

New framework for radiation protection legislation in Germany

by Goli-Schabnam Akbarian*

I. Sources of radiation protection legislation

The entry into force of a new Radiation Protection Act,¹ along with a revised Radiation Protection Ordinance,² on 31 December 2018 marked the start of a new legal regime for radiation protection in Germany. Formerly, radiation protection was primarily regulated through ordinances on the basis of the German Atomic Energy Act,³ namely through the Radiation Protection Ordinance of 20 July 2001 and the X-ray Ordinance in the version promulgated on 30 April 2003. Radiation protection was originally included within the Atomic Energy Act because at the time of the Act's entry into force in 1960, radiation protection was primarily an issue for nuclear industries. For this reason, the Atomic Energy Act authorised the protection of workers and members of the public at an ordinance level, rather than at the act level.

The focus on protection of workers and members of the public was in line with the 1959 Treaty Establishing the European Atomic Energy Community (EAEC Treaty).⁴ According to its Article 2, the "Community shall (...) establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied". According to its Article 30, "Basic standards shall be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionising radiations". "Basic standards" are, according to this Article, "(a) maximum permissible doses compatible with adequate safety; (b) maximum permissible level of exposure and contamination; (c) the fundamental principles governing the health surveillance of workers".

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1. *Gesetz zum Schutz vor der schädlichen Wirkung ionisierender Strahlung (Strahlenschutzgesetz – StrlSchG)* [Act to protect against the harmful effects of ionising radiation (Radiation Protection Act – StrlSchG)] of 27 June 2017, *Bundesgesetzblatt [Federal Law Gazette]* (BGBl.) I, p. 1966.
2. *Verordnung zum Schutz vor der schädlichen Wirkung ionisierender Strahlung (Strahlenschutzverordnung – StrlSchV)* [Ordinance to protect against the harmful effects of ionising radiation (Radiation Protection Ordinance – StrlSchV)] of 29 November 2018, BGBl. I, p. 2034.
3. *Gesetz über die friedliche Verwendung der Kernenergie und den Schutz gegen ihre Gefahren (Atomgesetz)* [Act on the Peaceful Utilisation of Atomic Energy and the Protection against its Hazards (Atomic Energy Act)] of 23 December 1959, as amended and promulgated on 15 July 1985, BGBl. I, p. 1565, as amended.
4. Treaty Establishing the European Atomic Energy Community (1957), 298 UNTS 167, entered into force 1 Jan. 1958 (consolidated version *Official Journal of the European Union* (OJ) C 203 (7 June 2016)).

However, this somewhat narrow understanding has been extended due to case law by the Court of Justice of the European Union (CJEU). In 1991, the European Parliament brought an action for annulment of Council Regulation (Euratom) 3954/87 of 22 December 1987.⁵ The Directive was based on Article 31 of the EAEC Treaty. The European Parliament was of the opinion:

that Article 30 *et seq.* of the EAEC Treaty, on the one hand, do not relate to so-called “secondary” radiation, that is, radiation emanating from contaminated products, but, on the other hand, concern only the protection of persons directly involved in the nuclear industry.⁶

The Court did not follow this restrictive interpretation and responded as follows:

There is no support in the relevant legislation for that restrictive interpretation, which cannot therefore be accepted. The indications are rather that the purpose of the articles referred to is to ensure the consistent and effective protection of the health of the general public against the dangers arising from ionising radiations, whatever their source and whatever the categories of persons exposed to such radiations.⁷

The Court has confirmed its position in the following years by the repeated statement “that the provisions of Chapter 3 of Title II of the EAEC Treaty are to be interpreted broadly in order to give them practical effect”.⁸

In 1997, the Council adopted Directive 97/43/Euratom of 30 June 1997.⁹ The directive addresses medical exposure, an issue that the EAEC Treaty does not mention explicitly. However, given the Court’s broad interpretation cited above, it is clear that the provisions of Directive 97/43/Euratom are considered to be “Basic Standards”.

II. Motivation for a new framework

The opportunity to draw up new legislation was offered by the obligation to implement Council Directive 2013/59/Euratom of 5 December 2013.¹⁰ The Basic Safety Standards Directive addresses the recommendations of the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103¹¹ and formulates them as European legal provisions. The Basic Safety Standards Directive thus follows

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5. Council Regulation (Euratom) 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency, OJ L 371 (30 Dec. 1987), p. 11.
 6. Judgment of 4 October 1991, *Parliament v. Council*, C-70/88, EU:C:1991:373, para. 13.
 7. Judgment of 4 October 1991, *Parliament v. Council*, C-70/88, EU:C:1991:373, para. 14, confirmed by Judgment of 27 October 2009, *ČEZ*, C-115/08, EU:C:2009:660, para. 112.
 8. Judgment of 12 February 2015, *Parliament v Council*, C-48/14, EU:C:2015:91, para. 35; see also Judgment of 10 December 2002, *Commission v Council*, C-29/99, EU:C:2002:734, para. 78, and Judgment of 27 October 2009, *ČEZ*, C115/08, EU:C:2009:660, para. 100.
 9. 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 Jul. 1997), p. 22.
 10. 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, OJ L 13 (17 Jan. 2014) (Basic Safety Standards Directive), p. 1.
 11. Valentin, J. (ed.) (2007), *The 2007 Recommendations of the International Commission on Radiological Protection*, Publication 103, *Annals of the ICRP*, Vol 37, Nos. 2-4, Elsevier.

the approach based on exposure situations introduced in ICRP Publication 103, distinguishing between planned, existing and emergency exposure situations.¹²

In addition to the “classical” area of practices where human activity deliberately leads to exposure (therefore a practice belongs to the category of planned exposure situation), the Basic Safety Standards Directive focuses on situations where the exposure already exists and a decision about its control has to be taken. If immediate action is required, an emergency exposure situation is in place, otherwise it is an existing exposure situation. An example for an existing exposure situation is radon, a radioactive gas that is formed by the radioactive decay of the small amounts of uranium that occur naturally in all rocks and soils and that can accumulate in indoor spaces and in workplaces. Other examples include gamma radiation emitted from building materials or contaminated sites.

In summary, radiation protection concerns far more areas than just nuclear safety or nuclear waste management. Therefore, with the scope of radiation protection legislation steadily growing over the years, and the most recent considerable extension set out in the Basic Safety Standards Directive, a formal legal basis, separate from the Atomic Energy Act, needed to be created. The Radiation Protection Act implements a mandate laid down in the German government’s coalition agreement of the 18th legislative period (2013-2017), which strives to modernise radiation protection legislation and adapt the basic structure of radiological emergency preparedness to tackle accidents at nuclear installations in light of the lessons learnt in Fukushima.

III. Structure and content of the new legislation

1. Radiation Protection Act

The Radiation Protection Act follows the Basic Safety Standards Directive’s approach based on planned, existing and emergency exposure situations. The approach used to date of distinguishing between practices and work activities is discontinued. The Radiation Protection Act contains, *inter alia*, the following provisions:

- general principles of radiation protection (justification, optimisation and dose limitation);
- definitions;
- dose limits for occupational and public exposure;
- reference levels (relevant for existing and emergency exposure situations);
- licensing and registration procedures;
- operational organisation of radiation protection (responsibilities and tasks of the radiation protection executive and radiation protection supervisor);
- provisions on emergency preparedness and response;

12. Cf. Council Directive 2013/59/Euratom of 5 December 2013, para. 7:

The provisions of this Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. Taking into account this new framework, this Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.

By adopting this situation-based approach, the Basic Safety Standards Directive has abandoned the distinction introduced by Directive 96/29/Euratom between practices, work activities – including those involving natural radiation sources – and interventions.

- provisions on indoor exposure to radon and radon in workplaces, on gamma radiation from building materials as well as on contaminated sites.

In contrast to this, the Atomic Energy Act focuses, roughly speaking, on issues concerning:

- nuclear safety;
- practices concerning nuclear fuel, including transport;
- the disposal of radioactive waste;
- liability and financial security.

Some of its provisions continue to apply in the field of radiation protection (see *infra*).

2. Radiation Protection Ordinance

Radiation protection legislation is an area of law that is prone to a high level of detail. The German government's coalition agreement of the current 19th legislative period therefore provides that with a view to improve the protection of health against exposure due to ionising radiation, the details of the Radiation Protection Act have to be specified at the ordinance level. The Radiation Protection Act reflects this in numerous authorisations to issue ordinances. Specific radiation protection requirements are therefore addressed in the new Radiation Protection Ordinance that also entered into force on 31 December 2018. The requirements include, *inter alia*:

- specific requirements on radiological surveillance;
- occupational exposure, including medical monitoring;
- safety and security of radiation sources;
- protection of the public and of the environment;
- exposure of persons for medical and non-medical purposes;
- exemption and clearance levels;
- requirements and conditions for clearance;
- conditions for dose assessment, reporting and information requirements.

3. Connection between radiation protection and atomic energy law

Despite the separation, the Atomic Energy Act remains connected with radiation protection law. First, the clearance levels laid down in the Radiation Protection Ordinance apply to the nuclear energy sector, including the dismantling of nuclear power plants. Also, the exemption levels that determine, *inter alia*, whether a practice involving radioactive substances needs a licence apply in the context of the Atomic Energy Act. Finally, the operator of a nuclear power plant or of a nuclear waste facility or whose practice requires, for other reasons, a licence under the Atomic Energy Act (e.g. transport of nuclear fuel), has to comply with the applicable requirements of the Radiation Protection Act. These include, for example, the provisions on the protection of workers or dose limits for occupational or public exposure.

On the other hand, the Radiation Protection Act stipulates that certain provisions of the Atomic Energy Act remain applicable, since in the past they have proven effective and suitable. These provisions concern the:

- verification of the reliability of individuals to ensure protection against misappropriation or release of radioactive material;

- liability;
- financial security;
- the requirements to subject the use of a licence to certain conditions and government supervision.

IV. Outline of innovations

The following points highlight some of the new features envisaged for each exposure situation.

1. *Planned exposure situations*

As outlined above, planned exposure situations formed the core of German radiation protection legislation in the past. The provisions governing practices under the former Radiation Protection Ordinance and the former X-ray Ordinance correspond largely to the provisions set out in Part 2 of the Radiation Protection Act, subject to amendments due to the requirements under the Basic Safety Standards Directive or due to implementation-related experience.

a. *Impact of altered exemption levels on handling licences*

In accordance with the requirements outlined in Annex VII to the Basic Safety Standards Directive, certain exemption levels have been lowered. However, exemption levels for total activity will remain unchanged. Lowering exemption levels should only minimally effect the issuance of handling licences as they are generally issued in connection with exemption levels for total activity. In spite of this, Section 197(4) of the Radiation Protection Act envisages a transitional provision for practices that previously did not require handling licences, but which now require one due to the lowering of exemption levels. Pursuant to this provision, licence applications must be submitted by 31 December 2019.

b. *Transport of radioactive materials*

In accordance with Article 2 of the Basic Safety Standards Directive, the transport of radioactive material is considered a planned exposure situation. Thus, the articles in the Basic Safety Standards Directive concerning planned exposure situations apply. This includes the provisions on protection against occupational exposure and public exposure.

Many of these provisions were not applicable under former radiation protection legislation, but this was changed under the new Radiation Protection Act. Now any undertaking that needs a transport licence under Section 27 of the Radiation Protection Act must ensure compliance with the protective provisions relevant for transport. This includes fulfilment of the obligation to set up organisational radiation protection requirements and to appoint the appropriate number of radiation protection supervisors with the requisite qualifications in radiation protection (see the licensing requirements in Section 29(1)(3) of the Radiation Protection Act). In the context of transport, the function of the radiation protection supervisor can be assumed by dangerous goods advisers appointed under the Dangerous Goods Transportation Act,¹³ provided they possess the requisite qualifications in radiation protection.

As the possession of the requisite qualifications in radiation protection is a new requirement, the transitional provision in Section 204 of the Radiation Protection Act

13. Gesetz über die Beförderung gefährlicher Güter (Gefahrgutbeförderungsgesetz – GGBefG) [Act on the Transportation of Dangerous Goods (Dangerous Goods Transportation Act – GGBefG)] of 6 August 1975, BGBl. I, p. 2121, as amended.

stipulates that proof of the requisite qualifications in radiation protection is to be provided by 31 December 2021. This is of particular relevance for holders of a transport licence acquired under the former radiation protection law where such a requirement did not exist. Section 204 of the Radiation Protection Act stipulates that a licence for transport granted before 31 December 2018 shall continue to apply as a licence pursuant to Section 29 of the Radiation Protection Act if evidence of the required qualifications in radiation protection is presented to the competent authority before the above-mentioned date.

c. *Dose limits*

Dose limits are determined for occupational exposure and public exposure. Dose limits are not envisaged for medical exposure of patients as exposure is deliberate and directly benefits patients for diagnostic or therapeutic purposes. Limits could reduce the effectiveness of the diagnosis or therapy and thus do more harm than good.¹⁴

▪ aa. *Dose limits for occupational exposure*

Compared to the former radiation protection law, the dose limits for occupational exposure have remained the same (see Sections 77 and 78 of the Radiation Protection Act). Thus, the dose limit for the working life dose of 400 millisieverts (mSv) per calendar year has also been maintained. However, there is one exception: the limit on the equivalent dose for the lens of the eye for individuals subject to occupational exposure has been reduced from 150 mSv per calendar year to 20 mSv per calendar year, thus transposing the provision stipulated in Article 9(3) of the Basic Safety Standards Directive. The decision to lower the dose limit is based on new scientific findings, which were analysed, in particular, by the ICRP.

▪ bb. *Dose limits for public exposure*

For individual members of the public, the limit for the sum of effective doses is 1 mSv per calendar year for exposure from practices requiring registration or licensing and other practices listed under Section 80(1) of the Radiation Protection Act. Under the former radiation protection law, the dose limit of 1 mSv per calendar year was assigned to one practice. This has been changed under the new legislation; the limit value of 1 mSv per calendar year now relates to the sum of the practices listed under Section 80(1) of the Radiation Protection Act. The amended provision serves to implement Article 12(1) and (2) of the Basic Safety Standards Directive.

Ascertaining exposures from the sum of all registered or licensed practices to comply with the dose limit for public exposure may well present a challenge. The German Commission on Radiological Protection has therefore adopted a Recommendation¹⁵ as to how the effective doses of members of the public should be estimated. Furthermore, a future, general administrative provision on further assumptions to be made and on the calculation methods to be applied for the determination of the exposure will give further guidance.

14. Compare Valentin, J. (ed.) (2007), *supra* note 11, number 323.

15. Strahlenschutzkommission [German Commission on Radiological Protection] (2015), *Umsetzung des Dosisgrenzwertes für Einzelpersonen der Bevölkerung für die Summe der Expositionen aus allen zugelassenen Tätigkeiten: Empfehlung der Strahlenschutzkommission* [Implementation of the Dose Limit for Members of the Public for the Sum of Exposures from all Authorised Practices: Recommendation by the German Commission on Radiological Protection], Adopted at the 274th meeting of the German Commission on Radiological Protection on 19 and 20 February 2015, Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.

d. *Dose constraints*

On the basis of ICRP Recommendation 103, the Basic Safety Standards Directive provides for dose constraints. They serve as a tool for optimising a practice. Accordingly, the Basic Safety Standards Directive defines dose constraint as “a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimization for a given radiation source in a planned exposure situation” (Section 4(22) of the Directive). The intention is thus not to exceed this upper bound and to reduce doses to levels as low as reasonably achievable.

Both the Basic Safety Standards Directive and the new German radiation protection legislation do not require the use of dose constraints. Rather, Section 72 of the Radiation Protection Ordinance obliges an undertaking to assess whether dose constraints should be established. In the case of outside workers, an undertaking must perform this assessment in co-operation with the undertaking of the external facility. Section 72 also provides that dose constraints should be set as part of the planning of operational radiation protection, if the activities performed are connected with exposures that require the allocation of the exposed person to category A¹⁶ and the protection measures are not already optimised by other radiation protection planning measures. These provisions are in line with Article 6(1) of the Basic Safety Standards Directive, which requires member states to “ensure that, *where appropriate*, dose constraints are established for the purpose of prospective optimisation of protection [...]” (emphasis added).

In summary, both the European and the German legislator have provided for a smooth introduction of this new optimisation tool. Where radiation protection has been organised in such a way that optimisation is fully in place, the setting of dose constraints may not be needed.

2. *Existing exposure situations*

Prior to the transposition of the Basic Safety Standards Directive, German radiation protection law addressed certain situations that are now categorised as existing exposure situations. Thus, the former Radiation Protection Ordinance set out certain rules for the protection of workers at specified workplaces involving radon, e.g. mines or water procurement facilities. As to the remediation of contaminated sites on the territory of the former German Democratic Republic (GDR), including the decommissioning and remediation of plant facilities and operating establishments for uranium mining, the former radiation protection law of the GDR continued to apply. As to the remediation of other contaminated sites, the Federal Soil Protection Act was applicable.

The following existing exposure situations are regulated in Part 4 of the Radiation Protection Act:

- protection against radon in indoor spaces and workplaces;
- contaminated areas (radioactive contaminated sites and contaminated areas following an emergency);
- protection against radioactivity in building materials; and

16. Category A persons are those who have occupational exposure due to activities that may result in an effective dose of more than 6 mSv or an organ equivalent dose exceeding 15 mSv for the ocular lens or an organ equivalent dose exceeding 150 mSv for local skin, hands, forearms, feet or ankles per calendar year (see Section 71 of the Radiation Protection Ordinance).

- existing exposure situations arising from an emergency and other existing exposure situations (e.g. contaminated goods in supermarkets).
- a. Characteristics

An existing exposure situation differs from a planned exposure situation because it has not been deliberately planned. In a planned exposure situation, exposure is intentionally caused by a practice and the dose received can be calculated in advance. In contrast to this, existing – and emergency – exposure situations are characterised by exposures that have been found and must be dealt with. Such exposures cannot be managed in the same manner as in planned exposure situations. Therefore, the radiation protection principles as well as certain tools used in planned exposure situations do not apply in the same manner in existing exposure situations whose control may – depending on the type and degree of the situation – require more flexible solutions.

The Basic Safety Standards Directive reflects this with regard to the principle of justification and dose limitation by stipulating in Article 5(a) and (c) as follows:

- (a) Justification: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.
- (c) Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.
- b. Reference levels

Instead of dose limits, ICRP Publication 103 has introduced the new instrument of reference levels for existing and emergency exposure situations. Reference levels are an instrument intended to implement the principle of optimisation. A reference level is not a dose limit. A dose limit means a value that shall not be exceeded for an individual. By contrast, a reference level is defined in the first sentence of Section 5(29) of the Radiation Protection Act as “in an existing exposure situation or in an emergency exposure situation, the specified level used as a benchmark to review the appropriateness of measures” (compare this with the definition contained in Article 4(84) of the Basic Safety Standards Directive). This definition reflects the philosophy expressed in ICRP Publication 103, number 228:

The chosen value for a constraint or a reference level will depend upon the circumstances of the exposure under consideration. It must also be realised that neither dose and risk constraints nor reference levels represent a demarcation between “safe” and “dangerous” or reflect a step change in the associated health risk for individuals.

- c. Radon

The purpose of a reference level is demonstrated very clearly with regard to radon. Section 124(1) of the Radiation Protection Act specifies a reference level for indoor annual radon concentration in air of 300 becquerel per cubic metre. The same reference level is specified in Section 126 for annual radon activity concentration in air in workplaces. Both reference levels serve to implement the corresponding provisions set out in Article 54(1) and Article 74(1) of the Basic Safety Standards Directive.

The reference levels are of relevance for the identification of areas with increased radon potential. According to Section 121(1) of the Radiation Protection Act, the

competent authority is obliged to identify areas in which it is expected that the average annual radon activity concentration in the air will exceed the above-mentioned reference levels in a significant number of buildings with indoor spaces or workplaces. These areas must be identified before 31 December 2020.

In radon prone areas, special protective measures have to be taken in order to prevent or significantly impede the entry of radon in new buildings. These measures include, e.g. the use of diffusion-resistant, convection inhibiting materials or constructions. The measures are not mandatory for existing buildings. Rather, for these types of buildings, information and education campaigns aim to induce owners to take protective measures on a voluntary basis. Also in view of this aim, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the competent authorities of the German federal states encourage identification of indoor spaces in which reference levels are exceeded and recommend technical or other means to reduce radon exposure (Section 125(2) of the Radiation Protection Act).

Furthermore, in radon prone areas radon concentrations must be measured in all workplaces located on the ground floor and basement level of buildings (see Section 127 of the Radiation Protection Act). If the radon activity concentration in the air at a workplace exceeds the reference level pursuant to Section 126 of the Radiation Protection Act, the party responsible for the workplace shall take action without delay to reduce the radon activity concentration in the air.

3. *Emergency exposure situations*

Emergency exposure situations are the third type of exposure situation addressed by the Basic Safety Standards Directive and transposed in Part 3 of the Radiation Protection Act. Article 97 of the Directive obliges member states to establish an emergency management system that ensures emergency preparedness and emergency response. This obligation is taken into account in the Radiation Protection Act essentially by means of the three elements outlined below.

▪ a. *Emergency plans*

In the framework of emergency preparedness, the federal government and the federal states shall prepare emergency response plans outlining the planned adequate responses in the event of an emergency on the basis of specific reference scenarios (Sections 97 to 100 of the Radiation Protection Act). The federal government shall prepare a general emergency response plan that will be supplemented with special ministry-specific emergency response plans. The federal states shall also prepare general and special emergency response plans that will supplement the general and special emergency response plans of the federal government.

▪ b. *Interlinking approach*

The authorities that, within their area of responsibility, perform emergency response tasks in the course of their everyday business in the implementation of federal laws also retain this responsibility and competence in the case of radiological emergencies. Those authorities will additionally apply the emergency response plans and the ordinances prescribed in Sections 94 to 96 of the Radiation Protection Act. For such decisions, emergency response plans are to be observed, as well as the radiological situation, and account taken of other relevant circumstances of the respective emergency.

▪ c. *Radiological situation report / federal radiological situation centre*

For supra-regional and regional emergencies, it is important for all authorities to have a uniform radiological situation report for the evaluation of radiological situations (Section 108 of the Radiation Protection Act). For supra-regional emergencies, the

radiological situation report shall be drawn up by the radiological situation centre to be set up by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. For regional emergencies, the radiological situation report shall generally be drawn up by the federal state concerned. The other tasks performed by the radiological situation centre are listed under Section 106 of the Radiation Protection Act.

V. Conclusion

This study provides an overview of selected topics addressed in the new radiation protection law. German radiation protection legislation has now been given its own comprehensive, formal foundation, thus confirming the importance of this area of law.