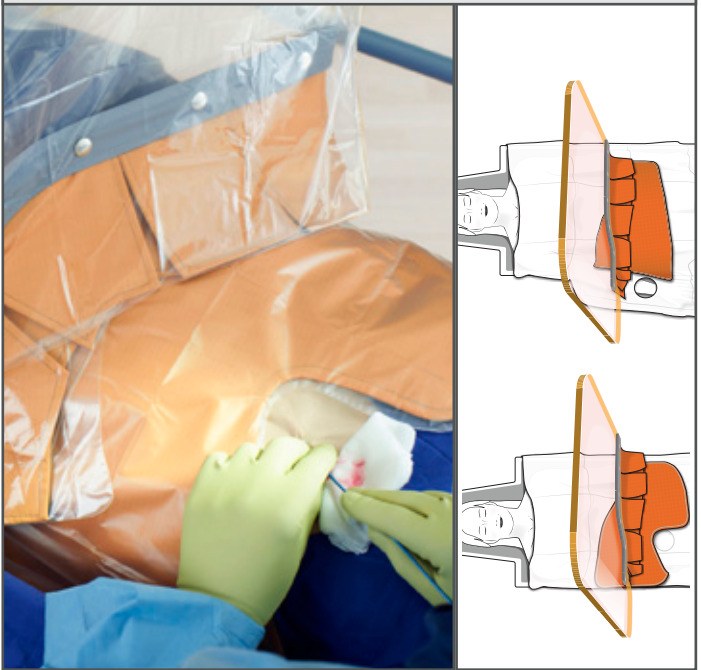


Fig. 7: Radiation shield with curtain in combination with radiation protective drape

▶ **According to the Radiation Protection Act, any exposure to radiation must be kept as low as possible, even below the specified limits.** <sup>22</sup>

## Radiation Protection Measures

The previous chapters have explained, from various perspectives, why it is essential to protect the lens of the eye in many radiologically assisted procedures. Even if the new limit of 20 mSv per calendar year for the equivalent dose of the lens of the eye is not exceeded, the optimization principle in radiation protection is still applicable: radiation exposure must be minimized to the greatest possible extent with reasonable effort (ALARA principle), even below the specified limits <sup>21</sup>. One aspect of user protection are measurements to determine and monitor the respective eye lens dose, the other is the use of radiation protection equipment in everyday medical practice.

In order to optimally use the protective effect of radiation protection equipment, it is essential to know the main source of radiation exposure for the eye. In radiologically assisted interventions, this is the scatter radiation emitted by the patient. During many procedures, the examiner turns his head rather in the direction of the monitors than the patient. Hence, in the various interventional disciplines, the scatter radiation emanating from the patient volume being irradiated is directed at the lenses of the examiner's eyes from diagonally below or diagonally to the side, depending on the position of the monitors and the position of the examiner's head.

The preferred radiation protection measure is the use of technical radiation protection measures. These do not represent any additional physical strain for the user and not only provide partial protection, but also form large protection zones when multiple devices are used in combination. Technical radiation protection measures can generally be categorized in ceiling-suspended (OT) and table-mounted protective devices (UT). Typical representatives of OTs are ceiling-suspended, transparent radiation shields. The UTs are table-mounted lower body protections with corresponding upper shields. X-ray protective mobile shields combine above-table and under-table protective devices or replace the table-mounted lamellas. <sup>22, 23, 24, 25, 34, 35</sup>

The protective effect of the technical radiation protection measures can be significantly improved using radiation protection drapes, which are positioned on the patient's body outside the field of view (FOV). These drapes absorb a significant proportion of the scatter radiation emanating from the irradiated patient volume. <sup>25, 26, 27, 28, 32</sup>



# Radiation Exposure of the Lens of the Eye

## Radiation Protection Measures

### Ceiling-Suspended Protective Face Shield



Fig. 8: Ceiling-suspended protective face shield

### Table-Mounted Lower Body Protection with Upper Shields



Fig. 9: Table-mounted lower body protection with upper shields

### Personal Protective Equipment (PPE)



Fig. 10: Radiation protective glasses with lateral protection

## Radiation Protection Measures

In terms of personal protective equipment (PPE), X-ray protective glasses and visors are the equipment of choice. For X-ray protective glasses, it is important that they fit as snug against the cheeks and temples as possible to ensure optimum protection. Glasses with additional lateral radiation protection are of particular advantage. <sup>29, 30, 31, 32</sup>

Irrespective of the efficient use of radiation protection equipment, there are aspects that are essential when dealing with ionizing radiation and therefore radiation protection in general. These include, for example, regular staff training, a maximum distance from the radiation source, reduced fluoroscopy periods and frame rates, a maximum tube-to-patient distance, a minimum detector-to-patient distance, close collimation, additional filtering and the choice of projection. When selecting X-ray equipment, devices where the X-ray tube is underneath the table should be preferred. <sup>30, 33</sup>

If all principles and possibilities of radiation protection are practiced in everyday clinical practice, and if the radiation protection equipment described is used as extensively as possible, it is likely that radiation users will work within the legal limits for the eye lens dose even at high-dose workplaces. <sup>34, 35</sup>



Fig. 11: Radiation protective visor

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