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FOURTH EUROPEAN IRPA CONGRESS, GENEVA, 22-27.6.2014 THE TRANSPOSITION OF THE PRINCIPLES OF RADIATION PROTECTION IN INTERNATIONAL AND EURATOM BASIC SAFETY STANDARDS

Augustin Janssens[1]

This paper was presented at the 4th European IRPA congress, as an invited contribution to explain the International and Euratom Basic Safety Standards in the light of the recommendations of ICRP. It covers a discussion of the concept of exposure situations and of the principles of protection in the current radiation protection system, and how these have been interpreted for the purpose of building a regulatory framework and of defining the scope of regulatory control.

The system of radiation protection

Since 1928, the International Commission on Radiological Protection (ICRP) offers recommendations on the principles on which radiation protection can be based. ICRP has developed and elaborated the International System of Radiation Protection on the basis of evolving understanding of the science of radiation exposures and effects, on value judgements taking into account societal expectations and ethics, and on experience gained in application of the system.

The latest main recommendations were published in ICRP Publication 103 [1]: *The 2007 Recommendations of the International Commission on Radiological Protection.* These formally replaced the Commission's 1990

[1] Augustin Janssens was formerly the head of the EC's radiation protection unit; no part of this presentation however should be regarded as representing the views of the European Commission, nor should it be referred to in interpreting the Directive or its implementation in national legislation; only the actual text of the Council Directive has value for this purpose

recommendations in ICRP Publication 60 [2]. ICRP P103 introduced a new approach to characterise exposure situations and categories of exposure. The new approach has affected the formulation of the principles of radiation protection, and has prompted an in-depth revision of the regulatory framework laid down in international standards. This paper reflects the thorough discussions that took place in that context and explains how the international standards have shed new light on important aspects of the system that are relevant to regulatory control, especially on the borderline between existing exposure situations and planned public and occupational exposures and on the scope of regulatory control.

Exposure situations and categories of exposure

The starting point of the reflections that lead to P103 was the idea that the system of protection applies equally to any controllable exposures [3]. *Controllable* exposure situations are those in which the dose to an individual "can reasonably be controlled by whatever means". The term *reasonable* should be understood from a societal perspective. For instance, it is in general not considered reasonable to relocate people living in areas with high natural radiation background, or to avoid travelling by airplane or spending time in the mountains, merely on grounds of radiation protection. Exposure situations that are essentially un-amenable to control are excluded from the system of protection and related legislation.

A *first* class of exposure situations encompasses those in which the *source* is controllable. This is the case when the exposure results from the introduction of a source, e.g. in a new practice. The exposure results from the conduct of the practice and ends when the practice is terminated and the source removed. A *second* class involves situations where the pathways of exposure are controllable but the source is not. A *third* class is where the exposed individual is in control, at least in part, of its own exposure. Members of the public are, in general, not expected to adjust their behaviour, and standards of protection are based on the assumption that they don't.

One of the major features of the recommendations in P103 is the application of the principles of justification and optimization to all classes of controllable exposure situations, characterized as planned, existing or emergency exposure situations. This approach evolved from the previous (P60) process-based approach that used the terms *practices*

and *interventions*. The Commission nevertheless has preserved the term "practice" to denote an activity that "causes an increase in exposure to radiation or in risk of exposure to radiation" (48). The term *intervention* now describes protective action that reduces exposure, and the terms *emergency* or *existing exposure* describe corresponding *situations*.

ICRP uses the term 'source' for any physical entity or procedure that results in a quantifiable radiation dose to a person or a group of persons. This is a broad definition, beyond the idea of a physical source. Semantically it is closer to the idea of "origin of exposure". *Sources* will often be part of a practice (or planned exposure situation), but also natural radiation sources are considered and the presence of radioactive substances in the environment in an emergency exposure situation is regarded as a "source".

An individual may be exposed to several *sources*. This may require an assessment of the total exposure of the individual from all sources within a single class of exposure situation. It is also necessary to consider the exposure of all individuals exposed by a given source or group of sources. ICRP has emphasized the primary importance of such source-related assessment, in particular for the application of the principle of optimization. This has led to the introduction of *dose constraints* as prospective source-related restrictions on the individual dose from a source in planned exposure situations and of *reference levels* in the other situations.

A distinction between public, occupational and medical exposures was introduced in the radiation protection system at a very early stage. Broadly speaking, occupational exposures are those incurred by workers as a result of their work, medical exposures are those delivered to patients and public exposures are any other. The distinction was made at a time that the radiation protection system was primarily concerned with what is now labelled as "planned exposure situations". The introduction of other exposure situations has led to a less straightforward delineation of occupational exposures (emergency workers, exposure as a result of radon in the workplace, etc.). Non-medical imaging exposures are in principle public exposures, but in specific cases are managed as medical exposures.

The principles of protection – justification, optimisation and dose limitation

The set of principles of protection applies equally to all controllable exposure situations: the principle of *justification*, the principle of *optimization* of

protection, and the principle of application of *limits* on maximum doses in planned situations.

Justification

ICRP distinguishes between two approaches to justification. The first approach is used in the introduction of new activities where radiation protection is planned in advance and "the necessary actions can be taken on the source" (cf the first class of controllable exposures). No planned exposure situation should be introduced unless it produces a sufficient net benefit to the exposed individual or to society to offset the radiation detriment it would cause. The second approach is used where exposures can be controlled mainly by action to modify the pathways of exposure on a collective or individual basis (cf classes 2 and 3) and not by acting directly on the source. Broadly speaking, the first approach applies to planned exposure situations and the second approach to existing and emergency exposure situations. Whether the radiation source already exists or not is a relevant distinction for the application of the principle of justification, but ICRP's focus on this aspect has led to interpretations as if it is the main basis of the definition of existing versus planned exposure situations.

Both optimization and justification allow for economic and societal factors, but justification decisions on grounds of the benefit to society, often involve a judgment far beyond the scope of radiation protection. At first, it was argued that radiation protection plays such a minor role in a government's decision to justify the introduction of a source, that the principle should be dropped from the ICRP system [3].

Optimization

The principle of optimization remains the cornerstone of the protection system. It has received new emphasis through the weight put on *dose constraints* and the introduction of *reference levels*. Most important is the recognition that the application of the principle is basically the same in any class of exposure situation. Irrespective of the exposure situation, the doses to be compared with a dose constraint or reference level are usually prospective, i.e. doses that may be received in the future, that can be influenced by decisions on protective actions.

Justification merely requires the net benefit to be positive ("do more good than harm"), *optimization* requires the net benefit to be maximum,

allowing for the economic and societal cost of protection measures, through the selection of the best option for protection under the prevailing circumstances.

Dose limitation

Dose limits apply in planned exposure situations only, but not to medical exposures. ICRP concluded that the existing dose limits recommended in P60 continue to apply and provide an appropriate level of protection. The dose limits for occupational and public exposures are the values of the effective dose to individuals that should not be exceeded. The distinction between the two categories essentially relates to differences in the distribution of detriment and benefit, to the extent that an individual can manage its own exposure, and to legal responsibility for the exposure. The first two aspects have been identified in P103 in the context of the bands of constraints and reference levels for workers and members of the public (Table 5 in section 5.9.3). While this table is not concerned with dose limits, it allows to understand why the dose limits for occupational and public exposures are very different (20 mSv and 1 mSv in a year respectively).

The considered total dose to an individual is the sum of doses from regulated sources in planned exposure situations. The summation of doses provides a guarantee against unwarranted separate consideration of different sources. If sources and corresponding reference groups of the population are defined properly however, it is exceptional that public exposures from different practices need to be considered together. For outside workers of course all doses incurred in different undertakings need to be added, under the responsibility of their employer. The earlier role of dose limits in ensuring an equitable distribution of individual doses has now been taken over by the concept of constraints.

Regulatory framework

Exposure situations

The latest ICRP recommendations have promptly been followed by the revision of the international Basic Safety Standards [4]. The IBSS have been structured along the three exposure situations, within which the different categories of exposure are considered.

It should be emphasized that ICRP's definitions of the three classes of exposure situations merely intended to convey the key messages on different

management approaches appropriate to situations. The ICRP definitions were essentially descriptive; they offered no clear delineation and they were not well suited to address the legal responsibilities for managing a situation from an operational or a regulatory point of view. The regime of regulatory control should indeed be quite different for a planned exposure situation, for which legal responsibilities for the operation of the facility or the conduct of the activities can be defined, and for the other situations where in general this is not the case.

Eventually in the IBSS a broader definition of planned exposure situations was introduced: "… a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source". Semantically, this definition links "planned" to "situation" (of exposure) rather than to "exposure" as such. Similarly, the term *practice* was defined more broadly as: "any human activity that introduces additional sources of exposure or additional exposure pathways (from existing sources), or modifies the network of exposure pathways from existing sources so as to increase the exposure or the likelihood of exposure of people or the number of people exposed".

In this way, while for ICRP all exposures to natural radiation sources are *a priori* managed as an existing exposure situation, this depends in the IBSS on whether the exposures are the result of, or are affected by, an activity. The distinction is best illustrated by the exposure of space crew to cosmic radiation: while the source obviously is an existing one, this is clearly a planned exposure situation. The same applies to aircrew, but then the formulation is not so explicit in the IBSS, as compared to the Euratom BSS [5].

The exposure of workers in NORM industries (handling or processing naturally occurring radioactive materials) is the direct consequence of their work. Hence, in principle, these industries should be managed in the same way as practices involving artificial, man-made, radiation sources within the overall framework of planned exposure situations. On the other hand, since naturally occurring radionuclides are ubiquitous, the scope of regulatory control of NORM industries needs to be narrowed down. The borderline is a regulatory decision rather than one deriving from first principles. The regulatory tools for this purpose can be different. In the IBSS, in general, NORM industries are part of the broad family of natural radiation sources regarded as existing exposure situations, but where the

activity concentrations exceed a threshold value, they are subject to the requirements for planned exposure situations. Inversely, the Euratom BSS *a priori* regard all NORM industries as practices, but below a threshold, and other conditions and criteria being satisfied, they are exempted from the corresponding requirements.

A similar issue arose with the exposure of workers to radon in their place of work. In line with overall Health and Safety policies, all exposures incurred by workers in the course of their work are part of occupational exposure. ICRP nevertheless limits the use of the term "occupational exposure" to radiation exposures "incurred as a result of situations that can reasonably be regarded as being the responsibility of the operating management". In the IBSS the allocation of such responsibility is a regulatory decision, and in general the employer, or the undertaking in which premises the worker operates, has the legal responsibility for the exposure to radon in workplaces, even where this does not directly result from the conduct of activities. If radon concentrations, after remediation, continue to exceed the reference level, then the exposure to radon at work is managed as a planned exposure situation. The occupational dose limit applies to all regulated exposures, including to radon at work, irrespective of the origin of radon ingress (in general from the earth's crust). While ICRP advocates that a dose of 20 mSv in year should not be exceeded, it does not regard this as a dose limit [6].

As defined by ICRP, the third principle of radiation protection, dose limitation, only applies to public and occupational exposures in a planned exposure situation. Any decision to apply dose limits in a given situation is essentially a means of regulatory enforcement however. It should be recalled that initially ICRP wanted to dismiss dose limits altogether, but stakeholders (regulators, industry) advocated that they should be maintained [7]. The ethical basis for the non-application of dose limits is that imposing a limit could be contrary to the interest of the protected individual (hence they do not apply in emergency exposure situations, nor to medical exposures). The applicability of dose limits therefore may be explained more easily without reference to exposure situations: a dose limit applies where the legislator has judged that it is not justified from a societal perspective to maintain an exposure situation, or to allow it to occur, if the exposure of one or more individuals is above this limit, except for the benefit of the exposed individuals themselves.

ICRP implicitly recognises the regulatory context of dose limits by applying the principle only to *regulated* sources. Also in the international and Euratom standards it is acknowledged that compliance with the dose limit for public exposures can only be checked by the regulator, who has access to the relevant information for all authorised practices.

Scope of regulatory control

ICRP has explained the historical and conceptual context of tools defining the scope of regulatory control in P104 [8]. In the end, it is for the legislator to decide how to make best use of regulatory resources and for the competent authorities to discharge their responsibilities as appropriate to the situation. Existing exposure situations for which no regulatory control is warranted, even though they are strictly speaking *controllable*, may be excluded from the scope of legislation, but there is no need for radiological criteria for this purpose. Criteria are needed only to define the scope of regulatory control in planned exposure situations, using the tools of exemption of practices form regulatory control and of clearance of materials originating from authorised practices. The management of NORM industries in the same way as practices has shed new light on these concepts.

In the IAEA Safety Guide RS-G-1.7 [9] the approach to define the scope of regulatory control was still based on the exclusion of levels of natural activity prevailing in the earth's crust (threshold values of 1 kBq/kg for the uranium and thorium decay chains, and 10 kBq/kg for K-40). While the IBSS developed a regulatory control scheme on the basis of exemption rather than exclusion, these threshold values were kept for the exemption of NORM industries and for the clearance of their residues. These values are also to be found in the Euratom BSS. Nevertheless, the latter allow for situations where the exempt concentration can be higher, for instance for segments of the decay chain in case of non-equilibrium, or where the values should be more restrictive, allowing for specific pathways of exposure (e.g. contamination of drinking water). Despite a slightly different structural approach to the management of NORM industries, both IBSS and Euratom BSS have introduced an effective dose of 1 mSv in a year as the exemption criterion for radionuclides of natural origin.

In earlier Euratom guidance [10] a criterion of 300 μSv per year was introduced, well below the dose limit, but having clarified the scope of

dose limits on public exposures the regulatory system was simplified so as to have a smaller set of dose criteria.

The Euratom BSS include the regulation of building materials on the basis of a reference level of 1 mSv per year (above the prevailing background radiation). Hence the criterion for clearance of residues from NORM industries into building materials is coherent with the management of building materials taken from the earth's crust.

Conclusion

The new IBSS and the new Euratom Directive reflect a coherent philosophy for the protection of all categories of exposed individuals in all exposure situations. This philosophy benefited very much from ICRP P103, but there are subtle differences that need to be explained. The approach in the international standards may contribute to a better understanding of radiation protection, and it should be allowed for in future recommendations of ICRP.

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PRESENTATION ON THE IMPLEMENTATION OF THE NEW EU BSS IN BELGIAN REGULATION

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1. Introduction

L'AFCN s'est engagée dès le début dans les travaux de mise à jour des directives Euratom existantes (89/618/Euratom, 90/641/Euratom, 96/29/ Euratom, 97/43/Euratom et 2003/122/Euratom). En particulier par une participation active au sein des négociations du Groupe des Questions Atomiques depuis novembre 2011 jusqu'en décembre 2013.

La publication le 17/01/2014 au Journal officiel de l'Union européenne de la nouvelle directive 2013/59/ Euratom du 5 décembre 2013 fixant les normes de base en radioprotection marque la fin de cette procédure au niveau européen.

La mise à jour des normes de base européennes en radioprotection consolide cinq directives existantes, tient compte des recommandations de la Commission Internationale de Protection Radiologique publiées en 2007 (CIPR 103) et met en cohérence le cadre européen avec les nouvelles normes de base de l'Agence internationale de l'énergie atomique, publiées en 2011.

A compter du 17 janvier 2014, la Belgique dispose d'un délai de 4 ans pour transposer cette nouvelle directive en droit national, et ajuster la réglementation nationale avec les normes internationales et européennes.

Les Euro-coordinateurs ont désigné l'AFCN comme pilote du projet de transposition réglementaire étant donné sa compétence en radioprotection.

La nouvelle directive promeut la protection des personnes vis-à-vis des rayonnements ionisants, en particulier, par l'application opérationnelle du principe de justification, par la prise en compte de l'approche graduée des risques liés à l'utilisation des rayonnements ionisants dans la mise en œuvre du système réglementaire et par la protection de la population vis-à-vis des sources naturelles de rayonnements ionisants.

La réglementation belge avait déjà anticipé le renforcement de certaines prescriptions, en particulier dans le domaine des applications médicales, de la gestion des sources radioactives non scellées, dans la gestion des urgences nucléaires et dans la gestion de la problématique du radon.

Dès à présent il est possible de déterminer quelques sujets à revoir (liste non exhaustive) :

Protection du travailleur :

- La limite de dose équivalente de 150 mSv sur 12 mois consécutifs pour le cristallin (œil), devra être modifiée et réduite à 20 mSv par an
- Obligation de l'enregistrement des expositions accidentelles ou non-prévues
- Nouvelles dispositions concernant l'organisation de la radioprotection des travailleurs (Radioprotection Officer (RPO) et Radioprotection Expert (RPE))

Protection du public :

- Etablir/modifier le plan radon national et introduire la notion de niveau de référence national
- Etablir un cadre réglementaire pour contrôler la radioactivité naturelle des matériaux de construction
- Renforcement des dispositions sur la transparence et l'implication du public (art 6 de la loi du 15/04/1994)

Cadre médico-légal :

- La directive introduit une nouvelle terminologie « exposition délibérée de personnes à des fins d'imagerie non médicale » et devrait conduire à application plus opérationnelle du principe de justification

Activités professionnelles selon le RGPRI :

- Modification du cadre réglementaire pour les industries NORM et le personnel navigant (situations d'exposition planifiées)

2. Contexte :

- Depuis 2001 l'AFCN contribue activement aux activités internationales et aux activités de recherche et développement afin de faire des propositions d'amélioration du cadre réglementaire.

Le ***mouvement d'harmonisation concernant les normes***, pousse les Etats Membres de l'UE à adopter une position commune.

La transposition des BSS devra se faire en cohérence avec les échanges européens et notamment en participant activement aux réunions du groupe HERCA, EACA[1].

- L'AFCN collabore au niveau national avec divers organismes, agences et services public fédéraux et régionaux tels que Centre de Crise, l'AFSCA, l'INAMI, l'ONDRAF, les SPF et SP régionaux,…

Des ***échanges réguliers et structurés*** ont été établis afin de couvrir des domaines de compétences communs, par exemple le contrôle de la qualité de l'eau de boisson, l'irradiation des aliments, l'étiquetage des produits de consommation, le transport des matières radioactives,…

- L'AFCN a promu la culture de sûreté et de sécurité au sein de son organisation et au niveau des exploitants/entreprises[2].

Pour ce faire l'AFCN a développé une culture de dialogue et consultation des parties prenantes telles que les organismes agréés, les exploitants/entreprises, le monde professionnel de l'éducation et le monde professionnel médical, etc. .

Depuis fin 2007, ***une consultation systématique des parties prenantes*** a été organisée en vue de recueillir les opinions de ceux qui seront les premiers concernés par l'application de ces nouveaux textes réglementaires.

La transposition des BSS devra respecter cette bonne pratique et envisager des réunions avec les diverses parties prenantes tout en respectant son rôle de pilote au niveau du travail réglementaire entre autres respecter la procédure PC005-02 dont le flowchart est en annexe.

Une première phase de consultation préalable qui se déroulerait durant le second semestre de 2014 permettrait à l'AFCN d'établir un livret blanc de la transposition et d'estimer le processus réglementaire le plus efficace en 2015.

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1 HERCA: Heads of the European Radiological protection Competent Authorities; EACA : European Association of Competent Authorities (transport safety).

2 Définition des BSS : "undertaking : means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);" .

- L'accident de Fukushima et ses conséquences internationales, l'évolution de la réglementation dans le domaine de la sécurité et les actions à entreprendre dans le cadre de l'IRRS sont des facteurs qui influenceront la révision du cadre réglementaire.

En 2009, l'AFCN prévoyait déjà la mise en œuvre de la restructuration de la réglementation qui devrait offrir un cadre structuré au développement des différents et nombreux projets en cours.

En 2014, l'IRRS dans son rapport de mission indique qu'il n'existe pas de document unique et compréhensif expliquant la politique et la stratégie dans le cadre de la sûreté nucléaire et pointe certains manquements réglementaires comme par exemple une définition claire des interfaces entre autorités compétentes.

Ce document devra être décliné à différents niveaux du cadre réglementaire, en particulier dans la définition claire des compétences et responsabilités des diverses autorités compétentes concernées.

Afin de résoudre certains des sujets ci-dessus, le travail obligatoire de la transposition des normes de bases et le large champ d'application couvert par la nouvelle directive (BSS) ***nous offre une opportunité de révision de la réglementation en profondeur.*** (Intégrer le travail de transposition des BSS dans le projet PR 1077 concernant la restructuration de la réglementation ?).

Cette restructuration pourrait renforcer la position de l'AFCN, simplifier le processus d'évolution des règlements au regard des avancements technologiques et des retours d'expérience des divers départements et experts de l'AFCN.

Eclaircir les échanges et interfaces institutionnels en Belgique en désignant plus clairement ***l'AFCN comme autorité de référence et d'expertise dans le domaine de la radioprotection***.

En effet, on peut imaginer de raccourcir efficacement la durée et le nombre de consultations obligatoires des projets réglementaires en clarifiant les domaines de compétences et le champ d'application laissé à l'appréciation de l'AFCN.

Comme il est plus aisé et rapide de produire des directives AFCN plutôt qu'un Arrêté royal, il serait opportun de définir un cadre réglementaire de base reprenant les objectifs et principes généraux de radioprotection,

ces derniers feraient l'objet de lois et d'arrêtés royaux (art 24 de la loi 15/04/1994).

Tandis que les prescriptions administratives et de bonnes pratiques plus ciblées par secteur professionnel seraient reprises dans des directives[3] AFCN.

Cette structure réglementaire serait également plus adaptées aux évolutions des technologies nouvelles et intégrerait plus rapidement la gestion des risques (en particulier processus de réévaluation du risque radiologique et le processus de justification de la pratique).

- Le retour d'expérience des services opérationnels a montré un risque à réduire en pratique le champ des missions de l'autorité de sûreté à la simple délivrance d'autorisations et à la réalisation d'inspections.

Les missions de l'autorité de sûreté sont bien plus vastes et plus complexes et il importe que cette réalité soit clairement traduite dans les modes d'organisation et de fonctionnement de l'autorité de sûreté.

L'approche graduée du cadre réglementaire est une des plus importantes recommandations internationales tant à l'AIEA (GSR part1-requirement 1) que dans les normes de bases européennes. Une analyse approfondie des processus réglementaires et une définition claire des critères de décision permettrait d'entrevoir une simplification administrative des autorisations et de mettre l'accent sur les inspections de l'AFCN.

Cette analyse se ferait en cohérence avec les standards et guides internationaux.

Cette approche graduée au sein des BSS, reprend une **description précise des processus d'autorisation**, il conviendra d'envisager ceux en vigueur à l'AFCN , de faire une analyse des ressources allouées et des simplifications administratives qui pourront être envisagées.

Cette réflexion au sujet des processus a été entamée dans le cadre des travaux du Management System et présente une interface avec les travaux de transposition des BSS.

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[3] (nature du document à clarifier dans la procédure réglementaire : note interne, note ou formulaire pour les acteurs externes à l'AFCN, publication au moniteur belge,…) .

L'AFCN devra être capable de définir/décrire les critères de décisions qui lui permettront de choisir le processus de notification, d'enregistrement ou d'autorisation en fonction du risque radiologique.

La réglementation actuelle est essentiellement basée sur la notion d'établissement classés et d'activités professionnelles alors que les BSS se déclinent en situations d'exposition et expliquent clairement le besoin d'intégrer un processus de justification dans les pratiques nucléaires. La problématique des produits de consommation, des matériaux de constructions,… nous amènera à **envisager de nouveaux processus** à l'AFCN.

- Le potentiel présenté par ***l'Internet, est un outil non négligeable*** à envisager dans le cadre de la simplification administrative.

Les adaptations réglementaires nécessaires pour permettre à l'AFCN la reprise de la gestion de la base de données des doses aux personnes professionnellement exposées (projet réseau dosimétrique) ne sont qu'un exemple.

Le principe de transparence, une des recommandation spécifique des BSS, est un outil intéressant pour développer ***la confiance du public*** dans son autorité compétente en radioprotection.

En effet, un des problèmes majeurs, un peu partout dans le monde, est que les autorités ne sont pas perçues comme indépendantes et protectrices de la santé. Un véritable changement dans cet état de choses demande un profond changement de mentalité et de pratiques. Un tel changement pourrait être facilité par une structure interactive d'information, de consultation de délivrance d'autorisation/agrément, de communication de rapports d'inspection[4].

3. Réglementations similaires à l'étranger :

Les relations bilatérales, en particulier avec la France, le Grand-Duché du Luxembourg et les Pays-Bas continuent d'apporter les échanges utiles à un enrichissement réciproque. La participation active de l'AFCN aux groupes de radioprotection créés par l'ASN contribue aux développements utiles en matières de protection des patients, des travailleurs et de la population.

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[4] Déjà d'application en France (ASN).

Une position multinationale nous permet d'harmoniser nos exigences en radioprotection tout en assurant un niveau minimum commun.

4. Retour d'expérience AFCN :

Chaque norme introduite doit avoir fait l'objet d'une analyse coût/bénéfice.

Cette analyse doit intégrer dans les différents projets en développement à l'AFCN : plan d'actions dans le cadre de l'IRRS ; projets réglementaires, développement de Cis-2, Sharepoint/Record Management.
Le plan stratégique de l'AFCN permettra de définir la priorité des actions à mener et les ressources qui pourront y être allouées.

Certains projets réglementaires déjà introduits au Ministre de tutelle devront être revus à la lumière de la transposition.
Le projet de loi introduit dès 2009 concernant la réorganisation du contrôle physique doit être analysé à la lumière des exigences des BSS et éventuellement revu.
En particulier en regard de la problématique des RPE et RPO, et à la liste des pratiques où l'AFCN estimera nécessaire la présence du RPO.

Le projet de révision du chapitre VII (PR 1130), intégrant l'approche graduée et dont un des objectifs est la simplification administrative devra intégrer les lignes directrices de la transposition des BSS : processus de justification des pratiques, gestion des risques radiologiques, réévaluation périodique de la justification,…
La note stratégique de ce projet réglementaire a déjà tenu compte de l'influence des BSS.

Les besoins réglementaires envisagés dans le cadre de la révision du chapitre VI, applications médicales et le projet réglementaire envisageant la médecine vétérinaire, pourront directement être repris dans le cadre de la transposition des BSS, en particulier le projet (PR1133 « optimisation des pratiques médicales ») établissant des contraintes de doses pour certaines pratiques, recommandation suggérée également dans le cadre du plan d'action de l'IRRS

5. Parties concernées et responsabilités :

D'une part les BSS sont une fusion de cinq directives européennes existantes actuellement transposées dans la réglementation nationale, et d'autres part les directives européennes non encore transposées telles que

par exemple la directive « drinking water » présentent des interfaces qui imposeront de contacter des acteurs nationaux et régionaux dans le cadre du travail de transposition.

La transposition des BSS demande de mettre en œuvre la transversalité nécessaire non seulement au sein de l'AFCN mais également au niveau régional, national et européen.

RIAD (Département Réglementation, Affaires Internationales & Développement) est le Département en charge de ces coordinations.

Ce processus réglementaire transversal devrait être géré dans le cadre d'un projet au sein de l'AFCN tout en intégrant l'expertise dans le cadre de la réglementation présente à RIAD.
Le sponsor proposé est le chef de Département RIAD (YP).

6. Méthodologie du projet :

A) Inventaire des besoins réglementaires :

Depuis janvier 2014, diverses séances d'informations concernant les BSS, ont eu lieu et il a été demandé aux divers départements et experts de définir leurs besoins par rapport au texte des BSS et la portée que la transposition des BSS pourraient avoir sur leur mission.

Certains projets réglementaires en cours peuvent d'ores et déjà être intégrés dans la transposition.
D'autres demandent une analyse plus approfondie, et certains textes existants doivent être modifiés.
Les BSS introduisent de nouveaux concepts tels que les situations d'expositions, et l'AFCN devra intégrer de nouveaux processus de contrôle réglementaire (produits de consommation, matériaux de construction, expositions aux sources de rayonnement naturel considérées comme exposition planifiée…)

La transposition étant étalée sur une période de quatre années, il est possible de prévoir une démarche participative des parties prenantes avant de faire une proposition de restructuration réglementaire.

Les intervenants étant des représentants des institutions fédérales et régionales, des exploitants/ entreprises, de BelV, des organismes agréés, des universités, du monde professionnel, du Conseil Scientifique, du Conseil Supérieur de la Santé, de sociétés scientifiques,…

Au sein de l'AFCN il sera utile d'établir l'inventaire des besoins en ayant assuré une compréhension commune des objectifs et contraintes liées au BSS et autres standards internationaux.

Un tableau de benchmarking est en annexe afin de définir les objectifs minimaux à respecter dans le cadre des activités des services opérationnels, des groupes de réflexions existants, des chefs de projet concernés par la réglementation.
RIAD organisera la coordination entre les départements et la cohérence des exigences réglementaires.

La démarche participative pourrait assurer une crédibilité des critères de décisions introduits dans le cadre réglementaire.

Etant donné le large éventail d'interlocuteurs, l'AFCN devra assurer une cohérence entre les exigences des divers secteurs et les standards internationaux. RIAD est en charge de cette analyse.

B) Objectifs à respecter :

Les objectifs repris dans les BSS devront être clairement définis pour chacun des thèmes abordés lors de la démarche de consultation :

- Application des situations d'exposition
- Application du principe de justification
- Approche graduée en fonction du risque radiologique
- Gestion des risques

C) Définitions des thèmes :

Une première consultation et analyse des textes réglementaires existants et en cours de réalisation nous permet d'ores et déjà de définir les thèmes à considérer :

1) Urgence

La formation des intervenants en cas d'urgence, est définie dans le cadre réglementaire de l'AR du 17/10/2003, cependant cette formation est prévue dans le cadre d'un plan d'urgence établi.

Les BSS définissent le besoin d'informer les intervenants au préalable.

De la même façon, l'information préalable des personnes du public susceptibles d'être affectées en cas d'urgence doit être mise en œuvre.

Une note a été rédigée en 07/07/2011, il convient de l'adapter et de l'intégrer dans un cadre réglementaire.

Il convient également d'établir un système de gestion d'urgence qui est un cadre juridique et administratif **établissant les responsabilités** dans les situations d'urgence.

Le projet en cours de révision de l'arrêté du plan d'urgence est concerné et devra tenir compte des BSS.

2) Radioprotection, Contrôle physique, RPE et RPO

Le contrôle physique actuellement défini dans le RGPRI, est une notion qui n'est plus présente dans les BSS, on parle d'expert en radioprotection (RPE) et de personne chargée de la radioprotection (RPO).

L'expert en radioprotection est une personne (un groupe de personnes) donnant des conseils sur le respect des obligations légales en matière d'exposition professionnelles et du public.
Il est un acteur du processus d'optimisation et de l'établissement de contraintes de doses.
La liste des domaines le concernant est reprise dans les BSS (art 82).

Les Etats membres doivent définir pour quels types de pratiques ils est nécessaire de désigner une personne chargée de la radioprotection.
Les tâches confiées à cette personne sont reprises dans les BSS (art 83).

Le projet de loi considérant la restructuration du contrôle physique, et le rôle des organismes agrées devront être revus à la lumière du projet de transposition des BSS.

L'AFCN devra définir des pratiques où le RPO doit être présent et envisager si une formation particulière devra lui être allouée. Tous les domaines professionnels sont concernés par cette analyse : établissements nucléaires de base, applications médicales à haut risque telles que radiothérapie, les thérapies métaboliques à l'aide d'émetteur alpha, les transports de matières radioactives, les expositions aux sources naturelles de rayonnement considérées comme situation d'exposition planifiée …

Le projet de loi considérant la restructuration du contrôle physique, et le rôle des organismes agrées devront être revus à la lumière du projet de transposition des BSS.

3) Expositions professionnelles :

Le concept des situations d'exposition, le travailleur intervenant en situation d'urgence, le contenu du passeport dosimétrique, l'intégration des doses dues au radon sur les lieux de travail pour les travailleurs extérieurs sont différents sujets qu'il faudra intégrer/modifier.
Le suivi médical des travailleurs, en particulier le travailleur intervenant en cas d'urgence devra être revu à la lumière des exigences des BSS.
Les projets (PR1122 et PR1043) réseaux dosimétriques et agréments des services de dosimétrie pour la dosimétrie interne sont impactés par les exigences des BSS.

4) Applications médicales :

Un thème incontournable est celui des applications médicales en particulier les «expositions délibérées de personnes à des fins d'imagerie non médicale»[5] et la problématique des patients asymptomatiques.

La responsabilité du prescripteur et praticien devrait être clarifiée et la collaboration développée dans un but de diminution de la dose eu patient.
L'application du principe de justification à différents niveaux (générique, patient) est un sujet de transposition.
Des échanges réguliers sont d'ores et déjà établis avec le SPF de la Santé publique et l'INAMI.

5) Niveaux d'exemption et de libération :

A ce jour un projet réglementaire concernant les niveaux de libération est à envisager. Un groupe de travail s'est réuni en novembre 2013 et en mai 2014 afin d'envisager les besoins du secteur.

Les BSS utilisent comme référence pour définir les seuils de libération et d'exemption le document RS-G-1.7. de l'IAEA en remplacement des valeur de concentration d'activités établies à l'annexe I de la directive 96/29/Euratom et en remplacement des seuils de libération recommandées dans le RP 122.
Cette modification devra faire l'objet d'une étude approfondie en Belgique.

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[5] Définition des BSS: «exposition à des fins d'imagerie non médicale»: toute exposition délibérée de personnes à des fins d'imagerie où la finalité principale de l'exposition n'est pas d'apporter un bénéfice sanitaire à la personne exposée.

Le RP 89 et RP 113 restent des outils utilisés au sein de la Communauté Européenne pour la gestion des gros volumes de matière.

D) Coordination des issues établies par thème :

Chaque groupe concerté devra établir des besoins de transpositions et une note stratégique (ou suivi de projet, Regulation Change request, note de réflexion, proposition de texte réglementaire, …) qui lui est propre. Un tableau reprenant le besoin réglementaire issu des BSS (Issue Identified), la situation actuelle dans la réglementation belge, la modification envisagée (Action Identified) sera présentée au groupe pour avis (Annexe 5 : Preliminary plan to implement BSS).

Exemple :

Thematic area	**Protection of aircrew**
Issue Identified	Activity to be managed as "Planned exposure"
	Art 9 GRR 2001
Action Identified	Modification Art 9 GRR 2001 : Classified the work activities involving natural radiation sources in Planned exposure and Existing exposure <u>Consequences:</u> Declaration of activity (already existing) Occupational dosimetry (already existing)

Un travail de coordination /vérification au sein de RIAD devra établir une note de synthèse reprenant les actions identifiées (février 2015).

Après benchmarking et au regard des conclusions, RIAD pourra établir une note stratégique définissant précisément les besoins réglementaires.
Une évaluation précise des textes réglementaires, une analyse et une évaluation des différents processus à mettre en œuvre permettront d'établir une fiche de faisabilité du projet (approche graduée du régime d'autorisation d'établissements, exemption des produits de consommations, exemption des matériaux de constructions, format de publication des rapports d'inspections, organisation de la formation préalable des intervenants, rédaction de guides/guidances, modifications de textes existants…).

Cette synthèse devra fournir une réévaluation de l'estimation des ressources à allouer au projet de transposition.

La définition des types de textes réglementaires nécessaires, l'intégration des obligations dues au BSS dans les projets en cours à l'AFCN.

Et elle permettra à l'AFCN de choisir entre une phase de restructuration complète de la réglementation qui intégrerait la transposition ou une phase de toilettage de la réglementation existante.
Un avis juridique extérieur pourrait permettre à l'AFCN d'évaluer le processus réglementaire optimal tout en respectant le délai de transposition.
La décision d'intégrer ou non la transposition des BSS dans un projet plus large de restructuration de la réglementation devra être fait le plus tard **en mai 2015.**

E) Estimation des ressources :

L'ampleur du projet et l'organisation des consultations la première année pourra être gérée dans le cadre de la gestion de projets à l'AFCN.

Préambule à la consultation par thème :

Préparation d'un tableau reprenant l'état actuel de la réglementation, les modifications imposées par les BSS et les conséquences pour le groupe cible.
Le plan d'action préparatoire au benchmarking sera réalisé au sein de RIAD et soumis à consultation au sein des différents départements et services concernés

Consultations par thème :

La consultation par thème sera organisée soit au sein des départements gérant le groupe de réflexion et en collaboration avec RIAD (ou le chef de projet). L'organisation de consultations et groupes de réflexion aboutira à un état des lieux qui permettra à l'AFCN de d'évaluer le processus réglementaire le plus efficient, afin de respecter le délai de la transposition (02/2018).

D'un point de vue plus pratique, lors des consultations par thème, il sera nécessaire que l'AFCN ait établi les lignes directrices de la transposition des BSS.
(Proposition de texte, orientation à suivre, attentes minimales, type de document à réaliser : Arrêté royal, directive/recommandation AFCN à publier au moniteur belge, note de l'AFCN, guide technique, brochure explicative…)

Afin de respecter les délais de transposition, la date de mai 2015 est une échéance importante à partir de laquelle il ne sera plus possible d'inscrire le projet de transposition des BSS dans l'exercice plus général de révision de la réglementation.

Réalisation de notes stratégiques par thème :

Chaque groupe de consultation établira pour février 2015 un note stratégique (ou autre document pertinent) afin de préciser, dans son domaine de compétence, les attentes par rapport à la transposition des BSS ainsi que l'intégration des travaux réglementaires déjà en en cours qui pourront intégrer le processus réglementaire propre au projet de transposition.

Synthèse et évaluation finale des besoins de transpositions :

La synthèse des réflexions et la rédaction d'une note stratégique devra être réalisée dès mai 2015. Elle devra définir précisément les options réglementaires choisies (lois, arrêtés royaux, arrêtés AFCN, notes, recommandations, guides,…) pour intégrer les exigences des BSS et faire un planning des modifications en assurant une cohérence de fond et de timing pour les différentes actions.

Processus réglementaire :

En janvier 2016 débutera la dernière phase de rédaction des textes réglementaires et du suivi du processus réglementaire y inclut les consultations obligatoires.

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PERSONAL VIEW ON THE PRESENT AND FUTURE CHALLENGES IN RADIATION PROTECTION BY THE YOUNG GENERATION

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Abstract
This paper is a personal reflection of the author, working as a recognized expert in health physics and prevention advisor at a university, on why the young generation should choose to develop a career in radiation protection.

1. Introduction
Being one of the various young professionals working within the area of radiation protection, and this already for some years, is in favour of the interesting nature of radiation protection as a field of activity at present. But does and will radiation protection still offer enough challenges to attract fresh blood to continue the work that has already been done? And what exactly are these challenges? This article is a personal reflection on these questions. It is written based upon the personal experience as a recognized expert in health physics and prevention advisor at a university.

2. Reasons for choosing a job in radiation protection
There are many reasons that are in favour of choosing a career in radiation protection. Some examples are highlighted below.

Radiation protection, there is something for everyone there
Radiation protection offers a variety in fields of activity as well as organizations in which one could work. The three main disciplines within radiation protection are: health physics, medical radiation physics and occupational medicine. All three of them require a specific scientific education, training and matching continuous development. The corresponding functions are characterized by the (possibly) exposed target groups on which they focus on the one hand, and their own particular job responsibilities on the other hand. In practice this does result in various

job possibilities in a broad range of organizations, such as licensees (e.g. universities, hospitals, nuclear power plants, …), recognized bodies, occupational medicine services and the government.

A job in health physics is a versatile job

Working within the field of health physics, and thereby executing the broad range of tasks listed in article 23 of the Royal Decree of 20 July 2001[1], definitely requires a highly scientific interest. To be able to perform an expert risk assessment and to determine the corresponding adequate preventive measures, a thorough knowledge of the activities and processes involving the use of ionizing radiation is essential. However, one should not solely focus upon the risks imposed by the use of ionizing radiation. Activities are usually characterized by a whole set of risks, arising from inherent features of materials and equipment used, among others. Accordingly, these risks and their (possible) interaction with the risk that follows on the use of ionizing radiation, should also be included in the risk assessment. Besides this, organization specific factors such as the prevailing HSE (Health, Safety & Environment) culture highly influence the practical radiation protection system within an organization. As a consequence the same type of activities in two different organizations does not automatically lead to an identical set of corresponding preventive measures.

The focus of practical radiation protection nowadays lies upon the development and enhancement of ALARA culture. As a consequence, aspects such as communication, stake holder involvement and education and training gain more and more interest in practical radiation protection. In other words, next to technical skills, soft skills prove to be indispensable for professionals in health physics (and in radiation protection in general) to support a successful establishment and embedding of a radiation protection culture within an organization.

Science doesn't stand still

Science, and therefore also the knowledge of ionizing radiation and radiation protection, is evolving continuously. Clearly, this rise of information can and will affect international recommendations and legislation with respect to these subjects. A rather recent example is the recommendation of the Internal Commission on Radiological Protection to reduce the dose limit

[1] Royal Decree of 20 July 2001 laying down the General Regulation for the protection of the public, workers and the environment against the hazards of ionizing radiation;

for the lens of the eye for occupational exposure from 150 mSv to 20mSv in a year, and its integration in Council Directive 2013/59/EURATOM of 5 December 2013[2]. In addition to the influence on legislation, the increased knowledge of ionizing radiation and radiation protection shall also lead to the optimization of existing devices and techniques involving the use of ionizing radiation, as well as to the development of new ones.

As a result of the evolution of science, radiation protection in daily practice doesn't stand still either. However, the extent of the effect on daily practice largely depends upon the nature and frequency of the organization's activities. *Example: The effect of the use of a new type of apparatus in a medical imaging department of a hospital will be much larger than the outcome of a similar situation within an average academic research laboratory. The difference in magnitude is due to the fact that, in most cases, techniques that make use of ionizing radiation only make up a small part of all techniques used within an academic research lab. What of course also partly finds its origin in the temporary nature of research projects at universities in general.*

Radiation protection will never be complete

What might discourage certain people, looks appealing to others: radiation protection will never be finished off. It so happens that similar to the field that aims at the well-being of workers, radiation protection focuses on continuous improvement. The ALARA principle being the core of exposure optimization, and as a consequence being heart of radiation protection in practice.

3. Challenges for radiation protection professionals

In the field of radiation protection at our university there are no short-time big changes in the air, as we know them for instance in the medical sector (e.g. radiation therapy by means of alpha emitters). This paragraph therefore focuses upon two rather general challenges (i.e. irrespective of the nature of the organization's activities) for radiation protection professionals.

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[2] COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

– The current public perception of radioactivity is rather negative. My personal experience does confirm this finding: researchers often mainly focus upon the risk following the use of ionizing radiation when they perform a prior risk assessment of their experiments. They overrate this specific risk compared to the other risks inherent to their experiments (e.g. chemical risks). Therefore *the creation of a more realistic (i.e. objective) general perception of radioactivity* still remains a challenging task for professionals in radiation protection. Besides, let us not forget the important role of general perception when drawing up legislation. It provides an answer on the question 'What is considered to be acceptable'. In addition, a more objective general perception of radioactivity might lead to a clearer (and thereby more attractive) image of radiation protection in general.

– For the organizations that did not yet *develop and maintain a close collaboration with the Internal Service for Prevention and Protection at Work (ISPPW)*, this definitely becomes a challenge for the near future. It is my personal conviction that integration of radiation protection within the well-being policies of an organisation, is one of the conditions for a successful radiation protection system, as well as the embedding of it within the culture of an organisation.

4. Conclusion

Although this article only discusses a few of them, radiation protection does offer a whole set of challenging reasons for the young generation to opt for a career within this area. Radiation protection itself however, is also still facing a challenge, namely the persistent challenge to attract the necessary number of new and highly motivated (young) professionals.

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CRITICAL REMARKS ON THE NEW EU BSS

as input to the panel discussion of the BVS/ABR meeting of
5 December 2014 in Brussels

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1. Short overview of the presentation

- Although the new EU BSS looks quite different and consolidates five directives and one recommendation, it contains few changes of substance
- The EU BSS still refers to the old dose coefficients because ICRP is not delivering further guidance yet
  - ICRP 100 and ICRP 103 are not implemented yet
  - The dose coefficients from the ICRP statement of 2009 on radon are at the high end and in my opinion too high
- Work activities are replaced by planned or existing exposure situations
  - However, in practice, this significant modification entails little changes in our current approach
- Exemption and clearance are treated in the new EU BSS in the same way…
  - But the many possibilities offered to member states result in a less stringent approach than the current approach in Belgium
- The EU BSS allows to dilute radioactive materials in specific circumstances

2. Although the new EU BSS looks quite different, it contains few changes of substance

The new European Union Basic Safety Standards (EU BSS) of 5 December 2013 is a long and complicated directive of 73 pages containing 109 articles and 19 annexes [1]. Many articles refer to other articles. These cross references make the directive difficult to read and to understand. The structure of the directive is unfamiliar with separate chapters on occupational, medical and public exposures. This structure is very different

from ICRP publication 103 [2] and from the IAEA BSS [3], both of which are structured along the type of exposure situation: planned, emergency or existing exposure situation. This difference in lay-out makes it difficult to compare the EU and IAEA BSS, although they are supposed to contain the same substance.

Another source of confusion in the EU BSS [1] is the mix up of old and new terminology. For example, the new directive uses practices and interventions interchangeable with planned, emergency and existing exposure situations. The definition of a *practice* in the EU BSS is: a human activity that can increase the exposure of individuals to radiation from a source and is managed as a *planned exposure situation*.

The new EU BSS [1] often leaves considerable room to member states. An example of this, is the graded approach to regulatory control, where member states are offered a lot of flexibility. Apart from general and specific exemption, they can opt for notification only. If not, then they still have three options to regulatory control. They can choose between exemption from authorization, registration and licensing. This very large flexibility will almost certainly result in member states taking different approaches for the same situation, thus increasing the level of disharmony in radiation protection legislation in the European Union.

The frequent use of "appropriate" and "may" is another example of the flexibility of the directive as regards action to be taken:

- "where appropriate": 34 matches
- "as appropriate": 24 matches
- "if appropriate": 8 matches
- "may": 95 matches

The new BSS directive [1] is like the previous BSS and medical directives [4,5] a minimum directive and not a harmonization directive, so that member states may adopt more stringent regulations. Unfortunately, the minimum in the EU BSS is almost always below the current Belgian legislation as will be shown below. This brings me to the conclusion that although the new EU BSS looks quite different, it contains few changes of substance.

3. The EU BSS still refers to the old dose coefficients

There are no tables with dose coefficients for the calculation of internal and external exposure annexed to the new EU BSS [1]. Instead, reference

is made to the relevant ICRP publications 116 and 119 [6,7], but these publications are not up to date as they are not based on the most recent general recommendations and biokinetic models.

- ICRP has adopted with publication 100 in 2006 a new biokinetic and dosimetric model for the gastrointestinal tract under the title "Human Alimentary Tract Model (HATM) for radiological protection" [8]. Eight years later, ICRP is still using the ingestion dose coefficients calculated with the model developed in publication 30 of 1979 [9].
- ICRP published in 2007 (publication 103) new general recommendations adapting the definition of effective dose to the progress of scientific knowledge [2]. Seven years later, ICRP is still using the superseded radiation and tissue weighting factors of publication 60 from 1991 [10].
- ICRP published in 2012 a compendium of dose coefficients (publication 119) [7], which is no more than a compilation of existing dose coefficients from publications 68, 72 and 74 [11,12,13] based on the ICRP 30 model of the gastrointestinal tract from 1979 [9], the ICRP 66 lung model from 1994 [14] and the ICRP 60 general recommendations from 1991 [10].

This brings me to the conclusion that the ICRP is not delivering consistent and up-to-date guidance on the dose coefficients.

4. The new ICRP dose coefficients for radon are at the high end

In the 2009 statement on radon, ICRP announces its intention [15]:

- To increase the dose coefficients for radon by about a factor of two
- To replace the current conversion conventions of ICRP 65 [16], which were derived from an epidemiological approach based on equality of detriment, with a dosimetric approach

4.1. The epidemiological approach

ICRP preferred in publication 65 from 1993 [16] the direct use of the epidemiological studies of miners over the indirect use of the ICRP 66 dosimetric model of the respiratory tract from 1994 [14]. The dose conversion factors, designated by the ICRP as conversion conventions, are calculated by comparing the radon progeny risk per unit exposure ($2.83\ 10^{-4}$ per WLM) with the detriment associated with a unit of effective dose. The value attributed to the total detriment from cancer and hereditary effects per unit effective dose in publication 60 [10] is higher for the general

public (7.3 10^{-5} per mSv) than for workers (5.6 10^{-5} per mSv), resulting in a lower conversion convention for the public compared to workers:

- Workers: 2.83 10^{-4} / 5.6 10^{-5} = 5 mSv per WLM
- Public: 2.83 10^{-4} / 7.3 10^{-5} = 4 mSv per WLM

Both the numerator and the denominator in the calculation of the dose coefficients *(conversion conventions in ICRP 65)* have changed since 1993. ICRP publication 115 in 2010 [17] has reviewed the epidemiological evidence relating to radon exposures, deriving a nominal risk coefficient of 5 10^{-4} per WLM, replacing the publication 65 value of 2.83 10^{-4}. The 2007 recommendations of the ICRP [2] decreased the value attributed to the detriment per unit effective dose:

- Workers: from 5.6 10^{-2} to 4.2 10^{-2} per Sv
- Public: from 7.3 10^{-2} to 5.7 10^{-2} per Sv

The ICRP 115 dose coefficients for workers and the public are more than two times higher than the ICRP 65 values:

- Workers: 5 10^{-4} / 4.2 10^{-5} = 12 mSv per WLM
- Public: 5 10^{-4} / 5.7 10^{-5} = 9 mSv per WLM

4.2. The dosimetric approach using the ICRP 66 lung model

Dose conversion factors are generally derived from dosimetry. However, a lot of factors affect the calculation of the dose coefficients using the ICRP 66 lung model [14], like the tissue-weighting factor for the lung, the partitioning of the radiation risk over the different radiation sensitive tissues in the lung, the radiation-weighting factor for alpha particles and the breathing rate. Specific to radon (decay product) exposure are the aerosol characteristics (unattached fraction and size distribution) and the equilibrium factor. More information on the dosimetric versus the epidemiological approach can be found in Vanmarcke [18].

The many parameters in the lung model and their broad uncertainty ranges cause a potential problem, because every step in a calculation increases the error. The result is a wide distribution of dose coefficients for radon. Nevertheless, the ICRP statement on radon announced the intention to replace the current conversion conventions of ICRP 65 with a dosimetric approach. According to the key-note presentation of John Harrison at the

IRPA conference in Geneva in June 2014 [19] the (preliminary) central estimates of the ICRP dose coefficients are:

- At home: 14 mSv per WLM
- In an indoor workplace: 21 mSv per WLM *(higher breathing rate at work than at home)*
- In a mine: 12 mSv per WLM *(higher aerosol concentration, and so a lower unattached fraction in a mine, compared to an indoor workplace or a home)*

These values, calculated with lung model, are higher than the values from the epidemiological approach and much higher than the values from publication 65 as shown in table 1.

Table 1. ICRP dose coefficients for radon at home and in an indoor workplace calculated according to publication 65 [16], publication 115 [17] and the ICRP statement of 2009 on radon [15].

(in mSv per WLM)	ICRP 65 *Epidemiological*	ICRP 115 *Epidemiological*	**Radon statement** ***Dosimetric***
Home	4	9	**14**
Indoor workplace	5	12	**21**

Shortly after the IRPA Geneva meeting, I expressed my concern on the high values of the proposed ICRP dose coefficients to the scientific secretary of ICRP. My main arguments are:

- The new dose coefficients are calculated conservatively using an unrealistic combination of unattached fraction and equilibrium factor.
- Inflating the radon contribution to the average radiation exposure will make all the other contributions look small, even medical imaging.
- Smoking determines more than 90% of the dose coefficient for radon, so that in radon prone areas with a low smoking rate more radon cancers are calculated than there actually are in the region.

What I suggest, is to continue to use the UNSCEAR dose conversion factor [20], which is about 50% higher than the ICRP 65 values and about half the new ICRP values.

4.3. ICRP uses an unrealistic combination of unattached fraction and equilibrium factor

The first argument has to do with the use by ICRP of an unattached fraction of 8% in combination to an equilibrium factor of 40%. In my PhD research

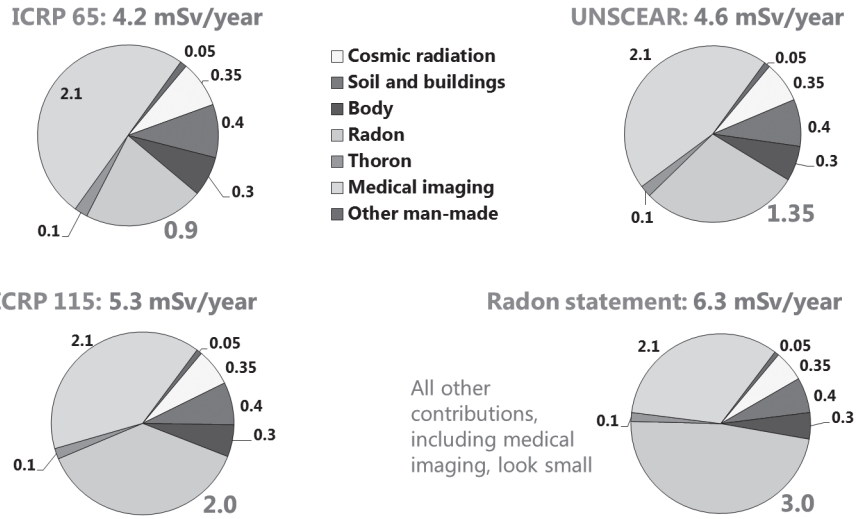
of the 1980's, I demonstrated that the equilibrium factor and the unattached fraction are strongly and negatively correlated [21]. The good correlation comes from the difference in deposition rate, which is more than an order of magnitude higher for unattached than for attached radon decay products. The data from my measurements in indoor air show, for an equilibrium factor of 40%, an unattached fraction of 5.5%, which is significantly lower than the 8% assumed by ICRP and hence results in a lower dose coefficient in the indoor environment.

4.4. Inflating the radon contribution will make all the other contributions look small

The average radon concentration in Belgian dwellings is about 50 Bq/m³. Depending on the selected dose coefficient, the radon exposure corresponding with 50 Bq/m³ is:

- ICRP 65 (epidemiological approach) [16]: 0.9 mSv/year
- UNSCEAR [20]: 1.35 mSv/year
- ICRP 115 (epidemiological approach) [17]: 2 mSv/year
- Radon statement (dosimetric approach) [15]: 3 mSv/year

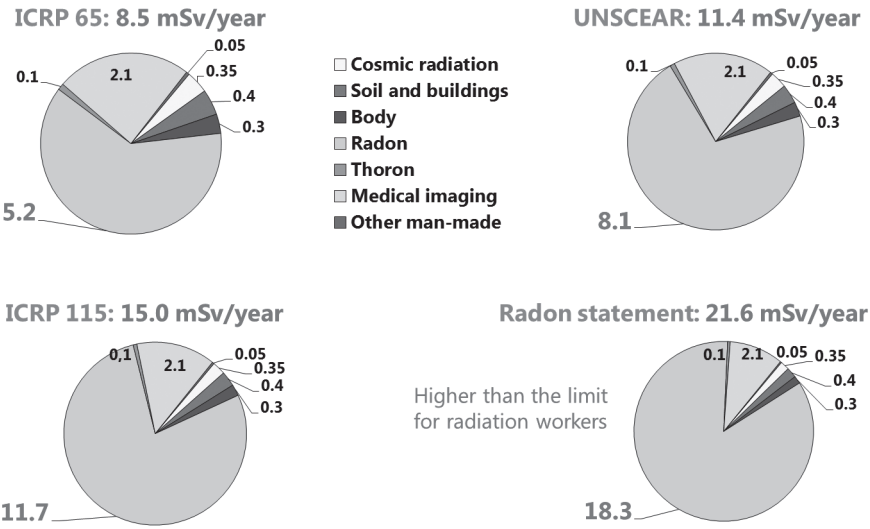
The implications of the different dose coefficients for radon are shown in figure 1 for the average radiation exposure in Belgium. The calculated effective dose ranges from 4.2 mSv/year with the epidemiological approach



of ICRP 65 up to 6.3 mSv/year with the dosimetric approach of the radon statement.

Fig 1. Average radiation exposure in Belgium according to publication 65 [16], publication 115 [17], the ICRP statement of 2009 on radon [15] and UNSCEAR [20].

The impact of the dose coefficient for radon becomes much larger if we perform the same calculation for a dwelling with a radon concentration of 300 Bq/m³, the new maximum reference level for radon in dwellings of the EU BSS (figure 2). The calculated effective dose ranges from 8.5 mSv/year



with ICRP 65 up to 21.6 mSv/year with the ICRP statement on radon. The latter value is higher than the limit for radiation workers of 20 mSv/year.

Fig 2. The radiation exposure in a dwelling of 300 Bq/m³ according to publication 65 [16], publication 115 [17], the ICRP statement of 2009 on radon [15] and UNSCEAR [20].

4.5. Smoking determines more than 90% of the dose coefficient for radon

Another important factor is the almost synergistic effect between radon and smoking. Many case-control studies to directly estimate the risk of lung cancer associated with residential radon exposure have been published. Individually these studies have a limited statistical power, but pooled together they provide strong, direct evidence of risk from residential radon. The study with the best statistical power is the European pooled residential case-control study of Darby from 2005 [22]. In this study, the absolute risks of lung cancer by age 75 years at radon concentrations of 0, 100 and 400 Bq/m³ are:

- In lifelong non-smokers: 0,4%, 0.5% and 0.7%
- In cigarette smokers: 10%, 12% and 16% *(25 times more risk to develop lung cancer)*

So smokers are, for the same radon exposure, an order of magnitude more at risk than non-smokers. Hence, the dose coefficient for radon is for more than 90% determined by smoking. A decrease in the ratio smokers to non-smokers will result in a comparable decrease in the dose coefficient. There are radon prone areas in Scandinavia with a low smoking prevalence where more lung cancers are calculated than there actually are in the area. As radon is not the only cause of lung cancer and even not the most important cause of lung cancer, this illustrates the fact that the dose coefficient for radon of the ICRP statement is at the high end and not applicable to areas with a low smoking rate. For non-smoking groups like children, the proposed dose coefficient is even an order of magnitude too high.

4.6. The long established UNSCEAR dose coefficient for radon

I was not happy with the ICRP 65 dose coefficients for radon because of the low values and I am not happy with the new ICRP dose coefficients because of the high values. Therefore, I suggest continuing to use the UNSCEAR dose coefficient for radon [20], which is about 50% higher than the ICRP 65 values and about half the new ICRP values.

The main reasons for keeping the UNSCEAR value are:

- The new ICRP dose coefficients for radon are not applicable for groups with a low smoking prevalence - and hence potential problems with every country coming up with another dose coefficient based on their own background cancer rates.
- Using the new ICRP dose coefficients would inflate the radon contribution to the radiation exposure and make all the other contributions, including medical imaging, look small.

5. Work activities are replaced by planned or existing exposure situations

In contrast to ICRP 60 [10], the previous EU BSS directive [4] made a distinction between three types of human activities: practices, interventions and work activities. Work activities were defined as exposures of workers or members of the public to natural radiation sources not used for their radioactive properties and leading to a significant increase in exposure.

The new EU BSS [1] does not make this distinction and assigns work activities to planned or existing exposure situations.

NORM industries, or the increase in exposure due to natural radiation sources in the non-nuclear industry, are considered planned exposure situations. Nevertheless, as the graded approach to regulatory control leaves considerable room to member states, few changes are needed in practice:

- < 1 mSv/year: exempted from regulatory control
- > 1 mSv/year: notification including
  - Supervised areas: radiological surveillance *where appropriate*; warning signs for ionizing radiation *if appropriate*, working instructions *if appropriate*
  - Category B workers: individual monitoring *if appropriate*

This graded approach is comparable with the current approach in Belgium.

Exposure of air crew to cosmic radiation is considered a planned exposure situation:

- < 1 mSv/year: exempted from regulatory control
- > 1 and < 6 mSv/year: the current approach
- > 6 mSv/year: the relevant requirements apply, allowing for the specific features of this exposure *(few air crew receive more than 6 mSv)*

This graded approach is very much the same as the current approach.

Exposure of spacecraft crew to cosmic radiation above the dose limits is managed as a specially authorized exposure. The Belgian ARBIS/RGPRI [23] limits the exposure with a special authorization to 40 mSv/year and 100 mSv over the whole career. As the dose at the International Space Station (ISS) is typically 0.4 mSv/day and twice as high in deep space, long-term space flights could result in higher doses than currently allowed in Belgium.

Radon exposure at work is exempted from regulatory control below 6 mSv/year or less than the national reference level (300 Bq/m³ or less). Above 6 mSv/year or exceeding the national reference level, notification is mandatory including:

- Supervised areas: radiological surveillance *where appropriate*; warning signs for ionizing radiation *if appropriate*, working instructions *if appropriate*

• Category B workers: individual monitoring *if appropriate*

The current Belgian reference level for radon in workplaces of 400 Bq/m³ has to be lowered to 300 Bq/m³ or less.

Radon exposure at home is considered an existing exposure situation with a national reference level for radon of maximum 300 Bq/m³. Member states have to establish a national action plan addressing the long-term risks from radon exposures in dwellings.
The current Belgian reference level for radon in dwellings of 400 Bq/m³ has to be lowered to 300 Bq/m³ or less.

6. Exemption and clearance

Exemption and clearance are treated in the new EU BSS [1] in the same way, but the many possibilities offered to member states result in a lot of flexibility. Member states can choose between three options to exempt practices from notification and two options to clear materials containing artificial radionuclides:

- Unconditional exemption and clearance levels
- Exemption levels for moderate amounts of material
- Conditional exemption and clearance of other amounts of material or other activity concentrations

Moreover, they can choose between two options for materials containing naturally occurring radionuclides:

- Unconditional exemption and clearance levels
- Conditional exemption and clearance of other amounts of material or other activity concentrations

6.1. Unconditional exemption and clearance levels for artificial radionuclides

Materials containing artificial radionuclides involved in a practice can be exempted from notification if the activity concentration is below the value in table A, part I, or if the total activity is below the value in table B. For mixtures of artificial radionuclides the weighted sum applies. The same values also apply for the clearance of materials from authorized

practices. The unconditional exemption and clearance levels of the EU BSS are compared in table 2 to the levels in the Belgian legislation: activity concentrations in annex IB (clearance levels) and total activity in annex IA (exemption levels) of the ARBIS/RGPRI.

Table 2. The unconditional exemption and clearance levels in the EU BSS [1] and the ARBIS/RGPRI [23] for some selected radionuclides.

Radionuclide	EU BSS		ARBIS/RGPRI	
	Concentration Bq/g	Quantity Bq	Concentration Bq/g	Quantity Bq
H-3	100	10^9	100	10^9
C-14	**1**	10^7	*10*	10^7
Co-60	0.1	10^5	0.1	10^5
I-131	*10*	10^6	**1**	10^6
Cs-137	**0.1**	10^4	*1*	10^4
Pu-241	*10*	10^5	**1**	10^5
Am-241	0.1	10^4	0.1	10^4

The new exemption and clearance levels for artificial radionuclides show a mixed picture. Some levels were raised, like I-131 and Pu-241, while others were reduced, like C-14 and Cs-137.

6.2. Exemption levels for moderate amounts of material

In case of moderate amounts of material containing artificial radionuclides, member states may use the activity concentration values of table B. These values were taken over from the previous EU BSS [4] *(activity concentrations values to exempt a practice from notification)* and were adopted as annex IA in the ARBIS/RGPRI (table 3). They are orders of magnitude higher than the values in table 2.

So, member states may continue to use these activity concentration values to exempt practices from authorization.

Table 3. Comparison of the EU BSS [1] levels for moderate amounts of material to the current levels in the ARBIS/RGPRI [23]: annex IA (exemption levels)

Radionuclide	EU BSS Concentration Bq/g	ARBIS/RGPRI Concentration Bq/g
H-3	10^6	10^6
C-14	10 000	10 000
Co-60	10	10
I-131	100	100
Cs-137	10	10
Pu-241	100	100
Am-241	1	1

6.3. Unconditional exemption and clearance levels for NORM materials

Values for exemption and clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny are compared in table 4 to the current FANC approach, which is based on a report of the European Commission from 2002, Radiation Protection 122, part II [24].

Table 4. Comparison of the EU BSS unconditional exemption and clearance levels for naturally occurring radionuclides in equilibrium with their progeny to the current FANC approach based on RP 122, part II.

Naturally occurring radionuclides	EU BSS Concentration Bq/g	Current FANC approach Concentration Bq/g
From the U-238 series	1	0.5
From the Th-232 series	1	0.5
K-40	10	10

The new exemption and clearance levels for the uranium and thorium series are twice as high as the values currently used by the FANC. What's more, for mixtures no weighted sum applies in the EU BSS, contrary to the FANC approach. This less stringent approach has important implications for NORM in the non-nuclear industry. For instance, in Belgium, there are more than 200 ha of phosphogypsum deposits above the current FANC levels but below the EU BSS levels.

6.4. Conditional exemption and clearance

There is yet another possibility, called conditional exemption and clearance, in case the amounts of radioactive substances or activity concentrations do not comply with the values in table A or table B. In that case an assessment is required to show compliance with the following criteria:

- The radiological risks to individuals caused by the practice have to be of no regulatory concern
- The practice has to be justified and inherently safe
- For artificial radionuclides
  - No workers have to be classified as exposed workers *(less than 1 mSv/year)* and the maximum individual dose to members of the public is of the order of **10 µSv** or less in a year
- For naturally-occurring radionuclides
  - The maximum individual dose to workers and to members of the public is of the order of **1 mSv** or less in a year

The individual dose criterion for substances containing artificial radionuclides is a 100 times smaller than for substances containing naturally-occurring radionuclides. This approach in line with the stronger aversion of people to exposure to artificial radioactivity compared to enhanced natural radioactivity. This tolerant attitude against exposure to natural radiation sources is clearly reflected in the EU BSS.

This conditional option leaves considerable room to member states. Indeed, article 18 of the ARBIS/RGPRI [23] requires an impact assessment to demonstrate that the maximum individual dose to a member of the public is of the order of 10 µSv or less in a year. Only if this condition is met, a separate license from the FANC can be granted for the clearance of materials below the exemption levels. In Belgium, the conditional exemption and clearance would allow for an extension of article 18 of the ARBIS/RGPRI [23] above the current exemption levels.

An example to make my point clear; the class I disposal site of Indaver in Antwerp for chemotoxic waste has a clay liner below and above. As this disposal facility is situated at quite a distance from a residential area, one could develop a scenario to dispose most of the short lived radioactive waste inventory *(category A waste of NIRAS/ONDRAF)*. Offering that much flexibility to member states will almost certainly result in divergent

approaches and in the case of my example, correspondingly very different waste costs.

7. The EU BSS allows to dilute radioactive materials in specific circumstances

The EU BSS does not permit the deliberate dilution of radioactive materials for the purpose of them being released from regulatory control. However, the last paragraph of article 30 of the EU BSS [1] allows:

- The mixing of materials if part of normal operation.

  As the cost of radioactive waste is a very important cost element, the choice of the "normal" operation process could favor mixing below the clearance levels.

- The authorization for the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.

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