

# The new radiation protection framework since 2019 – Implementation in Germany and comparison of some aspects in seven European countries

## Das neue Strahlenschutzrecht ab 2019 – Umsetzung in Deutschland und Vergleich einzelner Aspekte in 7 europäischen Ländern

### Authors

Reinhard Loose<sup>1</sup>, Michael Wucherer<sup>1</sup>, Michael Walz<sup>2</sup>, Ralf Adamus<sup>3</sup>

### Affiliations

- 1 Institute of Medical Physics, Nuremberg Hospital, Nuremberg, Germany
- 2 Ärztliche Stelle, TÜV-Süd, Frankfurt, Germany
- 3 Institute of Radiology, Erlangen University Hospital, Erlangen, Germany

### Key words

radiation safety, medicolegal Issues, EU Directive 2013/59 EURATOM, radiation protection law, radiation protection ordinance

received 28.07.2019

accepted 29.02.2020

### Bibliography

Fortschr Röntgenstr 2020; 192: 1036–1045

Published online: 14.4.2020

DOI 10.1055/a-1137-0096

ISSN 1438-9029

© 2020. Thieme. All rights reserved.

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

### Correspondence

Prof. Reinhard Loose

Institute of Medical Physics, Nuremberg Hospital, Paracelsus Medical University, General Hospital Nuremberg, Prof.-Ernst-Nathan-Str. 1, 90419 Nuremberg, Germany

Tel.: ++49/9 11/3 98 33 63

Fax: ++49/9 11/3 98 32 88

rloose@web.de

### ABSTRACT

**Purpose** The implementation of EU Directive 2013/59 EURATOM (EU-BSS) of 2014 led to a reorganization of radiation protection legislation in Germany in the form of a new radiation protection law Strahlenschutzgesetz (StrlSchG) of 2017 and a new radiation protection ordinance Strahlenschutzverordnung (StrlSchV) of 2018. For application of ionizing radiation

in medicine these changes affect radiology, nuclear medicine and radiotherapy. A comparison between the old and the new legal system analyses changes that are relevant for diagnostic and interventional radiology. For the important new regulation of unintended exposures, a comparison is made with the implementation of Art. 63 EU-BSS in 7 European countries.

**Material and methods** The provisions of the Röntgenverordnung (RöV) and the old Strahlenschutzverordnung (StrlSchV alt), which were valid until 2018, are compared with the new legislation of StrlSchG and StrlSchV for changes in radiation protection for patients, the population and occupational radiation protection of staff members. The occupational dose limit of the eye lens was reduced. The reduction by a factor of 7.5 results in new requirements for radiation protection equipment. New requirements in teleradiology are compared with the previous regulation, as well as the necessary involvement of medical physics experts (MPE) in high dose procedures, such as CT and fluoroscopic interventions. The regulation for unintended exposures of the German StrlSchV are analyzed in terms of their reporting criteria.

**Results** The principles of medical radiation protection in Germany have not changed as a result of the new radiation protection legislation from 2019 onwards. However, there are a number of changes and new requirements that must be considered and implemented. Important points are e. g. new regulations on teleradiology, early detection of diseases in asymptomatic individuals and reporting of unintended exposure of patients. As all new regulations are no longer found in only one single regulation, both knowledge of the StrlSchG and the StrlSchV are necessary.

### Key points:

- The EU Directive 2013/59 EURATOM (EU-BSS) was transposed into the new German radiation protection law 2018
- The basic regulations of the RöV and old StrlSchV remain unchanged
- Newly added regulations must be known and implemented in practice
- Many regulations of the EU-BSS are so vaguely formulated that they allow a wide scope for national implementation

## Citation Format

- Loose R, Wucherer M, Walz M et al. The new radiation protection framework since 2019 – Implementation in Germany and comparison of some aspects in seven European countries. *Fortschr Röntgenstr* 2020; 192: 1036–1045

## ZUSAMENFASSUNG

**Ziel** Die Umsetzung der EU-Direktive 2013/59 EURATOM (EU-BSS) von 2014 führte in Deutschland zu einer Neuordnung des Strahlenschutzrechts in Form eines neuen Strahlenschutzgesetzes (StrlSchG) von 2017 und einer neuen Strahlenschutzverordnung (StrlSchV) von 2018. Damit ergeben sich bei der Anwendung ionisierender Strahlen in der Medizin Veränderungen, die Radiologie, Nuklearmedizin und Strahlentherapie betreffen. In einem Vergleich zwischen alter und neuer Rechtsordnung werden die für die Radiologie relevanten Veränderungen analysiert. Für die wichtige neue Regelung meldepflichtiger Ereignisse wird ein Vergleich mit der Implementierung von Art. 63 EU-BSS in 7 europäischen Staaten durchgeführt.

**Material und Methoden** Die bis 2018 geltenden Regelungen der Röntgenverordnung und alten Strahlenschutzverordnung werden für die in der Radiologie relevanten Regelungen

zum Strahlenschutz für Patienten, die Bevölkerung und zum beruflichen Strahlenschutz des Personals mit dem StrlSchG und der StrlSchV verglichen und Veränderungen in ihrer Auswirkung bewertet. Aus der Herabsetzung der beruflichen Augenlinsendosis um den Faktor 7,5 ergeben sich neue Anforderungen an die Strahlenschutzrüstung. Die neuen Anforderungen in der Teleradiologie werden in ihren Auswirkungen mit den früheren Genehmigungen verglichen, ebenso wie die jetzt notwendige Hinzuziehung von Medizinphysikexperten bei dosisintensiven Verfahren wie CT und fluoroskopische Interventionen. Die in der deutschen StrlSchV getroffenen Regelungen für meldepflichtige Ereignisse werden mit ihren Kriterien zur Meldepflicht diskutiert.

**Ergebnisse** Die Grundlagen des medizinischen Strahlenschutzes in Deutschland haben sich durch das neue Strahlenschutzrecht ab 2019 nicht verändert. Es gibt allerdings eine Reihe von Veränderungen und auch neuer Anforderungen, die zu beachten und umzusetzen sind. Wichtige Punkte sind z. B. neue Regelungen zur Teleradiologie, Früherkennung von Krankheiten und Meldekriterien bei unbeabsichtigter zu hoher Exposition von Patienten. Da sich alle neuen Regelungen nicht mehr nur in einer Verordnung finden, sind sowohl Kenntnisse des StrlSchG als auch der StrlSchV notwendig.

## Introduction

The last fundamental recommendations of the International Commission on Radiological Protection (ICRP) in 2007 [1] were also included in the update of the Basic Safety Standards of the International Atomic Energy Agency (IAEA) in 2014 [2] Directive 2013/59/EURATOM (EU BSS) [3] issued by the European Union (EU) addresses essential contents of these two publications and replaces 5 older EU directives on radiation protection. Implementation in national law of all EU member states, which were also involved in the development of the EU BSS alongside scientific advisory bodies of the EU, had to take place by 2/2018 [4, 5]. As a consequence, the “Law on the Reorganization of the Right to Protection against the harmful Effects of Ionizing Radiation” (StrlSchG) [6] went into effect in 2017. The new “Ordinance on the Further Modernization of Radiation Protection Law” (StrlSchV) followed at the end of 2018 [7].

The new body of radiation protection law in effect since the end of 2018 have also resulted in a number of changes to radiology. Radiologists, medical physics experts and radiological technicians should be aware of the relevant changes in order to be able to deal with them sensibly in cooperation with authorities, committees and other professional groups.

The high number of inquiries to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the German Radiological Society (DRG), state and medical authorities in 2019 showed that there are still many uncertainties regarding the interpretation and application of the new radiation protection laws. One of the reasons for this is that no directive of the subordinate regulations has been updated as of early 2020.

The following presentation is intended to explain the regulations relevant to the radiological user as far as it is currently possible. Some aspects of this paper [8, 9] have already been published.

## Changes resulting from the new German Radiation Protection Laws

The new Radiation Protection Ordinance replaces the previously valid X-ray Ordinance and the “old” Radiation Protection Ordinance. Previously valid sub-regulations, i. e., directives (e. g., medical physics experts, recording requirements, quality assurance by medical authorities, specialist knowledge, expert testing) will remain in force until new directives or general administrative regulations are drawn up with reference to new radiation protection law. The directives should be updated in the next 1–3 years.

As a result of the new radiation protection laws, radiation protection will be restructured and adapted to the requirements of the EU BSS [10]. In many countries, this will require the restructuring of supervisory authorities since different authorities and, if necessary, ministerial institutions were previously responsible for the X-ray Ordinance and Radiation Protection Law, which in medicine are assigned to different radiological disciplines.

The Radiation Protection Law now elevates many fundamental protective measures, such as preliminary inspections by the authorities (licensing and notification procedures), the organization of radiation protection, dose limits, reporting obligations, as well as the handling of personal data and the tasks of authorities to legal status. This means that different interpretations and im-

► **Table 1** Tasks of a medical physics expert according to Section 132 of the Radiation Protection Ordinance

	an MPE assumes responsibility for the dosimetry of individuals and for the optimization of radiation protection, and is involved in the following tasks:
1.	quality assurance in the planning and implementation of application of radioactive substances or ionizing radiation on humans, including physical and technical quality assurance.
2.	selection of the equipment, devices and appliances to be used.
3.	monitoring the exposure of persons to whom radioactive substances or ionizing radiation are applied.
4.	monitoring compliance with the diagnostic reference values.
5.	incident investigation.
6.	conducting risk analysis for treatments.
7.	instruction and training of personnel involved in the application.

plementations by the federal states are no longer possible with respect to the X-ray Ordinance.

The Radiation Protection Law contains a number of paragraphs with the formulation “The Federal Government is authorized to determine by ordinance with the consent of the Federal Assembly ...” For the reader of the law, this means that associated detailed regulations can be found in the new Radiation Protection Ordinance. The rubric “Installations for the production of ionizing radiation” does not refer to X-ray equipment, but to linear accelerators in radiation therapy, for example. Radiological examination equipment is referred to as X-ray equipment in the Radiation Protection Ordinance and Radiation Protection Law. Definition of such equipment and X-ray devices comprises peripheral equipment including software, such as image processing and monitors.

The following text essentially refers to regulations that are relevant for facility operators of X-ray equipment. The order of the following points follows first the paragraphs of the Radiation Protection Law and then the Radiation Protection Ordinance.

## Medical physics experts

The requirements as to when a medical physics expert is to be engaged are regulated in Section 14 1,2 of the Radiation Protection Law. For decades, medical physics experts have been involved in radiation therapy treatment in close cooperation with radiotherapists and radiological technical assistants. A new provision in the Radiation Protection Law stipulates that, as of this year, a master's degree in physics or medical physics is a basic requirement for medical physics expert training. The new Radiation Protection Ordinance defines the tasks of the medical physics expert (► **Table 1**) and related integration into the radiation protection organization (Section 132, Radiation Protection Ordinance). The new element is that a medical physics expert must be available during dose-intensive X-ray examinations. The medical physics expert must possess the requisite expert knowledge for such tasks. In radiology, CT and fluoroscope-based interventions are considered dose-intensive applications. The extent to which a medical physics expert is involved depends on the type and number of examinations or treatments and on the number of devices used. At present, there is no certainty in Germany that a sufficient num-

ber of medical physics experts with the required expert knowledge is available. Training programs and support measures at state level are under discussion. It is likely that there will be programs in centers in large hospitals that have several medical physics experts and which may be able to provide physicists to operators with fewer devices. Proposed demand figures for medical physics experts published in this journal [11] indicate that about 15 facilities (CT, angiography facilities) will require one full-time medical physics expert.

Where appropriate, the medical physics expert may also be appointed as an additional radiation protection officer. By the end of 2022, medical physics experts must be available for all systems that are considered dose-intensive. Effective immediately, availability is required for devices that have been reported to the authorities starting in 2019.

In a circular of 11/2019 from the BMU to the highest state authorities, the transitional solution, whereby every medical physics expert can be used in radiology even without the specialist qualification “X-ray diagnostics”, was extended by one year to December 31, 2021.

## Teleradiology

Section 5 (38) “Definitions” of the Radiation Protection Law now states that the teleradiologist must have the “required expertise” in radiation protection for the respective application and not, as previously, “general expertise”. However, neither the Radiation Protection Act nor the Radiation Protection Ordinance stipulates what the required expertise means for the teleradiologist, so that up to now this has been understood to mean the expertise required for the performance of the respective examination (content of previously issued model authorizations). It is still uncertain whether there will be a directive on teleradiology. The minimum time required for doctors to acquire specialist knowledge is still 36 months for general expert knowledge, and 6 to 18 months for specialist knowledge (usually 12 months). This regulation resolves the previous conflict that, for example, a physician with the required expertise at a university hospital may independently assess and report CT scans during night or weekend service, but not for a small peripheral hospital within the scope of teleradiology. The

content of the specialist knowledge remains unchanged. As a result of insufficient coverage with fully qualified doctors on duty, some university and large hospitals had therefore abandoned teleradiological care of neighboring smaller hospitals.

Section 14 (2) c) of the Radiation Protection Law requires “a regular and close involvement of the teleradiologist in the clinical operation of the radiation protection officer”. This regulation is intended to strengthen the so-called “regional principle”, i. e. closer local cooperation in which the teleradiologist is to be involved in clinical conferences and/or case discussions in addition to the reporting of findings and through regular on-site visits to the teleradiology-supported clinic. This is intended to prevent teleradiology providers from not knowing personally the clinics and cooperating staff they serve. Existing authorizations continue to be valid; for new approvals, different model authorizations of the federal states have been created. More precise specifications were made in a circular of 2/2020 from the BMU to the higher state authorities. In order to remove any ambiguities in the concept of “regular and close involvement of the teleradiologist in the clinical operation of the radiation protection officer”. They define the time intervals of a maximum of 12 months of a presence at the operator’s site, the appointment of a managing teleradiologist for providers with several teleradiologists and the involvement of the teleradiologist in important meetings or case conferences through personal presence or by means of communication technologies.

Permission for teleradiological care beyond night, weekend and holiday service can be granted if there is a need with respect to patient care. These approvals, previously limited to 3 years, are now extended to 5 years in Section 14 of the Radiation Protection Law.

## Research

Regarding procedures in research projects, the Radiation Protection Law had already contained changes which were summarized by the Federal Office for Radiation Protection as follows: The approval requirements for the previous detailed authorization process have been streamlined and the procedure is now subject to deadlines (Section 31 of the Radiation Protection Law). The previous simplified procedure for cases of so-called accompanying diagnostics is designed as a notification procedure (Sections 32 to 35 of the Radiation Protection Law) and is also subject to deadlines. The essential innovation is that persons of majority age who are unable to give their consent and ill may now also be included. Designation is checked independently of the opinion of the Ethics Commission. However, the procedure may only be started after the research project has been approved by an ethics commission registered with the Federal Office for Radiation Protection (Section 33 paragraph 3 no. 2 of the Radiation Protection Law). Sections 133 to 143 of the Radiation Protection Ordinance contain specific statements on consent, information, restrictions on use, further obligations and quality assurance, regarding activities in which medical offices and medical physics experts are also included.

## Exposure of carers and comforters

Exposure of carers and comforters should be limited (Section 76 (2) of the Radiation Protection Law). Therefore, according to Section 122 of the Radiation Protection Ordinance, directives should be drawn up and clarified according to Section 124 of the same ordinance, additional information should also be offered. Even an unintentional exceeding of the effective dose of 1 mSv is considered a significant occurrence. As for occupationally-exposed persons (see Section 72 of the Radiation Protection Ordinance), the determination of dose guidance values should be reviewed within 6 months after the start of an activity as a means to optimize radiation protection.

## Dose limits for occupationally-exposed persons

Dose limits for occupationally-exposed persons are regulated in Section 78 of the Radiation Protection Law. They remain unchanged at 20 mSv for the whole body dose, and 500 mSv for the skin and extremities.

In the past, the occupational limit of the eye lens dose was 150 mSv/a. Following a recommendation of the ICRP [12], the limit in the Basic Safety Standards (BSS) of the IAEA and in the EU BSS was reduced to 20 mSv/a [13]. The background is recent epidemiological data from Hiroshima, Nagasaki, Chernobyl and personnel in space stations, which call into question the previous threshold value model. Studies of doctors who have worked for many years with large numbers of cases on an interventional basis also show an increased incidence of lens opacities (cataract). This reduction of the threshold value by a factor of 7.5 is not unproblematic with respect to feasibility. The previous limit value of 150 mSv/a was practically never reached under normal medical working conditions. In particular, interventional fluoroscopic procedures in radiology, cardiology and vascular surgery can result in excess of 20 mSv/a. Consequently there are new requirements for the optimization of occupational radiation protection of interventional radiologists, but also of other persons working in the controlled area, as well as for areas of application less considered so far (e. g. mobile C-arms with limited protection devices or non-radiological applications with higher exposure values) [14–18].

According to Section 72 of the Radiation Protection Ordinance, the determination of dose guidance values as an instrument for the prospective optimization of occupational radiation protection shall be reviewed within 6 months after the start of an activity (for existing activities until January 1, 2020, see Section 191 of the Radiation Protection Ordinance) [19]. Currently there is still the problem that no calibrated lens dosimeters are available in Germany. In order to ensure compliance with the dose limits for the lens of the eye at individual workplaces, other radiation protection measurands, e. g. thermoluminescence dosimetry, can be used for measurement purposes.

## Screening examinations

In the future, further early detection procedures for groups of persons may be approved in addition to the early detection procedure approved until the end of 2018 – mammography screening (Section 84 of the Radiation Protection Law). A recent publication [20] contains an analysis of the new legal situation of early detection and the evaluation of service offerings, using CT scans as an example. The authors come to the conclusion that none of the offered CT screening measures are currently approved, so that their utilization represents a violation of the law. A General Administrative Regulation [21] of the BMU described the principles and procedures for the scientific evaluation of early detection tests for non-communicable diseases; this document serves as a directive for the Federal Office for Radiation Protection and describes the participation of experts and specialist groups. The Federal Office for Radiation Protection is responsible for assessment. Section 86 of the Radiation Protection Law grants an authorization to determine the special requirements for screening examinations. Applications for early detection examinations can be submitted to the Federal Office for Radiation Protection by professional associations, for example. After scientific examination of the higher benefit compared to the risks of the procedure, a narrow legal framework is to be established as a regulation for the submitted examination procedure, which will be monitored by the authorities and medical association bodies. Currently, the early detection of lung cancer using low-dose CT for persons with high tobacco consumption is already under consideration. The program for early detection of breast cancer, which was valid until December 31, 2018, continues to exist in terms of content, but has been adapted to the new Radiation Protection Law by a new Breast Cancer Early Detection Ordinance. Whereas breast cancer screening requires no individual justification, this is necessary, for example, in the early detection of lung cancer, since a risk profile (age, smoking history) must be established for each person in question. Other scientifically discussed screening tests include CT examination of the coronary vessels and CT colonography [22].

## Documentation requirements

According to Section 85 of the Radiation Protection Law, documentation obligations for radiation applications in humans were extended. In the case of exposure data, the records should also contain a justification if diagnostic reference levels have been exceeded, which according to Section 122 of the Radiation Protection Ordinance are to form the basis of the examinations (e. g. obesity). Since no further explanations are made in the Radiation Protection Ordinance, it remains open how levels are to be used for comparison. According to Section 1 of the Radiation Protection Ordinance, diagnostic reference levels are related to patient groups, and Annex 14 also distinguishes between values that apply to a single examination versus a group of examinations. Application of a diagnostic reference level to an individual patient examination is not provided according to current European documents (Radiation Protection 185 of the European Commission

[23]). To meet this requirement, at least a regular comparison of dose values with the national diagnostic reference levels (e. g. averaged from 10 consecutive X-ray applications of the corresponding examination type) is required, as well as based on the tasks of the medical physics expert according to Section 132 of the Radiation Protection Ordinance. The Federal Office for Radiation Protection directive and a publication on the handling of diagnostic reference levels in X-ray diagnostics [24, 25] describe a related procedure for checking exceeded values. In the meantime, the BMU has clarified in a circular of 1/2020 to state authorities that not every single incident exceeding the diagnostic reference level must be justified, but only compliance with the mean value of at least ten patients. According to Section 125 para. 2 of the Radiation Protection Ordinance, the Federal Office for Radiation Protection must review at least every three years whether the national diagnostic reference levels need to be updated.

The recording and documentation of exposure data had already been specified for most devices and radiation applications in the past; according to Section 195 of the Radiation Protection Ordinance, this applies to all devices as of January 1, 2024. A new requirement in Section 114 of the Radiation Protection Ordinance is that an X-ray facility must have a function that electronically records the parameters for determining the exposure of the persons examined and which makes them available for quality assurance. According to Section 195 of the Radiation Protection Ordinance, this requirement must be fulfilled for newly installed CT or fluoroscopic equipment starting January 1, 2021, otherwise starting January 1, 2023. In the case of interventions, the screening device must display the exposure assessment parameters during use (for devices put into service before December 31, 2018, otherwise starting January 1, 2021).

According to Section 122 of the Radiation Protection Ordinance, the exposures of persons receiving ionizing radiation shall be regularly evaluated and assessed for each type of examination. Although a dose management system (DMS) is not required anywhere in radiation protection law, but in connection with the tasks for a medical physics expert, the requirements for incidents and for diagnostic reference level comparisons as well as European recommendations, it can be assumed for larger radiological departments and practices that a demand-oriented DMS, no matter whether stand-alone or, e. g., integrated in PACS or RIS, will be useful in future. There are still a few hurdles to overcome when implementing a DMS, e. g. with regard to the provision of relevant exposure data and a uniform nomenclature for the types of examination or procedures.

The requirements for archiving examinations and treatments (Section 127 of the Radiation Protection Ordinance) have not changed in principle. However, the wording and individual versions have been somewhat changed. According to Section 85 of the Radiation Protection Law, records are to be secured against unauthorized access and unauthorized changes. The retention periods for adults are 10 years and for minors up to the age of 28. Acceptance tests must be kept for the duration of operation of equipment, now at least 3 years after a new acceptance test, constancy tests at least 10 years.



► **Table 2** Criteria for reporting significant events in radiology in Germany.

application	application type	threshold type	threshold value	frequency/comments
group (cohort)	CT fluoroscopic intervention	action threshold	3 × DRL	once, afterward check reporting limit
		reporting threshold	2 × DRL	average of 20 previously performed identical applications using identical device
person (individual)	CT	reporting threshold	brain: CTDI <sub>vol</sub> > 120 mGy body: CTDI <sub>vol</sub> > 80 mGy	once
	diagnostic fluoroscopy	reporting threshold	DFP > 20 000 cGy × cm <sup>2</sup>	once
	fluoroscopic intervention	reporting threshold	DFP > 5000 cGy × cm <sup>2</sup>	once if within 21 days deterministic skin damage appears

## Unintended radiation exposure

A further innovation in Section 90 of the Radiation Protection Law is the obligation to report unintentional radiation exposures (significant incidents) to the competent supervisory authority. Section 108 of the Radiation Protection Ordinance refers to the catalog of criteria in Annex 14. Exemptions to the reporting requirement include all projection radiographs (including mammography) and digital volume tomographies of the teeth and jaw. A distinction is made between examinations (X-ray diagnostics/nuclear medicine), interventions (radioscopic interventions) and treatments with ionizing radiation or with open radioactive substances. Regarding X-ray imaging, there is a differentiation between increased radiation exposure of groups of people (collective approach) or a single person (individual approach). The former occurs when the diagnostic reference level of a single examination is exceeded by more than 200 % (action threshold) (equivalent to a factor of 3 of the DRL) and the average value of the last 20 previous investigations of the same type of examination using the same equipment (reporting threshold) is exceeded by more than 100 % (twice the DRL). In the CT examination of an individual, any exceeding of the Computed Tomography Dose Index (CTDI<sub>vol</sub>) in a brain examination of 120 mGy and in a CT of the rest of the body of 80 mGy must be reported immediately to the authorities. For fluoroscopic examinations, the reporting threshold is a total dose area product (DAP) over 20 000 cGy\*cm<sup>2</sup>. Furthermore, there is an obligation to report if deterministic skin damage of second or higher degree occurs during fluoroscopic procedures within 21 days and the DAP value has exceeded 50 000 cGy\*cm<sup>2</sup>. The criteria for significant incidents are summarized in ► **Table 2**.

The notification process should be in writing to the responsible regulatory authority with detailed information about the examination and the patient. The authority examines the process and, if necessary, takes further measures with the system operator. Measures taken to prevent further excess exposures must also be reported. For this purpose, risk management must be introduced to detect and avoid incidents. The Federal Office for Radiation Protection collects the incidents in a register [26] and makes them available to the public in anonymous form via a central platform.

It should be noted in particular that there is a reporting obligation only in the case of unintentional over-exposure. For example, there are frequent inquiries as to whether CT brain perfusions with protocols of CTDI<sub>vol</sub> values of 200 to 300 mGy are reportable. As these dosages are known before the start of the examination, there is no unintentional over-exposure and therefore no reporting obligation.

Other criteria for reporting significant occurrences are:

Any repetition of an application, in particular due to a confusion of body parts, an adjustment error or a previous equipment defect, if the criterion of the individual approach is fulfilled for the resulting additional exposure.

Any confusion of persons, if the criterion of the individual approach is fulfilled for the resulting additional exposure.

Any occurrence of a deterministic effect that could not be expected for the specified examination.

This implementation in Germany of Art. 63 EU BSS is only one of many possibilities within the EU member states, as the EU directive in Art. 4 (99) uses a very “soft” definition:

*“unintended exposure” means medical exposure that is significantly different from the medical exposure intended for a given purpose.*

The European Society of Radiology (ESR) has published a white paper on this subject [27], in which both the results of a survey within the national ESR member societies and recommendations for the implementation of Article 63 EU BSS are provided. The ESR recommends that reporting criteria be based on physical exposure parameters, which are output by the X-ray modalities in the form of DICOM dose parameters, e. g. CTDI<sub>vol</sub>, DLP, AGD, DAP. In practice, indications of the effective dose or pure text formulations are of little use. The survey showed that in mid-2018 only about 50 % of the countries had made a more precise definition of “unintended exposures” and clarified the reporting criteria.

► **Table 3** shows the implementation of the reporting criteria for Ireland [28], Great Britain [29], Spain [30], Belgium [31], Switzerland [32] and Austria [33]. With the exception of Germany, the other countries use effective doses or purely text-based criteria, and are therefore not suitable for the direct use of physical exposure parameters. The use of purely text-based criteria may be based on a lack of transposition of the EU BSS into a sub-legislative set of rules of the member states, but is thus in breach of the deadline for implementation in national law. Implementations

► **Table 3** Reporting criteria for unintended (over) exposures for other European countries.**Ireland: MERU [26]****Exposure much greater than intended, for example:**

- Diagnostic overexposure (including nuclear medicine) of an adult as a result of more than twice the exposure intended (\* see example below) that leads to an overexposure of > 10 mSv or 20 times the dose intended, regardless of the dose level.
- Diagnostic overexposure (including nuclear medicine) of a child as a result of more than twice the exposure intended that leads to an overexposure of > 3 mSv or 15 times the dose intended, regardless of the dose level.
- Deterministic effects produced as a result of interventional radiology.
- Dose given to carers without consent that is greater than medical council directives of 3 mSv, and 15 mSv for adults 60 years or over.

**Exposure where none intended, for example:**

- Dose to the breastfed child over 1 mSv.
- Inadvertent dose to foetus over 1 mSv.
- Incorrect patient (radiology, nuclear medicine or radiotherapy) exposed to over 1 mSv.

**United Kingdom: IR(ME)R [27]**

Incident: notification codes, categories and criteria. Unintended exposure:

All radiology modalities including nuclear medicine and radiotherapy CT imaging

	<b>Dose of Procedure</b>	<b>Reporting Criteria</b>
2.1	Intended dose less than 0.3 mSv	3 mSv or above (adult) 1 mSv or above (child)
2.2	Intended dose between 0.3 mSv and 2.5 mSv	10 or more times than intended
2.3	Intended dose between 2.5 mSv and 10 mSv	25 mSv or above
2.4	Intended dose more than 10 mSv	2.5 or more times than intended
3	Interventional/cardiology	Where there has been NO procedural failure AND 10 or more times the Local Diagnostic Reference Level AND/OR observable deterministic effects excluding transient Erythema
5	Foetal	All modalities where there has been a failure in the procedure for making pregnancy enquiries AND the resultant foetal dose is 1 mGy or more

**Spain: [28]**

Royal Decree published on 31 October 2017 (Art.14)

- A system for the registry and analysis
- A procedures to inform the prescriber, the practitioner and the patient involved
- A declaration to the Health authority

**Belgium: [29]**

FANC

Dose estimation by a recognized medical radiation physicist for:

- Clinically significant accidental or unintended exposure
- Accidental or unintended exposure of a minor or an unborn child when expected dose > 1 mSv

**Switzerland: [30]**

Notification of the Federal Health Office (BAG)

He or she must report the following medical radiation incidents to the supervisory authority within 30 days:

- Unforeseen exposures which have caused or could have caused moderate organ damage, moderate functional impairment or more serious damage to the patient;
- Patient or organ mix-ups during therapeutic exposures or during diagnostic exposures in the high-dose range;
- Unforeseen exposures where the patient has received an effective dose of more than 100 mSv.

**Austria: [31]**

Section 16 (2): An appropriate system, commensurate with the radiological risk of medical radiological procedures, shall be used to record and analyze events involving actual or potential accidental medical exposure or unintentional exposure.

using effective doses are problematic, since they require the operator to convert the physical exposure parameters into effective doses on the basis of tables or calculation rules and thus represent a much more complex procedure that is not recommended by the essential safety requirements [27].

## Personal life-long radiation protection registry number

According to Section 173 of the Radiation Protection Ordinance and Section 170 of the Radiation Protection Law, the Federal Office for Radiation Protection assigns unique, personal, life-long radiation protection registry numbers for monitored persons. These are to replace the previous radiation passport numbers by June 30, 2019 and in the future improve the allocation of individual dose values from occupational radiation exposure, so that if this deadline is missed, it is recommended to contact the competent supervisory authority or the Federal Office for Radiation Protection.

## One device – several radiation protection officers

In recent years, in most German federal states several radiation protection officers have been responsible for an X-ray system, e. g. among attending physicians who use C-arms of a hospital or in a radiological group practice. Every person responsible for radiation protection must report to the competent authority. In individual federal states, such as Bavaria, the use of a device by different and legally-independent users with regard to ensuring radiation protection tasks has so far been regulated by the appointment of radiation protection officers. The new Radiation Protection Ordinance expressly states that independent users of X-ray equipment can contractually regulate among themselves how they manage their responsibility as radiation protection officers with respect to legal and medical authorities. This creates more transparency in how the responsibility for occupationally-exposed persons and patients is regulated in a radiation protection organization.

## Instruction and updates

Furthermore, Section 63 of the Radiation Protection Ordinance requires that the instruction be given orally in a comprehensible form. Alternatively, according to Section 63 (3) of the Radiation Protection Ordinance, after application to the competent authority, the annual instructions may also be offered via e-learning, effective immediately. If this variant is preferred to personal attendance, however, a test must subsequently be passed successfully. In addition, online participants must have the possibility to ask questions on radiation protection topics to persons familiar with the subject. This new type of instruction has the potential to reach a higher percentage of instructed personnel in various areas.

The time frame for updating the knowledge or expertise in radiation protection within 5 years remains unchanged. This period has never been questioned, which is why many occupationally-exposed persons can prepare themselves for the next update courses in which they will be taught the essential updates in radiation protection law.

## Supervision of trainees

The old X-ray Ordinance and former Radiation Protection Ordinance stipulated that trainees and apprentices at training X-ray facilities were only allowed to participate under the direct supervision of the responsible radiation protection officer. Section 82 of the Radiation Protection Ordinance now states that trainees and apprentices may only participate “in the presence and under the supervision of a person who has the required specialized knowledge of radiation protection”. Qualified radiological technical assistants having the requisite specialist knowledge are now allowed to train students at X-ray facilities under their constant supervision.

## Standard operating procedure (SOP)

According to Section 121 (1) of the Radiation Protection Ordinance, starting in 2019, standard operating procedure (SOP) must now be prepared for all procedures. Since 2001/2002, written standard operating procedure (SOP) have been required for frequent examination procedures and reviewed accordingly by the medical authority. The BMU has taken into account the criticism that the use of less common procedures shows weaknesses in quality and reproducibility in the Radiation Protection Ordinance. From 2019 onwards, written standard operating procedure (SOP) must be drawn up for all examination procedures, i. e. also for procedures that are performed less frequently than weekly. This document can describe, among other things, how the radiation exposure of the persons examined is recorded electronically, since sole documentation on paper is probably no longer permissible. The dose values, such as DAP, dose length product (DLP), CTDIvol, Average Glandular Dose (AGD) must be digitally transferred to a Radiology Information System (RIS) or Picture and Archiving System (PACS) for archiving and evaluation. Written standard operating procedure (SOP) for infrequently performed applications particularly prevent application errors outside of normal routine tasks; they are also helpful tools, e. g. when training new employees.

## X-ray pass

The regulation on the X-ray pass (Section 28 para. 2 of the X-ray Ordinance) no longer applies, i. e. the X-ray pass need no longer be actively offered to the patient. However, the Federal Office for Radiation Protection recommends continuing to offer patients an X-ray passport until new documentation systems are implemented.



## Summary

The requirements of the EU BSS were implemented in German law by the new radiation protection regulations. The fundamental regulations of the X-ray Ordinance and the old Radiation Protection Ordinance were largely adopted. However, there are a number of changes and also new requirements that must be observed and implemented. Since all new regulations are no longer to be found only in one ordinance, knowledge of both the Radiation Protection Law as well as the Radiation Protection Ordinance is necessary. Important points for radiology are listed below.

- Role of the medical physicist
- Teleradiology
- Research
- Exposure of carers and comforters
- Dose limits for occupationally-exposed persons
- Individual early detection of diseases of asymptomatic persons
- Documentation requirements
- Reporting criteria for incidents (unintended overexposure)
- Personal life-long radiation protection registry number
- Multiple radiation protection officers for a single X-ray device
- Instruction and updates
- Supervision of trainees
- Standard operating procedure (SOP)
- X-ray pass

In the new Radiation Protection Ordinance many paragraphs begin with the sentence “The person responsible for radiation protection must ensure that...”. The terminology of the new radiation protection regulations has thus also been adapted, and the reader of the Radiation Protection Ordinance is more directly informed about what has to be observed, e. g. regarding the responsibility of the radiation protection officer. This means that employees who use ionizing radiation must observe the radiation protection regulations, even if they are not personally responsible. In the old ordinances, the responsibility of the personnel responsible for radiation protection was summarized in so-called collective paragraphs (e. g. Section 15 of the X-ray Ordinance). The newly-created possibilities for individual early detection of asymptomatic persons have, for example, initiated a test for the early detection of lung cancer. The introduction of notification criteria for unintentional exposures has led to an intensive discussion on the necessity, introduction and functions of dose management systems.

## Conflict of Interest

The authors declare that they have no conflict of interest.

## References

- [1] The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2–4)
- [2] Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. IAEA 2014, ISBN 978-92-0-135310-8
- [3] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. <https://eur-lex.europa.eu/eli/dir/2013/59/oj>
- [4] Torresin A, Evans S, Lizio D et al. Practical recommendations for the application of DE 59/2013. Radiol Med 2019; 124: 721–727. doi:10.1007/s11547-019-01031-x
- [5] The Current Status of Uptake of European BSS Directive (2013/59/Euratom) Requirements – Results of a Pilot Survey in European Radiology Departments with a Focus on Clinical Audit. Insights Imaging 2019; 10: 50. doi:10.1186/s13244-019-0734-6
- [6] Strahlenschutzgesetz (StrlSchG): Bundesgesetzblatt Jahrgang 2017 Teil I Nr. 42, ausgegeben zu Bonn am 3. Juli 2017.
- [7] Strahlenschutzverordnung (StrlSchV): Bundesgesetzblatt Jahrgang 2018 Teil I Nr. 41, ausgegeben zu Bonn am 5. Dezember 2018.
- [8] Wucherer M, Loose R, Hertlein T. Das neue Strahlenschutzrecht ab 2019. Radiopraxis 2019; 12: 67–75
- [9] Walz M, Wucherer M, Loose R. Was bringt die neue Strahlenschutzverordnung? Radiologie 2019; 59: 457–466
- [10] Informationen und Links des BFS (auch zu StrlSchG und StrlSchV). Im Internet (Stand: 11.1.2020): <http://www.bfs.de/DE/themen/ion/anwendung-medizin/forschung/neuregelung-strahlenschutzrecht.html>
- [11] Arbeitsgemeinschaft Physik und Technik in der bildgebenden Diagnostik – Positionspapier zur Umsetzung des Entwurfs der EU-Richtlinie “EURATOM Basic Safety Standards”. Fortschr Röntgenstr 2014; 186: 419–422. doi:10.1055/s-0034-1368939
- [12] 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)
- [13] Dose limits to the lens of the eye: International Basic Safety Standards and related guidance. Ann ICRP 2015; 44 (Suppl. 1): 112–117. doi:10.1177/0146645314562321
- [14] Rehani MM. Eye dose assessment and management: overview. Radiation Protection Dosimetry 2015; 165: 276–278
- [15] Ciraj-Bjelac O, Rehani MM. Eye dosimetry in interventional radiology and cardiology: current challenges and practical considerations. Radiation Protection Dosimetry 2014; 162: 329–337
- [16] Efstathopoulos EP, Pantos I, Andreou M et al. Occupational radiation doses to the extremities and the eyes in interventional radiology and cardiology procedures. British Journal of Radiology 2011; 84: 70–77
- [17] Vano E, Kleiman NJ, Duran A et al. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. J Vasc Interv Radiol 2013; 24: 197–204
- [18] Galster M, Guhl C, Uder M et al. Exposition of the Operator's Eye Lens and Efficacy of Radiation Shielding in Fluoroscopically Guided Interventions. Fortschr Röntgenstr 2013; 185: 474–481
- [19] Einführung von Dosisrichtwerten (Dose Constraints) zum Schutz vor beruflicher Strahlenexposition bei der Umsetzung der Richtlinie 2013/59/Euratom in das deutsche Strahlenschutzrecht, Empfehlung der SSK (2015), BAnz AT 10.08.2015 B3.
- [20] Brix G, Nekolla EA, Griebel J. Früherkennung von Krankheiten mittels radiologischer Bildgebung: Neue Rechtslage und Bewertung von Leistungsangeboten am Beispiel von CT-Untersuchungen. Fortschr Röntgenstr 2020; 192: 139–149
- [21] Allgemeine Verwaltungsvorschrift zur wissenschaftlichen Bewertung von Früherkennungsuntersuchungen zur Ermittlung nicht übertragbarer Krankheiten, (StrlSchGVwV-Früherkennung), BAnz AT 14.12.2018 B6.
- [22] Anforderungen an die Rechtfertigung individueller Früherkennungsuntersuchungen mit ionisierender Strahlung, Empfehlung der SSK, Band 61, (2007), ISBN 987-3-87344-141-5.
- [23] European Commission, Radiation Protection N 185. European Guidelines on Diagnostic Reference Levels for Paediatric Imaging, 2018. Luxembourg; ISBN 978-92-79-89877-8

- [24] Leitfaden des BfS zur Handhabung der DRW in der Röntgendiagnostik vom 15.8.2017. Im Internet (Stand: 11.1.2020): <https://www.bfs.de/SharedDocs/Downloads/BfS/DE/fachinfo/ion/leitfaden-drw-roe.html>
- [25] Schegerer A, Loose R, Heuser LJ et al. DRW für Röntgenanwendungen: Aktualisierung und Handhabung. *Fortschr Röntgenstr* 2019; 191: 739–751
- [26] Melde- und Informationssystem für bedeutsame Vorkommnisse bei Strahlenanwendungen am Menschen. [https://www.bfs.de/DE/themen/ion/anwendung-medizin/bevomed/bevomed\\_node.html](https://www.bfs.de/DE/themen/ion/anwendung-medizin/bevomed/bevomed_node.html); Stand: 11.1.2020
- [27] How to manage accidental and unintended exposure in radiology: an ESR white paper. *Insights into Imaging* 2019; 10: 1–6. doi:10.1186/s13244-019-0691-0
- [28] HIQA Ireland. Statutory notifications for accidental or unintended medical exposures to ionising radiation (2019). Im Internet (Stand: 11.1.2020): <https://www.hiqa.ie/sites/default/files/2019-10/Guidance-notification-of-significant-events.pdf>
- [29] Care Quality Commission, England 2019. Im Internet (Stand: 11.1.2020): <https://www.cqc.org.uk/guidance-providers/ionising-radiation/irmer-incident-notification-codes-categories-criteria>
- [30] Real Decreto 601/2019, de 18 de octubre, sobre justificación y optimización del uso de las radiaciones ionizantes para la protección radiológica de las personas con ocasión de exposiciones médicas. BOE 31 octubre 2019.
- [31] Federal Agency for Nuclear Control (FANC), Inhalt eines “Royal Decree” das wahrscheinlich im März 2020 veröffentlicht wird (private communication).
- [32] Strahlenschutzverordnung vom 26. April 2017 (StSV) 814.501. Im Internet (Stand: 11.1.2020): <https://www.admin.ch/opc/de/official-compilation/2017/4261.pdf>
- [33] Verordnung der Bundesministerin für Gesundheit und Frauen über Maßnahmen zum Schutz von Personen vor Schäden durch Anwendung ionisierender Strahlung im Bereich der Medizin (Medizinische Strahlenschutzverordnung – MedStrSchV) StF: BGBl. II Nr. 375/2017 [CELEX-Nr.: 32013L0059].