ISSN - 0250 - 5010

ANNALEN
VAN
DE BELGISCHE VERENIGING
VOOR
STRALINGSBESCHERMING

VOL. 34, N° 3, 2009 4e trim. 2009

REVISION PROCESS OF THE BSS AND THE DIRECTIVES OF THE EUROPEAN UNION (part 1)

Driemaandelijkse periodiek
1050 Brussel 5

Périodique trimestriel
1050 Bruxelles 5

ANNALES
DE
L'ASSOCIATION BELGE
DE
RADIOPROTECTION

Hoofdredacteur — Mr C. Steinkuhler — Rédacteur en chef
Rue de la Station 39
B- 1325 Longueville

Redactiesecretariaat — Mme Cl. Stiévenart — Secrétaire de Rédaction
Av. Armand Huysmans 206, bte 10
B- 1050 Bruxelles - Brussel

Ce numéro contient les textes des exposés présentés lors de la réunion organisée par l'Association belge de Radioprotection à Liège le 19 juin 2009.

Dit nummer bevat de teksten van de uiteenzettingen ter gelegenheid van de vergadering van de Belgische Vereniging voor Stralingsbescherming in Luik op 19 june 2009.

SOMMAIRE — INHOUD

Annales de l'Association belge de Radioprotection, Vol.34, n°3, 2009
Annalen van de Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 3, 2009

PROGRESS WITH THE REVISION OF THE EURATOM BASIC SAFETY STANDARDS AND CONSOLIDATION WITH OTHER COMMUNITY LEGISLATION

Augustin Janssens
European Commission
Directorate-General for Energy and Transport
L-2920 Luxembourg

Liège, 19 June 2009

Abstract.

The revision of the EURATOM Basic Safety Standards (Directive 96/29/EURATOM) was undertaken to allow for the new ICRP Recommendations (Publication 103) as well as to consolidate all radiation protection legislation in a single BSS Directive. In line with ICRP the new Directive will allow for the three exposure situations: planned, existing and emergency. This required significant restructuring, together with the consolidation or recast. The new Directive will fully integrate all natural radiation sources, introducing more binding requirements for NORM industries, building materials, radon in dwellings and workplaces. The protection of the environment is now within the scope of the Directive. The Directive develops the concept of a graded approach to regulatory control, so that it is commensurate to the risk and to the effectiveness of such controls. In this context also the concepts of exemption and clearance have been worked out in more detail and new consideration is being given to the harmonisation of exemption and clearance levels. Further issues that emerged from the revision process are the definition and use of constraints and reference levels, as introduced by ICRP, and the principle of justification, in particular with regard to the deliberate exposure of people for reasons other than medical (e.g., for security screening). The revision and recast process is scheduled to be completed by mid 2010. Harmonisation with the International Standards (IAEA and co-sponsors) is vigorously pursued in view of co-sponsorship by EURATOM.

1. Consolidation of the Community legislation

The Community *acquis* derived from Title II, Chapter 3 of the Euratom Treaty, constitutes a consistent and evolutionary legislative framework, with the Basic Safety Standards Directive [1] as principal piece of legislation, and supplemented by eight binding instruments (in addition to non-binding Recommendations and Communications) covering the following fields:

- Medical applications of ionising radiation: Directive 97/43/EURATOM [2]
- Information in case of radiological emergency: Decision 87/600/EURATOM and Directive 89/618/EURATOM [3]
- Protection of "outside workers": Directive 90/641/EURATOM [4]
- Shipment of radioactive waste and substances: Directive 2006/117/EURATOM, and Regulation (EURATOM) No 1493/93 [5]
- Foodstuffs and feeding stuffs regulations in case of a future accident: Regulation (EURATOM) No 3954/87 (in addition to EC legislation following the Chernobyl accident)
- Control of high-activity sealed radioactive sources and orphan sources: Directive 2003/122/EURATOM ("HASS Directive") [6].

The Commission undertakes the simplification of its "*acquis*" of Community legislation by the codification of related acts (without modification, e.g., amendments or complementary legislation) or recasting these if necessary (e.g., allowing for different definitions). Such recast will be undertaken for the five main Directives (all except shipment of radioactive waste).

The Basic Safety Standards Directive (96/29/EURATOM) introduced in 1996 some new features in order to meet the needs prevailing at that time. A specific Title VII was introduced for the regulatory control of work activities involving natural radiation sources. With the exception of aircrew exposure, the Directive left the responsibility for the identification of NORM industries and of workplaces with high radon concentrations with national authorities. The concepts of exemption and clearance were introduced, but it was up to Member States to establish clearance levels, allowing for the general criteria (e.g., individual doses less than about 10 μSv) and Community guidance.

This flexibility was needed in order to achieve consensus on the inclusion of these new features at a time when there was little experience with such

matters, so that it was difficult to judge their impact and regulatory burden. The experience gathered since 1996, with transposition in national legislation (due by May 2000) and with operational implementation, demonstrated a need for enhanced harmonisation. The identification of NORM industries by Member States was not fully coherent and different clearance levels were introduced for the dismantling of nuclear installations. Thus a revision of the Basic Safety Standards to strengthen these requirements was undertaken.

2. Revision of the Basic Safety Standards

The Community's Group of Experts established under Article 31 of the EURATOM Treaty has established a work programme for the revision of the Basic Safety Standards. Initially it followed a topical approach, now the Group is at the stage of actual drafting of the recast Basic Safety Standards. Working Parties took on board the redrafting of requirements on natural radiation sources, on exemption and clearance, and on a graded approach to regulatory control. In the course of drafting additional issues emerged that touched upon the interpretation of Publication 103, especially the distinction between exposure situations, in a regulatory context.

2.1 Exposure Situations

The revision of the EURATOM Basic Safety Standards will take account of the new ICRP recommendations [7]. While these do not necessarily require major changes in regulatory requirements, we believe they offer a much more coherent and understandable framework. Hence the Commission undertakes to structure the requirements along the concepts of planned, existing and emergency exposure situations, and will highlight the role of optimisation below suitable constraints and allowing for reference levels.

The distinction between the three exposure situations has proven very helpful in structuring the Standards. While the principles of protection according to ICRP are very much the same, the distinction between the exposures situations matters in a regulatory context. Hence we need very precise definitions; we need to do better than the somewhat loose descriptive formulations in ICRP Publication 103.

For instance, ICRP defines a planned exposure situation merely as one involving the planned operation of sources. This has led to a lot of

controversy with regard to "sources that already exists when a decision on control has to be taken". We strongly believe that when an activity significantly affects or alters an exposure situation caused by existing sources, such as NORM or cosmic radiation, this is a planned exposure situation. Hence NORM industries and the exposure of aircrew are part of planned situations and the activities can be labelled as practices. On the other hand NORM materials with levels of activity concentration that are common in the earth's crust should be exempted from the requirements for practices.

Truly existing exposure situations are those for which the exposure results from where you are, rather than what you do. Radon ingress in a dwelling, from soil, is not related to any activity, so it yields in general an existing exposure situation.

Another matter is the placing on the market of commodities, which clearly is an activity. However, if the radioactive substances arise from an existing exposure situation, then it is more convenient to manage such commodities in the same context. Hence, building materials and contaminated food are managed under the heading, "Existing Exposure Situations".

There are other boundaries where pragmatic choices need to be made. High levels of radon in the workplace are the responsibility of the employer and should be managed in the same way as occupational exposure. An emergency exposure situation eventually leads to the existing situation of living in a contaminated area. The delineation in this case requires a management decision. In the case or NORM industries the boundary proceeds through identification of those existing situations which should be managed as a practice, or inversely, those which can be exempted from such requirements. Hence the criteria for identification and for exemption should match.

2.2 Natural radiation sources

The Working Party on natural radiation sources undertook in the first place the harmonisation of the identification and regulatory control of NORM-industries. The Working Party agreed on a "positive list" of types of industries that will be subject to controls in all Member States. It will be the task of the national authorities to inform the concerned industries and to make sure that they understand the radiation protection issue and take, if necessary, appropriate measures to reduce exposures within the overall

Health and Safety policy of the undertaking.

The industries (those listed and such other industries as identified at national level) will be requested to investigate activity concentration levels at any point of their process. Where any such levels exceed 1 Bq/g for the U-238 or the Th-232 series, or 10 Bq/g for K-40, the industries will also need to assess the resulting exposure of workers. On the basis of this assessment a graded approach to regulatory control will be applied. Where doses are all below 1 mSv, the practice is exempted. Where doses are in the range of 1 to 6 mSv per year the only requirement is to review whether optimisation calls for further reduction of exposures, and whether the exposures remain broadly the same over many years. In view of the fact that there is in general no risk of accidental exposure, there is no need for individual dosimetry or medical surveillance. In the exceptional case that doses exceed 6 mSv per year the full set of requirements for classified workers will apply.

The WP also looked into requirements for building materials. On the basis of earlier guidance [8] requirements for the placing on the market and use of building materials will be incorporated in the Basic Safety Standards. The activity concentration index I (weighted sum of Ra-226, Th-232 and K-40 activities) may be translated into two classes of building materials depending on whether a common reference level of 1 mSv per year (above background) would be exceeded. This is the only reference level that will be imposed through the Directive. Indeed leaving a free choice to Member States would lead to very complex requirements to allow for free trade within the EU.

Currently, radon in dwellings is excluded from the scope of Directive 96/29/EURATOM and covered by a Commission Recommendation (90/143/EURATOM). Raising the recommendations to the level of binding requirements was prompted by the recent findings from epidemiological surveys, confirming the expected lung cancer risk at levels of the order of 100 Bq m^{-3}.

Radon in workplaces will be subject to a reference level, provisionally below 1000 Bq m^{-3}. A common lower boundary of this range may lead to a harmonised threshold for incorporation of doses from indoor radon in the workplace in individual dose records. Eventually the reference level in workplaces may be set equal to the one in dwellings.

Member States will be required to establish a national action plan which will also cover radon in dwellings. The action plan will offer transparent information on the scope and objectives pursued at national or regional level, define the rationale for the conduct of surveys and for the delineation of radon-prone areas or other means of identification of affected buildings, and establish reference levels (maximum 400 Bq m^{-3} for existing, 200 Bq m^{-3} for new dwellings) and building codes.

2.3 Exemption and Clearance

The current requirements for regulatory control are a two-tier system: reporting of practices above exemption criteria, and prior authorisation for broad categories of practices. IAEA [9] had introduced a three-tier system: notification, registration and licensing. The Working Party undertook to identify which type of practices will be subject to each pillar, which general conditions need to be fulfilled and which is the content of requirements laid down upon registration or as part of a specific operating licence. As part of the graded approach exemption from any requirements is built in at all levels of control. Specific exemption is a powerful tool in addition to the criteria for general exemption of practices from the scope of the requirements.

Directive 96/29 had introduced exemption values in terms of activity (Bq) and activity concentration (Bq/g). In addition, the reuse or recycling of materials with negligible levels of contamination, especially arising from dismantling, can be authorised so that the materials are released from regulatory requirements, subject to compliance with clearance levels. The clearance levels should be established in such a way that individual doses would be below about 10 μSv (and collective doses below 1 man Sv), taking Community guidance into account. Such guidance has been adopted by the Group of Experts for specific materials such as metals (scenarios for steel, copper and aluminium), buildings and building rubble, and default values for any type of material [10].

Meanwhile the IAEA adopted similar guidance in RS-G-1.7 [11], on the basis of scenarios to a large extent inspired by those underlying RP 122. The IAEA levels were not specifically developed for the purpose of clearance, but it was suggested to use them for this purpose. The Group of Experts came to the conclusion that for the sake of international harmonisation it should be considered to introduce the RS-G-1.7 values

rather than those in RP-122. A study [12] investigating whether the differences between the two approaches and series of values has any significance in practical terms has just been concluded. In general the RS-G-1.7 values are equal to or higher than those in RP 122, but the differences can rather well be explained through the scenarios and assumptions.

The Experts also considered the introduction of the same concentration values for applying the concepts of exemption and clearance. It has been investigated whether lowering the exemption values will affect any consumer goods placed on the market. A single set of numbers would be of great benefit to the simplification and understanding of the Basic Safety Standards. While the study concluded that there would be indeed no adverse practical consequences, it also highlighted some Member States' reluctance to abandon the old numbers already incorporated in national law. In addition IAEA's transport standards committee (TRANSC) advocates keeping the existing values both for transport and in general for "moderate" quantities.

2.4 Graded approach

The current requirements are a two-tier system: reporting of practices above exemption levels or other criteria, and prior authorisation for broad categories of practices. IAEA had introduced a three-tier system: notification, registration and licensing. The Working Party identified which type of practices will be subject to each pillar, which general conditions need to be fulfilled and which is the content of requirements laid down upon registration or as part of a specific operating licence.

The current system for exemption of apparatus and of consumer goods relies very much on the concept of "type approval". This concept was not worked out further and there is a lack of harmonisation of conditions for type approval and corresponding decisions in the EU. This needed to be worked out in more detail and a system of mutual recognition (or at least allowance for) type approvals granted in other Member States was introduced.

3. Structure

The structure of the new Basic Safety Standards Directive was thoroughly revised, firstly to accommodate the incorporation of the other Directives as part of the recast process and secondly, to allow for the distinction

introduced by ICRP between planned, emergency and existing exposure situations.

The EC has endorsed this distinction and provisions for emergency and existing exposure situations have been laid down in specific titles (Title XI and XII respectively). On the other hand it was thought preferable to have, for example, a Title on "the protection of workers" (Title VII), which deals with all aspects of occupational exposure, including emergency workers and the follow-up to accidental exposure of workers. Hence there is a Title VI on "justification and regulatory control of planned exposure situations", but the chapters on the protection of workers, patients and members of the public (VII, VIII, IX respectively) are not part of an overall Title on "planned exposure situations" (as is the case with the revision of the international standards.) The overall "system of protection" has been taken up in Title III. It mirrors the wording used in ICRP Publication 103 and gives most weight to the principle of optimisation subject to constraints and reference levels. The bands of constraints/reference levels proposed by ICRP (0-1 mSv, 1-20 mSv, 20-100 mSv) will be introduced explicitly, including the societal criteria that ICRP listed for each band (Table 5 of Publication 103). Title IV lays down requirement for regulatory control and puts requirements on Member States' regulatory authorities, for the management of all three exposure situations. This Title also incorporates most of the requirements relating to the control of high-activity sealed sources (HASS). Directive 2003/122 on high activity sealed sources and orphan sources has very specific features which are not easily incorporated elsewhere in the new Directive.

The overall structure of the new recast Directive is given in Table 1. The incorporation of the requirements of the five Directives in each heading is not straightforward: no changes are allowed to the content of the requirements, unless really necessary and duly justified. It is essential to keep track of the changes in order to facilitate the later adoption process.

Table 1: Original outline of new EURATOM BSS

Preamble	
Title I	Subject Matter and Scope
Title II	Definitions
Title III	System of Protection
Title IV	Responsibilities for Regulatory Control
Title V	Requirements for Education and Training
Title VI	Justification and Regulatory Control of Planned Exposure Situations
Title VII	Protection of Workers, Apprentices and Students
Title VIII	Protection of Patients and Other Individuals Submitted to Medical Exposure
Title IX	Protection of Members of the Public
Title X	Protection of the Environment
Title XI	Emergency Exposure Situations
Title XII	Existing Exposure Situations
Title XIII	Final Provisions

The original outline kept separate titles for the emergency and existing exposure situations, which facilitated the drafting of the new provisions. This led to some provisions for the emergency exposure situations to appear in title VII, while on the other hand exposure of workers to radon was kept together with radon in dwellings in the title on existing exposure situations. This was not very neat and it was proposed to have a clear 3 x 3 matrix structure with the categories of exposure (occupational, public and medical) on the one hand, and the three exposure situations on the other hand. There was a clear preference for a structure with comprehensive requirements for each category of exposure (see Table 2).

Table 2: New matrix structure of the EURATOM BSS

OCCUPATIONAL EXPOSURE	PUBLIC EXPOSURE	MEDICAL EXPOSURE
Planned exposure situations	Planned exposure situations	Planned exposure situations
Emergency exposure situations	Emergency exposure situations	Emergency exposure situations
Existing exposure situations	Existing exposure situations	

4. Current draft

The current draft of the recast Directive still follows the original outline. Each title is briefly described in this chapter.

4.1 Subject matter and scope

The subject matter and general purpose of the Directive are laid down in Title I. The general objective is the health protection of workers, members of the public and patients. The recast introduces complementary objectives on the control of sealed sources and on providing information to the public in the event of a radiological emergency.

Title I also points at the three exposure situations, introduces radon in dwellings and exposure to building materials in the scope of existing exposure situations, and explicitly introduces consideration of exposure of biota in the environment as a whole.

4.2 Definitions

Title II defines the terms used in the Directive, on the basis of the 5 Directives in the recast and updated for compatibility with ICRP publication 103. There are few changes except for obsolete terms such as "work activities" and "intervention levels" being deleted and ambiguities such as the role of the under-taking and of the employer, the concept of (exposed) workers and the term "sources" (radiation sources, high activity sealed sources etc.) being resolved. A few new terms were introduced such as the concept of "reference level" and the three exposure situations.

4.3 System of protection

Title III specifies the main elements of the system of protection: justification of practices, optimisation of protection and limitation of individual doses. This is not essentially different from the current BSS. Additional text has been incorporated on the more prominent use of the concept of "dose constraint" and on "reference levels".

The current dose limits for practices are kept, but the annual dose limit for occupational exposure will be simply 20 mSv per year. There should be no need for averaging over 5 years, except in special circumstances specified in national legislation.

There is still discussion whether there is need for a precautionary reduction of the dose limit for the lens of the eye. We hope to receive ICRP guidance on this matter before adoption of the Directive.

4.4 Responsibilities, education and training

The section on education and training in the current draft was meant to be a separate Title, to be elaborated with the EUTERP platform. Unfortunately, apart from an improved definition of the Radiation Protection Expert and the introduction of the Radiation Protection Officer, there was little substance in this Title, and the secretariat thus incorporated it in Title IV. The Article 31 Experts nevertheless still prefer to incorporate this limited material in Title V, for better visibility.

The further sections of Title IV are:

– institutional infrastructure;
– control of sealed sources (including 5 Annexes);
– emergency management system;
– system of enforcement.

4.5 Justification and authorisation

These two concepts were brought together in one title in view of the fact that they are the two main pillars of regulatory control. Also, the more elaborate requirements for the type approval of apparatus or consumer goods relate both to justification and to authorisation.

The concept of justification is described very much in the same terms as before. However, the special issue of non-medical exposures (previously called “medico-legal exposures) is worked out in more detail.

The concept of “medico-legal” exposures was already introduced in Directive 97/43, and there was a requirement that “special attention shall be given for exposures on medico-legal grounds. It was soon realised after the adoption of the Directive that this concept covered a very broad range of very different situations. This was thoroughly discussed at a conference in Dublin in 2002, and a follow-up conference will take place in October 2009.

The graded approach to regulatory control was introduced (registration and licencing) and there is now explicit provision for exemption at all levels of the control regime. The general clearance levels are introduced as a baseline for exemption (values taken from RS-G-1.7). Flexibility is retained for Member States to decide on specific exemption and clearance levels.

NORM industries are now fully incorporated in the requirements for regulatory control.

4.6 Occupational exposure

Title VII deals with occupational exposure of workers, apprentices and students, emergency workers, workers in identified NORM industries, aircrew and space-crew.

Emergency workers are subject to a dose limit of 50 mSv or, for specific cases identified in national emergency plans, an appropriate reference level. In the current Directive provision was made also for "specially authorised exposures". There is still discussion whether this provision needs to be maintained.

The graded approach to arrangements for occupational exposure is made more explicit, with a threshold of 1 mSv per year. The categories A and B workers are preserved. For workers in NORM industries, as part of the graded approach, and if doses are in the range 1 to 6 mSv, it is sufficient to keep the exposures under review.

4.7 Medical exposure

Title VIII covers the protection of patients and other individuals submitted to medical exposure. There are very few changes to Directive 97/43, except the removal of "medico-legal" exposures to Title VI and emphasis being given to the information to patients, to interventional procedures, diagnostic reference levels and dose indicating devices. A new feature is the introduction of accidental or "unintended" exposures.

4.8 Public exposure

Title IX covers the exposure of members of the public with little changes to title VIII of the current BSS. More precise requirements on the establishment of discharge authorisations have been introduced, with reference to Commission Recommendation 2004/2 (Standard information).

4.9 Protection of the environment

The subject matter and general purpose of the Basic Safety Standards is the health protection of the population and workers against the dangers of ionising radiation; this includes the protection of the human environment as a pathway from environmental sources to the exposure of man. In line with ICRP Publication 103 it is now felt that this should be complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole. ICRP has indeed reconsidered the paradigm on the relationship between health and environmental protection.

This extension of the scope of the Basic Safety Standards Directive will enable a better integration of the EURATOM legislation with overall environmental legislation adopted under EC Treaty provisions, as well as the observance of international agreements, such as the OSPAR Convention on the protection of North-Atlantic waters, and meet the concerns of stakeholders.

While Chapter 3, "Health & Safety" of the EURATOM Treaty only relates to the health protection of workers and members of the public, the policies for the protection of man and the environment should be coherent. For instance, environmental criteria as well as dose constraints should be considered for the authorisation of discharges of radioactive effluent.

For a long while the separate Title on environmental protection (Title X) was left blank. It has proven very difficult to translate the guidance of ICRP as well as the outcome of EU-funded research (ERICA, PROTECT) into precise, enforceable legal requirements. Now there is a draft text, which is not very demanding, but which some experts still consider disproportionate or not applicable in the absence of an approved methodology.

4.10 Emergency exposure situations

Title XI deals with emergency exposure situations and builds on recent guidance of ICRP (to be published). The old approach of an emergency plan with different intervention levels is replaced by a more comprehensive system comprising

– threat analysis;

– overall emergency management system;

– emergency response plans for identified threats;

– pre-planned strategies for the management of each postulated event.

The key difference is that each strategy should aim at keeping doses below the reference level, optimising the available preventive and protective actions rather than justifying each action.

The requirement for cooperation between Member States will be strengthened.

New Annexes list the elements to be included in the management system and in the emergency response plan. Further Annexes are incorporated from the Directive on public information.

4.11 Existing exposure situations

This new title XII deals with the long-term management of contaminated territories and with natural radiation sources, in particular:

– radon in dwellings, public buildings and workplaces;
– building materials.

An Annexe gives an indicative list of items to be covered in the national action plans for radon. For building materials a reference level has been set at 1 mSv/y, translated through the activity concentration index defined in Radiation Protection 112. An indicative list of types of building materials considered for control in view of the emitted gamma radiation has been included in an Annex.

5. Prospects

The Group of Experts under Article 31 of the EURATOM Treaty endeavours to finalise the text of the new Directive by Spring 2010, under the mandate of the current Group. A lot of work remains but the prospects of achieving this goal are good. The text of the Experts and their Opinion will be the basis of a Commission proposal scheduled for 2010. Adoption of the Commission's proposal by the Council may take another few years and, taking into account the time granted for transposition into national legislation, it may not be before 2014 that the requirements become truly effective.

Meanwhile the Commission is closely following the revision of the international Basic Safety Standards. As a result of the decision making rules in the European Union, the EC has so far never formally co-sponsored the international Standards. It is now envisaged to do so, in the same way as for the document laying down the Safety Fundamentals. The aim is to harmonise as far as possible the definitions and requirements, both reflecting the ICRP Recommendations.

It should be emphasised, however, that the EURATOM Standards and the international Standards will still look very different, on the one hand because the structures are not the same and neither is the amount of detail in existing legislation or requirements that needs to be incorporated; on the other hand because of the legally binding nature of the EURATOM Standards, applicable to the 27 Member States of the European Union.

6. References

[1] Council Directive 96/29/EURATOM OF 13 May 1996, laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (Official Journal L-159 of 29.06.1996, page 1).

[2] Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM (Official Journal L-180 of 09.07.1997, page 22).

[3] 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 L-357 of 07.12.1989, page 31).

[4] Council 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 L-349 of 13.12.1990, page 21).

[5] Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel (Official Journal L337 of 05.12.2006).

[6] Council Directive 2003/122/EURATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (Official Journal L346 of 31.12.2003).

[7] The 2007 Recommendations of ICRP, Annals of the ICRP, Publication 103, International Commission on Radiological Protection, 2008, Elsevier

[8] Radiation Protection 112, Radiological Protection principles concerning the natural radioactivity of building materials, Luxembourg (1999).

[9] International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, International Atomic Energy Agency, 21 March 1996, Vienna.

[10] RADIATION PROTECTION 122, "Practical Use of the Concepts of Clearance and Exemption, Part I – Guidance on General Clearance Levels for Practices", Part II – Application of the Concepts of Exemption and Clearance to Natural Radiation Sources", Luxembourg (2000).

[11] International Atomic Energy Agency, "Application of the Concepts of Exclusion, Exemption and Clearance", Safety Standards Series No. RS-G-1.7, Vienna (2004)

[12] "Comparative Study of EC and IAEA Guidance on Exemption and Clearance Levels", Radiation Protection 157, Brenk System Planung, 2009, Luxembourg

Annales de l'Association belge de Radioprotection, Vol.34, n°3, 2009
Annalen van de Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 3, 2009

NEW SCIENTIFIC INSIGHTS RELEVANT FOR THE REVISION OF THE BSS

Wolfgang-Ulrich Müller
Institut für Medizinische Strahlenbiologie
Universitätsklinikum Essen
D45122 Essen

Although radiation research during recent decades has brought forward a lot of information on radiation risk, there are still some unresolved problems and sometimes surprising results emerge in fields, for which the situation seemed to be clear. This is particularly true for:

- Dependence of radiosensitivity on
  - age
  - gender
  - the individual in general
- The cataract issue
- The cardiovascular issue
- The radon issue
- The low dose problem and DDREF

Some of these aspects have obvious implications on the new version of the Basic Safety Standards (BSS), others have to wait for more data.

1 Dependence of radiosensitivity on age

In general, there is a dependence on age in the sense that younger individuals (the fetus, in particular), show the highest radiosensitivity and the elderly the lowest. For lung cancer, however, there are indications that risk is increasing again for individuals older than about 50 compared to those in the range of 30. Some examples for age dependence are quoted in the following list, others can be found in the various UNSCEAR reports on radiation-induced cancer risk ([17-20]:

- Leukaemia (foetus; [8])
- Thyroid carcinoma (young children; [10])

- Basal cell carcinoma (children and teens; [16])
- Breast cancer (young girls; [3])
- Lung cancer (individuals older than 50; [23])

Many biological factors have been identified that explain this age dependence. Among others these are: cell proliferation, cell differentiation, enzyme status, genetic predisposition, genomic instability, hormone status, immune competence, repair characteristics. The possibility, however, is lacking up to now to come up with a final quantitative calculation of radiosensitivity in dependence on age taking into consideration all the known factors.

In any case, all the information that we have obtained with regard to radiation risk for the unborn child points to a high radiosensitivity of this period of human life. Therefore, radiation protection measures must aim at a very effective system to protect the unborn child.

2 Dependence of radiosensitivity on gender

Some national and international institutions [1, 20] concluded that the relative risk of radiation-induced cancers is roughly double as high in women as in men. In terms of absolute risk the difference is much smaller, because the "spontaneous" frequency of tumours is lower in women compared to men. A review currently in preparation by the German Strahlenschutzkommission (SSK, Commission on Radiological Protection) shows that this problem is not as simple as it is expressed in the two sentences above. (The review of the SSK is still under discussion; after approval it will be published on the SSK homepage, www.ssk.de; most probably, an English version will be published soon after the German version.)

3 Dependence of radiosensitivity on the individual in general

Radiotherapists are very well aware that people respond differently to radiation exposure. Similar experiences have been obtained after radiation accidents. Thus, physical dose does not describe radiation risk sufficiently; it is the response of the individual body to this dose that is relevant. A lot of efforts have been put into research to find biological indicators that describe individual radiosensitivity quantitatively. Up to now, no universally applicable technique has been identified. This is not surprising,

because similarly to age and gender dependence of radiosensitivity, individual radiosensitivity depends on many factors and mechanisms. Thus, one has to expect that several assay systems are required to describe the individual response to a specific radiation dose.

Right now, individual radiosensitivity does not play a role in radiation protection. There are two reasons for this: on the one hand, as mentioned above, up to now there are no assay systems available that allow a quantitative calculation of individual radiosensitivity; on the other hand, it is assumed that individual radiosensitivity is not important in the dose range that is relevant in radiation protection. The latter is true for most people who are occupationally radiation-exposed; but there are employees with life-time doses of several hundred milliSievert, and for them individual radiosensitivity might be very relevant.

4 The cataract issue

Until recently, there was the firm conviction that eye cataracts are deterministic effects with a threshold dose of about 1 to 2 Gy after acute exposure and 5 to 6 Gy after chronic exposure. This opinion has been challenged, meanwhile, by several observations. In various populations radiation-induced cataracts have been observed at clearly lower doses than 1 to 2 Gy: survivors in Hiroshima and Nagasaki [14, 15], CT patients [12], astronauts [5], radiologic technologists [4], and Chernobyl clean-up workers [24]. Currently, an increase after doses as low as 0.25 Gy has been described and some researchers even assume that no threshold dose exists at all (for a review and recommendations, see www.ssk.de; right now, there is only a German version available, but an English version will follow soon).

These results definitely require some re-thinking in radiation protection.

5 The cardiovascular issue

For quite some time, it was thought that radiation-induced cardiovascular diseases are a problem only in the high dose range, i.e. markedly more than 10 Gy. Studies, in particular, in Hiroshima and Nagasaki have revealed that this is not the case [21]. Several decades after the bombings a statistically significant increase in the number of cardiovascular diseases in the exposed group has been diagnosed, starting, at least, in the range of 0.5 Gy. Right now, it is not clear whether lower doses are also relevant and whether a

chronic or fractionated exposure shows the same results as those of the acute exposure in Hiroshima and Nagasaki.
One of the major tasks of radiobiologic research in this context is the clarification of the underlying mechanisms. One of the most favoured hypotheses is the assumption that due to radiation-induced damage to the lining of blood vessels in the heart, oxygen supply of heart cells is impaired resulting in fibrosis. Clearly, research is necessary in this field to obtain more insight.
For radiation protection these new findings might mean that besides tumour risk the most frequent health problem in humans, cardiovascular diseases, has to be taken into consideration, too.

6 The radon issue

As long as only uranium miner studies existed, it was always argued that for various reasons the data obtained in those studies are not useful for risk estimations in dwellings. Meanwhile, the situation has changed, because several long-term studies on radon risk in residences have been published [6, 7, 13, 22]. These studies suggest that a statistically significant increase in risk is observed in the range of 100 to 200 Bq m^{-3} [6] and that about 5% of all lung cancers can be attributed to radon in dwellings [22].
These findings require some action with respect to the BSS, because now data are available for the real situation and not only extrapolations based on uranium mines.

7 The low dose problem and DDREF

Tumour risk in adults after doses below about 100 mSv is an unresolved problem. Epidemiology cannot answer this question, because the "spontaneous" tumour frequency is so dominant that radiation-induced effects cannot be detected. Thus, our hope rests on the elucidation of the biological mechanisms acting in the low dose range. Meanwhile, we know quite a number of those mechanisms:

- Adaptive response
- Apoptosis
- Bystander effect
- Cell-cycle checkpoints
- Genetic predisposition
- Genomic instability

- Hormone effects
- Immunological effects
- Repair

just to name the most prominent mechanisms.

A frequently observed misuse of our knowledge consists in an approach to pick up only one or a few of these mechanisms in order to "prove" that tumour risk is either much lower or much higher than assumed in radiation protection. It is, of course, required to include all the mechanisms in risk estimations. And this has to be done in a quantitative manner. We are far away from being able to do this in the moment, but we hope that we will achieve this goal in the future.

Likewise unresolved is also the question whether a "dose and dose-rate effectiveness factor" (DDREF) exists in the low dose range. ICRP argues that the actually observed radiation-induced tumour risk of about 10% per Gy should be halved (DDREF = 2) [9], BEIR suggests a DDREF of 1.5 [2], and a recent publication doubts, whether a DDREF should be applied at all [11], because there is no convincing evidence in epidemiological studies of humans. SSK had expressed its opinion that the DDREF should be abandoned already during the public consultation of ICRP 103.

If the DDREF is actually abolished, then problems might arise with respect to the justification of the current dose limits in radiation protection. It will not be easy to justify that the dose limits are not changed, when the DDREF no longer exists.

8 What might be done in the context of radiation protection regulations?

8.1 Dependence of radiosensitivity on

8.1.1 age

There are already regulations (protection of the foetus by the monthly uterus dose limit, protection of people below the age of 18). But the 100 mSv per year limit for the planning of permanent relocation suggested by ICRP seems to be too high.

8.1.2 gender

There will be a lot of discussion necessary. It will be particularly important to start studies with the explicit intention to look for gender differences. If

it turns out that there is a significant difference one possibility to solve the problem might be: Calculating doses for women and men separately; this will lead to the effect that under identical exposure conditions women will reach the dose limits earlier than men.

8.1.3 the individual in general

Right now, we do not have the techniques to determine individual radiosensitivity precisely; this might change in the future and discussions should prepare for that situation.

8.2 The cataract issue

The 150 mSv per year as dose limit for the lens of the eye seems to be too high. The not easily to be answered question, however, is: which value should be chosen instead?

8.3 The cardiovascular issue

We need more data, before decisions can be made; but discussions are necessary already now to be prepared.

8.4 The radon issue

Again, something should be done, the problem is: how should the exact values look like?

8.5 The low dose problem and DDREF

The necessity to do extensive research in this field has been recognized by several funding organizations (e.g. EPA, the EU); but it will take time and a lot of brainstorming before solutions that have implications on radiation protection will be obtained. DDREF needs some reconsideration.

References

[1] Anonymous BEIR VII: Health Risks from Exposure to Low Levels of Ionizing Radiation. Washington: The National Academies Press, 2006.

[2] Anonymous BEIR VII: Health Risks from Exposure to Low Levels of Ionizing Radiation. Washington: The National Academies Press, 2006.

[3] Bhatia,S.; Sklar,C. Second cancers in survivors of childhood cancer. Nat. Rev. Cancer **2**: 124-132; 2002.

[4] Chodick,G.; Bekiroglu,N.; Hauptmann,M.; Alexander,B.H.; Freedman,D.M.; Doody,M.M.; Cheung,L.C.; Simon,S.L.; Weinstock,R.M.; Bouville,A.; Sigurdson,A.J. Risk of cataract after exposure to low doses of ionizing radiation: a 20-year prospective cohort study among US radiologic technologists. Am. J. Epidemiol. **168**: 620-631; 2008.

[5] Cucinotta,F.A.; Manuel,F.K.; Jones,J.; Iszard,G.; Murrey,J.; Djojonegro,B.; Wear,M. Space radiation and cataracts in astronauts. Radiat. Res. **156**: 460-466; 2001.

[6] Darby,S.; Hill,D.; Auvinen,A.; Barros-Dios,J.M.; Baysson,H.; Bochicchio,F.; Deo,H.; Falk,R.; Forastiere,F.; Hakama,M.; Heid,I.; Kreienbrock,L.; Kreuzer,M.; Lagarde,F.; Makelainen,I.; Muirhead,C.; Oberaigner,W.; Pershagen,G.; Ruano-Ravina,A.; Ruosteenoja,E.; Rosario,A.S.; Tirmarche,M.; Tomasek,L.; Whitley,E.; Wichmann,H.E.; Doll,R. Radon in homes and risk of lung cancer: collaborative analysis of individual data from 13 European case-control studies. Brit. Med. J. **330**: 223-228; 2005.

[7] Darby,S.; Hill,D.; Deo,H.; Auvinen,A.; Barros-Dios,J.M.; Baysson,H.; Bochicchio,F.; Falk,R.; Farchi,S.; Figueiras,A.; Hakama,M.; Heid,I.; Hunter,N.; Kreienbrock,L.; Kreuzer,M.; Lagarde,F.; Makelainen,I.; Muirhead,C.; Oberaigner,W.; Pershagen,G.; Ruosteenoja,E.; Rosario,A.S.; Tirmarche,M.; Tomasek,L.; Whitley,E.; Wichmann,H.E.; Doll,R. Residential radon and lung cancer—detailed results of a collaborative analysis of individual data on 7148 persons with lung cancer and 14,208 persons without lung cancer from 13 epidemiologic studies in Europe. Scand. J Work Environ Health **32 Suppl 1**: 1-83; 2006.

[8] Doll,R.; Wakeford,R. Risk of childhood cancer from foetal irradiation. Brit. J. Radiol. **70**: 130-139; 1997.

[9] ICRP : The 2007 Recommendations of the International Commission on Radiological Protection; ICRP Publ. 103. Elsevier, 2008.

[10] Jacob,P.; Kenigsberg,Y.; Zvonova,I.; Goulko,G.; Buglova,E.; Heidenreich,W.F.; Golovneva,A.; Bratilova,A.A.; Drozdovitch,V.; Kruk,J.; Pochtennaja,G.T.; Balonov,M.; Demidchik,E.P.; Paretzke,H.G. Childhood exposure due to the Chernobyl accident and thyroid cancer risk in contaminated areas of Belarus and Russia. Brit. J. Canc. **80**: 1461-1469; 1999.

[11] Jacob,P.; Ruhm,W.; Walsh,L.; Blettner,M.; Hammer,G.; Zeeb,H. Cancer risk of radiation workers larger than expected? Occup. Environ. Med. 2009.

[12] Klein,B.E.; Klein,R.; Linton,K.L.; Franke,T. Diagnostic x-ray exposure and lens opacities: the Beaver Dam Eye Study. Am. J. Public Health **83**: 588-590; 1993.

[13] Krewski,D.; Lubin,J.H.; Zielinski,J.M.; Alavanja,M.; Catalan,V.S.; Field,R.W.; Klotz,J.B.; Letourneau,E.G.; Lynch,C.F.; Lyon,J.I.; Sandler,D.P.; Schoenberg,J.B.; Steck,D.J.; Stolwijk,J.A.; Weinberg,C.; Wilcox,H.B. Residential radon and risk of lung cancer: a combined analysis of 7 North American case-control studies. Epidemiology **16**: 137-145; 2005.

[14] Nakashima,E.; Neriishi,K.; Minamoto,A. A reanalysis of atomic-bomb cataract data, 2000-2002: a threshold analysis. Health Phys. **90**: 154-160; 2006.

[15] Neriishi,K.; Nakashima,E.; Minamoto,A.; Fujiwara,S.; Akahoshi,M.; Mishima,H.K.; Kitaoka,T.; Shore,R.E. Postoperative cataract cases among atomic bomb survivors: radiation dose response and threshold. Radiat. Res. **168**: 404-408; 2007.

[16] Ron,E.; Preston,D.L.; Kishikawa,M.; Kobuke,T.; Iseki,M.; Tokuoka,S.; Tokunaga,M.; Mabuchi,K. Skin tumor risk among atomic-bomb survivors in Japan. Cancer Causes Control **9**: 393-401; 1998.

[17] UNSCEAR: Annex F: Radiation carcinogenesis in man. Sources, Effects and Risks of Ionizing Radiation. New York: United Nations, Sales No. E.88.IX.7, 1988: 405-544.

[18] UNSCEAR: Annex A: Epidemiological studies of radiation carcinogenesis. Sources and Effects of Ionizing Radiation. New York: United Nations Publications; Sales No.E.94.IX.11, 1994: 11-184.

[19] UNSCEAR: Annex I: Epidemiological evaluation of radiation-induced cancer. New York: United Nations, 2000: 297-450.

[20] UNSCEAR: Annex A: Epidemiological studies of radiation and cancer. Effects of ionizing radiation. New York: United Nations, 2006: 13-322.

[21] UNSCEAR: Annex B: Epidemiological evaluation of cardiovascular disease and other non-cancer diseases following radiation exposure. Effects of ionizing radiation. New York: United Nations, 2006: 323-383.

[22] Wichmann,H.E.; Rosario,A.S.; Heid,I.M.; Kreuzer,M.; Heinrich,J.; Kreienbrock,L. Increased lung cancer risk due to residential radon in a pooled and extended analysis of studies in Germany. Health Phys. **88**: 71-79; 2005.

[23] Wing,S.; Richardson,D.B. Age at exposure to ionising radiation and cancer mortality among Hanford workers: follow up through 1994. Occup Environ Med **62**: 465-472; 2005.

[24] Worgul,B.V.; Kundiyev,Y.I.; Sergiyenko,N.M.; Chumak,V.V.; Vitte,P.M.; Medvedovsky,C.; Bakhanova,E.V.; Junk,A.K.; Kyrychenko,O.Y.; Musijachenko,N.V.; Shylo,S.A.; Vitte,O.P.; Xu,S.; Xue,X.; Shore,R.E. Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. Radiat. Res. **167**: 233-243; 2007.

Annales de l'Association belge de Radioprotection, Vol.34, n°3, 2009
Annalen van de Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 3, 2009

REVISION OF THE EUROPEAN BASIC SAFETY STANDARDS DIRECTIVE ON RADIOLOGICAL PROTECTION AND RECAST - SOME VIEWPOINTS

Manfred Helming
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), Division General Aspect of Radiological Protection

19th of June 2009, Liege, Belgium

With respect to the currently ongoing work for a new European Basic Safety Standards Directive, three major sources of improvement have to be taken into account:

- Experience with the old Directive and subsidiary recommendations and guidelines,
- Regulatory approaches in the Member States for issues without or with less detailed requirements in the old Directive and
- New scientific findings on the effects of ionising radiation.

From this viewpoint the following topics are of primary concern:

- Exemption and clearance values for artificial radionuclides,
- Exemption and clearance values for naturally occurring radionuclides (NORM),
- High sensitivity of the lens of the eye,
- Applicability of the Dose-Dose Rate-Effectiveness-Factor (DDREF = 2),
- Gender specific radiation sensitivity,
- Sensitivity of the skin and
- Drinking water requirements.

Exemption and clearance values for artificial radionuclides:

The new Draft Directive seeks harmonisation with the exemption and clearance approach and the respective values of the IAEA by fully adopting the Safety Guide RS-G-1.7. The latter provides exemption and clearance values irrespective of the amounts of material to be exempted or cleared from a planned activity and is supposed to replace the values of RP 122 - Part I (as well as RP 89 and RP 113). Furthermore it is proposed to remove the exemption values (Bq/g) for moderate amounts as provided by RP 65 and the old Directive.

Since the aforementioned EU-documents currently form an essential basis for the national exemption and clearance legislation in many member states, it is to be carefully examined and verified whether the proposed changes are a step forward towards an improved concept with better scenarios and parameters and therefore with more realistic, consistent and reliable values. Looking at the concept of RS-G-1.7 itself, it seems to be questionable whether this general requirement is really met. Besides other arguable aspects concerning individual scenarios and parameters, especially the low probability-1 mSv/a-approach appears to be unbalanced with the dose limit for the public which is 1 mSv/a. However, harmonisation on its own is not a sufficient argument for making the changing to the new values.

Comparing the rounded values of RS-G-1.7 and RP 122, it turns out that about 10 of the RS-G-1.7-values are by a factor of 10 lower. This raises concern with respect to possible implications to exemption and clearance practices in industry, research and medicine. On the other hand, about 100 values are 10 or 100 times higher, which is less restrictive and therefore asks for justification and reasoning from radiation protection point (more realistic scenarios and parameters). Looking at the unrounded figures, the two sets of exemption and clearance values even differ to a much greater extent.

Exemption and clearance values for naturally occurring radionuclides (NORM):

The Draft Directive also seeks harmonisation with the IAEA approach concerning the exemption and clearance values for NORM (Naturally Occurring Radioactive Material). IAEA Safety Guide RS-G-1.7 provides a value of 1 Bq/g which applies to the radionuclide of the U-238- and the Th-232-decay chain, respectively, and a value of 10 Bq/g for K-40. A sum

formula to take account of the simultaneous presence of radionuclides of the two mentioned decay chains and of K-40 is not intended. The basis for the IAEA – concept is the general distribution of these radionuclides in earth‘s crust worldwide, and not a dose concept as it would typically be common and appropriate in radiation protection.

In connection with the Draft Directive it was argued that the above values represent a level of protection where the effective dose liable to be incurred by an individual due to the exemption and clearance practice would be less than 1 mSv/a for workers and of the order of 0.3 mSv/a or less for members of the public. The radon exposure of workers (except where radon is the dominant pathway) and the exposure of the public by the consumption of contaminated drinking water are basically excluded. If it turns out later that the exemption and/or clearance of a practice or material cause problems to the drinking water supply, the practice shall be made subject to the regulations.

The described concept cannot be supported at all. The reasons are the following:

- The exemption and clearance values of 1 Bq/g for each of the above decay chains does not correspond with exposures of the public are around or below 0.3 mSv/a as stated by the EC. Neither does it guarantee compliance with 1 mSv/a, which - for comparison - is the general level of protection of the public in planned activities. Public exposures might amount up to several mSv/a (in some cases even up to 10 mSv/a or more). The exclusion of the drinking water pathway does not generally change these assessments, because other pathways may also contribute substantially to the public exposure, too (ingestion or inhalation of dust, radon)
- The ground and drinking water pathway is the most crucial pathway in a number of cases of reusing or disposing NORM. The contamination of ground and drinking water by NORM can – depending on the characteristics and on the amount of the material and on the local circumstances - build up very high exposures to the public (10-20 mSv/a). Excluding or ignoring this pathway is not a way to solve the problem, because actions taken later – when contaminations appear in the drinking water supply – often are costly and require long term remediation.

- For occupationally exposed workers the 1 mSv/a – criterion is hardly met.
- To top it all off, in cases where both decay chains (U-238 and Th-232) are present, problems escalate because exposure may approximately double.

For more details see examples in Annex 1 (only for the U-238-decay chain). These examples of exposure assessment were taken from the source document which formed the basis for the current German radiation protection legislation with respect to the reuse and disposal of NORM-residues.

High sensitivity of the lens of the eye:

The German Radiation Protection Commission (German SSK) analysed the studies available on radiation induced cataract and came to the following conclusions:

- Additional cataracts are observed above cumulative exposures of about 0.5 Gy (for acute and protracted exposure) and for exposures around 1 Gy the relative risk is about 1.5.
- The threshold for radiation induced cataracts (if it exists) lies with high probability below 0.8 Gy.
- The confidence intervals for the estimation of the possible thresholds often include zero which means that the existence of a threshold is not certain.
- Assuming 20 years of occupational exposure close to the current dose limit for the lens of the eye of 150 mSv/a, a cumulative dose of 3 Sv is build up which is 6 times higher than the dose where additional cataracts are observed. 3 Sv correspond to a risk more than double the spontaneous cataract rate.

Based on the above findings the German SSK recommends:

- Adjustment of the current radiation protection legislation to the new finding,
- Consequent application of the available means of protection,
- Identification of work places with high risk for the lens,
- Application of appropriate dosimetry and dose estimation for the lens of the eye,

- Examination of the lens within the general medical examination and surveillance of occupationally exposed individuals (where appropriate),
- Research to understand and quantify dose–effect–mechanism (the new findings indicate a change of the current radiation protection paradigm)

The English version of the above recommendation of the SSK on radiation induced cataracts will be available on the SSK-WEB-page in short time.

The current revision of the German radiation protection legislation seizes the above suggestions. Concerning the dose estimation, the development and calibration of an appropriate dosimetry approach is under way.

With respect to the subsequent revision of the German radiation protection regulations it is under discussion if - despite missing knowledge about the dose–effect–mechanism and about the existence of a threshold - the precautionary principle would require to introduce both, a lower annual dose limit for occupational exposure (in the range between 20 and 30 mSv/a) and, in addition, a life time dose limit (in the range between 400 and 600 mSv).

Applicability of the Dose-Dose Rate-Effectiveness-Factor (DDREF = 2):

The position of the German SSK concerning the DDREF is very clear:

- There is no evidence of lower risk coefficients at low doses or dose rates compared to prompt high exposures
- Studies show that actually observed risks are higher than those based on DDREF = 2 which is a strong underestimation
- The concept of a DDREF should not apply any longer in the system of radiation protection

Currently an update of the above position of the German SSK is under way taking into account all new information available, including possible radiation induced heart and circular diseases at exposures above 0.5 Sv. A further strengthening of the reasons to abandon the DDREF-concept is expected.

In the light of the new situation, possible options in order to keep the level of protection are:

- Lower the annual dose limits for occupational exposure to 10 mSv/a

- Introduce dose constraints for occupational exposure, e.g. 10 mSv/a for the annual exposure (limit: unchanged 20 mSv/a) and 100 mSv for the life time exposure (limit in Germany: 400 mSv)
- Other solutions possible

By now, many questions around this issue are open. That is why, so fare, no changes have been made in Germany. Some of these questions are: Are the proposals meaningful and realisable with respect to the system of radiation protection currently in operation? What would be the practical implications? How to integrate dose constraints into the legal and practical system of radiation protection currently focussing on dose limits and optimisation? Which consequences (practical and legal) should follow when dose constraints are exceeded? Do dose constraints finally give any additional benefit?

Gender specific radiation sensitivity:

The international Commission on Radiological Protection (ICRP) in its latest publication (ICRP 103) confirms the position that for the purpose of radiation protection the effective dose for males and females should be calculated the same way. Accordingly the ICRP provides age and gender averaged organ weighting factors (w_t), also for the male and female breast and for the gonads. Other international Organisations conclude gender specific differences in the radiation sensitivity which may possibly be relevant to radiation protection.
The available studies are currently examined by the German SSK in order to give advice on whether a gender specific adaption of the system of radiation protection is demanded.

Radiation sensitivity of the skin:

The study by Preston et al. “Solid Cancer Incidence in Atomic Bomb Survivors” (Radiation Research 168, 1-64, 2007) makes the following statements on radiation induced skin cancer:

- For exposures above 1 Gy more than 50% of the skin cancer is radiation related
- ERR/Gy (above 1Gy) for non-melanoma cancer is 1.2 (90%-CI: 0.57 - 2.3)

- ERR/Gy in a linear model for non-melanoma cancer is 0.58
- Higher values are found for females and for persons exposed under the age of 30y

These observations justify the question whether the current skin protection concept by limiting the organ dose (1 cm^2 of the most highly exposed area) and limiting the effective dose (average over whole skin) is still a sufficient protection of the skin against stochastic radiation effect.
The issue is currently examined by the German SSK.

Drinking water requirements:

The Drinking Water Directive is not part of the recast process in connection with the current revision of the European Basic Safety Standards Directive on Radiological Protection and therefore not on the agenda of the running discussions in this respect. However, it is more than overdue now to finally provide the missing annexes to the Drinking Water Directive. Otherwise the Drinking Water Directive will continued not to be fully applicability by the Member States as it has been the case since entering into force of the Directive in 1998.

The German drinking water measurement program which was finished in 2008/09 covers a good portion of both, the major water suppliers and the overall drinking water supply in Germany, and led to the conclusions that – although drinking water in Germany generally does not cause danger or an immediate substantial health risk to the public – a comprehensive surveillance and control system of the drinking water supply on the basis of clear and executable criteria is urgently needed. Therefore it was decided to go ahead and make the necessary amendments to the German Drinking Water Ordinance with respect to radioactivity and to integrate the EC-recommendation on radon and radon decay products in the drinking water. The respective legislation process is under way.

Annex 2 gives an overview of the results of the German drinking water measurement program.

Annex 1

Table1: Exposures of the public (1 Bq/g U-238sec)
Scenario: Living at a dumpsite

Pathway	age group	ashes	slag	waste rock
All pathways	***< 1 year***	***3.80***	***3.62***	***23.75 mSv/a***
All pathways	1-2 years	1.17	1.00	6.54 mSv/a
All pathways	2-7 years	1.54	1.37	8.41 mSv/a
All pathways	adults	0.78	0.63	4.48 mSv/a

Dominant age group: < 1 year (for details see table 2)

Table 2: Exposures of the public (1 Bq/g U-238sec)
Scenario: Living at a dumpsite

Pathway	age group	ashes	slag	waste rock
Inhalation/dust	< 1 year	0.011	0.005	0.22 mSv/a
External exposure	< 1 year	0.053	0.053	0.053 mSv/a
Radon	< 1 year	0.107	0.0.05	0.329 mSv/a
Groundwater	< 1 year	3.487	3.487	23.058 mSv/a
Surface water	< 1 year	0.005	0.005	0.105 mSv/a
Total	< 1 year	3.80	3.62	23.75 mSv/a
Total (without DW)		0.31	0.13	0.69 mSv/a

Table 3: Exposures of the public (1 Bq/g U-238sec)
Scenario: Living at an open landfill

Pathway	age group	ashes	slag	waste rock
All pathways	***< 1 year***	***1.45***	***1.35***	***2.88 mSv/a***
All pathways	1-2 years	1.34	1.25	2.53 mSv/a
All pathways	2-7 years	0.94	0.84	1.76 mSv/a
All pathways	adults	0.46	0.39	0.81 mSv/a

Dominant age group: < 1 year (for details see table 4)

Table 4: Exposures of the public (1 Bq/g U-238sec)
Scenario: Living at an open landfill

Pathway	age group	ashes	slag	waste rock
Inhalation/dust	< 1 year	0.011	0.005	0.022 mSv/a
External exposure	< 1 year	0.228	0.228	0.228 mSv/a
Radon	< 1 year	0.021	0.001	0.026 mSv/a
Vegetables/dust	< 1 year	0.142	0.071	0.283 mSv/a
Groundwater	< 1 year	1.046	1.046	2.306 mSv/a
Total	< 1 year	1.45	1.35	2.88 mSv/a
Total (without DW)		0.40	0.30	0.57 mSv/a
Ingestion of dirt (age group: 1–2y):				
		0.717	**0.717**	**1.43 mSv/a**

Table 5: Exposures of workers (1 Bq/g U-238sec)
Scenario: Working on a dumpsite

Pathway	age group	ashes	slag	waste rock
Inhalation/dust	adults	0.128	0.064	0.255 mSv/a
Ingestion/dirt	adults	0.019	0.019	0.039 mSv/a
External exposure	adults	0.632	0.632	0.632 mSv/a
Radon	adults	0.021	0.001	0.073 mSv/a
Total	adults	0.800	0.716	0.999 mSv/a

Table 6: Exposures of workers (1 Bq/g U-238sec)
Scenario: Street construction

Total	adults	0.279	0.507	0.676 mSv/a

Annex 2

Violations of the indicative dose of 0.1 mSv/a (applying different sets of criteria):
560 drinking water supply facilities sampled (out of about 14 500)

Results:

I. Criteria of the EC-Directive with draft annexes (radionuclides U-238, U-234, Ra-226 and Ra-228; reference person: adults with a consumption of 730l/a):

1 supplier > 0.1 mSv/a

II. The same criteria like I., but also including Pb-210, Po-210 and Rn-222:

57 suppliers > 0.1 mSv/a
17 suppliers > 0.3 mSv/a
8 suppliers > 0.5 mSv/a
2 suppliers > 1 mSv/a

III. The same criteria like II., but also including children below 1 year as reference persons with a consumption of 170 l/a (adults 350 l/a):

131 suppliers > 0.1 mSv/a
35 suppliers > 0.3 mSv/a
15 suppliers > 0.5 mSv/a
0 supplier > 1 mSv/a

Annales de l'Association belge de Radioprotection, Vol.34, n° 3, 2009
Annalen van de Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 3, 2009

PROCESSUS DE RÉVISION DES BSS

Jean-Paul Samain
Conseil Scientifique des Rayonnements ionisants
auprès de l'Agence Fédérale de Contrôle Nucléaire

Les normes de base en sûreté, plus connues sous leur acronyme de BSS, occupent une place éminente dans l'arsenal des normes et recommandations de l'AIEA.

Elles s'inscrivent dans le processus désormais bien connu d'élaboration de la réglementation en sûreté nucléaire et en radioprotection dans le monde ; partant de la compilation des études faites par l'UNSCEAR traduites en *recommandations* par la CIPR. L'AIEA les décline en modèle de prescriptions réglementaires. Les BSS jouent, en quelque sorte, le même rôle pour l'ensemble des pays que les directives EURATOM pour les pays de l'Union européenne, hormis qu'elles n'ont de caractère contraignant que pour les activités internes de l'AIEA et ses activités de coopération technique avec les pays qui en bénéficient.

Elles ont pour vocation de couvrir toutes les situations d'exposition aux rayonnements ionisants, que ce soient les dose reçues par les travailleurs, les doses reçues par le public en général, dans les expositions médicales, l'exposition aux sources artificielles utilisées dans l'industrie, l'enseignement ou la recherche ou même les sources d'origine naturelle. Ces normes doivent donc bien s'appliquer à l'ensemble des installations industrielles, artisanales ou commerciales et à toutes les activités qui impliquent une exposition aux rayonnements ionisants. Elles constituent la base de référence pour la réglementation dans les états membres de l'AIEA.

La version actuellement en vigueur date de 1996 et a été publiée comme « Publication 115 » dans la série « Sûreté » des documents édités par

l'AIEA. Ce document répond dans une très large mesure aux recommandations contenues dans la publication n°60 de la CIPR. Ces normes de base sont non seulement le fait de l'AIEA mais ont été coparrainées par un ensemble d'organisations appartenant au système des Nations-Unies : FAO, OIT, OMS mais aussi par l'AEN de l'OCDR et l'OPS[1].

C'est en 2005, à l'annonce de la parution imminente de nouvelles recommandations de la CIPR[2] actualisant la publication 60 que le principe d'une révision des normes de base (BSS) a été envisagé. Ce sont la Commission des Normes de sûreté de l'AIEA (CSS) et ses Comités spécialisés, le RASSC e.a., assistés par un secrétariat inséré dans la division de la Sûreté nucléaire de l'AIEA qui ont déterminé l'ampleur de la révision et la méthode pour y parvenir. Les coparrainneurs habituels, auxquels pourraient se joindre la Commission européenne, le Programme des Nations-Unies pour l'environnement (UNEP), l'ICRP elle-même et l'IRPA, participent à ce processus.

Le pilotage et l'exécution de cette révision se fait au sein de l'AIEA, sous la direction d'Eliana AMARAL et est suivi essentiellement pas le Comité RASSC qui en est le comité de référence. Ce comité, et dans la foulée la CSS, ont émis des conseils pour baliser ce processus de révision :

- Maintenir le rôle des normes de base comme la référence internationale pour la radioprotection dans tous les domaines.
- Reconnaître le besoin de stabilité dans les normes internationales et donc, ne changer que si cette évolution est parfaitement justifiée.
- Maintenir un lien étroit avec la CIPR.
- Impliquer les Comités de l'AIEA et les parraineurs dans le processus de révision.
- Rechercher et tenir compte des commentaires des Etats membres sur l'actuelle version.
- Aider les pays en développement à participer.

[1] OPS = Organisation panaméricaine de la Santé.

[2] C'est désormais la publication n°103.

La révision des BSS s'inscrit bien entendu dans le processus d'élaboration des documents de l'AIEA ; il y porte le nom de **DS379.**

L'élaboration d'une première version (draft 0) a conduit après consultation du Comité RASSC à la publication d'un draft 1.0 en juillet 2008. La CSS avait insisté sur la transparence du processus de révision et c'est dans cet esprit – et aussi pour répondre à une recommandation précise de la CSS – que le secrétariat a publié au mois d'août suivant une version bâtonnée où les évolutions par rapport à la version actuelle (publication 115) apparaissaient clairement et où des commentaires pour les expliquer étaient également inclus.

Cette publication à la mi-2008 est vraiment le point de départ du processus de révision avec une dizaine de réunions du secrétariat portant sur l'ensemble du document ou sur des thèmes choisis, une réunion de revue avec les parraineurs ainsi qu'un avis du RASSC et puis de la CSS.

Plus de 1200 commentaires écrits ont été reçus et ont été introduits – ou non – dans le texte. Les Comités (RASSC, WASSC, etc.) ont examiné à nouveau le texte à la fin de 2008 en émettant un avis aussi bien sur les commentaires spécifiques que sur des sujets substantiels.

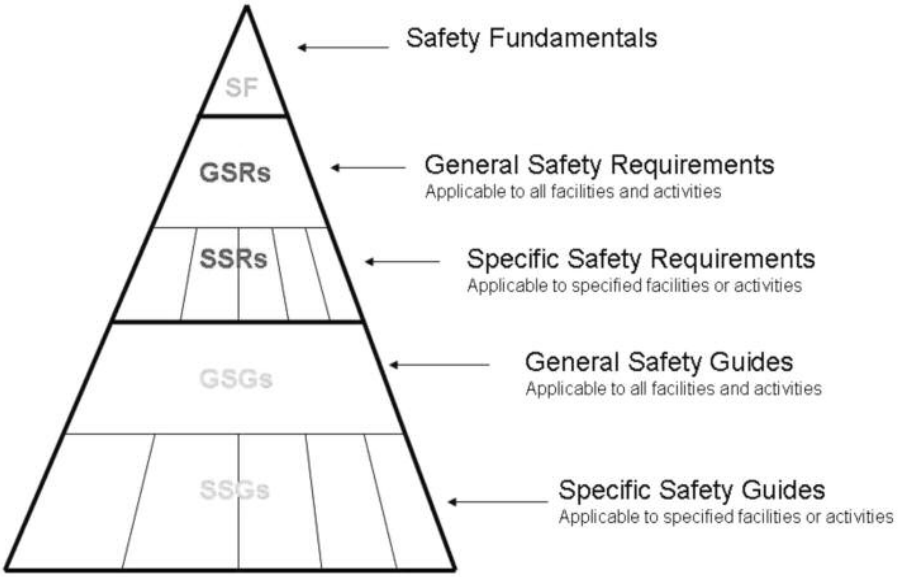
L'AIEA a encore organisé un atelier au Qatar au début de 2009, 3 réunions de rédaction en février et mars ainsi qu'une réunion de revue avec les parraineurs en avril. Au cours de cette réunion, toutes les remarques et suggestions formulées par les Comités de l'AIEA ont été prises en considération. A l'issue de cette réunion, deux sujets importants restent en discussion :

- La justification de l'utilisation des rayonnements ionisants pour obtenir des images du corps humain à des fins non médicales ; elle nécessite une meilleure argumentation sur le plan juridique.
- La fixation de niveaux de référence pour le radon est postposée en attendant les résultats d'une réunion de la CIPR en novembre 2009[3].

Enfin, la migration du document vers le nouveau format des recommandations de l'AIEA a été approuvée ainsi que la méthode pour y parvenir.

[3] C'est dire l'importance de la déclaration de la CIPR qui a considéré un doublement du risque radon par rapport aux valeurs traditionnelles et, par conséquent, une division par 2 des concentrations déclenchant des actions.

Quelques mots d'explication sont nécessaires pour situer la nouvelle architecture des normes de sûreté de l'AIEA. Sous l'impulsion de son président, la CSS a élaboré une hiérarchie unifiée pour les normes internationales de sûreté. Au sommet d'une pyramide à trois étages, se trouvent les principes fondamentaux de sûreté (SF-1) publiés en 2006[4]. Au second étage, les prescriptions de sûreté contiennent les exigences minimales qui doivent s'appliquer soit de manière générale à toutes les activités mais peuvent aussi viser spécifiquement certaines installations ou activités. A la base de la pyramide se situent les guides, également applicables de manière générale ou se rapportant plus spécialement à certains domaines.



Le futur proche du travail de révision apparaît clairement. Il s'agit pour le secrétariat de travailler les sujets à caractère éditorial et d'identifier les exigences minimales pour la migration vers le nouveau format. Comme la CSS l'a requis, la version 2.0 qui a été publiée au début de mai 2009 dans un format comparable au texte actuel sera soumise à l'approbation des comités lors de leur session de fin 2009. Entretemps, le secrétariat en étroite collaboration avec les parraineurs poursuivra son travail de transposition

[4] Il faut noter que la Commission européenne est associée à cette publication.

vers le nouveau format. C'est dire que plusieurs réunions de travail sont au programme des experts des états membres et des organisations qui parrainent.

L'approbation de plusieurs chapitres du texte et de la nouvelle structure par les principaux comités (RASSC et WASSC) est attendue pour la fin de cette année 2009.

Par ailleurs, l'AIEA a manifesté la ferme intention de continuer à impliquer les pays en développement dans le processus en organisant des ateliers régionaux.

La complexité et la minutie du processus de révision explique que celui-ci prendra un retard de 1 à 2 ans vis-à-vis des prévisions initiales; c'est sans aucun doute le prix à payer pour assurer la rédaction d'un document de qualité, correspondant au format exigé pour sa lisibilité et largement supporté par la communauté internationale au travers de l'implication étroite des parraineurs. Notons que la diffusion d'un draft des BSS dans le nouveau format s'accompagnera obligatoirement d'un document indiquant clairement les évolutions et la justification de celles-ci.

La publication le 1er octobre 2009 du draft 2.5 constitue une nouvelle étape intéressante dans ce processus. Ce document est censé refléter l'examen par la 26e session du comité RASSC de tous les commentaires émis sur la version 2.0. Une évolution supplémentaire résulte de la prise en compte des commentaires soumis par les membres de RASSC eux-mêmes. Le document comprend les prescriptions générales (« overarching requirements ») dégagées lors de la réunion du Secrétariat des 9 au 11 septembre 2009 et les modifications subséquentes du texte. Les prescriptions qui sont considérées de détail (= not overarching) sont formulées par une expression comme « has to » ou une expression similaire au lieu de « shall ». Un texte extensif sur la protection radiologique de l'environnement a été ajouté ainsi qu'un certain nombre de prescriptions relatives à la mission des autorités de sûreté dans les situations d'exposition des travailleurs dans la section consacrée aux expositions planifiées (planned exposure situations). Les sujets encore non résolus sont indiqués.

Les travaux de la session de novembre du RASSC sont consacrés à l'examen de ce draft. Un séminaire sur le radon aura lieu en décembre : il doit prendre en compte la dernière déclaration de la CIPR sur ce sujet.

C'est au début de 2010 que l'AIEA devrait solliciter les états membres pour qu'ils apportent leurs commentaires. Cette consultation sera clôturée en mai 2010 et un rapport sur ces commentaires sera présenté aux sessions des comités en juin.

L'approbation du texte est espérée pour la fin de 2010 en vue de sa soumission finale à la CSS en mars 2011.

La structure du texte est désormais vraisemblablement figée.

L'introduction, qui en constitue la première section, décrit le contexte et la raison d'être des BSS et définit le champ d'application et les concepts utilisés dans le document. Celui-ci se décline ensuite en quatre sections.

La section 2 comprend les prescriptions générales pour la radioprotection et la sûreté énonçant les responsabilités des gouvernements, des autorités de sûreté et des autres parties prenantes, les prescriptions pour la gestion; les exigences découlant de l'implémentation des principes de radioprotection doivent être intégrées dans les systèmes de gestion des organisations (« management system »).

La section 3 s'applique aux situations d'exposition planifiées (Les *pratiques* dans le jargon actuel) et se décline en prescriptions génériques et en prescriptions s'adressant respectivement à l'exposition des travailleurs, du public et à l'usage médical. Les prescriptions génériques comportent les prescriptions administratives relatives à la déclaration, aux systèmes d'autorisation et à l'exemption et à la libération ainsi que celles visant à l'application des principes de la radioprotection (justification, optimisation et limites de doses), au contrôle réglementaire de l'imagerie à usage non-médical et la sûreté des sources.

La section 4 s'applique aux situations d'urgence par des prescriptions génériques et des prescriptions visant le public en général et les travailleurs qui interviennent dans ces situations. Elle envisage aussi la transition de la situation d'urgence vers la situation d'exposition existante.

Enfin, la section 5 régit les situations d'expositions existantes par des prescriptions génériques, des prescriptions visant plus particulièrement le public et les travailleurs respectivement. Elle introduit aussi des prescriptions spécifiques à la remédiation dans les zones contaminées, au radon dans les lieux de travail et les habitations et les radioisotopes dans les

marchandises (matériaux de construction, les denrées alimentaires, l'eau potable, etc.) y compris quand elles proviennent de régions contaminées à la suite d'un accident.

Les annexes, actuellement au nombre de 4 visent les critères d'exemption et de libération, la catégorisation des sources scellées d'usage habituel, des limites pour les situations d'exposition planifiée et les critères à utiliser dans la préparation et la gestion des situations d'urgence radiologique.

Le document se clôt avec un glossaire très étendu définissant l'ensemble des termes utilisés.

La version 2.5 d'octobre 2009 comporte déjà certaines évolutions intéressantes de notre point de vue. La consultation des Etats membres au début de 2010 constituera une étape cruciale dans ce processus.

Sachant que la prochaine version des BSS aura toutes les chances d'être le texte de référence en matière de radioprotection dans le monde au cours des deux prochaines décennies, il est essentiel que les parties concernées consacrent le temps et l'énergie nécessaires à apporter des commentaires pertinents dont l'AIEA devrait tenir compte pour finaliser ces nouveaux BSS au cours de l'année prochaine.

Sur le site de l'AIEA ….

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1):

Safety Fundamentals

The Safety Fundamentals SF-1 presents the fundamental safety objective and principles of protection and safety and provides the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establish the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by

the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The safety requirements use 'shall' statements with statements of associated conditions to be met. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

The long-term set of Safety Requirements includes a General Safety Requirements applicable to all facilities and activities with a graded approach and composed of a set of publications addressing the following seven areas: Governmental and Regulatory framework, Leadership and Management for Safety, Radiation Protection and Safety of Radiation Sources, Safety Assessment, Predisposal Management of Radioactive Waste, Decommissioning and Termination of Activities, and Emergency Preparedness and Response. This is complemented by a set of six Facilities and Activities specific Safety Requirements on Site Evaluation for Nuclear Installations, Safety of Nuclear Power Plants with one volume on design and construction and one volume on commissioning and operation of Nuclear Power Plants, Safety of Research Reactors, Safety of Nuclear Fuel Cycle Facilities, Safety of Radioactive Waste Disposal Facilities and Safe Transport of Radioactive Material.