Characterization of Radioactive Waste Products in the Context of the New German Radiation Protection Ordinance and of Relevant International Standards[1]

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Abstract

A survey is given on the new German Radiation Protection Ordinance (RPO) and on the basis of the underlying system of radiation protection. Emphasis is laid upon the system of exclusion, exemption, and clearance in the context of radioactive wastes from practices and of production residues from work activities. The role of national and international standards in the process of harmonization of provisions of other ordinances and of guidelines with the new RPO as well as some open questions are discussed.

1 The Amendment of the German Radiation Protection Ordinance of 2001

On July 1st, 2001, the German Government has amended the Radiation Protection Ordinance (RPO) [1] thereby implementing two new Council Directives - the Euratom Basic Safety Standards [2] and Directive 97/43/Euratom on health protection of individuals in relation to medical exposure [3] in Germany. The respective ordinance was issued on the basis of an amendment of the Atomic Energy Law of May 3rd, 2000 [4]. Together with the RPO, nine other related ordinances were amended.

The German Government has used the occasion of the amendment for a complete re-structuring of the RPO. The new RPO consists of five parts:

- Part 1 (§§ 1-3) - General provisions - gives the objective of the ordinance, defines its scope and contains detailed provisions on definitions. The objective of the Ordinance is the *protection of man and of the environment*, against the negative effects of ionizing radiation.
- Part 2 (§§ 4-92) deals with the protection of man and the environment against radioactive substances or ionizing radiation resulting from goal oriented uses in connection with practices.
- Part 3 (§§ 93-104) - Protection of man and the environment against ionizing radiation emanating from natural sources - covers certain types of work activities involving the presence of natural radiation sources leading to non-negligible exposures.
- Part 4 (§§ 105-110) deals with the protection of consumers in connection with the addition of radioactive substances to products.
- Part 5 (§§ 111-118) contains joint provisions applicable to all parts of the ordinance such as transitional and final provisions and administrative fees.

In this paper, some basics of the new ordinance and of the underlying system of radiation protection are discussed. Emphasis is laid upon aspects of exclusion, exemption and clearance in the particular context of radioactive waste from practices and of production residues from work activities. For a

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more general discussion of the RPO see ref. [5]. In refs. [6-9], some special aspects of this paper are further elaborated.

The new RPO is a very complex, technical ordinance, comprising besides 118 provisions 14 annexes. As a result of this new RPO, many other ordinances, standards and technical guidelines need to be harmonized with the new provisions. In this context, the importance of recent national and international standards for the practical application of the RPO and of related ordinances and guidelines is discussed. Finally, some open questions are outlined.

2 The Current System of Radiological Protection

The fundamental principles of radiological protection are *justification*, *limitation* and *optimization* [10,2]. They are laid down in the first chapter of Part 2 of the RPO:

- § 4 - Justification - ensures that new types of practice resulting in exposure to ionizing 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.
- § 5 - Dose limits - enumerates the dose limits of the ordinance applicable to members of the public and exposed workers.
- § 6 - Dose reduction - makes it compulsory to avoid any unnecessary exposure. The principle of optimization requires that, even if a practice does not exceed the relevant dose limits, exposures have to be kept as low as reasonably achievable.

Given the omnipresence of natural radiation and radiation exposures, it is necessary to establish a concept of radiological protection in order to put the principles of radiological protection into operation. The concept used in the RPO is based on the terms *exclusion, authorization* and *exemption*. Any human activity or source which may lead to non-negligible radiation exposures need authorization unless they are excluded or exempted from regulation.

The concept of exclusion means that any exposure whose magnitude or likelihood is essentially not amenable to control is deemed to be excluded from regulation. It also comprises uncontrollable exposures which cannot be restricted under any conceivable means. Such exposures are for instance exposures originating from K-40 in the body, from cosmic radiation at ground level, from unmodified concentrations of natural radionuclides in most raw materials, and from fallout caused by past nuclear testing in the atmosphere. If the potential exposures are negligible they are excluded from regulatory control following the principle of the Roman law "*de minimis non curat lex*".

The concept of exemption determines what practices and sources (and their waste) may - and what may not - be freed *a priori* from all regulatory control. There are two reasons for exempting a source or an environmental situation from regulatory control:

- One is that the source gives rise to small individual doses and small collective doses in both normal and accidental conditions.
- The other is that no reasonable control procedures can achieve significant reductions in individual and collective doses.

Exemption is necessarily a source-related process, while the triviality of the dose is primarily individual-related. It follows the principle of the Roman law "*de minimis non curat praetor*".

However, exemption should not be granted to permit practices that would otherwise not be justified.

Practically, the source-relationship of exemption is put into effect by exempting materials from regulatory control if their total activities A_i and activity concentrations C_i are below exemption levels (Freigrenzen) FG_i. Values of the FG_i are given in Appendix III of the RPO for both the total activities and the activity concentrations of the individual radionuclides. If several radionuclides are present it is required that

$$\sum_i A_i / FG_i \leq 1 \text{ and } \sum_i C_i / FG_i \leq 1 \qquad (1)$$

to allow the material to be exempted.

The legal fixation of exemption levels requires the definition of a trivial dose. As discussed in ref. [7] the trivial individual effective dose is of the order of 10 to 100 μSv per year. This statement is based on considerations either of the acceptable annual individual risk taking into account the ICRP risk factors [11] or of the natural radiation background and its variability. Both approaches merely result in an order of magnitude for the trivial dose and not in a single numerical value as required for an ordinance. The RPO assigns a dose criterion for triviality of 10 μSv per year for a single source or practice in order to ensure compliance with the principle of trivial dose in case of several exempted practices.

After defining a dose criterion of triviality, exemption levels are the result of modeling exposure pathways on which exempted materials, practices, and sources potentially could lead to radiation exposures at the workplace or for members of the general public. The principles for exemption and methods for establishing exemptions levels are laid down in refs. [12,13]. A detailed account on the derivation of exemption levels and their application in the RPO is given in ref. [7].

2.1 What materials are radioactive?

In the system of exclusion, authorization, and exemption, the term *radioactive substance* is of crucial importance since on its basis the system is extended to cover the *clearance of radioactive waste* which in the new RPO [1] is extensively regulated for the first time on the basis of Article 5 of the Euratom Basic Safety Standards [2].

The term radioactive substance has been newly defined in a legal sense in § 2 of the amended Atomic Energy Act [4]. According to this definition, radioactive substances (nuclear fuels and other radioactive substances) are substances that contain one or more radionuclides and whose radioactivity or activity concentration with respect to nuclear energy or radiation cannot be neglected. In this legal definition of radioactive substances, the physical meaning of "radioactive" is confined to the term radionuclides. Radioactive substances are those that are subject to the Atomic Energy Act's protection and supervision regime and 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 levels of the RPO;

i.e. substances whose handling will be subject to authorization.

Substances are not radioactive in the legal sense of the Atomic Energy Act if their activities "may be neglected" [10]. This is the case if they are cleared from regulatory control according to section 9 (§ 29) of the new RPO. The provisions of § 29 for the first time comprehensively stipulate the conditions of clearance of radioactive substances, the past RPO just gave in § 4 some regulations for radioactive waste.

2.2 Clearing of Radioactive Substances

In addition to provisions regulating delivery and storage of radioactive waste (§§ 72-79), the new RPO includes provisions on treatment and packaging of radioactive waste (§ 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 shall thereby be prevented.

According to the new RPO, a clearance procedure is possible for such radioactive substances with negligible radioactivity if they originate:

1. from use, treatment, handling of:
   a) man-made radioactive substances or
   b) radioactive substances of natural origin whose nuclear properties are used,
2. from practices subject to authorization 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.

The term clearance is defined in § 3 Nr. 15 as an act of state issued by an authority which releases solid or liquid radioactive substances and moveable objects, instrumentation, buildings and building rubble, excavated soil, and sites, which are activated or radioactively contaminated, from the regulatory control by the Atomic Energy Act and by the RPO. The RPO distinguishes between (unconditional) clearance and specific clearance depending whether these substances are subject to no restrictions regarding their future use, application, recycling, re-use or disposal or not. The Ordinance distinguishes different types and paths of clearance for particular materials and objects such as solid materials for disposal, materials in liquid form to be disposed by incineration in a corresponding plant, buildings to be demolished, and scrap metal to be recycled.

Clearance requires that surface contaminations and activity concentrations of such substances are below defined surface contamination limits and clearance values given in Appendix III of the new RPO and have received clearance. After clearance, such substances are no longer radioactive substances. They fall under relevant specialized law, especially the Closed Substance Cycle and Waste Management Act [14].

As stated in the Euratom Basic Safety Standards [2], the effective dose for individual members of the population resulting from clearance of radioactive substances shall be of the order of 10 μSv or less for any member of the public and the collective dose for the population shall be less than 1 man-Sv in a year. This is the basis for the clearing levels given in Appendix III of the RPO. For the derivation of the clearance values see refs. [15-17].

The exemption and clearance values of the new RPO differ considerably (e.g. table 1), since different models and exposure pathways underlie the derivation of exemption levels and clearance

values. When compared with the exemption levels, the clearance values tend to be the lower (table 1). This sometimes causes confusion and concern in the public since the differences can only be understood on the basis of knowledge about the underlying models and about the conservatisms implemented in these models. It would be desirable to have just one set of radionuclide-specific clearance and exemption levels to allow both exemption of practices and clearance of materials from regulated practices as it is discussed in the context of radionuclides in commodities, *e.g.* [18]. A plethora of different values leads to confusion.

Table 1: Comparison of exemption levels and (unconditional) clearance values expressed in specific activities for some selected radionuclides.

Radionuclide	Exemption levels in Bq/g	Clearance values in Bq/g
U-238sec	1	0,009
Pu-239	1	0,04
Pb-210++	10	0,02
Co-60	10	0,1
Cs-137	10	0,5
Sr-90+	100	2
I-131	100	2
I-125	1000	3
P-32	1000	20
Re-186	1000	1000[1]
Cl-36	10000	8
Tc-99	10000	10
C-14	10000	80
Fe-55	10000	200
S-35	100000	60
H-3	1000000	1000

[1] if not noted otherwise the exemption levels are to be taken as clearance values for radionuclides with half-lives less than 7 d.

It is also problematic that the exemption levels given in the RPO are values rounded to orders of magnitude, revealing the character of the exemption concept, while the more-precisely given clearance values pretend a level of reliability, which cannot be derived from the underlying concept of clearance.

2.3 Practices and Work Activities

On the basis of the Euratom Basic Safety Standards [2] the scope of the new RPO was widely extended. It applies both to *practices* and *work activities*. Practices are defined as 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, except in the case of an emergency exposure. Work activities are defined as human activities which are not practices, but where the presence of natural radiation sources may lead 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.

In the new RPO, part III (§§ 93-104) deals for the first time with the protection of man and the environment against ionizing radiation emanating from natural sources as a consequence of work activities. As natural radiation is omnipresent, the protection concept differs considerably from the one concerning practices. In particular it does not contain a clause about justification. Three principal areas are subjected to new regulations:

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

The new RPO explicitly lists possibly critical working areas in annex XI based on an examination by the German Radiation Protection Commission [19]. 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.

The protection of aircraft personnel against cosmic radiation is regulated in § 103 of the RPO. 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 organizing work schedules in order to avoid high doses.

Generally, § 93 states that for work activities the system on dose limitation developed in the chapters on practices applies.

2.4 Residues from Work Activities

With respect to the topic of this paper, the consideration of production residues is of importance. They are related to the frequently used terms *naturally occurring radioactive materials* (NORM) and *technologically enhanced naturally occurring materials* (TENORM). Up to now, the international practice is vague in relation to the controllability of exposures from other natural sources, including waste from industries processing NORM. As stated above as examples of exposures excluded from regulatory control it was referred to exposure from "unmodified concentrations of radionuclides of radionuclides in most raw materials" [10].

The IAEA Basic Safety Standards [10] discusses two approaches. One approach is to exclude respective industries unless the activity levels in materials used were such that the doses being received were sufficiently high to cause concern. The other approach follows from a decision that specified industries should be subject to regulation, i.e. that they constitute a practice in the context of these standards.

While the effects of radiation in the specified working areas listed in Annex XI of the new RPO on members of the public are negligible, the situation is different with regard to residues which might lead to a non-negligible exposure of members of the public. Therefore, it is laid down in the RPO that 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 (§ 97). The residues subject to supervision are listed in Annex XII. They have to be supervised and may only be released from supervision through a procedure which is modeled in accordance with the clearance procedure in § 29 (§ 98).

NORM and TENORM residues are exempted from supervision if the activity concentrations of each of the radionuclides of the U-238 and Th-232 decay chains are below 0.2 Bq/g. In addition, raw materials of the technological processes listed in Annex XII of the RPO, which contain

naturally occurring radionuclides are exempted from supervision. A graded system of limiting activity concentrations for residues from work activities is set up in Annex XII of the RPO which decide about release or not from supervision.

The release from supervision can be either unconditionally for further use, recycling, etc. or for disposal in the framework of the Closed Substance Cycle and Waste Management Act [14]. The Ordinance states under which circumstances this is the case; mainly, certain paths of disposal have to be followed. If residues cannot be released from supervision because of their specific activities the authorities can decide about further protection measures and the way in which these residues can be disposed.

3 Some Aspects of Quality

In the process of harmonization of the provisions of other ordinances and guidelines with those of the new RPO also other improvements will be made in order to update them with respect to the state of science and technology. Since practical measures in radiological protections always are relying on measurements of exposures and activities and since comparison of measurement results with legal limits, levels and guideline values provide the basis for actions to be taken in radiological protection as well as for decisions about clearance of radioactive substances and about release of residues from supervision, the quality of the measurements is of prime importance.

Since the previous RPO was issued in 1989, important developments in quality assurance and quality control have been made. Trace-ability of measurements and evaluations has become a *conditio sine qua non* and standardization of procedures, certification and accreditation of measurement laboratories have become top issues.

In particular with respect to the characterization of waste and residues, some aspects of these developments shall be discussed here, namely:

- *uncertainties in measurement* and
- *characteristic limits*, such as decision thresholds, detection limits and confidence limits.

Measurement uncertainties and characteristic limits have become fundamental data for the judgment about measurement results and for the characterization of measurement procedures. Increasingly, they are referred to in national and international ordinances and guidelines.

For the calculation of measurement uncertainties standardized procedures are laid down in the ISO Guide to the Expression of Uncertainty in Measurement (GUM) [20]. These procedures are in accordance with German national standards DIN 1319-4 [21] and DIN V ENV 13005 [22] and with recommendations by EURACHEM [23] for application in analytical chemistry.

The important point of these standards and recommendations is that for a measurement result a complete standard uncertainty has to be given which takes into account all known sources of uncertainties. On the basis of a Bayesian theory of measurement uncertainties [24] this includes contributions to uncertainty which can be determined from repeated or counting measurements (type A) as well as those which can only be obtained from other sources (type B). These type B uncertainties comprise all information available about previous measured data, experiences about the measurement procedures and processes or about the characteristics of relevant material, phenomena or instruments, specifications and information obtained from manufacturers, data from

calibration and other certificates as well as uncertainties which are attributed to data from handbooks and compilations.

According to the state of science and technology, for each measurement its associated standard uncertainty according to the GUM has to be given. With the standards cited [20-23] complete standard uncertainties can be given for each measurement result obtained by any measuring procedure in an unambiguous way.

On the basis of complete standard uncertainties according to refs. [20-23] also the characteristic limits, such as decision threshold, detection limit and limits of the confidence interval can be derived on the basis of DIN 25482-10 [25] and ISO 11929-7 [26], respectively, in a straightforward way.

These characteristic limits allow for the following statements or decisions:

- The decision threshold decides the question whether a result of a measurement indicates a true value of the measurand larger than zero. In practice, this decides whether a dose or an activity different from zero has been observed.
- The detection limit is the smallest true value of the measurand which can be reliably determined and thereby qualifies the measurement procedure with respect to legal or other requirements.
- The confidence limits enclose a confidence interval which contains the true value of the measurand with a pre-selected probability.

The recognition that every result of a measurement has an uncertainty and that the capabilities to measure any quantity is downwards limited by background effects or blanks causes some problems with respect to the practical application of the provisions laid down in the new RPO. Some of them will be discussed in the next chapter.

4 Some Open Questions

One problem arises from the fact that materials to be cleared or released from supervision usually are not homogenous. Thus, the specific activity on which a decision about clearance or release has to be based is not a well defined quantity. It is not yet decided whether the specific activity of each individual sample has to be below the respective limit or whether this has to hold for the mean, the median or the expectation value of the distribution of specific activities in the material. Since the clearance values and release limits are based on models of exposure pathways, the expectation value of the activity distribution may be the most adequate quantity to use for a decision. However, whether this will be the case is still under discussion.

A second problem arises from measurement uncertainties. If each measured result is uncertain, how does uncertainty affect a decision about compliance with legal limits and, if confidence intervals are used in demonstrating compliance, which confidence level has to be adopted? The RPO and relevant technical guidelines do not yet give any advice in this respect. As discussed elsewhere [27], first attempts have been made to cope with these problems in Austria by dealing in standards the problems of legal limits and uncertainties [28,29]. In Germany and other countries, this is still an open problem.

A third problem deals with decision thresholds and detection limits. It appears frequently in accounting of radioactive emissions from nuclear facilities and of the radioactive inventories of

waste when measured data are below the decision threshold. Frequently, then the detection limit or some percentage of it is used in the account. This is a complete misuse of the detection limit which has the purpose to qualify a measurement method, not to substitute missing data. If a result of a measurement is below the decision threshold, a true value of zero of the measurand must not be excluded and a zero value has to be adopted. If the assumption of a true value of zero matters, the detection limit, i.e. the sensitivity of the measurement has to be decreased as such that a true value of zero does not matter anymore.

5 Conclusions

The new German Radiation Protection Ordinance of July 20, 2001 is an ambitious piece of legislation, in particular with respect to the new provisions for the clearance of radioactive waste from practices and for the supervision of residues from work activities. International standards of metrology such cited in refs. [20-22,25,26] will have increasing impact on the characterization on waste and residues.

The multitude of innovations in the new RPO provide a sophisticated basis for an adequate protection of man and the environment against the dangers from ionizing radiation. For the characterization of waste and residues they are a challenge for both, the practical application and for the further development of legal regulations in radiological protection.

6 References

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