



Opinion of the German-Swiss Association for Radiation Protection e.V. with regard to the implementation of the Directive 2013/59/Euratom

(Prepared by the FS Working Groups Training, Disposal, Natural Radiation and Legal Affairs, confirmed by the Executive Board in October 2014)

Translated by B. Lorenz, AKR, June 2015

The European Council adopted the new Euratom Radiation Protection Basic Safety Standards (BSS EU) on 5th December 2013 and published on 17.01.2014 the Directive 2013/59 /Euratom in the Official Journal of the European Union [1]. The directive forms a solid pillar for radiation protection in Europe and aims to, jointly and fundamental, further develop radiation protection according to the state of science and technology and aims to harmonize it within the European countries. All EU regulations on radiation protection are summarized in the Directive 2013/59/Euratom (Euratom Directive). The Directive unites five existing and relevant radiation protection guidelines: the previous Radiation Protection Basic Safety Standards [2], the Patient Directive [3], the Directive on the protection of outside workers [4], the Directive on informing the general public about a radiological emergency [5] and the Directive on the control of high-activity sealed radioactive sources and orphan sources [6]. Additionally is the Commission's recommendation to radon in buildings in the new directive integrated [7]. Until 8th February 2018, the Member States have to transpose these standards into national law and develop the national framework effectively. In Germany, the Federal Ministry of Environment, Nature Conservation, Nuclear Safety and Construction is responsible for that. (BMUB).

The Euratom Directive covers - as described in Article 2 "Scope" paragraph 1 and 2 - all artificial and natural sources of radiation. It takes into account all exposure situations, i.e. any planned, existing as well as any emergency exposure and integrates the protection of workers, of the public, of patients and of the environment. The implementation of the Euratom Directive is therefore of central importance for radiation protection and for the use of radiation.

The German-Swiss Association for Radiation Protection (FS) unites experience and technical knowledge in all areas relevant for radiation protection. The association is independent and not committed to economic or political interests. In addition, the FS is as member of the IRPA (International Radiation Protection Association) embedded in an international network, in particular with the European partner associations. Through its 14 Working Groups, the association represents a practical radiation protection and has specialist expertise on radiation protection in all applications of ionizing and non-ionizing radiation in medicine, research and technology. Our goal is a practical radiation protection based on the current state of science and technology in the public interest and the interest of public health [8].

It is a principal objective of the Association for Radiation Protection to elaborate statements on topical issues professionally and also advise and have an influence on the implementation of the Euratom Directive in Germany. Even before the adoption of the Euratom Basic Safety Standards, it was the topical issue of the annual meeting of the FS [9].

After general considerations, the present document reviews

- the emphasis on the optimization principle by introducing dose constraints (Chapter III, Section 1, Articles 6 and 7 of the Euratom Directive)
- clearance procedures including the formal equality of clearance and exemption values (Chapter V Section 2 Article 30 and Annex VII of the Euratom Directive)
- the introduction of radiation protection experts besides radiation protection officers (Article 84 of the Euratom Directive),
- equality of work in the NORM industry with activities of the deliberate application of radioactive substances (Article 23, 66 and Annex VII of the Euratom Directive) and
- regulations on radon indoor and at workplaces (Article 54, 74 and 103 Euratom Directive).

1. General Considerations

1.1 *Preserving things that are proven*

The German radiation protection rules, formulated in particular in the Atomic Energy Act [10], in the German Radiation Protection Ordinance (StrlSchV) [11] and in the X-ray Ordinance [12], have been grown and refined over decades. They are a fact of life and known to those who need to follow them. The Directive 2013/59/Euratom [1] is based on the one hand on the previous Basic Safety Standards (Directive 96/29/Euratom [2]) and the other hand on the basic recommendations of the ICRP (International Commission on Radiological Protection) on radiation protection of 2007 [13]. The ICRP emphasizes here in particular the principle of "continuity and stability". As a guideline for the implementation of the European Directive into the German radiation protection law, therefore, the FS recommends also, that proven rules are preserved and changes should be made only where there is a need for improvements.

Arrangements, which have been proven by the German Radiation Protection Ordinance and should be maintained, are for example:

- dose constraints for medical applications (Article 6 of the Euratom Directive)
- arrangements for the clearance of radioactive residues
- set up the organization with radiation protection supervisor and radiation protection officer
- limit of 0.3 mSv/a for discharges through the water or air path in accordance with § 47 StrlSchV.

1.2 *Discretionary clause*

The new Euratom Directive contains a number of "discretionary clauses", often described with the words "as appropriate" and ultimately represent the result of a compromise. This concerns for example the following Articles:

- In accordance with Chapter III, Section 1, Article 6 dose constraints will be established, where appropriate, for the purpose of prospective optimization radiation protection for occupational exposure, public exposure and medical exposure.
- According to Chapter VIII, Section 1, Article 65 (2) the competent authority shall establish, where appropriate, authorised limits as part of the discharge authorisation.

- According to Chapter VIII, Article 74 (2) Member States shall promote action to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourage, where appropriate by technical or other means, radon concentration-reducing measures in these dwellings.

This approach opens up in the practical implementation of the directive discretion, which can be advantageous because it gives the possibility of maintaining proven regulations in Germany (see 1.1).

On the other hand, from the "discretionary clauses" also unnecessary restrictions may result which may hinder or impede the processes and are not in line with a safe and practicable radiation protection.

1.3 New terminology only when there are really new facts

The German version of the Euratom Directive contains terms that are not yet to find in the German law. This concerns, for example, the radiation protection expert and the organ equivalent dose. Especially the various equivalent doses and organ doses often lead to confusion, so that the FS recommends here, to follow the new DIN 6814-3 with regard to the terminology.

For the implementation of the directive, it is helpful for users when they can come back to the use the hitherto customary terminology. Here, however, the goal of European harmonization in radiation protection must not be lost. Considering this aspect, the introduction of new terminology is inevitable and a case by case weighting process will show, whether the benefits by the user to keep the usual terminology are not detrimental to the purpose of harmonization.

For newly installed terms, we would recommend to check if this term is already in use in other, related jurisdictions, such as the transport regulations and their future use in radiation protection could give rise to confusion (e.g. package design approval).

2. Tools for optimization

Chapter III, Section 1 includes in Articles 6 and 7 "tools for optimization" in radiation protection.

2.1 Optimization instead minimization

In principle, optimization is an important tool in radiation protection and is required, for example, since 1994 by the Swiss Radiation Protection Ordinance. In Germany, this is known so far also under the somewhat misleading minimization rule. This means a minimization of the total dose, without impairing the benefits of the application (for example, in medicine) unduly.

The FS supports the introduction of the term optimization. Moreover, it is advantageous, as in the directive included, to optimize exclusively doses. The previous German rules to minimize contamination and to dose reduction, also based on the latest state of science and technology, leading to far in the radiation protection practice. For instance, meanwhile demands are known which have only been caused by the fact that measurement devices are now able to detect extremely low contaminations.

2.2 Using dose constraints moderate and reasonable

In accordance with Article 6, dose constraints shall be established, where appropriate, for the purpose of prospective optimization of radiation protection for occupational exposures, public

exposure and medical exposure. The dose constraints are as effective doses or organ equivalent doses set for a reasonable time period. In Article 7 reference values are required for emergency exposures and existing radiation exposure, whereas the choice of the reference values in addition to the requirements for radiation protection takes into account also social criteria. In addition, reference values for existing Radon exposure for the population and workers are set. The wording of Articles 6 (1) and 7 (2) gives a lot of freedom for implementation.

Previously, dose reference values ("dose constraints") were a discretionary provision in the Euratom Directive.

Dose constraints and diagnostic reference values for medical exposure of patients are a common practice in Germany and laid down in the corresponding guidelines for radiation applications in medicine. In medicine, these values have an important radiation protection function as "best practice".

In addition, internal dose thresholds or dose reference values are suitable in occupational radiation protection just as an expression of "best practice" and they are used in nuclear facilities, in research and in the industry. Establishing and monitoring compliance with internal dose reference levels are the responsibility of the Radiation Protection Officer. So internal reference values are already part of the current practice of controlling occupational exposures.

In our view, the current system is in practice both in research and technology as well as in medicine understood and accepted. We see no need for a change here.

We propose to refrain from a further determination of dose reference values (dose constraints) in the Radiation Protection Ordinance, because otherwise it is possible, that the ALARA principle may partially become terminated. People might think that when the dose level of the dose constraints is reached no further optimization would be needed; believing that below the dose constraint, anything is o.k.

2.3 § 47 StrlSchV has proven (Article 67 Euratom)

Discharges of radioactive substances from plants or facilities on the water or air path are a commonly cited example, when talking about dose constraints.

In the Euratom Directive, releases are dealt with in Chapter III "public exposures", Section 1, Article 65 and 68. Under Article 65 (2), the competent authority, where appropriate, establish authorised limits as part of the discharge authorisation that take into account the results of the optimisation of radiation protection and reflect good practice in the operation of similar facilities. An additional limit for radioactive discharges through the water and air path is not specified in the Euratom Directive.

In Germany and in Switzerland discharges are already subject to a limit of 0.3 mSv/a. This limit is established, proven and pursued from the outset the aim that also underlies the idea of the dose constraints. In addition, the limit has provided an enormous legal certainty in licensing procedures based on the Atomic Energy Act. This might be challenged by a downgrade to a dose constraint level. Therefore, there is no reason to move from that limit to a dose constraint.

3. Exemption values and clearance levels

3.1 Content of the Euratom Directive

Chapter V of the Euratom directive regulates in Section 2, Article 30 "Release from

regulatory control". Under Article 30 (2) materials for disposal, recycling or reuse may be released from regulatory control, provided that the activity concentrations for solid material do not exceed the clearance levels set out in Table A of Annex VII or comply with specific clearance levels, which are determined by the national authority. The general exemption and clearance criteria set out in Annex VII, paragraph 3 need to be followed.

Annex VII, Table A Part 1 contains nuclide specific clearance levels of activity concentration (in kBq/kg) for any types of waste and any amounts that may serve as default values.

Annex VII paragraph 3 contains the general exemption and clearance criteria and allows for the exemption of small quantities with activity concentrations in kBq/kg in accordance with Annex VII Table B, column 2. (The clearance values in Annex VII Table A Part 1 for any amounts are in any case lower or equal to the exemption values in Table B).

Example:

For Co-60, the clearance level and the exemption value for any amount and any type of waste is 0.1 kBq/kg in accordance with Annex VII, Table A Part 1.

For small amounts (small usually means < 1 t) the exemption value is 10 kBq/kg according to Annex VII Table B, column 2.

Annex VII paragraph 3 e) regulates in particular the cases in which the amounts of radioactive substances or the activity concentrations do not meet the conditions laid down in Tables A and B. In those cases a review of the clearance can be carried out, whereby for artificial radionuclides the effective dose for a person of the public shall be in the range of 10 μ Sv per year (known as 10- μ Sv-concept). For natural radionuclides, this figure is at 1 mSv.

3.2. Current situation in Germany (§ 29 StrlSchV)

Since many years in Germany there is the possibility of unrestricted clearance but also the conditional clearance acc. § 29 StrlSchV. The corresponding nuclide specific clearance values are laid down in Appendix III, Table 1 StrlSchV. The unrestricted clearance includes substances generally, demolition waste and excavated soil with an expected mass of more than 1000 Mg/a, land areas and buildings for re-use and further use. The conditional clearance regards solid substances to be disposed of on landfills with an expected mass of less than 100 Mg/a or more than 100 Mg/a, substances to be disposed of in an incineration plant with an expected mass of less than 100 Mg/a or more than 100 Mg/a, buildings for demolition and metal debris for recycling. Basis for this approach is the 10- μ Sv-concept.

3.3 Opinion of the FS regarding clearance

Since many years in Germany, there is the possibility of the unrestricted clearance, but there are also clearance scenarios under conditions, which are determined for disposal in a landfill or in an incinerator, for buildings for demolition and for melting metals. The protection aim of these conditions is a clearance, which clearly and primarily protects the public and allows at the same time an optimized waste management. It is currently regulated that clearance levels, including those for conditional clearance, do not exceed the exemption values.

The new Euratom Directive now includes clearance levels which can serve as default values

(amounts > 1 Mg) for materials for any amount and any type and which as new exemption values may be significantly lower than the current clearance values.

As part of a meaningful reduction in waste volumes, however, special clearance levels also above these exemption values can be an important tool for handling large quantities of substances to be disposed of, as long as the 10- μ Sv-concept is fulfilled.

Therefore, the previous German clearance practice should not be changed. Because the decisive criterion remains the 10- μ Sv-concept, regardless of whether it is an exemption value or a clearance level. The Euratom Directive particular allows in Annex VII, Section 3 e) national regulations on different clearance paths. Therefore, the proven practice in Germany should, in accordance with the regulations of the new Euratom Directive, remain in any case.

4. Radiation protection officer (RPO) and radiation protection experts

4.1 Radiation protection experts and radiation protection officers according to the Euratom Directive

In Chapter IX, Section 1 "Institutional Infrastructure", Article 82 of the Euratom directive defines the function and tasks of a radiation protection expert, which in accordance with Article 82 (1) ", gives competent advice to the undertaking on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure." Article 82 (2) describes the scope of the consultation.

Article 84 (1) of the directive stipulates to designate a radiation protection officer (RPO) in the undertaking who reports directly to the undertaking. Article 84 (3) involves the relationship between RPO and Radiation protection expert: The tasks of the RPO may be carried out by a radiation protection unit or a radiation protection expert.

4.2 Radiation protection officers (RPO) are the backbone of radiation protection

The German radiation protection law lays the responsibility for radiation protection in the hands of the radiation protection supervisor and provides for a qualified radiation protection officer (RPO) for his assistance. The Directive 2013/59/Euratom defines now two radiation protection professionals: the "Radiation Protection Expert" and the "Radiation Protection Officer". The description of job profiles is unfortunately overlapping. In practice, this must not result in a conflict potential. The German provisions for the RPO, who has besides responsibilities and duties also competencies and rights to instruct, have proved effective. The RPOs have a significant share of the current high level of radiation protection in Germany.

From the perspective of the FS, the introduction of radiation protection experts should be possible without fundamentally changing the existing and proven model, consisting of radiation protection supervisor and RPO.

The Euratom Directive does not specify whether the radiation protection expert is an external consultant or an internal employee, who performs the advisory function and is designated specifically. Thus, the undertaking has the possibility of using an outside consultant on an individual basis for selected activities. Such procedures can be quite advantageous from the perspective of the FS, as at timely limited elevated workload, the work can be done by external radiation protection experts and tasks can be done with the necessary care in time.

The performance of experts according StrlSchV (e.g. for leak tests) or according X-ray Ordinance (approval of X-ray equipment) remains unaffected.

5. Integration of natural sources of radiation

With the new Euratom Directive, protection against natural radiation sources is completely integrated in the general requirements of radiation protection. Industries, in which materials are processed, which contain naturally occurring radionuclides to an extent, that on the grounds of the radiation protection cannot be disregarded (NORM industries), will be treated as other activities. This means, inter alia,

1. Activities associated with naturally occurring radioactive material and which lead to relevant exposures of workers or members of the public, have to be identified by the Member States (Article 23). For the assessment of national conditions the listed industries in Annex VI have to be considered. The experience since 2001 shows that a final defining of "relevant" industries (also in view of constant changes in the economy) is not very practical. The "capture" of special cases, such as currently regulated in § 102 StrlSchV, leads to a series of problems, because very different interpretations of this provision are practiced in the Federal States of Germany. The FS therefore advocates a regulation which is primarily oriented to the radioactivity of materials and takes into account the limited exposure of small amounts (mass range kg up to a few tons) appropriately.
2. The exemption values / clearance levels in accordance with Annex VII Table A Part 2 EU BSS for naturally occurring radionuclides, which are given for all the radionuclides of the decay chains of U-238 and Th-232 with 1 Bq/g, are not compatible with the currently models used in Germany for dose determination (BglBb). The FS points out that it may be in conflict with the law enforcement when in Germany lower exemption values will be introduced, as it may also affect the free movement of goods (incl. waste for recycling).
3. By lowering the threshold, at which radiation exposures in workplaces in NORM industries needs to be included in radiation protection, from the current 6 mSv/a to 1 mSv/a, the number of the affected working places will significantly increase. To perform the related authorization and supervision requires appropriate staffing of the competent authorities. This fact should be considered absolutely when implementing the Euratom Directive into national law.
4. The determination of radiation exposures by external employees, who are active in many cases in the NORM industries for maintenance of plants, requires an efficient and appropriate implementation. For this dose values below which the dose can be neglected, could be useful.
5. In the future, the dose limit for members of the public relates to the sum of all authorized activities (Article 66). Thus, in this sum releases of NORM industries need to be included. There is urgent need for the development of calculation methods and, if necessary, for sufficiently long transition periods to avoid restrictive authorizations or refusing authorizations based on over-restrictive dose assessments. Landfill workers and employees in waste management companies, that depose or reuse cleared NORM-substances (current term: "residues"), may receive additional occupational doses up to 1 mSv/a also in the future. Thus, dealing with these exposures requires a new regulation.

6. The principle of "justification", which was not considered previously for NORM industries, applies now also for NORM industries (Article 5). The fundamental decision on unjustified activities is a sovereign task. The practical implementation of the justification principle for concrete activities in the field of NORM industries is still unclear. However, efforts in radiation protection would inappropriately increase when each individual case that is not released from the provisions of radiation protection according to Article 26, requires a case-specific justification.

6. Existing situations: radon exposures

Protection against radon exposure has a high priority in the EU Directive. For the first time mandatory provisions for protection against indoor radon (Article 74) including working places (Article 54), that are not allocated to the NORM area, are demanded from the Member States. In Article 103, a Radon action plan will be demanded from the Member States. Here a partially new terminology (reference value, Article 7) is introduced, which to date the German radiation protection law does not know. And a relative large leeway is given to the Member States in national implementation by using a variety of vague terms (examples: areas with potentially higher radon concentrations in Annex XVIII, point 2 of the Euratom Directive; promoting measures etc. (Article 74 of the Euratom Directive)). These in itself, because of the possibility of acknowledging national specialities, positively assessed margins, however, also carry the risk that they will be transferred - in the sense of a political compromise - into national law.

The FS calls for the clearest possible regulations as unclear regulations ultimately fought out on the back of the concerned and the authorities and, as the case may be, before the courts. The appropriateness of supervision should also be taken into account (see also point NORM), for example by restriction to actually relevant areas.

As regards to the radon problem the FS considers as a problem the dose coefficients for conversion of exposure values (e.g. Bq/m³) in an effective dose (in mSv/a). While Switzerland refers to the new ICRP recommendation 115, in Germany the effective dose conversion factor is still unchanged calculated according to ICRP 65. This leads under the same exposure conditions to different dose values of about the factor 2. Just for a German-Swiss Association we advocate therefore for a uniform approach. Currently, the ICRP is preparing new calculations. The results are to be seen.

7. Final remark

The new Euratom Basic Safety Standards on Radiation Protection were published as Directive 2013/59/Euratom in January 2014 and need to be transformed into national law until 02/2018. The directive aims at harmonizing radiation protection in Europe and will lead to a comprehensive renewal of the German radiation protection ordinance.

The German-Swiss Association on Radiation Protection would like to use its expertise in radiation protection and bring in its manifold practical experience into the process of implementation of the Euratom Directive into national law. Here in this document we comment some issues that in our mind are topical and relevant for radiation protection.

This regards, inter alia, the emphasis on the optimization principle by introducing dose constraints, the principle equality of exemption values and clearance levels, the introduction of radiation protection experts besides the radiation protection officers (Article 84 Euratom Directive), the equality of working in the NORM industries with deliberately working with radioactive substances (Article 23, 66 and Annex VII Euratom Directive) as well as the provisions on Radon indoor or at working places (Article 54, 74 and 103 Euratom Directive).

In summary, we would like to recommend the following:

1. Regulations, which have been proven by the German radiation protection ordinance should remain preserved. (Section 1.1)
2. The margin of "discretionary clauses" should be used in the practical implementation to the full extent and unnecessary restrictions should be avoided. (Section 1.2)
3. When introducing new terminology, one should weigh whether the benefits by the user to use the hitherto customary terminology could not be a disadvantage for the purposes of harmonization (e.g. the "radiation protection expert" and the "organ equivalent dose"). (Section 1.3)
4. The term optimization should be applied consistently and optimization should solely be used with regard to dose terms. (Section 2.1)
5. A further provision of dose reference levels ("dose constraints") in the radiation protection ordinance in addition to the previously existing applications (example medicine) is not necessary. (Section 2.2)
6. The previous German clearance practice should be continued. (Section 3)
7. The radiation protection expert should be introduced as an external or internal consultant, without fundamentally changing the existing and proven model in Germany, consisting of radiation protection supervisor and the radiation protection officer. (Section 4)
8. For naturally occurring radioactive materials (NORM industry) a final definition of the "relevant" industries should be avoided. Instead, there should be a regulation that is primarily oriented to the radioactivity of substances and takes into account the limited exposure from small amounts (mass range kg up to a few tons). (Section 5)
9. Regarding the radon problem (calculation of the dose coefficients), a uniform approach should be realized in Europe and Switzerland, and the results of the new calculations by ICRP should be waited for. (Section 6)

Literature

[1] 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 to repealing Directives 89/618/, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union no. L 13/1 from 17/01/2014

[2] Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, Official Journal of the European Union no. L 159, 06.29.1996

[3] Directive 97/43/Euratom of 30 June 1997 on health protection of individuals from the dangers of ionizing radiation in relation to medical exposure, Official Journal of the European Union No. L 180, 09.07.1997

[4] Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas, Official Journal of the European Union no. L 349, 13.12.1990

[5] Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, Official Journal of the European Union no. L 357, 07.12.1989

[6] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources, Official Journal of the European Union no. L 346/26, 31.12.2003

[7] Commission Recommendation 90/143/Euratom of 21 February 1990 on protection of members of the public against indoor exposure to radon, Official Journal of the European Union no. L 80 from 27.03.1990

[8] <https://www.fs-ev.org>

[9] European Radiation Protection in the Essen practice test, 45th Annual Meeting of the German-Swiss Association for Radiation Protection and the Austrian Association for Radiation Protection, 24th to 26 September 2013 Essen, ISSN 1013-4506, TÜV Media GmbH

[10] Act on the Peaceful Utilization of Atomic Energy and the Protection against its Hazards (Atomic Energy Act – AtG) of 15 July 1985 (Federal Law Gazette I p 1565), as amended by Article 5 of the Law of 28 August 2013 (I, p. 3313)

[11] Ordinance on the protection against damage and injuries by ionizing radiation (Radiation Protection Ordinance - StrlSchV) of 20 July 2001 (Federal Law Gazette I p 1714; 2002 I, p 1459), as amended by Article 5, paragraph 7 of the Law of 24 February 2012 (Federal Law Gazette I, p. 212)

[12] Ordinance on the protection against damage and injuries caused by X-rays (X-ray Ordinance - RöV), 30. April 2003 (Federal Law Gazette I, p. 604), last amended by Article 2 of the Decree of 4 October 2011 (BGBl. I S. 2000)

[13] ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103, Ann. ICRP 37 (2-4)