

THE NEW GERMAN RADIATION PROTECTION ORDINANCE 2001

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On 1 August 2001, the new German Radiation Protection Ordinance entered into force,¹ thereby replacing the former Ordinance of the same name (see *Nuclear Law Bulletin* Nos. 16, 18, 19, 28, 44, 52 and 59). Implementing two new Council Directives – the Euratom Basic Safety Standards² and Directive 97/43/Euratom on health protection of individuals in relation to medical exposure³ (see *Nuclear Law Bulletin* No. 60), and taking into account new scientific developments, the new Ordinance provides a comprehensive basis for the protection of man and the environment.

Under German law, the legal basis for radiation protection is the 1959 Atomic Energy Act (the consolidated text of this Act including amendments up to 1985 was published in the Supplement to *Nuclear Law Bulletin* No. 36). This Act governs the two comprehensive ordinances covering radiation protection: the 1989 Radiation Protection Ordinance and the 1987 X-ray Ordinance (see *Nuclear Law Bulletin* Nos. 39, 47 and 59). Both ordinances had to be revised in order to harmonise them with the new Euratom directives. The revision of the X-ray Ordinance is expected to be accomplished in early 2002, and only then will the implementation of the said Euratom directives be complete.

To permit full implementation of the European requirements, the main legal basis for the Ordinance, the Atomic Energy Act, had to be amended.⁴ Compared to the Radiation Protection Ordinance of 1989, the new Ordinance has been completely re-structured to enhance its clarity and implementation. It is still, however, a very complex, technical piece of legislation, comprising

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1. Full title: Ordinance for the Implementation of Euratom Directives on Radiation Protection of 20 July 2001, published in *Bundesgesetzblatt* 2001 part I p. 1714; text also available on www.bmu.de.
2. Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, OJ L159 of 29.06.1996 page 1.
3. Council Directive 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 L180 of 09.07.1997 page 22.
4. Amendment of 3 May 2000, *Bundesgesetzblatt* part I, p. 636, corr. p. 1350.

118 provisions and 14 annexes. As a result of this new Ordinance, a whole range of other ordinances needs to be harmonised with the new radiation protection provisions.⁵

Due to the scientific and legal complexity of the underlying questions, it took five years to revise the Ordinance. Thus, the European deadline for implementation of the directives was – as in other Member states of the European Union – not met. During the negotiating process, however, a sound basis for a comprehensive revision of the Ordinance was formed. The German Radiation Protection Commission discussed the draft Ordinance and issued two recommendations which were taken into account during drafting of the Ordinance. As Germany is a federal State, the constituencies (*Länder*) took part in the discussion from the very beginning. Moreover, opinions of other Federal ministries concerned had to be taken into account, and trade unions, other institutions, scientists and individuals competent in the field of radiation protection were heard. Not only scientific and technical aspects of radiation protection were taken into account but also pragmatic approaches, legal issues and the experience of the constituencies in implementing radiation protection legislation.

Structure of the 2001 Ordinance

Part 1 – General provisions – states the objective of the Ordinance, defines its scope and contains a rather detailed provision on definitions. The objective of the Ordinance is the protection of man and – as it is explicitly mentioned – the environment, against the negative effects of ionising radiation.

Part 2 deals with the protection of man and the environment against radioactive substances or ionising radiation resulting from goal oriented uses in connection with practices.⁶ Its provisions are applicable to the use of ionising radiation emanating from artificial sources.

Part 3 – Protection of man and the environment against ionising radiation emanating from natural sources – covers certain types of work activities⁷ involving the presence of natural radiation sources leading to non-negligible exposure, such as spas, mines or aircraft operation. This inclusion of natural radiation sources follows the European model; it is without precedent in former German ordinances.

Part 4 deals with the protection of consumers in connection with the addition of radioactive substances to products, and Part 5 contains joint provisions applicable to all parts of the Ordinance such as transitional and final provisions, administrative fees.

Protection of man and the environment with regard to practices

The provisions in Part 2 of the Ordinance apply to “practices”, *i.e.* human activities that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties.

5. See under Chapter “National Legislative and Regulatory Developments” of this *Bulletin*.

6. This term builds on the definition of “practice” in the Euratom Basic Safety Standards: A human activity that can increase the exposure of individuals to radiation from an artificial source, or from a natural radiation source where natural radionuclides are processed for their radioactive, fissile or fertile properties, except in the case of an emergency exposure.

7. Cf. Article 40, para. 1, Euratom Basic Safety Standards.

General principles of radiation protection

To underline their importance, the fundamental principles of radiation protection are enumerated in the first chapter of Part 2 of the Ordinance, following a recent tendency in both national and international law-making to give this section a prominent place in the piece of legislation.

Section 4⁸ – Justification – ensures that new types of practice resulting in exposure to ionising radiation must be justified by their economic, social or other benefits in relation to the health detriment they may cause. Existing types of practice may be reviewed if there is new scientific evidence regarding their consequences. Germany plans to enact a specific ordinance enumerating “unjustified” types of practices where, *e.g.*, the same effect can be achieved without using radioactive substances.

Section 5 – Dose limits – enumerates the dose limits of the Ordinance, drawing specific attention to the dose limits applicable to members of the public and exposed workers.

Section 6 – Dose reduction – makes it compulsory to avoid any unnecessary exposure. Moreover, even if a practice does not exceed the relevant dose limits, exposures have to be kept as low as reasonably achievable in the specific situation.

Licences, Approvals, Clearance

This chapter comprising Sections 7 to 29 is a central piece of the Ordinance. Here, **provisions on licences** for handling, treatment or use of radioactive substances, construction and operation of installations requiring a licence, transportation of radioactive substances or of waste containing nuclear fuel, imports and exports requiring a licence, work at external facilities or installations requiring a licence as well as on the procedure for new type approvals are to be found. These provisions are basically the same as in the old Ordinance. A licence is also required for medical research. In future, the application of radioactive substances or ionising radiation requires a licence issued by the Federal Office for Radiation Protection. An ethics commission is involved in this procedure.

The Euratom Basic Safety Standards (Article 5) provide the basis for comprehensive regulations on how to release radioactive substances from control according to radiation protection legislation (“**clearance**”). Until now, there were only precedents of individual cases at constituency level; they are now substituted by a transparent, legally binding regime at the federal level (Section 29). However, the introduction of such a standardised procedure led to questions from concerned individuals and communities who feared that landfill sites might be flooded with radioactive waste, thus adding a political dimension to the scientific and technical discussion. It was – and still is – difficult to convince people that the new concept provides an environmentally sound and responsible way to deal with the disposal of the substances in question.

Not all radioactive substances may be subjected to clearance; it is imperative that the substances or materials in question have only a negligible level of radioactivity. A clearance procedure is possible for such radioactive substances with negligible radioactivity if they originate:

1. from use, treatment or handling of:
 - a) man-made radioactive substances; or

8. Sections mentioned are those of the Ordinance.

- b) radioactive substances of natural origin whose nuclear properties are used;
- 2 from practices subject to authorisation within the scope of the Atomic Energy Act:
(storage, treatment, processing, and other usage of nuclear fuels, operation, other possession, decommissioning, safe enclosure of a facility and dismantling of a facility or parts of a facility);
or
3. from operation of accelerators.

Of crucial importance is the new definition of “**radioactive substance**” in the Atomic Energy Act (Section 2): Radioactive substances (nuclear fuels and other radioactive substances) within the meaning of this Act are substances that contain one or more radionuclides and whose radioactivity or activity concentration with respect to nuclear energy or radiation cannot be neglected. Whereas the former definition of radioactive substance was based on a physical substance concept, the term is now defined in a legal sense: those radioactive substances that are subject to the Atomic Energy Act’s protection and supervision regime are those which are explicitly regulated by these provisions.

In general, *radioactive substances* within the meaning of the Atomic Energy Act are, thus, substances that contain man-made radionuclides – or radionuclides of natural origin whose nuclear properties are to be used – and whose radioactivity and radioactivity concentration exceed the exemption limits of the Radiation Protection Ordinance; *i.e.* substances whose handling will be subject to authorisation.

The cases in which the activity of radioactive substances “may be neglected” have also been redefined. With respect to clearance, the relevant provision stipulates that the activity of radioactive substances from practices subject to authorisation may be neglected when such substances are below defined clearance levels and have received clearance. After clearance, such substances are no longer radioactive substances within the meaning of the Atomic Energy Act; they fall under relevant specialised law, especially the Closed Substance Cycle and Waste Management Act.⁹

Clearance is issued by an authority, not by a private individual. It is by definition an act of State. It is issued under the prerequisites laid down in the Ordinance which distinguish between (unconditional) clearance and specific clearance, both of which have the effect that the substance in question loses its legal qualification as “radioactive”. Whereas “cleared” substances are subject to no restrictions regarding their future use, application, recycling, re-use or disposal, “specifically cleared” substances may not be recycled or re-used and they have to be disposed of in a landfill or waste incineration plant. The Ordinance contains different prerequisites for different types and paths of clearance (*e.g.* liquid substances, building rubble and excavated soil, sites, etc.).

The clearance levels are defined in such a way that the effective dose for individual members of the population from those substances shall be **of the order of 10 µSv or less** for any member of the public. Thereby, the Ordinance follows the internationally accepted scientific concept that release from control is acceptable if it leads only to a trivial dose. That means radiation exposure shall be of the order of 10 µSv or less in a year for any member of the public and the collective dose for the population shall be less than 1 man-Sv in a year. These criteria are also set forth in Annex I of the Euratom Basic Safety Standards.

9. *Gesetz zur Förderung der Kreislaufwirtschaft und Sicherung der umweltverträglichen Beseitigung von Abfällen (Kreislaufwirtschafts- und Abfallgesetz)* of 27 September 1994, *Bundesgesetzblatt* part I, p. 2705.

To enhance the transparency of the procedure, the Ordinance lays down various documentation and reporting requirements, forbids the intentional dilution or mixing of substances in order to comply with the clearance levels, and obliges the competent authority to follow any hints that the 10 μ Sv concept might be exceeded.

Dose limits for occupationally exposed persons

The most important improvement in order to enhance the protection of occupationally exposed persons is the reduction of the annual effective dose from 50 mSv to 20 mSv (Section 55, para. 1). As before, there are significantly lower limit values for persons under 18 years, who may receive only 1 mSv per year (Section 55, para. 3).

The new Ordinance takes a different approach in the protection of women of childbearing age and pregnant women as well as nursing mothers. According to Section 55, para. 4, the body dose accumulated at the uterus over one month shall not exceed 2 mSv (as compared to 5 mSv in the old Ordinance). This constitutes a precautionary measure in case a pregnancy has not yet been discovered.

Following the Euratom Basic Safety Standards, a dose limit for an unborn child which might be exposed to radiation due to the mother's occupation is established: the foetus may not receive more than 1 mSv from the time pregnancy is determined until birth (Section 55, para. 5). It is a novelty in German radiation protection law that an individual dose limit is fixed for the foetus. This has the effect of ensuring that its direct, immediate protection is now possible whereas before, the unborn child could only be protected via the mother. The old Ordinance achieved adequate protection of the foetus by prohibiting pregnant women from remaining in restricted access areas. This strict prohibition is, legally, the strongest means available to achieve the aim which is the comprehensive protection of the unborn child. It constitutes, at the same time, a strong interference with the mother's right to practice her profession and, therefore, is only justified if it is the best means available to achieve that aim.

A different, more adaptable way to achieve protection is through arrangements of working places in such a way that limit values can be kept safely, as is the general approach for the protection of professionally exposed persons (Section 43, para. 1).

With the foetus having its own dose limit, it is now possible to directly protect the foetus rather than simply via the mother's dose limit. Therefore, it is no longer indispensable to keep pregnant women out of restricted access areas as long as the foetus' dose limit (or, of course, other dose limits such as the uterus dose) is not exceeded. In a given situation, a strict prohibition might not be sufficiently justified any more: According to the new Ordinance, restricted access areas are areas where individuals might receive 6 mSv effective dose per year, whereas the old Directive required 15 mSv per year. Therefore, significantly more work places are now situated in restricted access areas which would add to the severity of the interference with the mother's right to practice her profession as the extension of restricted access areas would limit the range of suitable work places even more – this might be one more reason for employers to prefer male workers.

On the other hand, the foetus can be protected in an equally effective manner without strict denial of access. In addition to its own dose limit, other precautionary measures are prescribed. For example, women have to be informed on possible risks due to radiation (Section 38, para. 3), and they may only work in restricted access areas if the person responsible for radiological protection or the radiological protection officer allows it and guarantees, through adequate measures of supervision which have to be documented, that the relevant dose limits are kept [Section 37, para. 1, No. 2(d)].

Dose limits for members of the public

Following the Euratom Basic Safety Standards, the new Ordinance explicitly lays down 1 mSv p. a. as limit for effective dose through “practices” in a year for members of the public (Section 46, para. 1). This improves the protection of members of the public who, in the past, could be exposed to 1,5 mSv per year. Germany did not make use of the possibility allowed by the Euratom Directive to authorise a higher effective dose in a single year provided that the average over five years does not exceed 1 mSv; 1 mSv is a strict dose limit which has to be kept every single year. It is, however, not excluded that persons receive additional doses through natural radiation or in the course of medical treatment.

Protection of air and water

In line with the old Ordinance, the new legislation establishes dose limits for the discharge of radioactive substances into air or water (Section 47). This goes beyond the requirements of the Euratom Directives (which is permitted according to Article 54 of the Euratom Basic Safety Standards) but is regarded as necessary to keep the high level of protection as compared to the old Ordinance. The dose limits are relevant not only for the operation of installations or facilities, but also apply to their planning.

Protective measures against incidents

Section 48 stipulates that the planning of structural or other technical protective measures against incidents in or at nuclear power plants is to be based on the assumption that only an effective dose of 50 mSv may be released into the environment. In addition, body dose limits to avoid deterministic effects are included in the protection concept. These provisions are not only valid for nuclear power plants but also for local interim storage facilities and federal facilities for the safe-keeping and ultimate storage of radioactive waste. Protective measures against incidents in or at other facilities have to be tailored in view of their potential to cause damage including the likeliness of an incident (Section 50). This provision also applies to the decommissioning of facilities and installations. The German Government will issue case-oriented guidelines on such protective measures.

Radioactive waste

In addition to provisions regulating delivery and storage of radioactive waste (Sections 72-79), the new Ordinance includes provisions on treatment and packaging of radioactive waste (Section 74). Thereby it is guaranteed that the authorities competent for the disposal of this waste are informed on the amounts of waste and the respective transports. Also, a loss of radioactive substances is prevented.

Application of radioactive substances or ionising radiation to the human body in medical research

A separate chapter is dedicated to the application of radioactive substances or ionising radiation to the human body in medical research which essentially implements the detailed provisions of Directive 97/43/Euratom on health protection of individuals in relation to medical exposure. A first Part (Sections 80-86) deals with therapeutic medicine and dentistry, a second part deals with medical research.

The first Part starts with its own provision on justification – additional to the general one set out in section 4 – which requires that when applying radioactive substances or ionising radiation to the human body, the potential risk due to radiation must be outweighed by positive effects on human health. In radiotherapeutic practices, a medical physics expert must be involved (Section 82, para. 4).

The second Part states clearly under which – narrow – conditions the application of radioactive substances in medical research is admissible. For example, the test person has to agree in writing, and the bodily doses have to be monitored and documented, as do the results of the tests.

Protection of man and the environment against ionising radiation emanating from natural sources

Following the structure of the Euratom Basic Safety Standards, a separate Part deals with the protection of man and the environment against ionising radiation emanating from natural sources. Sections 93-104 concentrate on “work activities”, i.e. activities which are not practices and as such are covered by the second part of the Ordinance – within which the presence of natural radiation sources leads to a significant increase in the exposure of workers or members of the public which cannot be disregarded from the radiation protection point of view. As natural radiation is omnipresent, the protection concept differs considerably from the one concerning practices. Three principal areas are subjected to new regulations:

- increased exposure of workers in specific working areas;
- increased exposure of members of the public due to the production of residues;
- and exposure of aircraft operating personnel to cosmic radiation.

A Chapter on basic principles corresponds to the one introducing the regulations on “practices” but does not contain a clause on “justification” as that would be inadequate when dealing with a naturally occurring phenomenon. Section 93 states that for working practices, the system on dose limitation developed in the chapters on practices applies.

Protection of workers

The German Radiation Protection Commission has examined possibly critical working areas. These are, *e.g.*, underground workplaces, mines and spas. They are explicitly mentioned in Annex XI. Those working places are subject to control, exposures must be estimated, and the competent authority has to be informed if it is possible that the exposure exceeds 6 mSv per year. Persons carrying out such work activities may not receive more than 20 mSv in a year (Section 95); this is combined with body doses. Special safeguards apply to pregnant women and persons under 18 years of age.

Section 103 regulates the protection of aircraft personnel against cosmic radiation. The limit value for flying personnel is 20 mSv per year. The limit for an unborn child which is exposed due to the profession of the mother is 1 mSv. Aircraft crews must be informed on the risks of cosmic radiation, and the doses have to be monitored and communicated to the crew members if they wish. The assessed exposure has to be taken into account when organising work schedules in order to avoid high doses.

Protection of members of the public

The effects of radiation in specified working areas as listed in Annex XI on members of the public are negligible, therefore no specific protection measures are regarded necessary. The situation is different with regard to residues. Residues must be subject to supervision if their recycling or disposal could lead to an exposure of members of the public to more than 1 mSv as a guideline value (Section 97). This is the case with residues listed in Annex XII – they have to be supervised and may only be released from supervision through a procedure which is modelled on the clearance procedure in Section 29 (Section 98). Such residues may only be released from supervision if the guideline value of 1 mSv for members of the public is not exceeded even without further precautionary measures. The Ordinance states under which circumstances this is the case; mainly, certain paths of disposal have to be followed.

Protection of consumers in connection with the addition of radioactive substances to consumer goods

Sections 105-109 implement the principle¹⁰ that the deliberate addition of radioactive substances in the production of foodstuffs including drinking water, toys, personal ornaments and cosmetics or the import or export of such goods is not permitted. The addition of radioactive substances to these goods is not justified as a possible benefit would be outweighed by an additional exposure of workers and members of the public. Although the Euratom Directive only forbids the addition of radioactive substances, the German Ordinance also forbids the activation of radioactivity of such goods because for the consumer, it is irrelevant whether, *e.g.*, the radioactivity results from an addition of a substance or from activation.

Addition of radioactive substances to consumer goods or medical products is subject to a stringent licensing procedure. One of the strict prerequisites is that members of the public do not receive an exposure which is higher than approximately 10 µSv. Producers of such consumer goods have to make sure that such goods are taken back after use without any costs for consumers. The consumer, on the other hand, is obliged to send them back.

Prospects for this new legislation

The new Ordinance will contribute significantly to the further prevention or at least minimisation of the adverse effects of radiation exposure. Its implementation is within the competence of the German constituencies. In regular meetings with representatives of the constituencies dealing with radiation protection, their experience with this new piece of complex legislation will be discussed and information on how to implement it in the most efficient way will be exchanged. Trade unions, institutions, scientists, enterprises and interested individuals will report on their experience with the new regulations. The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety has initiated a project to closely examine the situation of women working in the field of radiation protection, and it plans to examine whether the Ordinance takes their needs sufficiently into account or not. The entry into force of the new Ordinance is an important step in the improvement of radiological protection but no reason to lessen further engagement in this field of environmental policy – optimising radiation protection is an ongoing process where continued contributions from all sectors concerned – experts, scientists, lawyers – are of crucial importance for the further development of a comprehensive protection system.

10. Article 6, para. 5, Euratom Basic Safety Standards.