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COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

COUNCIL DIRECTIVE

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

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MAIN ABREVIATIONS

ALARA – As Low As Reasonably Achievable

Article 31 Group of Experts - the Group of Experts, established under Article 31 of the Euratom Treaty

BSS – Basic Safety Standards

DG – Directorate General of the European Commission

ESOREX – European Study on Occupational Radiation Exposures

EAEC – European Atomic Energy Community, grounded through the Euratom Treaty

EU – European Union

Euratom - European Atomic Energy Community

FAO – Food and Agricultural Organisation

HASS – High-Activity Sealed Sources

HERCA - Heads of European Radiological protection Competent Authorities (EU, Switzerland, Norway, Iceland)

IAEA – International Atomic Energy Agency

ICRP – International Commission on Radiological Protection

ILO – International Labour Organisation

IRPA – International Radiation Protection Association

NEA (OECD) – Nuclear Energy Agency to the Organisation for Economic Co-operation and Development

NORM - Naturally Occurring Radioactive Material

PAHO - Pan American Health Organization

UNSCEAR – United Nations Scientific Committee on the Effects of Atomic Radiation

WHO – World Health Organisation

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MEASUREMENT UNITS

mSv (millisievert) - The dose received by an individual is expressed with a special unit Sv (sievert) which physically expresses the absorbed radiation energy per unit mass in a given tissue, but actually is modified so as to express the health detriment by weighing different organs or tissues as well as radiation types; 1 Sv = 1000 mSv

Bq (becquerel) The unit for the activity of radioactive decay, corresponding to one disintegration per second.

TERMINOLOGY[1]

ALARA – see Principle of optimisation

Artificial source of ionising radiation - Ionising radiation emitted by radiation generators (e.g. X-ray machine) or by radionuclides that are man-made (e.g. by irradiation of stable nuclides or as a result of fission of uranium in a nuclear reactor).

Clearance level - Level of activity concentration in materials (e.g. from a decommissioned reactor) that may be released from regulatory control for free circulation on the market (for reuse or recycling) or for conventional waste disposal.

Dose limit - Limit of annual exposure for an individual (worker or member of the public) that is not allowed to be exceeded.

Dose constraint - Restriction on the exposure to an individual from a single source, lower than the dose limit. Dose constraint is used as a starting point for the optimisation of protection; a dose constraint should not be planned to be exceeded, but if it is exceeded, this does not constitute a legal infringement in the same way as a dose limit.

Emergency exposure situation - An exposure situation resulting for instance from a nuclear accident and that needs to be managed as a matter of urgency. The possible occurrence of such an event and its management has to be envisaged already during normal operation of the installation.

Existing exposure situation - An exposure situation that already exists at the time it is discovered so that it cannot be planned for in advance. All natural radiation sources are managed as an existing exposure situation if they are not affected significantly by human activities.

Exemption level - Level of activity or activity concentration of radioactive materials used in a practice, above which this practice needs to be notified to the competent authority.

Exposed worker - A worker who may be exposed to ionising radiation as a result of working in a regulated practice.

Ionising radiation - High energy electromagnetic radiation, or particles, capable of producing ions while passing through matter.

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[1] These definitions are included for clarification and not for use in a legal context as in current Community legislation.

Medical exposure - The deliberated exposure of an individual for the purpose of medical diagnosis or treatment.

Medico-legal exposure - The deliberate exposure of an individual for insurance or legal purposes without a medical indication.

Natural sources of ionising radiation - Ionising radiation from cosmic or terrestrial origin. The latter includes long-lived radionuclides present in the earth's crust since the beginning of time.

Occupational exposure - Exposure of a worker that is the legal responsibility of his employer.

Outside worker - An exposed worker whose occupational exposure arises in different undertakings, other than the one of his employer.

Planned exposure situation - An exposure situation that results from a planned activity or from the planned introduction of a radiation source.

Principle of justification - This principle requires that all planned activities involving ionising radiation result in a net benefit to individuals and to society, outweighing the health detriment of radiation exposure.

Principle of optimisation - This principle requires that all exposures be subject to radiation protection in such a way that they are As Low As Reasonably Achievable ("ALARA"), allowing for medical, economic and social considerations.

Public exposure - Exposure of a member of the public which does not qualify as an occupational or medical exposure.

Reference level - Restriction on the exposure to an individual similar to a dose constraint but for application in an emergency or existing exposure situation. The difference is that in such situations the prevailing exposure may happen to exceed the reference level, hence optimisation of protection should focus on reducing such exposures down to below the reference level in the first place.

1. SECTION 1: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Identification: Lead DG - Directorate-General for Energy Agenda planning2008/ENER/002

1.1. Organisation and timing

In 2005, the Group of Experts referred to in Article 31 of the Euratom Treaty[2] (the Article 31 Group of Experts) started discussions on a possible revision of the Euratom Basic Safety Standards, established according to Article 30 of the Euratom Treaty. The Article 31 Group of Experts set up several topical working groups to analyse the need for revision (Annex III). In order to support the review and revision of existing requirements, the European Commission launched several studies and established networks for discussion of particular challenges. In addition, in 2009 a public consultation was carried out on the specific topic of natural radiation sources.

For the purpose of the current Impact Assessment, a Steering Group was set up, composed of representatives of the interested services – Secretariat General, DG External relations, DG Employment, Social Affairs and Equal Opportunities, DG Information Society and Media, DG Freedom, Justice and Security, DG Joint Research Centre, DG Research, DG Health and Consumers, DG Energy. The group had two meetings and finalised its work in October 2010.

The Impact Assessment Board assessed the draft Impact Assessment Report submitted in November 2010 and February 2011 and issued opinions on 17 December 2010 and 22 March 2011. In the light of the opinions DG ENER revised the Impact Assessment Report in several areas. In particular, the problem definition was improved by clarifying the problems and their scale (See Section 2, Sub-section 2.1). The main problems focus on insufficient protection (2.2.1-4), the complexity of the legislation (2.2.5) and risk perception associated with the protection of the environment (2.2.6). The report now highlights the data presented in the annexes on the number of radiologists, medical procedures resulting in high doses, number of employees in NORM industries receiving doses higher than the public etc. The status and nature of Recommendations of the International Commission on Radiological Protection (ICRP) and International Basic Safety Standards are now explained better in Section 2 to provide better relation with the specific objective to ensure coherence with international standards and recommendations. A new paragraph is introduced in Section 2.2.4 to explain why the current legislation on exposure to natural radiation sources does not address all health issues adequately and how the options will allow to achieve a substantial reduction of exposure to indoor radon beyond the impact of the current Commission Recommendation 90/143. The presentation of the objectives in Section 3 is improved thus ensuring a better link between the problems and the objectives. An additional objective was added in line with the problem definition and the broader range of options. The rationale for choosing policy options is explained both in relation to topical issues and with response to possible legal (simplification) instruments (Section 4). Following the recommendation of the Board, the range of options is expanded to include different options for the scope of the legislation (See Section 4, subsection 4.5) and envisages non-legislative measures as part of Option 3. The

[2] Group of public health experts, appointed by the Euratom Scientific and Technical Committee, to advice the European Commission in the establishment of basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The current composition of the group includes experts in radiation protection regulation, scientists in radiobiology and epidemiology, medical doctors and other radiation protection professionals.

proposal within Option 2 to establish a harmonised annual dose limit of effective dose to exposed workers is now better explained. In Section 5 the impact analysis now benefits from better identification of the industries and workers concerned and the cost for the business and administration. In addition, analysis on stakeholders' concerns on dose constraints, clearance levels and the requirements on the protection of the environment is introduced in Section 5. The potential enforcement costs for the competent authorities is presented as a general assumption since not enough information is available on the institutional, decision making and enforcement systems in the Member States. However, since none of the Options will result in establishment of new administrations or require major restructuring it is expected that the enforcement costs will be relatively low. For instance, the establishment of national dose registries is not a new requirement; the costs for establishment of registries are already incurred and the administrative costs for adjusting the existing records should not be significant. In Section 6 the effectiveness, efficiency and coherence of the options are assessed and additional comparison tables are included to match the underlying analysis. The impact analysis of some of the aspects of the options is improved and the available data is better used.

The observations of the Impact Assessment Board concerning lack of justification for the proposed legislative measure in Options 5 and 6 for protection of non-human species are correct. Indeed for now there are no agreed criteria for protection of the non-human species. However, the principle for protection can already be introduced in the scope of legislative measure. Since action on this issue is recommended by ICRP and is consistent with the draft international standards, and in the light of the simplification effort, these options are legitimate.

The Board has also underlined the importance of the timing of this initiative –with regard to the nuclear crisis in Japan following the earthquake and tsunami of 11 March 2011. In this respect it has to be noted that all the options envisaged in the Impact Assessment propose further development of the existing requirements on emergency management systems, emergency preparedness and international co-operation. Options 3 and 6 offer comprehensive framework which includes also the requirements for information of the public, now established in separate piece of legislation. Options 3 and 6 introduce more challenging requirements on emergency preparedness and response compared to current Directive 96/29/Euratom. While the establishment of dose reference levels for the introduction of countermeasures is still a national responsibility, the Directive for the first time gives indication of the range of doses within which such a reference level should be chosen, in general 20-100 mSv. In addition, Options 2, 3 and 6 require that Member States cooperate in the establishment of cross-border emergency plans. These options will considerably contribute to the harmonisation of emergency plans and of national responses to emergencies.

1.2. Information sources

This impact assessment is based on a wide range of information sources:

– European Commission initiatives - projects, studies, networks, conferences, workshops, public consultation and other fora;

– public consultation on a "Proposal for new requirements on natural radiation sources in the Basic Safety Standards Directive";

– recommendations of the International Commission on Radiological Protection (ICRP);

– cooperation at international level.

1.2.1. Projects, studies, networks, conferences

In order to assess the implementation of current EU legislation and to identify problem areas, the Commission (DG ENER) initiated and supported several projects and studies on specific radiation protection issues, the result of which were published in the Radiation Protection Series of the European Commission[3]. The projects, studies and conferences identify challenges with the implementation of the current radiation protection legislation and problem areas which are not sufficiently covered by the current system of protection. Possible solutions are proposed. Summaries of the results are given in Annex II.

1.2.2. Public consultation

The Commission launched in 2009 a topical consultation on a "Proposal for new requirements on natural radiation sources in the Basic Safety Standards Directive".

The Working Party Natural Sources of the Article 31 Group of Experts offered a comprehensive approach to the regulation of NORM industries, radon and building materials. This document was published on the Commission website and was also highlighted on the EAN_{NORM} website[4]. The consultation period was 02/02/2009 - 20/04/2009.

A summary of the consultation (Annex IV), and of how the different opinions had been taken care of, was published on the EAN_{NORM} website in April 2010. The summary was also presented to the Article 31 Group of Experts in June 2009 and the comments were further discussed and treated by Working Parties of the Group of Experts.

1.2.3. Recommendations of the International Commission on Radiological Protection (ICRP)

The International Commission on Radiological Protection (ICRP) plays a key role in updating scientific knowledge on radiation risks and setting standards in radiological protection. The new ICRP Recommendations for a System of Radiological Protection were adopted in 2007 (ICRP Publication 103, see Annex II.1). While ICRP Publication 103 does not change the dose limits for occupational exposure and for public exposure, the methodology for calculating the doses has changed. ICRP also calls for a system of protection of non-human species. The key role that ICRP plays in setting standards in radiological protection accelerated the process of revision of the Euratom BSS and IAEA BSS (see also section 2.1.4).

The Article 31 Group of Experts recommended to the Commission that the revision of the BSS should incorporate both the philosophy and the technical aspects of the new ICRP Recommendations.

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[3] Publications in the Radiation Protection Series of the European Commission can be found on http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm.

[4] The result of the consultation can be found on the website of the European ALARA network for NORM industries (EAN_{NORM}) webpage under http://www.ean-norm.net/lenya/ean_norm/live/news.html

1.2.4. Cooperation at international level

The revision of the Euratom Basic Safety Standards has benefited from continuous interaction with two organisations representing major stakeholders, namely the Heads of European Radiological protection Competent Authorities (HERCA), the International Radiation Protection Association (IRPA) and European Atomic Forum (FORATOM):

– HERCA: The outline of the revision of the BSS was presented to HERCA at meetings in December 2008 and 2009 as well as in June 2010. The response of the radiation protection authorities' representatives was positive and HERCA did not raise any important issue calling for changes in the approach.

– IRPA: Presentations on the ongoing revision of the Euratom BSS have been made at the International IRPA Congress (Buenos Aires 2008) and at European Congresses organised by IRPA (Brasov, 2006, Helsinki 2010) as well as at annual meetings of the European IRPA societies. The European IRPA branch has set up a working party to collect input from their societies on the ongoing revision of the international and the Euratom BSS.

– FORATOM has set up special expert groups to follow the process of revision of Euratom Basic Safety Standards. The Commission services were in constant interaction with FORATOM and their concerns were thoroughly discussed.

More information on the role of these stakeholder groups is provided in Annex I.

The European Commission has also cooperated closely with the IAEA and other international organisations on the revision of the International Basic Safety Standards. The International Basic Safety Standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionising radiation. They are approved by IAEA Board of Governors and are of non-binding nature. The main document in radiation protection is Safety Standards N° 115 "International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources", IAEA, 1996. In 2006, IAEA together with other international organisations (FAO, ILO, the NEA/OECD, PAHO and WHO) undertook the revision of Safety Standards N° 115. This ongoing activity is also driven by the new ICRP Recommendations 103, published in 2007. The relationship between Euratom and international standards is discussed in further detail in section 2.1.4.

2. SECTION 2: PROBLEM DEFINITION

2.1. Context of the initiative

2.1.1. Introduction

For as long as they have been on the planet, human beings have been exposed to ionising radiation from natural sources, and since the last century also to man-made (artificial) sources. There are two main contributors to natural radiation exposure – cosmic radiation and radionuclides present in the earth's crust. The artificial sources of radiation are used in various areas of life – in electricity generation and other industrial sectors, in medicine, education and research. The exposure to ionising radiation, both from natural and artificial sources, is liable to affect the health and life of humans as well as non-human species.

Ionising radiation causes damage to living tissue. The resulting health detriment relates either to cell killing, with clinically observable health consequence at high doses, or cell mutation and corresponding late effects (cancer, genetic deficiencies). The late effects are assumed to have no threshold in terms of dose, the probability of occurrence being proportional to the accumulated dose to an individual. The harmful effects of ionising radiation are known for nearly a century. The need for protection was recognised at the time of the conclusion of the Treaty establishing the European Atomic Energy Community (Euratom Treaty). Since 1958, when the Euratom Community (EAEC) was established, ionising radiation is used more and more in other sectors of life than the nuclear industry, e.g. in medical applications for diagnosis and therapy, in industrial applications, and in research.

Chapter III, Health and Safety, of the Euratom Treaty, entrusts the Community with the responsibility for the establishment of uniform basic safety standards for the health protection of workers and the general public against the dangers arising from ionising radiation (Article 30 – 33). Chapter III further includes requirements in primary legislation on the control of levels of radioactivity in the environment (Articles 35 – 39).

Article 31 of the Euratom Treaty also lays down the procedure for the establishment of these Standards, in particular that the Commission shall seek the opinion of a Group of Experts ("Article 31 Group of Experts").

The International Commission on Radiological Protection (ICRP), since its creation in 1927, has always played a key role in updating scientific knowledge on radiation risks and setting standards in radiological protection. The Community legislation has always followed the recommendations of the ICRP. This worldwide recognised and respected scientific organisation has recently issued new guidance on the system of protection (ICRP Publication 103, 2007). ICRP sheds new light on the coherent application of the principles throughout any exposure situation and irrespective whether the source of radiation is man-made or natural.

Apart from accident situations, doses are so low that direct health effects are not observed. The absence of a dose threshold for low-dose cancer causation however calls for a special protection regime based on the three fundamental principles of *justification* of practices or activities, *optimisation* of protection and *limitation* of exposures. The most recent update of scientific data on radiation effects (undertaken by ICRP, see Section 1.3.1 and Annex II.A. point 1) did not result in the dose limits being revised. ICRP calls however for more efficient application of the concept of optimisation of protection (doses shall be As Low As

Reasonably Achievable (ALARA)) by the introduction of *constraints* and *reference levels*. The principle of justification also remains important, in particular in medical applications.

2.1.2. Affected population and current levels of exposure

The population that needs to be protected against the dangers arising from ionising radiation includes workers, members of the public as well as patients in medical applications of ionising radiation. Correspondingly, radiation protection relates to *occupational* exposure, *public* exposure and *medical* exposure. Radiation protection is also concerned with the protection of the environment, including non-human species, against ionising radiation.

The number of exposed workers in the EU is approximately 1 million[5] including around 170 000 working in nuclear industry, 680 000 in medicine, 110 000 in industry, 60 000 in education and 27 000 employed in workplaces with enhanced exposure to natural radionuclides[6]. Most of the exposed workers are employed by the undertakings conducting practices with ionising radiation. However, there is an important fraction of workers working for employers providing services to different undertakings, in particular itinerant workers doing for instance maintenance work in different nuclear facilities ("Outside Workers"). These workers in general receive much higher accumulated annual doses than workers permanently employed in the nuclear industry, and therefore merit special attention. An important fraction of workers in industries processing Naturally Occurring Radioactive Materials (NORM) (e.g. in mines, phosphate ore processing, ceramic industries) receive doses above the dose limit for members of the public. In 2004, the number of workers in NORM industries in the EU which are currently regulated as exposed workers was 27 000[7]. Studies estimate the actual number of exposed workers in EU NORM industries to be around 85 000 (2004). While there is some information on this category of exposed workers, the absence of a regulatory framework in some Member States does not allow giving a precise picture.

The world-wide average radiation exposure of an individual member of the public accounts to 3.0 mSv/year and is dominated by exposure to natural radiation sources and medical applications (see Annex VI, Figure IV). Artificial radioactivity in the environment contributes only little to this average radiation exposure.

The assessment of the exposure of the population to levels of radioactivity in the environment does not allow for a possible detriment to non-human species and the environment itself. The radiation protection experts are convinced that in any known current situation (except the area in proximity to the site of Chernobyl) there is no observable detriment to non-human species. The assumption that there is no effect at all is currently not based on well defined criteria and a proper scientific assessment however.

Radon, a natural radioactive noble gas entering buildings from the soil below and exhaled from some building materials, is a major contributor to population exposure. Radon concentrations are also highly variable from one building to another. While the extent of the radon issue is defined by regional geological features rather than by State boundaries, the

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5 European Study on Occupational Radiation Exposures (ESOREX), 2004.

6 It should be noted that this figure reflects workers who are currently being monitored and doses registered. Since the present BSS Directive leaves to MS to decide whether or not monitoring of workers in these sectors is relevant, the number of workers could actually be higher.

7 European Study on Occupational Radiation Exposure (ESOREX), 2004.

affected regions extend all over Europe. Recent epidemiological studies[8] have confirmed the causation of lung cancer by exposure to radon, and the World Health Organisation (WHO) now ranks indoor radon as a major health issue. Another type of indoor exposure is due to radioactivity in building materials. There are currently no agreed criteria for the use of building materials in new construction, neither for natural stones nor for the recycling of residues from NORM industries into building materials.

As regards the exposure of patients, the world trend presented by UNSCEAR[9] is that between 1997 and 2007 the radiation exposure of the population due to medical diagnostic examinations increased by approximately 70%. This trend is the strongest in countries with a high level of healthcare, all EU Member States falling under this category, where the exposure from medical uses is on average now equal to about 80% of that from natural sources. This trend is caused mostly by the rapid increase in the use of new, high-dose, X-ray procedures and in particular computed tomography (CT) scanning. According to the UNSCEAR 2008 report: "for several countries, this has resulted, for the first time in history, in a situation where the annual collective and per caput doses of ionising radiation due to diagnostic radiology exceeded those from the previously largest source (natural background radiation)."

2.1.3. Community radiation protection legislation

Following the entry into force of the Euratom Treaty, a comprehensive set of legislation establishing basic safety standards has been enacted on the basis of Article 31 of the Treaty (see Annex V). The main pillar of that legislation is Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Euratom BSS Directive).

The BSS Directives have been regularly updated in 1962, 1966, 1976, 1980, 1984 and 1996[10], taking account of advances in scientific knowledge on the effects of ionising radiation in line with the recommendations of ICRP and on the basis of operational experience. Medical exposures have been included in specific legislation since 1984[11]. Specific problem areas are covered in three "associated directives" – High activity sealed sources (HASS) Directive[12], Outside Workers Directive[13] and Public Information Directive[14].

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8 Darby S et al. (2006). Residential radon and lung cancer. Scan J Work Environ Health, 32 Suppl 1: 1-83

9 Sources and Effects of Ionizing Radiation, United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) report 2008.

10 Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, OJ L 159, 29.6.1996, p. 1.

11 Currently **Council Directive 97/43/Euratom** of 3 September 1997 on health protection of the individuals against the dangers of ionising radiation in relation to medical exposure, repealing 84/466/Euratom of 3 September 1984 (Medical Directive);

12 **Council Directive 2003/122/Euratom** of 22 December 2003 on the control of high-activity sources and orphan sources (HASS Directive)

13 **Council Directive 90/641/Euratom** of 4December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (Outside Workers Directive)

14 **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 (Public Information Directive)

In 2005 the European Commission published "A strategy for the simplification of the regulatory environment: the better regulation initiative" (COM/2005/535 final) as a response to the European Parliament's and Council's requests to simplify EU-legislation and enhance its quality. This action is undertaken in the context of the Lisbon strategy for achieving growth and jobs in Europe. This initiative is the basis for attempting the consolidation of all above legislation.

2.1.4. International context

The current Euratom BSS Directive followed the recommendations of ICRP from 1990. The Directive was transposed and implemented in the Member States as of 13 May 2000.

Since 2000, radiation protection science, in an international context, has evolved, and ICRP issued new international recommendations (ICRP Publication 103, 2007) and new scientific findings (e. g. sensitivity of the lens of the eye) are published.

ICRP has always been recognised to give state-of-the-art guidance on the methodology for dose assessment, on dose limits, and on the overall radiation protection philosophy. While for this reason the Euratom legislation has always, since 1959, closely followed ICRP, there is no legal obligation to do so. The ICRP makes recommendations, which are followed world-wide on a voluntary basis. ICRP issues no regulatory requirements, but its guidance is also incorporated in the International Basic Safety Standards. The organisations sponsoring the International Basic Safety Standards now also pursue a major revision of these standards, led by the IAEA and along the recommendations of ICRP.

The EAEC Community has been invited to also sponsor the international Basic Safety Standards. This possible co-sponsorship has been an opportunity for the Commission to be involved very actively in the revision of the international standards as well, in order to pursue the best possible coherence to the two documents. The international standards are now close to final drafting (draft 4.0 was endorsed by IAEA's Committees in December 2010). The text is close to the draft Euratom Directive proposed by the Article 31 Experts in February 2010, but there are important differences. A detailed comparison with draft 3.0 of IAEA was made in June 2010 (see Annex XII).

There are two main reasons why referring to or incorporating the International BSS in Community legislation is not feasible. On the one hand, the Euratom Community is bound by the Treaty to establish uniform basic safety standards. Incorporating the International BSS in a community act is difficult. The language of the International BSS does not correspond to EU legal drafting rules. The international requirements are also sometimes far too detailed and go beyond the idea of "basic" standards in the Euratom Treaty. The requirements of the Euratom BSS need to allow for EC internal market rules. On the other hand, the International BSS allow for the fact that States in the whole world, with different level of development of regulatory and technological infrastructure, must be able to comply with the requirements. The Community legislation is more ambitious.

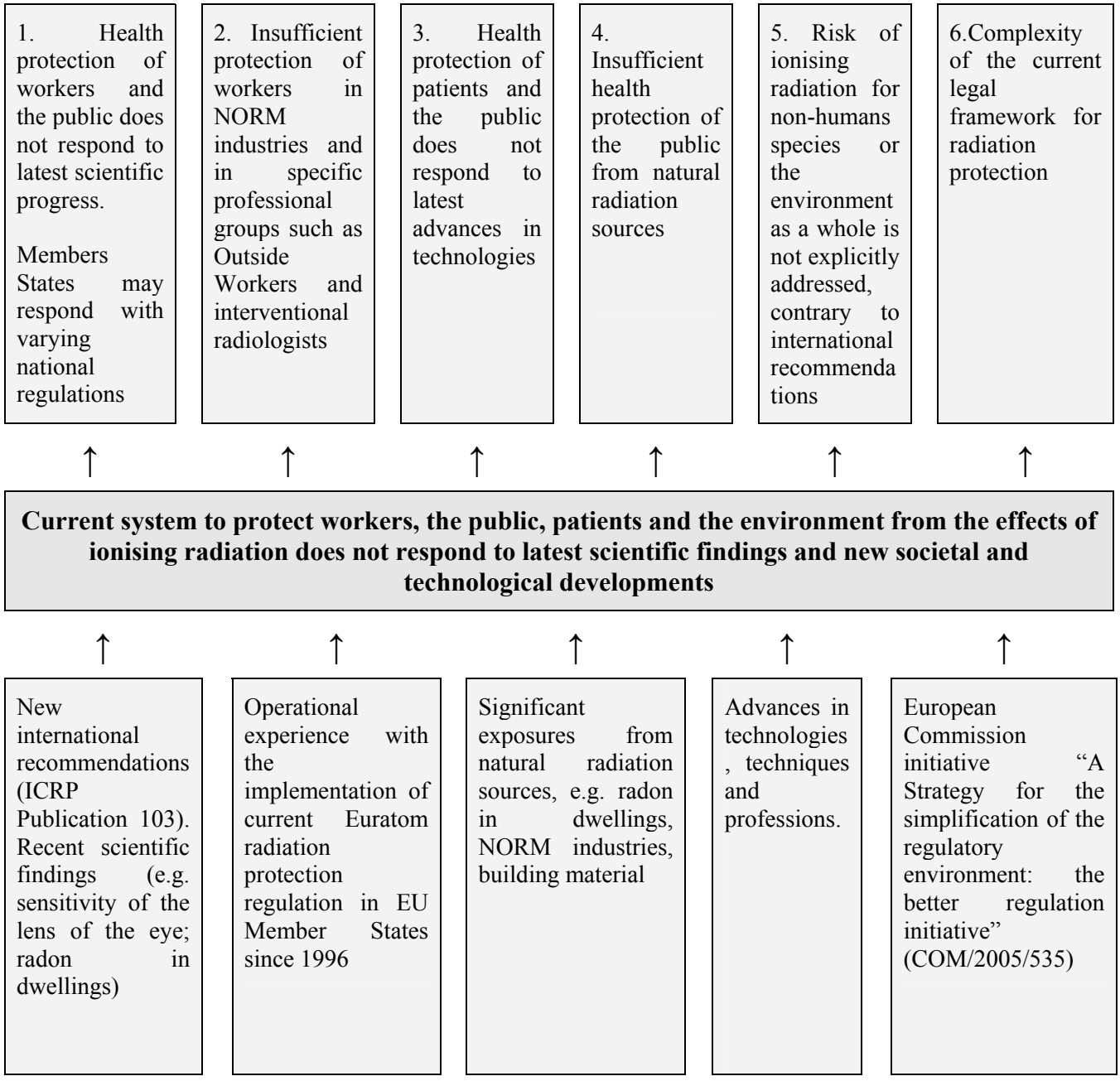
Hence, relying only on the International Basic Safety Standards to ensure further development of good practice in radiation protection would be contrary to the high standard currently achieved in Community legislation. The Euratom standards are binding to EU Member States, whereas the International Basic Safety Standards are not (or only in specific contexts). If the binding Euratom Basic Safety Standards were left unmodified, Member States would be frustrated in their desire to adjust their legislation to the new recommendations of ICRP. In

addition, problems resulting from different requirements, especially numerical criteria, between the International and Euratom Basic Safety Standards could become increasingly important. To avoid such inconsistencies, all Community legislation under Chapter III of the Euratom Treaty would in fact need to be withdrawn, which is obviously not acceptable. It should be borne in mind that ever since the first Euratom Basic Safety Standards (1959) and International BSS (1962) Europe has been very much in advance of the rest of the world.

2.2. Underlying problems

The current system to protect workers, the public, patients and the environment from the effects of ionising radiation does not respond any longer to the latest scientific findings and new societal and technological developments. Figure 1 summarises the problem definition.

Figure 1: Graphical presentation of the problem definition



2.2.1. Health protection of workers and the public does not respond to latest scientific progress

The current Radiation Protection legislation reflects the status of radiation protection in the 90ies, in particular the basic safety standards laid down in Directive 96/29/Euratom. These standards have, since 1959, been regularly updated in the light of developments in scientific knowledge of radiation effects and the corresponding changes in the overall protection philosophy. ICRP, which recommendations have over more than 50 years been the basis of the Community legislation, has issued new recommendations in 2007 (ICRP Publication 103).

ICRP plays a key role in updating scientific knowledge on radiation risks and accordingly defining the dose limits, as well as the methodology for the assessment of the dose. ICRP introduces a modified methodology to calculate doses based on latest knowledge on radiation risks. Doses calculated according to the new methodology will be different from doses calculated according to the methodology given in the current BSS Directive, which will impair the control of compliance with the dose limits, especially for workers. Different calculation methods will also lead to a gap between Euratom and international standards. In the EU, this will concern the assessment of exposure of more than 1 million exposed workers.

ICRP is also publishing new scientific data providing evidence for a higher radiosensitivity of the lens of the eye. Maintaining current organ dose limits for the lens of the eye would result in a high incidence of radiation induced cataract in specific professions such as interventional radiologists, as can be observed already now.

2.2.2. Insufficient protection of workers in NORM industries and in specific professional groups such as Outside Workers and interventional radiologists

Industries processing natural occurring radioactive material extracted from the earth's crust (NORM industries) accumulate and concentrate natural radiation sources resulting in enhanced radiation exposures of workers and, if material is released to the environment, of the public. Either the industries use the material (e.g. production of thorium compounds) or they are involved in the extraction itself (e.g. mining of ores). The BSS Directive introduced already in 1996 requirements on work activities involving natural radiation sources. The requirements offered maximum flexibility to Member States to decide for instance which NORM industries were of concern, and on the required level of protection for workers. This has been cause of very different levels of achievement in controlling NORM industries and in protecting workers in these industries. This situation is not compatible with the Community's role in setting uniform standards for the protection of workers and the public. The available data demonstrates that the workers in NORM industries may receive doses higher than the limit for the public. In France 17% of the monitored workers in NORM industries received effective doses above the 1mSv annual limit for the members of the public (See Annex VIII(E)). NORM industries which may lead to considerable exposures of workers are listed in Annex VIII.B. Although no exact data on the size of these industries are available, the dimension of the issue can be estimated through the following examples: 381 enterprises in the EU extract crude petroleum and natural gas, 293 enterprises produce lead, zinc and tin and the number of enterprises mining iron ores is estimated to 40[15]. Data on the number of exposed workers in NORM industries are also scarce. In 2004, the number of workers in

[15] EUROSTAT Basic Statistic for 2007

NORM industries in the EU which are currently regulated as exposed workers was 27 000[16]. Studies estimate the actual number of exposed workers in EU NORM industries to be around 85 000 (2004).

There are professional groups specialised in specific tasks involving high radiation exposures, and receiving the highest doses among exposed workers in Europe. These specialised workers are mostly in the category "Outside Workers", as not being employed by the undertaking in which they operate, but providing services in different installations. It is important that this category of workers receives adequate protection and that their doses are properly recorded. Increasing specialisation of skilled workers in the nuclear industry also calls for an enhanced mobility of these workers, crossing borders within the EU and beyond. Variations in the interpretation of current requirements have led to different national implementations, e.g. of the dose limit for occupational exposure and the requirements on individual radiation passbooks, creating obstacles for the mobility of these specialists. The regulation of the protection of Outside Workers is currently split between BSS Directive 96/29/Euratom and Outside Workers Directive 90/641/Euratom. This situation is an obstacle to a comprehensive set of requirements for overall worker protection, in particular with regard to the responsibilities of the undertaking and the employer for the protection of Outside Workers. The number of Outside Workers in Europe that would benefit from better protection amounts to approximately 100 000[17].

Technological developments in medical applications of ionising radiation, in particular the minimally invasive interventional radiology procedures, result in an increasing number of interventions performed by a single radiologist in a high radiation environment, leading to substantial doses to the body and in particular to the lens of the eye. The epidemiological studies in this respect were discussed in 2006 in the framework of the EU scientific seminar "New Insights in Radiation Risk and Basic Safety Standards" (Annex II.B. Radiation Protection № 145) and are more recently summarised in a review by the Article 31 Group of Experts Working Party on Research Implications on Health and Safety Standards[18]. Health protection of individuals from this professional group needs improvement, not only for the lens of the eye. This group of professionals is estimated to amount in Europe to approximately 12 000.

2.2.3. Health protection of patients and the public does not respond to latest advances in technologies

In the medical area, important technological and scientific developments, e.g. in X-ray computed tomography imaging (CT), in minimally invasive interventional radiology procedures and in nuclear medicine, have also caused a notable increase in the exposure of patients. As an example in France the number of performed medical procedures in the period 2002-2007 has increased by only 2%. However, the annual dose per capita from these procedures increased by 57% in 5 years (see Annex VII). While high dose CT procedures are generally for the benefit to the diagnosis of the patient, recent years have indicated that too many examinations are carried out although the CT procedure would not be necessary for the diagnosis. The IAEA[19] estimates that in economically advanced countries more than 20% of

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16 European Study on Occupational Radiation Exposure (ESOREX), 2004.

17 European Study on Occupational Radiation Exposure (ESOREX), 2004.

18 See Annex 2 of the Summary Report of the Article 31 Group of Experts meeting, 3–5 November 2009

19 http://rpop.iaea.org/RPOP/RPoP/Content/PastEvents/justification-medical-exposure.htm

the radiological examinations may not be justified; in special cases this can be as high as 45%, and even up to 75% for specific techniques. With the ever-growing use of radiological imaging there is a corresponding increase in non-justified exposures. An issue of particular concern is the rapidly growing use of high-dose procedures (e.g. CT) on children, where the higher sensitivity to radiation and the longer available time to develop the disease may lead to an observable increase in cancer rates in a few decades. A further problem resulting from the new technologies is an increase in the reported cases of unintended high exposures in radiotherapy and in interventional radiology, sometimes with severe individual consequences. These issues have been highlighted in a recent Communication of the Commission to the Council[20].

Advances in imaging technology using ionising radiation have similarly benefited its non-medical applications, where new issues, not foreseen a decade ago, emerged. Security screening with X-rays, e.g. of passengers in airports, normally involves very low individual screening doses. However, in the case of routine screening the frequency of exposure and the number of exposed individuals may quickly become significant thus requiring specific justification and regulatory response to ensure adequate protection of the public[21].

2.2.4. Insufficient health protection of the public from natural radiation sources

Radon is a radioactive gas that emanates from rocks and soils and tends to concentrate in enclosed spaces such as underground mines and houses. Studies on indoor radon and lung cancer provide strong evidence that radon causes a substantial number of lung cancers in the population; the proportion of lung cancers attributable to radon ranges from 3% - 14%. It is after smoking the second known cause of lung cancer. Exposure to radon in dwellings was addressed in 1990 in a Commission Recommendation[22]. The, now confirmed, causation of lung cancer by exposure to radon calls for strengthening radon mitigation policies in Europe through binding requirements, in line with WHO guidelines[23]. Public health strategies to prevent radon in new buildings through appropriate building codes and to remediate existing building allow reducing the radon risk and the number of lung cancers. In Sweden, for example, more than 10% of dwellings show radon concentrations above 200 Bq/m^3, which is considered a level, new buildings should not exceed, putting a considerable fraction of the population at enhanced risk of developing lung cancer. The respective percentage varies between Member States ranging from very low in the Netherlands, over less than 1% in United Kingdom to 12% in Finland (see also Annex IX). Even though the extrapolation is difficult, one could say that some 10 million European citizens are concerned by this health issue.

The Commission Recommendation of 1990 already raised the issue at an early stage and recommended reference levels which are still used in most Member States and close to the most recent international recommendations (even though now WHO and ICRP advocate a

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20 The Commission adopted on 6 August 2010 a Communication (COM/2010/0423) discussing in more detail today's issues in medical uses of ionising radiation and calling, among others, for enhanced regulatory control of medical practices and for strengthening certain requirements of the Medical Exposure Directive.

21 The use of security screening devices in airports has been addressed in a Communication from the Commission to the Council and the Parliament, adopted in June 2010 (COM(2010)311, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0311:FIN:EN:PDF

22 Commission Recommendation 90/143/Euratom of 21 February 1990 on the protection of the public against indoor exposure to radon (OJ L-80)

23 WHO Handbook on indoor radon, World Health Organisation, 2009, ISBN 978 92 4 154767 3

maximum reference level of 300 Bq/m³ rather than 400 Bq/m³ in the Commission Recommendation). The experience with the Recommendation, in most Member States, however was that it is not sufficient to establish reference levels; tangible results can only be achieved through a constant and ambitious programme to make progress in reducing radon concentrations in existing and new dwellings. The establishment of such a "Radon Action Plan" should become a mandatory requirement; in addition the Commission should be kept informed of such plans and on the identification of radon prone areas.

Natural radioactivity in building materials also contributes to the exposure of the public and can lead to exposures above the dose limit for members of the public. A coherent and uniform framework for the protection of the public against building materials with high levels of radioactivity, either from the recycling of residues from NORM industries or from other sources, is still missing. To give an indication of amounts of building materials, the production of granite (crude or roughly trimmed) in the EU in 2009 was around 4.5 billion kg. The production of porphyry, basalt, quartzite and other monumental or building stone (crude, roughly trimmed, cut) in the EU in 2009 was around 15 billion kg[24].

2.2.5. The risk of ionising radiation for non-humans species, or the environment as a whole, is not explicitly addressed, contrary to international recommendations

The radiation protection approach prevailing in 1996 was based only on the health protection of man, without explicit consideration of a possible detriment to other species. Overall, there has been a growing concern in society for the protection of the environment, and the fact that this is not explicitly addressed with regard to ionising radiation contributes to the lack of acceptance. In 2002, the European Commission (at the time DG Environment) hosted a main stakeholder conference (Stakeholder's conference on approaches to environmental radioactivity, Luxembourg, 2-3 December 2002) concluding on the need for a revision of the BSS to ensure the protection of the natural environment. While it is generally believed among radiation protection specialists that the exposure of biota does not call for additional measures, there are currently neither criteria nor an agreed methodology for demonstrating compliance with environmental standards. Such demonstration is warranted by widespread public and political perception that nuclear industry causes an environmental detriment. In addition, the protection of the environment against radiation is pursued under a number of international agreements (for instance under the OSPAR Convention). Also ICRP now advocates the explicit assessment of the impact of ionising radiation on non-human species, as part of an overall environmental policy rather than one looking only into environmental pathways of human exposure and corresponding health detriment. ICRP has already published a methodology for the assessment of exposures to biota (ICRP Publication 108).

2.2.6. Complexity of the current legal framework for radiation protection

The analysis of the legislation enacted under Article 31 of the Euratom Treaty (Annex V) reveals that the Medical Directive[25], High activity sealed sources (HASS) Directive[26], Outside

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24 EUROSTAT PRODCOM Database 2009

25 **Council Directive 97/43/Euratom** of 3 September 1997 on health protection of the individuals against the dangers of ionising radiation in relation to medical exposure, repealing 84/466/Euratom of 3 September 1984 (Medical Directive);

26 **Council Directive 2003/122/Euratom** of 22 December 2003 on the control of high-activity sources and orphan sources (HASS Directive)

Workers Directive [27]and Public Information Directive[28] are closely linked with the BSS Directive 96/29, developing further the requirements of this Directive or referring to different texts of the BSS Directive. As these issues have been developed over a long period of time (1989-2003), the respective legislative acts are not streamlined. They, therefore, constitute a complex set of legislation, which is cumbersome to read and apply. This problem was identified in the context of the Commission's policy of simplification of Community legislation.

2.2.7. Opinion of the Article 31 Group of Experts

Article 31 of the Euratom Treaty defines a specific procedure for the elaboration of basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation - "the basic safety standards shall be worked out by the Commission after it has obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts, in particular public health experts, in Member States". Thus, the Group of Experts established in accordance with Article 31 of the Euratom Treaty is involved in all Euratom initiatives in the radiation protection field.

The Article 31 Group of Experts has assisted the Commission in analysing the implications of the new ICRP Publication 103, and has concluded that it justified a comprehensive review of the Community radiation protection legislation. They eventually recommended to revise the Euratom Basic Safety Standards and, in the context of the simplification initiative, other related legislation. The Article 31 Group of Experts also looked into operational experience and new technical developments since the adoption of the Basic Safety Standards Directive and the Medical Exposure Directive. The Experts set up various working parties to resolve technical issues, to assist the Commission in drafting new or modified requirements, and to help with the simplification efforts.

In February 2010, at the end of their 5 years mandate, the Experts issued an Opinion[29] on the revision of Directive 96/29/Euratom and the integration of the other directives (Council Directive 97/43/Euratom, Council Directive 90/641/Euratom, Council Directive 2003/122/Euratom, Council Directive 89/618/Euratom). The Opinion is based on the results of the studies and networks commissioned by the European Commission (see Annex II) and the reports of the Article 31 Group of Experts Working Parties. The principal observations of the Working Parties, as reflected in the opinion of the Article 31 Group of Experts, are listed in Annex III., in particular the concept of a "graded approach" to regulatory control (see Annex X) which may have a positive economic impact. The issues addressed by the Experts, other than the core issues discussed in the previous sections and the abovementioned "graded approach", are not analysed in further detail in this report.

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27 **Council Directive 90/641/Euratom** of 4December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (Outside Workers Directive)

28 **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 (Public Information Directive)

29 http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

Bearing in mind Article 31 of the Euratom Treaty, the Commission has an obligation to take the Opinion of the Experts into account if it proposes new or revised radiation protection legislation.

2.3. Baseline Scenario

All things remaining equal, i.e. without new or revised Community legislation, the problem areas described in Section 2.1 will continue to exist and, in the absence of Community legislation harmonising the national requirements, will show little prospect for improvement. Indeed, Member States may align with the new ICRP Recommendations or scientific evidence through their own interpretation or through the International BSS, as far as some of the changes that are needed would be made in the international standards. The Euratom Community is obliged to establish *uniform* basic safety standards and any abstention from action will infringe the Treaty. Euratom legislation would loose its status of being at the top of scientific knowledge and good practice and would no longer be in line with international recommendations and standards.

The problem of incoherence of Community legislation will aggravate with the introduction of new specific pieces of legislation that may be proposed in future by EU legislation. While Member States have so far accommodated these incoherencies in national legislation, the discrepancies may cause a significant regulatory burden over the next decades.

The exposures in medical applications will probably further substantially increase over the next decades (see the world trend between 2000 and 2008 in Annex VI, Figures 3 and 4). In particular, in the absence of a requirement to report accidental exposures in radiotherapy or other high-dose medical applications the regulatory authority will not be in a position to intervene and correct the management or equipment failures that are the cause of such accidents.

The exposures in non-medical imaging, e.g. for security screening, will also increase substantially over the next decades, because of the necessity to enhance security measures at airports and public buildings. The lack of clear radiation protection requirements as for other public exposure may result in a proliferation of devices for security screening not only in airports but also in schools, public buildings etc. This may not only lead to high cumulative exposures to some individuals but also to a high collective dose in the EU.

Without a comprehensive radiation protection system incorporating both artificial and natural radiation sources the current lack of balance will continue to prevail, and will perpetuate the misunderstanding that “artificial” radiation is more harmful than "natural" radiation.

In addition, the absence of uniform community legislation may result in different regimes of regulatory control to be imposed by Member States, both with regard to NORM industries and to the production of building materials, which may affect the functioning of the internal market. Different levels of protection for workers in NORM industries and for the public from building materials will continue to exist.

In summary, the baseline scenario is expected to show the following important trends:

– Members States may respond to new developments by introducing national regulations which will vary within Europe;

– the current set of Euratom legislation would not be streamlined and simplified;

– the overall exposure of patients will continue to increase and may give rise in future to an observable health detriment in some categories of exposed individuals;

– different levels of protection of workers and the public against natural radiation sources would continue to exist.

2.4. Community right to act

According to Article 2(b) of the Euratom Treaty "…the Community shall, as provided in this Treaty …. Establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied". Accordingly, in the Treaty's Preamble, the Member States declare that they are *"resolved to create the conditions necessary for the development of a strong nuclear industry"* and also *"anxious to create conditions of safety necessary to eliminate hazards to the life and health of the public".* Community is mandated to *"establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied."* Therefore, the competence of the European Atomic Energy Community to regulate in the field of the health protection against ionising radiation is explicitly recognised by the Euratom Treaty.

According to the principle of subsidiarity, in areas where the Community has no exclusive power to act, it should only act "if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community". The exclusive nature of the Euratom Community's legislative powers under Articles 30 and 31 of the Euratom Treaty does not require, in principle, the application of the principle of subsidiarity.

3. SECTION 3: OBJECTIVES

The general objective of this initiative is to ensure a high level of protection of workers and the general public, including patients exposed in medical applications of ionising radiation. This general objective could now be extended to the protection of the environment as a whole.

In the light of the problem definition in Section 2, Community legislation shall respond to the latest scientific findings and new societal and technological developments to the benefit of improved protection of workers, the public, and patients. There is also a need to ensure coherence of existing Community legislation in this field. At the same time, the EU should strive to reach coherence with the international recommendations, and thus create the most advanced and comprehensive EU legal framework for nuclear safety, security and non-proliferation.

The main objective of this initiative is translated into four specific objectives:

1. to bring the health protection of workers, the public and patients in line with latest scientific data and operational experience,

2. to streamline existing EU legislation in the field of radiation protection,

3. to ensure coherence with international standards and recommendations,

4. to cover the whole range of exposure situations, including exposure to natural radiation sources at home, as well as the protection of the environment.

4. SECTION 4: POLICY OPTIONS

In the light of the problem definition and the objectives, credible policy options should be considered in two different areas:

– Improving the protection in the identified subject matter areas (2.2.1-2.2.5),

– Reducing the complexity of existing radiation protection legislation (2.2.6).

To align EU radiation protection legislation to latest scientific progress, implementing ICRP Recommendation 103 (see *problem 2.2.1*), the dose calculation methodology and the dose limit for the lens of the eye stipulated in the current Basic Safety Standards need to be amended. In order to provide a uniform level of protection for Outside Workers and for workers in NORM industries (see *problem 2.2.2*), the requirements in the current Basic Safety Standards on NORM industries need to be strengthened and an annual dose limit for occupational exposure needs to be imposed. These amendments can only be achieved through a revision of the Basic Safety Standards Directive.

To respond to the technological progress in medical imaging procedures and to enhance the protection of patients (see *problem 2.2.3*), the two requirements on justification and optimisation in the current Medical Exposure Directive need to be strengthened. Appropriate protection of the public from non-medical imaging procedures (see *problem 2.2.3*), such as airport security screening, requires to include specific requirements in the Basic Safety Standards Directive and to amend the Medical Directive correspondingly.

Improving the protection in the identified subject matter areas, as discussed above, could be achieved through the simultaneous amendment of the Directives affected by scientific and technological progress, the Basic Safety Standards Directive, and the Medical Exposure Directive, without addressing the complexity of existing radiation protection legislation. To address the issues identified with regard to radon, building materials and the protection of non-human species, this option relies on the development of non-legislative measures, such as guidance and recommendations.

A table supporting this analysis with more details is provided in Annex XI.

With regard to the complexity of existing radiation protection legislation (see *problem 2.2.6*), different methods to achieve simplification have been analysed

– Codification or recast of all Community legislation;

– Revision of the BSS and integration of the other Directives into the BSS.

It is only possible to codify or recast legislative acts with the same legal instrument (e.g. Directives with Directives, Regulations with Regulations). Regulations, Decisions, Recommendations cannot be part of a recast without changing the binding or non-binding character of the requirements. As Euratom legislation uses all legal instruments, codification of all Community legislation (Annex V), is not possible.

Not all Euratom Directives are directly concerned with radiation protection. Some acts (for instance Directive 2006/117/Euratom) are of administrative nature, others (for instance Directive 2009/71/Euratom) concern only a certain type of installations or practices. Although overall they contribute to a better protection of the population their subject matter is different from the other radiation protection legislation. Thus bringing them together with acts establishing scientific criteria and general requirements will not contribute to the simplification and clarity. In addition since Directive 2009/71/Euratom is not yet transposed in national legislation, it is not at this stage sensible to consider its inclusion in a recast.

Thus we concentrate on the relevant Directives which are the Basic Safety Standards Directive, the Medical Directive[30], the High activity sealed sources (HASS) Directive[31], the Outside Workers Directive[32] and the Public Information Directive[33]. A pure codification of these relevant Directives is also not possible, as there are differences in definitions, scope of application etc. A recast of these Directives is technically feasible. A recast with minimal changes, while reducing the number of legal acts, will not satisfy the specific objectives of the current initiative, and contribute little to the improvement of protection in the identified subject matter areas, as discussed above. In addition, only a thoroughly revised structure of the BSS Directive 96/29, gives the requirements of the other Directives a logical place in the overall architecture.

Therefore, the only credible solution reducing the complexity of radiation protection legislation which is compatible with the other objectives for amendment of the legislation is the revision of the Basic Safety Standards Directive and the simultaneous integration of the Medical Exposure Directive, the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive.

The issues raised in *2.2.4 Public exposure to natural radiation sources* and in *2.2.5 Protection of the environment (non-human species)* could be solved either by extending the scope of the revised Basic Safety Standards Directive, to cover these areas, or by the development of new Directives exclusively for these purposes, or by non-legislative measures, such as guidance on national action plans for radon, or guidance on the protection of the environment (See Annex XI). Binding requirements on national action plans for radon, however, can only be achieved through legislative measures. Stand-alone Directives on all three issues would be contrary to the simplification policy. With regard to building materials a stand-alone Directive would, in addition, not allow to ensure coherence with the management of residues from NORM industries. With regard to the protection of the environment, a stand-alone Directive would not ensure coherence with the protection of human health from environmental radioactivity.

In conclusion, public exposure to natural radiation sources and the protection of the environment can only be efficiently addressed through a revision of the Basic Safety

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30 **Council Directive 97/43/Euratom** of 3 September 1997 on health protection of the individuals against the dangers of ionising radiation in relation to medical exposure, repealing 84/466/Euratom of 3 September 1984 (Medical Directive);

31 **Council Directive 2003/122/Euratom** of 22 December 2003 on the control of high-activity sources and orphan sources (HASS Directive)

32 **Council Directive 90/641/Euratom** of 4December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas (Outside Workers Directive)

33 **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 (Public Information Directive)

Standards Directive. For this purpose two distinct policy options have been considered, the two aspects being unrelated to each other. The assessment of these two options does not depend on whether the revision of the Basic Safety Standards Directive is combined with a revision of the Medical Directive or with the integration of the four identified Directives. The comparison is less transparent however if the amendments to the other four Directives are considered at the same time. For the sake of completeness a final option is evaluated, which consists of a combination of the two options broadening the scope together with the consolidation of all Directives. The combination of the two options should be considered only if they are both found to be an efficient solution to their respective problem areas. Similarly, the combination with the consolidation of all Directives is considered only if this is found to be an efficient solution to the need for simplification in its own right.

Option 1: Maintaining the status quo of existing legislation,

Option 2: Revision of Basic Safety Standards and Medical Directive,

Option 3: Revision and consolidation of Basic Safety Standards and Medical Directive, and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive (non-legislative measures to address natural radiation issues and the protection of non-human species, see Annex XI),

Option 4: Revision of the Basic Safety Standards Directive and broadening the scope to cover public exposure to natural radiation,

Option 5 Revision of the Basic Safety Standards Directive and broadening the scope to cover protection of non-human species,

Option 6 Revision and consolidation of the Basic Safety Standards Directive and Medical Directive, integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive and broadening the scope to cover public exposure to natural radiation and protection of non-human species.

In summary:

№	Options
1	Status quo
2	Revision of BSS and Medical Directives
3	Revision and consolidation of BSS and Medical Directives and integration of three other Directives
4	Revision of BSS broadening the scope to natural radiation sources
5	Revision of BSS broadening the scope to the protection of non-human species
6	Revision and consolidation of BSS and Medical Directive, integration of the other three Directives, and broadening the scope both for the natural radiation sources and protection of non-human species

4.1. Option 1: Maintaining the status quo of existing legislation

This policy option entails no action to be taken. While in 1996, the existing body of Community legislation overall offered adequate protection to workers, members of the public and patients, it no longer serves the needs resulting from changes in technology and in society.

There would also be no legislative response to the many detailed amendments required to improve the issues described in Section 2.2. With regard to the assessment of the health detriment this option would not allow for the latest scientific knowledge as provided by ICRP.

4.2. Option 2: Revision of Basic Safety Standards and Medical Directive

The development in science, as published in ICRP Recommendation 103, affects the BSS Directive 96/29/Euratom which is based on the earlier ICRP Recommendation 60 (published in 1990), as well as, but to a lesser extent, the Medical Directive 97/43/Euratom. Technological and societal developments also affect both Directives. Option 2 would mean to undertake the necessary amendments in each of these two Directives separately.

The changes in the BSS Directive 96/29 will cover the following issues:

1. Dose calculation methodology and organ dose limits for the lens of the eye according to latest scientific publications from ICRP

   The revision of the BSS will allow updating the methodology to calculate doses based on latest knowledge on radiation risks as published by ICRP. This will align the dose calculation methodology required by the BSS with international standards allowing the correct assessment of exposure of more than 1 million exposed workers and a control of compliance with the dose limits. The revision of the BSS will also present an opportunity to reduce significantly the organ dose limits for the lens of the eye as a response to latest scientific data providing evidence for a higher radiosensitivity of the lens of the eye. The reduction of the organ dose limit for the lens of the eye will ensure a high level of protection for certain categories of workers, in particular interventional radiologists.

2. Occupational exposure in NORM-industries

   Exposures due to natural radiation sources are already within the scope of Directive 96/29/Euratom (Title VII). The requirements, however, offer maximum flexibility to Member States to decide which NORM industries are of concern, and on the required level of protection for workers. This has been cause of very different levels of achievement in controlling NORM industries and in protecting workers in these industries. Therefore, the requirements on natural radiation sources are strengthened. In addition, importance is given to natural radiation sources in the ICRP Recommendations. The revision of the Directive allows defining precise criteria for the identification of industries of concern and applying requirements for the protection of workers in a similar way, irrespective of whether their exposure occurs in a NORM industry or for instance in nuclear industry.

3. The dose limits for occupational exposure

Since 1990, it is internationally recognised and recommended that workers should in average not be exposed to more than 20 mSv/year, allowing for some averaging over time. This recommendation is already reflected in Directive 96/29/Euratom, where the dose limit for occupational exposure is set to 100 mSv in a consecutive period of five years, subject to a maximum annual exposure of 50 mSv. The flexibility in this requirement, however, has led to different national definitions of the dose limits, representing an obstacle for outside workers crossing borders. It is now proposed to set an annual dose limit for occupational exposure to the internationally recommended value of 20 mSv, without the possibility of averaging over 5 years, in order to ensure a harmonised dose limit within Europe. Any deviation from the internationally recommended value of 20 mSv is not an option.

The changes in the **Medical Directive** will affect the following areas.

1. Strengthening certain Medical Directive requirements for protection of patients and other individuals submitted to medical exposure.

   The definition of medical exposure needs to be brought in line with the latest ICRP Recommendations, e.g. to include "carers and comforters". Requirements on medical exposure procedures need reinforcement through specifically addressing justification of the exposure of asymptomatic individuals, provision of appropriate information to patients enabling their informed consent, considering staff exposure in justification process, further restricting the use of equipments that do not provide adequate information about the radiation doses and incorporating the patient doses in the reports from the examination. *Optimisation* of protection shall be strengthened through inclusion of interventional procedures in the group of procedures for which Diagnostic Reference Levels (DRLs) are required, requirements for periodic revision of the DRLs and closer involvement of the Medical Physics Expert in the medical radiological procedures. Unintended and accidental exposures receive new, comprehensive consideration, including provisions on risk assessment for radiotherapy and on recording, reporting and responding to accidents in medical exposure procedures.

2. New approach to "medico-legal exposures", as defined in the Medical Directive.

   The conclusions of the International Symposium on Medico-legal exposures, organised by the Commission in 2002, propose to take medico-legal procedures out of the definition of medical exposure. Based on the conclusions of this conference, the Article 31 Group of Experts proposed in 2005 to replace the term "medico-legal procedures" by the concept of "non-medical imaging exposures" and to change the definition of medical exposure, to include a reference to the intended benefit to the health or the well-being of the exposed individual. Requirements for radiation protection in relation to the new category of non-medical imaging exposure are developed in the revised Basic Safety Standards Directive, including those for justification, regulatory control, optimisation of protection, dose constraints and dose limits. The proposed draft requirements were discussed at the international meeting organised by the Commission on 8 and 9 October 2009 in Dublin.

The other related Directives - **Outside Workers Directive, Public Information Directive** and **High activity sealed sources Directive** - will remain unchanged. This results in a "no change situation" in terms of simplification.

4.3. Option 3: Revision and consolidation of Basic Safety Standards and Medical Directive, and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive

This option offers the revision of the Basic Safety Standards Directive by extending the requirements to medical exposure, public information, outside workers exposure and high-activity sealed sources. Within this policy option, the BSS Directive 96/29 and the related legislative acts (Medical Directive 97/43/Euratom, Outside Workers Directive 90/641/Euratom, HASS Directive 2003/122/Euratom, Public Information Directive 89/618/Euratom, Commission Recommendation 90/143/Euratom) will merge and the requirements of BSS Directive and Medical Directive will at the same time be upgraded to the latest scientific knowledge and regulatory experience.

In addition to the changes in Directive 96/29/Euratom and Directive 97/43/Euratom as described in Option 2, Option 3 will offer the following opportunities:

1. Better management of radiation sources which are not under regulatory control (because the source has been abandoned, lost, misplaced or stolen) will be achieved through the incorporation of the corresponding requirements from the HASS Directive into the emergency preparedness regime, now under Directive 96/29/Euratom. The definition of high activity sealed sources (HASS) will be aligned to the definition in the international Code of Conduct (IAEA).

2. The specific requirements for the protection of the outside workers (Outside Workers Directive) will be added to the requirements for all exposed workers in Directive 96/29. This will offer a comprehensive approach to the protection of occupationally exposed people clearly defining the responsibilities of the undertaking responsible for the radiation source and the employer of an outside worker. Member States will be required to establish National Dose Registries which cover all exposed workers. Radiation passport should also be established for each individual outside worker.

3. The requirements for informing the public before and in case of an emergency (Public Information Directive) are part of the arrangements for the management of emergency exposure situations and will fit in the requirements for emergencies currently established in Title IX of Directive 96/29/Euratom.

Merging the above mentioned five Directives should be a major step in terms of the simplification of the acquis in radiation protection to the benefit of improved protection of outside workers and the public. For this purpose, the overall Directive must be substantially re-structured in order to ensure that the simplification also improves the clarity of the text and better operational implementation of the radiation protection principles. While the opportunity of merging these Directives is taken for incorporating further amendments, those are of no significance in terms of the impact analysis.

This option relies on non-legislative measures for solving the problems described in sections 2.2.4 (protection from natural radiation sources) and 2.2.5 (the risks of ionising radiation to the non-human species). As indicated in Annex XI non-legislative measures like guidance may advise Member States how to establish action plans for reducing the impact to health of radon. However, there is no binding requirement for the establishment of such plans, nor tools for the management of radon exposures in dwellings, buildings with public access and workplaces. In addition Option 3 would result in the need of amending the current

Commission Recommendation of 21 February 1990 on the protection of the public against indoor exposure to radon which is no longer fully in line with international recommendations.

4.4. Option 4: Revision of BSS broadening the scope to natural radiation sources

With this option, a comprehensive approach to the management of exposures due to natural radiation sources will be incorporated within the overall set of requirements of the Euratom BSS. The requirements will reflect the distinction between planned and existing exposure situations, as made in ICRP Publication 103. While occupational exposure to natural radiation sources (as well as public exposure from residues or effluents from NORM industries) is already considered in Options 1 to 3, the exposures to natural radiation sources that will explicitly be incorporated relate to public exposure in the domestic environment:

1. **Indoor exposure to radon** in dwellings. The new requirements build upon the Commission Recommendation 90/143/Euratom, and require national Action Plans for indoor Radon to be established.

   The recent epidemiological demonstration of lung cancer causation by radon exposure calls for the Commission Recommendation adopted in 1990 to be upgraded and incorporated in the BSS Directive 96/29/Euratom. Upgrading the Recommendation to binding requirements will on the one hand enhance uniformity within the EU with respect to the protection of the public from exposure to radon, on the other hand flexibility needs to be preserved to adjust national policies to geological features and type of buildings (see Annex IX.). The new BSS Directive will set the upper boundary for the reference level for indoor radon, in line with a statement from ICRP in November 2009. Member States will be required to identify radon prone areas in order to prevent that new buildings exceed the reference level and to focus efforts for remedial work in existing dwellings.

2. **Building materials** with high concentrations of naturally occurring radionuclides will be required to be monitored; an index is defined so as to determine which materials are liable to exceed the reference level.

   Within this option it is proposed to bring also building materials with high levels of naturally occurring radionuclides under regulatory control. At present the regulation of the radiation exposure due to building materials is established in the Member States based on national decisions. Some harmonisation was achieved with EU guidance on "Radiological Protection Principles Concerning the Natural Radioactivity of Building Materials", published 1999, as N° 112 in the Radiation Protection Series of the European Commission. A radioactivity index was defined in Annex II of this publication. This guidance recommended the establishment of dose criterion between 0.3 mSv – 1 mSv per year for introducing regulatory control. On the basis of this recommendation a uniform reference level will be proposed.

4.5. Option 5: Revision of BSS broadening the scope to the protection of non-human species

The subject matter and general purpose of the BSS Directive 96/29/Euratom is the health protection of the population and workers against dangers of ionising radiation. This Directive applies to the protection of the human environment, but only as a pathway from environmental sources to the exposure of man. In line with the new ICRP Recommendations,

it will be complemented with specific consideration of the exposure of biota in the environment as a whole. The aim would be to require Member States to consider suitable protection of non-human species in their radiation protection legislation.

So far no specific environmental impact assessment was required for the possible detriment to non-human species, under the assumption that if man was protected (through environmental pathways of exposure) then also non-human species are protected. While the human health detriment includes cancer causation as an important risk to an individual person, such types of effects on biota are in general irrelevant in terms of their ecological impact. It is expected that ICRP will provide guidance on the application of a radiation protection system in 2011-2012. Pending such further guidance it is up to national authorities to translate the new requirement in reasonable licensing conditions.

The requirements for the protection of the environment would therefore not be very demanding at this stage. It would still be timely, before adoption of the Directive by the Council, to include harmonised criteria on the basis of the forthcoming ICRP recommendations.

4.6. Option 6: Revision and consolidation of BSS and Medical Directive and integration of the other three Directives, and broadening the scope both for the natural radiation sources and protection of non-human species

This option includes all the elements of Option 3 (revision of the Basic Safety Standards Directive and integration of the other four Directives). The revision of the Basic Safety Standards includes all identified issues, and broadens the scope to include the whole range of exposure situations, including indoor public exposure to radon and to building materials, and all categories of human and non-human exposures.

5. SECTION 5: ANALYSIS OF IMPACTS

Nuclear energy continues to play an important role in Europe's energy production, not only in view of the sustainable and secure supply of energy but also with regard to the policy of decarbonisation of energy production. Radiation sources have also found uses outside nuclear energy, especially in medical diagnosis and therapy, but also in other applications in industry and research.

Radiation protection legislation is an essential condition for the health protection of workers, the public and patients. In addition to this health perspective, the possible impact of radiation protection legislation on these important economic sectors to be sustained or further developed is not within the scope of this analysis.

5.1. Analysis of the impact of Option 1

Option 1 would not effectively change the radiation protection requirements at EU level. This option would however have a negative impact in the light of the changes in technology and society that emerged since 1996.

Further analysis of the possible evolution of the impact of this option for the different aspects of radiation protection is presented in Section 2.3.

5.2. Impact analysis of Option 2

Option 2 envisages an update of BSS Directive 96/29 and the Medical Directive 97/43. The substantial changes that result from the latest scientific recommendations of ICRP and from related studies that have been conducted and operational experience over the past years, as well as from the working parties of the Article 31 Group of Experts, have been analysed in terms of their economic impact, the impact on environmental protection, the social impact in particular for health and safety at work, and finally in terms of their regulatory benefit or possible burden.

5.2.1. Health and Social impacts

Protection of workers. The social impact of the revised BSS relates essentially to health and safety at work.

The proposed reduction of current dose limits for the lens of the eye will lead to an improved protection of workers, in particular certain medical professionals, and will substantially reduce the risk of developing radiation induced cataract.

Within Option 2 industries processing materials with high levels of naturally occurring radionuclides (NORM-industries) will be strengthened. Exposures to NORM used or processed in specific industries are already in the scope of Directive 96/29/Euratom (Title VII). However, the current requirements are non-specific and unclear leaving it for Member States to decide on the level of control of the exposures in this sector. As a consequence there is a lack of a comprehensive picture of actual doses to workers in NORM industries and there are considerable differences between Member States regarding the control of occupational exposures, resulting in different treatment of the workers and to different restrictions on the management of residues. The integration of NORM industries in the radiation protection framework will offer equal treatment to workers occupationally exposed in these industries, and ensure appropriate health protection for exposed workers. In addition, radiation protection will become an essential component of overall work hygiene. Due to the fact that according to the current legislation Member States can choose which radiation protection measures, if any, apply to workers in the NORM industries, it is estimated that currently only one third of the workers who may receive considerable radiation exposures in these industries are considered as exposed workers.

Protection of patients. In the medical area, the proposed changes will lead to improved protection of individual patients and aim to guarantee good medical practice and further technological development without undue increases of the population exposure. This will be achieved by improved implementation of the principle of justification of individual medical exposures and by strengthening the legal requirements for optimisation of protection and for prevention of unintended exposures. The corresponding actions at national level to meet the revised legal requirements should lead to the integration of radiation protection concerns in the overall public health policy. The strengthening of the requirements for medical applications of ionising radiation will thus meet the conclusions laid down in Communication COM/2010/0423.

5.2.2. Environmental impact

While NORM industries will now be subject to regulatory control in the same way as other practices, this will most of times require restrictions on occupational exposures rather than on

discharges of radioactive effluent, which will in general be exempted. The comprehensive management of residues from NORM industries will however be instrumental in ensuring that the huge volumes of solid residues will be disposed of so as to preclude ground water contamination or excessive levels of radioactivity in building materials in which residues are being recycled. It should be noted that in this option the regulation of NORM residues still does not fit in an overall approach to the regulation of building materials.

5.2.3. Economic impact

Functioning of the internal market. With regard to NORM industries (see 5.2.1), the new Directive shall thus include a clear and well-structured set of requirements as well as a positive list of which types of industries are of concern. This will ensure equal treatment of the industries. There is little information on the actual industries affected by these requirements, which indeed results from the current lack of reporting in the absence of firm requirements. Although no exact data on the size of these industries are available, the dimension of the issue can be estimated through the following examples: 381 enterprises in the EU extract crude petroleum and natural gas, 293 enterprises produce lead, zinc and tin and the number of enterprises mining iron ores is estimated to 40[34].

The introduction of an annual dose limit for occupational exposure, which no longer allows for flexible national interpretations, will facilitate mobility of workers across borders. The new Directive will emfasise the role of dose constraints within th eoveral principle of optimisation. The use of this concept is not new, but it's prominent role in particular for the protection of workers should allow a better protection. On the other hand nuclear industry is afraid that this will prompt the regulatory authorities to intervene directly in the establishment of dose constraints, which in their view would be counter-productive (See Annex XIII). This concern is alleviated by clearly stating that dose constraint is merely an opeartional tool for optimisation, not a limit.

The revision of exemption and clearance values, in the context of the graded approach to regulatory control (Annex X), is liable to have an economic impact. On the one hand, the lowering of the exemption levels will have a minor economic impact. The study published by the Commission in Radiation Protection N° 157 (Annex II.B, p.9) demonstrates *inter alia* that these changes will in general not add a burden for the Member States or the stakeholders, in particular as regards consumer goods in which radionuclides are incorporated. On the other hand, there is benefit in having the same values for both exemption and clearance, in terms of simplification and coherence of the requirements. Using the same values for the two concepts would also enhance public acceptance and facilitate useful (justified) application of radioactive substances in consumer goods.

The harmonisation of clearance levels was not achieved in the 1996 Directive and shall be pursued with the new Directive. The use of clearance levels is important for the dismantling of decommissioned nuclear installations, which is a very important economic aspect. Very large volumes of materials with a potential for recycling (e.g. steel) and with nothing but trace amounts of radioactive substances, below clearance levels, can be made available so as to save natural resources and energy. For other materials it allows to avoid the cost of disposal as radioactive waste (Annex X.B). While difficult to quantify, it is clear that the economic benefit of the new requirements facilitating the application of the concept of clearance could

[34] EUROSTAT Basic Statistic for 2007

be equally important. Nuclear industry prefers the clearance levels laid down in national legislation following the publication of default values in Radiation protection 122, Part I. The industry would also prefer th especific clearance levels for metals, building rubbler etc. (See Anex XIII) to be attached to the future Directive. This desire was balanced against international harmonisation and the flexibility for regulators to use the concept of clearance. The industry concerns will be to some extend met by emphasising the role of such specific clearance levels.

Administrative costs for companies. Should the Member States follow the proposed "graded approach" to regulatory control as described in Annex X.A, then the administrative burden for the regulated entities will be reduced. It offers more flexibility and in principle a more efficient use of regulatory resources. At the same time, the industry will benefit from the regime of specific exemption or from the regime of registration rather than the full licensing procedure as is the case in most Member States so far.

Administrative costs for public authorities. The revision of the BSS along operational experience should not have a major impact on national legislation The burden of transposition in national law should be minimal, except for some new features such as the regulation of NORM industries (for those Member States who do not yet properly regulate these matters).

While the graded approach to regulatory control in principle should allow saving resources also for the regulatory authority and thus reduce the regulatory burden, its application also requires a lot of judgement to be exercised by the competent authorities, and hence possibly better competencies and qualifications. However, the estimation of the necessary resources is extremely difficult as far as it depends on each particular national situation (the structure of the state administrative organisation, the level of development of regulatory bodies etc.).

Coherence of the Euratom Directives with the international standards will also have a positive impact on the efficiency of national regulations. It will avoid that experts in the national competent authority need to be familiar with two sets of requirements, and they will benefit from the comprehensive body of guidance and training material provided by IAEA without being confused by different definitions or a different regulatory approach. Most important is the harmonisation of values that may have an impact on trade.

Within Option 2 it is proposed to enhance the graded approach to regulatory control by introducing two levels of authorisation – registration and licensing. This will align the Euratom BSS with the International BSS which offers the same concept. This option also allows maintaining uniformity of exemption values in Euratom and International BSS as well as the harmonisation of clearance levels (default values).

5.2.4. Coherence and clarity of legislation

The amendment of BSS Directive 96/29 and Medical Directive 97/43 will clarify the requirements, align the definitions and better describe the concepts of protection of workers (BSS Directive) and the patients (Medical Directive).

5.3. Impact Analysis of Option 3

The consolidation of five Directives in Option 3 offers a significant benefit in terms of simplification. The simplification of Community legislation should be followed by a similar

effort at national level which, together with a clear allocation of regulatory responsibilities, should reduce the regulatory burden and make the regulatory efforts more efficient.

The Option 3 adds to Option 2 the subject matters of the Outside Workers Directive, Public Information Directive, and the HASS Directive. In fact, BSS Directive 96/29/Euratom and the Medical Directive will be amended as in Option 2 and merged with the Outside Workers Directive, Public Information Directive and HASS Directive. The radon and non-human species issues will be addressed by non-legislative measures.

Within this option the economic, social and environmental impacts concerning the changes in BSS Directive 96/29/Euratom and Medical Directive would be broadly as described under Option 2. For the other three directives, even though they are not substantially changed, there are additional benefits resulting from being merged with the BSS Directive, which is evaluated as follows:

5.3.1. Health and social impact

Protection of workers. The incorporation of the Outside Workers Directive should also have a positive health and social impact through the envisaged clarification of the responsibilities, for the protection of the outside worker, of the employer and of the undertaking carrying out the practice. The establishment of national centralised networks for the dose records and of an individual radiological monitoring document (radiation dose passport) will represent an important benefit for the health protection of Outside workers.

The combination of the Basic Safety Standards Directive and the Medical Exposures Directive will have a positive impact on the health protection of medical professionals, in particular those receiving high doses in the course of their work, such as interventional radiologists. Indeed, the medical profession often looks only into the Medical Directive, and ignores the measures in the BSS Directive for their own protection.

Protection of members of the public: The Public Information Directive establishes rules for informing the public and emergency workers about the health protection measures before and in the event of emergency. This should be part of the emergency arrangements, which are currently established in Title IX of BSS Directive 96/29/Euratom. The consolidation of the Public Information Directive within the overall framework of the emergency exposure situations in the BSS will allow a more coherent application of this Directive with regard to public exposures. The importance of a clear strategy for emergency preparedness and for adequate response plans and coordination in view of cross-border consequences has been dramatically emphasised through the nuclear accident on 11 March 2011 in the Fukushima NPP in Japan.

Guidance on establishment of national action plans for reducing the risks from indoor radon exposure will again draw the attention of the Member States to this problem and possible actions for solving it. However this action will have added value only if Member States follow the proposed advice, which in the absence of binding requirements is probably not the case.

The impact on protection of patients and on protection of members of the public, in normal planned situations, does not change compared to the one associated with Option 2.

5.3.2. Environmental impact

Option 3 will have the same environmental impact as Option 2.

5.3.3. Economic impact

The envisaged improvements in the field of occupational exposure will have a positive economic impact on undertakings.

The incorporation of the Outside Workers Directive into the BSS Directive should improve the system for recording the doses of outside workers thus facilitating their mobility. There is also an economic benefit: maintenance work in nuclear installations as well as certain dismantling operations is best carried out by specialised teams operating in different installations and the above requirements will enhance the mobility of workers within Member States and across borders.

5.3.4. Coherence and clarity of legislation

Option 3 envisages integration of five Euratom Directives into one piece of legislation. This will simplify and clarify the radiation protection requirements. In general the regulatory authorities will benefit from better structured and understandable Euratom radiation protection legislation. This should improve the level of correct transposition.

The incorporation of the HASS Directive should be an opportunity for aligning the definition of HASS with the definition in the Code of Conduct of IAEA, which will now be incorporated in the IAEA Standards. This would be an important aspect in meeting the objective of international harmonisation, and avoid national authorities to run two separate inventories.

5.4. Impact Analysis of Option 4

Option 4 includes the features of Option 2 with regard to the revision of Basic Safety Standards Directive and the associated impacts; the additional impact is discussed below.

5.4.1. Health and social impact

Option 4 will have a very positive impact on the health of the public. The implementation of restrictions on the level of radon in buildings will considerably reduce the health risks (lung cancer risk) for the public from this source. International public health policies (WHO) consider the radon issue to have high priority. In the long run national action plans for radon mitigation will have a positive impact on lung cancer incidence, even though smoking is still the main cause of lung cancer. Radon is the second known cause of lung-cancer and radon-related lung cancer is one of the most frequent cancers overall. It will therefore be an important achievement if the new Directive would achieve a substantial, progressive, reduction of indoor radon concentrations.

5.4.2. Environmental Impact

This Option does not have impact on the environment.

5.4.3. Economic impact

The introduction of reference levels for radon in buildings will not have an economic impact as far as the requirements on indoor exposure to radon in Commission Recommendation 90/143/Euratom are already largely introduced throughout the European Union. The efficiency of remedial policies will however be enhanced through the establishment of national action plans.

Option 4 offers to establish in the BSS Directive specific requirements for building materials based on the guidance in Radiation Protection N° 112. Upgrading this guidance to the level of a binding requirement is liable to have an impact on the market and on the building profession. In order to mitigate negative market effects, the Article 31 Group of Experts recommended setting a single reference level of 1 mSv for building materials (upper part of the range given in the guidance) and a corresponding classification system. In this way the fraction of materials that would be subject to national restrictions will be further limited (first by the list with specific materials, then by the 1 mSv criterion). It should be underlined that the need for characterisation of building materials does not imply that all batches need to be monitored: if there is no important change in the origin or composition of the material the initial assessment remains valid. Hence the cost of monitoring should be minimal. The cost of labelling for the building industry is to the benefit of the consumer. Further harmonisation will be pursued through the standards of the European Committee for Standardization (CEN TC 351). The harmonisation of the requirements on building materials will benefit the producers who now face different national restrictions and will simplify transboundary movement of building materials within the EU. Further information on types of material and amounts can be found in Annex VIII.A.

5.4.4. Coherence and clarity of legislation

The incorporation of the regulation of radon and building materials in the overall radiation protection framework will lead to more comprehensive radiation protection legislation, which covers all exposure situations.

Radon and building materials being also covered by the International BSS, Option 4 offers also coherence with these standards. The chosen reference levels are in line with the latest scientific data presented by ICRP in November 2009.

5.5. Impact analysis of Option 5

Option 5 includes the features of Option 2 with regard to the revision of Basic Safety Standards Directive and the associated impacts; the additional impact is discussed below.

5.5.1. Health and social impact

This Option does not have specific health and social impact.

5.5.2. Environmental Impact

The actual environmental impact is probably very small. However, the requirements will allow providing reassurance that this assumption is actually true. The benefit of the new provisions on the protection of non-human species is thus more in terms of demonstration of compliance with overall environmental policies.

5.5.3. Economic impact

The introduction of protection criteria for non-human species will in general not lead to further restrictions on discharges of radioactive effluent. If Member States' competent authorities make full use of the screening tools developed under the research programme, the explicit inclusion of environmental criteria in the establishment of discharge authorisations would be very exceptional. The administrative burden for the industry is therefore expected to be small. The benefit for the industry, and for society as a whole, would be a better political and public acceptance if compliance with overall environmental criteria is explicitly demonstrated. The nuclear industry rased concerns that the inclusion of the protection of the environment in legal act may lead to a high cost for demonstrating compliance. However, without such Euratom legal framework it is up to the competent national authorities to decide on this issue, which may provide even less stability in the requirements. The industry concerns will be alleviated if indeed ICRP provides recommendations on the radiation protection system within the next year or so.

5.5.4. Coherence and clarity of legislation

In view of the fact that currently there are no agreed environmental criteria, it was considered to leave this project to be covered later in Community legislation. This would however be contrary to the simplification policy of the Commission and also would not ensure a coherent radiation protection system covering humans and non human species. The Article 31 Experts therefore recommended to include the requirements already now in the Commission proposal, rather than adding another piece of legislation a few years later.

The incorporation of the protection of the environment within the scope of the Euratom Basic Safety Standards is coherent with the revised International Basic Safety Standards.

5.6. Impact analysis of Option 6

Option 6 includes the features of Option 3 and the associated impacts; the additional impact is discussed below.

5.6.1. Health and social impact

Option 6 will have a very positive impact on the health of the public. The implementation of restrictions on the level of radon in buildings will considerably reduce the health risks (lung cancer risk) for the public from this source. International public health policies (WHO) consider the radon issue to have high priority. In the long run national action plans for radon mitigation will have a positive impact on lung cancer incidence, even though smoking is still the main cause of lung cancer.

5.6.2. Environmental Impact

The actual environmental impact is probably very small. However, the requirements will allow providing reassurance that this assumption is actually true. The benefit of the new provisions on the protection of non-human species is thus more in terms of demonstration of compliance with overall environmental policies.

5.6.3. Economic impact

Upgrading the guidance on building materials to the level of a binding requirement is liable to have an impact on the market and on the building profession. The cost of labelling for the building industry is to the benefit of the consumer. Further harmonisation will be pursued through the standards of the European Committee for Standardization (CEN TC 351). The harmonisation of the requirements on building materials will benefit the producers who now face different national restrictions and will simplify transboundary movement of building materials within the EU.

The introduction of protection criteria for non-human species will in general not lead to further restrictions on discharges of radioactive effluent. If Member States' competent authorities make full use of the screening tools developed under the research programme, the explicit inclusion of environmental criteria in the establishment of discharge authorisations would be very exceptional. The administrative burden for the industry is therefore expected to be small. The benefit for the industry, and for society as a whole, would be a better political and public acceptance if compliance with overall environmental criteria is explicitly demonstrated.

5.6.4. Coherence and clarity of legislation

This Option covers all exposure situations and categories of exposure in a coherent framework and adds significantly to the clarity of all requirements, both existing and new requirements resulting from the broader scope. This broader scope is fully coherent with the revised International Basic Safety Standards.

6. SECTION 6: COMPARING THE OPTIONS

The different options are analysed in this section with regard to their effectiveness in achieving the objectives, their efficiency, including their economic, environmental, health and social impact as described in Section 5, and in terms of their coherence with overall Euratom and EC legislation.

6.1. Effectiveness

Option 1 does not meet the specific objectives of this initiative, but it must be emphasised that current Community legislation still offers in most situations satisfactory protection of workers, patients and members of the public, which is the general objective of Community legislation under Chapter III, Health and Safety, of the Euratom Treaty. It is included as a baseline scenario for the comparison of the other options. Option 2 fully responds to the first objective and improves to some extent the coherence of Euratom radiation protection legislation and it is also coherent with corresponding requirements in international standards, thus meeting three of the specific objectives. Option 3 fully meets the objective of coherence and clarity, and allows additional specific aspects of operational experience to be addressed. It also meets the Commission's policy of simplification. Options 4 and 5 both meet the objective of coherence with international recommendations as well as of covering the whole range of issues in radiation protection. Both options meet specific aspects of the objective for broadening the scope of radiation protection legislation. Their combination, in Option 6, together with undertaking an effort for consolidation similar to Option 3, is most effective in achieving all objectives.

6.2. Efficiency

Option 1 is taken as a baseline scenario for the comparison of the other options. Hence the benefits of Options 2 and 3 must be compared to the current situation. The comparison of the impact of options 2 and 3 demonstrates the efficiency of different sets of updated operational requirements, respectively in the BSS and Medical Directive and in the three other Directives, which will be achieved.

An overview of the different components of the assessment is given in table 1. Both positive and negative impacts are qualified in terms of their relative importance (minor, important, very important). The overall balance, irrespective of weighing of different aspects or components of all options, is positive.

As it is demonstrated in the table, all benefits of Option 2 are kept in Option 3, with additional benefits in particular in terms of the simplification of legislation and it also enhances some positive aspects of option 2.

Option 4 broadens the scope of current legislation and this may imply a certain administrative cost for the industry. However the benefit in terms of public health will be very important, and meet the objectives of WHO in the fight against lung cancer. The similar benefit in regulating building materials needs to be balanced against the regulatory burden and the cost of monitoring and labelling for the building industry. However, it also enhances the efficiency of the control of residues from NORM industries, envisaged in options 2 and 3.

Option 5 also broadens the scope of current legislation and this may imply a certain administrative and economic cost. The actual environmental benefit of this option would be small. Nevertheless, it is expected that this option will significantly contribute to the understanding and acceptance of radiation detriments.

Option 6 adds up the benefits and detriments of all previous options. The overall benefit is thus maximised.

Table 1: Summary of the comparison of options 2 to 6 (See Annex XIII for extended table)

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Economic	(+)	(+)	(+)	(+)	(+)
Functioning of the internal market	(+)	(+)	(+)	(+)	(+)
Administrative burden on businesses	(+)	(+)	(+)(-)	(+) (-)	(+)(-)
Regulatory authorities	(-)	(+)	(-)	(-)	(+)(--)
Environment	(+)	(+)	(+)	(++)	(++)
Protection of the environment	(+)	(+)	(+)	(++)	(++)
Social and Health	(+)	(++)	(++)	(+)	(++)
Health and safety at work	(+)	(++)	(+)	(+)	(++)
Mobility of workers and experts	(+)	(+)	(+)	(+)	(+)
Protection of patients	(+)	(+)			(+)
Protection of the public	(+)	(+)	(++)	(+)	(++)
Coherence and clarity of legislation	(+)	(++)	(+)	(+)	(++)
International coherence	(+)	(+)	(+)	(+)	(++)
Overall impact	+	++	++	+	+++

6.3. Coherence

The consolidation of five Directives in a single Basic Safety Standards Directive with a broader scope (Options 4, 5 and 6) is an important development to ensure the overall coherence of the entire radiation protection legislation with other EU policies. Coherence within radiation protection legislation is pursued in specific objective 2 and international coherence in specific objective 3. Where other legislation currently refers to the Directive 96/29/Euratom (e.g. the Directive on shipment of radioactive waste) this will be automatically transferred to the new Directive, with little impact (for instance the definition of radioactive waste by reference to exemption levels introduced in Options 2 and 3). New legislation under Chapter III of the Euratom Treaty, the adopted Directive on nuclear safety of nuclear installations (Council Directive 2009/71/Euratom) and the proposed Directive on radioactive waste and spent fuel management (COM(2010)618 final).), are complementary to the Basic Safety Standards and not affected by any of the options that have been proposed. Legislation and policies outside the remit of the Euratom Treaty would be strengthened by the new Euratom Directive(s): Within the remit of EC legislation, Council Directive 93/42/EEC on medical devices would find a clearer reference to criteria that should be met through the updated Medical Directive (Options 2, 3 and 6), the Directive on construction products (Council Directive 89/106/EEC) would find clear criteria for the characterisation of building materials in Option 4 and 6. The policy to prevent malevolent use of radiation sources will benefit from strengthened requirements in the HASS Directive under Options 3 and 6; the overall policy on indoor air quality (including radon) will benefit from the broadened scope to natural radiation sources in Options 4 and 6, and coherence with overall environmental policies and legislation on Environmental Impact Assessment will benefit from the new requirements in Options 5 and 6. Option 6 offers the best possible coherence with all other policies.

6.4. Conclusion

Option 6 addresses all problems identified and meet all of the objectives. Option 3 would still address the main issues and meet most of the objectives if the burden of broadening the scope of the legislation would not be warranted. Option 2 is eligible if the increase in clarity and coherence, in line with the Commission's policy of simplification of legislation, would appear to be insufficient to warrant a major simplification of current legislation. The analysis of the options in terms of efficiency supports the conclusion that Option 6 should be pursued, as the most effective, efficient and coherent policy option.

7. SECTION 7: MONITORING AND EVALUATION

Core indicators for the level of the achievement of the specific objectives are the accuracy of the transposition and the implementation of the policy in the Member States. The following indicators can be established for the implementation of the chosen policy option in the different subject matter areas:

7.1. Indicators for the implementation of the new regulatory approach to the management of exposures due to natural radiation sources:

– the identification of radon prone areas in the Member States and action plans to manage long term exposures to radon;

– the identification of new types of NORM industries;

– the number of undertakings from the NORM industry under regulatory regime and the number of exposed workers within this industry.

The monitoring of the implementation of the policy for the protection from radon exposures can be done by establishing a reporting obligation for the Member States, to submit to the European Commission the identified radon prone areas and action plans.

Information on the implementing measures and national practices as well as relevant statistics for the implementation of the proposed regulatory policy to NORM Industries can be discussed in the framework of the European ALARA Network for naturally occurring radioactive materials. This may include information on the number of undertakings within this industry, submitted to authorisation regime after the implementation of the revised BSS Directive, the number of exposed workers etc.

7.2. Indicators for the success of the comprehensive approach to the occupational exposure and the proposed recast of Outside Workers Directive and BSS Directive 96/29:

– the establishment of national dose registries for the results of the individual monitoring of exposed workers;

– the number of outside workers and their individual doses.

The ESOREX project will be used to monitor the implementation of the proposed comprehensive approach to the occupational exposures from artificial and natural sources. In particular, from this network the Commission will receive information on the number of workers in the radon prone areas, number of exposed workers in the different industries, doses per industry and per country, number of outside workers and their doses.

7.3. Indicator for the level of harmonisation of the authorisation regime

Indicator for the level of harmonisation of the authorisation regime throughout Euratom Community as a result of the proposed graded approach to the authorisation of practices involving radioactivity is the ratio of practices in the Member States submitted to registration and licensing.

The main monitoring tool for this indicator would be the communication of the draft national transposing measures (Article 33 from Euratom Treaty). The analysis of the transposing measures will give an overview of the licensed and registered practices in the Member States and information to what extend Member States have followed the proposed graded approach to the authorisation regime. The European Commission may issue recommendations with regard to the transposition of the Basic Safety Standards

Directives (see p.7.6 below).

7.4. Indicators for the improvement of radiation protection in medicine:

– number of countries using diagnostic reference levels, referral guidelines and clinical audit;

– number of countries maintaining up-to-date national records of population doses from medical exposure procedures;

– number of countries introducing reporting system(s) for unintended and accidental medical exposures;

– doses to population from medical exposure procedures - to avoid a steep increase, e.g. like in the United States of America in the past decade[35];

– number of unjustified medical exposure procedures, e.g. full-body scanning of asymptomatic individuals – to be reduced as far as possible;

– optimised medical radiological procedures – reduced discrepancies in the doses from the same procedure in different countries or in-between hospitals.

The indicators related to medical exposure will be monitored through dose collection exercises for the European Union (consecutive Dose Data projects, Dose Data -2 launched in August 2010), through the established European Medical ALARA Network (EMAN) and through exchange of data on specific topics between the Commission, the Member States, the IAEA and the WHO. Express ad-hoc data collection will be launched, when appropriate, using HERCA network.

7.5. Indicators for the implementation of the regulatory approach to non-medical imaging exposure (NMIE) would be:

– number of NMIE practices identified in the Member States;

– number of (formal) justification decisions taken by national regulations;

– dose constraints and other regulatory requirements established for the justified practices in the Member States;

– in the case of introduction of routine security screening of people using ionising radiation – the number of people screened, the doses to the population from the practice and the availability of non-ionising alternative to the screened individuals.

The indicators related to the non-medical imaging exposure will be monitored through HERCA, ad-hoc exchange with the Member States and organisation of periodic meetings, similar to Dublin 2002 and 2009. Further information will be sought from DG MOVE in relation to security screening at airports.

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35 http://www.ncrponline.org/Publications/160press.html

7.6. The Euratom Treaty offers in addition general monitoring tools for the implementation of the Basic Safety Standards:

– According to Article 33 of the Euratom Treaty the Member States have the obligation to communicate to the Commission the draft national provisions for transposition of the Community radiation protection legislation. On the basis of this information the Commission is in a position to make appropriate recommendations for harmonising the provisions applicable in this field in the Member States. This monitoring tool will be used for all areas of the chosen policy. However, it will have a major impact in areas like the harmonisation of the authorisation regime through the graded approach to the authorisation.

– Article 35 of the Treaty requires Member States to carry out continuous monitoring of the level of radioactivity in the air, water and soil in order to ensure compliance with the basic safety standards. Member States are obliged to communicate periodically information from this monitoring to the Commission (Article36 from Euratom Treaty). This allows the Commission to be informed on the level of radioactivity to which the public is exposed and respectively the implementation of the BSS.

The level of harmonisation between Euratom BSS and IAEA BSS will be assessed by the services of DG ENER once the two documents are in their final stage of preparation. This issue is also subject to continuous interaction between the European Commission and IAEA. A provisional table of correspondence has been prepared in June 2010, discussed by the Article 31 Group of Experts and transmitted to IAEA.

ANNEX I

Organisations in Radiation Protection

Heads of the European Radiation Control Authorities (HERCA) is an informal body of high-level ("heads") representations of national authorities with competence in radiation protection. This group was constituted in May 2007 on the initiative of French Nuclear Safety Authority (ASN) and brings together the heads of European radiation protection authorities. At their request, five working groups have been set up to examine a series of themes considered by the authorities as problematic. Each working group is jointly chaired by representatives of different national authorities. The first working group, devoted to the question of "radiological passports", met in 2008. Two other working groups are devoted to the themes of "justification" and "new medical techniques".

The Commission was invited to inform on progress with the revision of the BSS at meetings in December 2008 and 2009 as well as in June 2010. At the meeting in June 2010 a working document comparing extensively the draft Euratom BSS with draft 3.0 (January 2010) of the International BSS was presented by the Commission, and the group further supported the Euratom approach.

International Commission on Radiological Protection (ICRP) is an independent Registered Charity, established to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation.

ICRP is the worldwide recognised scientific society in radiation protection. Based on the latest available scientific information of the biology and physics of radiation exposure, its recommendations lay out the philosophy and the technical benchmarks in the radiation protection area. Without being of obligatory nature, ICRP recommendations are internationally recognised for the development of radiation protection rules all over the world. A few years ago, ICRP started to revise their Recommendations for a System of Radiological Protection taking account of the latest scientific findings. In view of the importance afforded to ICRP's recommendations and to ensure that the new recommendations adequately and appropriately address national issues and concerns, the ICRP has initiated an open process involving two phases of international public consultation. The ICRP has received input from a broad spectrum of radiation protection stakeholders, ranging from government institutions and international organisations to scientists and non-governmental organisations. The draft recommendations have been discussed at a large number of international and national conferences and by many international and national organisations with an interest in radiological protection. The European Commission, with the support of the Article 31 Group of Experts, took part in these discussions.

International Radiation Protection Association (IRPA) is an international non-profit organisation that enlists individuals as members who are also members of an affiliated national or regional Associate Society. Today, there are 46 associated societies around the world with membership of nearly all professionals with operational responsibilities in radiation protection. The primary purpose of IRPA is to provide a medium whereby those engaged in radiation protection activities in all countries may communicate more readily with each other and through this process advance radiation protection in many parts of the world. This includes relevant aspects of such branches of knowledge as science, medicine, engineering, technology and law, to provide for the protection of man and his environment from the hazards caused by radiation, and thereby to facilitate the safe use of medical, scientific, and industrial radiological practices for the benefit of mankind.

International Atomic Energy Agency (IAEA) is an independent international organisation, related to the United Nations system, which seeks to promote the peaceful use of nuclear energy. The IAEA was established as an autonomous organisation on 29 July 1957 with headquarters in Vienna, Austria. Today, IAEA has 151 member states. The IAEA serves as an intergovernmental forum for scientific and technical cooperation in the peaceful use of nuclear technology and nuclear power worldwide. The programs of the IAEA encourage the development of the peaceful applications of nuclear technology, provide international safeguards against misuse of nuclear technology and nuclear materials, and promote nuclear safety (including radiation protection) and nuclear security standards and their implementation. A big part of the IAEA´s statutory mandate is the establishment, and promotion, of advisory international standards and guides. 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 ionising radiation. They are issued in the IAEA Safety Standards Series, and cover nuclear safety, radiation protection, radioactive waste management, the transport of radioactive materials, the safety of nuclear fuel cycle facilities and quality assurance. The main document in radiation protection is Safety Standard 115 "International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources", edition 2003. These Standards, co-sponsored by FAO[36], ILO[37], OECD/NEA[38], PAHO[39] and WHO[40], are based on assessments of the biological effects of radiation made by the United Nations Scientific Committee on the Effects of Atomic Radiation, and on the recommendations of the International Commission on Radiological Protection and the International Nuclear Safety Advisory Group. In 2006 IAEA together with the cosponsors undertook revision of Safety Standard 115. This is ongoing activity also driven by the new ICRP Recommendations 103, published in 2007.

European Atomic Forum (FORATOM) is a trade association for the nuclear energy industry in Europe. Its main purpose is to promote the use of nuclear energy in Europe by representing the interests of this important and multi-faceted industrial sector. The membership of Foratom is made up of 16 national nuclear associations. Foratom also represents some of the continent's largest industrial concerns. Nearly 800 firms are represented.

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[36] Food and Agriculture Organisation of United Nations
[37] International Labour Organisation
[38] Organisation for Economic Cooperation and Development, Nuclear Energy Agency
[39] Pan American Health Organisation
[40] World Health Organisation

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established by the General Assembly of the United Nations in 1955. Its mandate in the United Nations system is to assess and report levels and effects of exposure to ionising radiation. Governments and organisations throughout the world rely on the Committee's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures.

ANNEX II

Projects, Studies, Scientific Radiation Protection Publications

A. Summaries of the scientific publications, projects and studies

1. **Publication 103 of ICRP.** After eight years of discussions, involving scientists, regulators, and users all around the world, the International Commission on Radiological Protection adopted its new recommendations on 21 March 2007 (published in December 2007).

The new Recommendations (Publication N° 103) have two primary aims:

- to take account of new biological and physical information and of trends in the setting of radiation safety standards; and

- to consolidate and rationalise the previous Recommendations (Publication N° 60) and the supplementary reports, issued since their publication in 1991.

The present Recommendations update the radiation and tissue weighting factors in the quantities equivalent and effective dose and update the radiation detriment, based on the latest available scientific information of the biology and physics of radiation exposure. They maintain the Commission's three fundamental principles of radiological protection, namely justification, optimisation, and the application of dose limits, clarifying how they apply to radiation sources delivering exposure and to individuals receiving exposure.

The Recommendations evolve from the previous process-based protection approach using practices and interventions by moving to an approach based on the exposure situation. They recognise planned, emergency, and existing exposure situations, and apply the fundamental principles of justification and optimisation of protection to all of these situations. They maintain the Commission's current individual dose limits for effective dose and equivalent dose from all regulated sources in planned exposure situations. They re-enforce the principle of optimisation of protection, which should be applicable in a similar way to all exposure situations, subject to the following restrictions on individual doses and risks; dose and risk constraints for planned exposure situations, and reference levels for emergency and existing exposure situations. The Recommendations also include an approach for developing a framework to demonstrate radiological protection of the environment.

2. **European Study on Occupational Radiation Exposure** (ESOREX)**.** The ESOREX was established in 1997 to collect information on how individual monitoring is structured in MS and how data are recorded and reported. The project consisted of surveys on radiation monitoring and exposure of workers for the period from 1995 to 2005. The data

collected have allowed statistical evaluation of occupational radiation exposure in different work sectors. The analysis of different years allowed the evaluation of changes and trends after the implementation of the BSS Directive 96/29.

The objective of this European Union survey is to provide the Commission and the national competent radiation protection authorities with reliable information on how personal radiation monitoring, reporting and recording of dosimetric results is structured in European countries. The survey resulted in the following main conclusions:

- To ensure that outside workers receive the same level of protection as workers permanently employed by a licensee, it is imperative that the Outside Workers Directive is coherently incorporated in the Basic Safety Standards Directive 96/29. Definitions need to be made consistent, and the responsibilities of an undertaking and of the employer of an outside worker for the protection of the outside worker need to be clearly defined.

- To allow free movement of outside workers within Europe it is necessary to establish a harmonised dose limit for occupational exposure. It is therefore recommended to abandon the current dose limit of 100 mSv averaged over 5 years (with a yearly maximum of 50 mSv) and to introduce a single year dose limit of 20 mSv.
- The establishment of a national dose registry allows tracking the doses of exposed workers nationally, in particular the doses of outside workers.

- The introduction of an individual radiological monitoring document (Radiation Passbook) for each outside worker shall further facilitate recording and reporting of individual exposure data. The radiation passbook of an outside worker should furthermore allow undertakings to be informed about the dose history of an outside worker and to easily check compliance with requirements on education and training, medical surveillance and with dose limits.

3**. "European ALARA Network for naturally occurring radioactive material – NORM**" is a forum for communication, knowledge exchange, identification of problems and discussions about possible solutions on different topics related to NORM. The European Commission has used the workshops organised by the European ALARA Network for NORM (EAN_{NORM}) and its website for presenting and discussing different proposals for modifications in the 96/29 Directive with regard to NORM (see public consultation on natural radiation sources). The main European ALARA Network held in 2005 a workshop (**9th European ALARA Network Workshop)**, that focused on the control of the exposure received by workers from natural radiation sources, in particular workers in the NORM industries and exposure to radon. The Workshop recommended that national authorities should develop long-term action plans for addressing occupational radon exposures and that the EC clarifies the Scope of Title VII of the BSS Directive, in particular to which workplaces it applies. It also recommended that the regulatory system applied to NORM should focus on significant risks and a graded approach is necessary.

4. **European Platform on Training and Education in Radiation Protection (EUTERP)** was established in 2006 following the results of a survey carried out on behalf of the European Commission and published as Radiation Protection N° 133. EUTERP recommends that the status of the "qualified experts" in the directive is enhanced with particular requirements for their involvement in the supervision and execution of radiation protection tasks. In addition it is proposed to establish two levels of expertise - Radiation Protection Expert and Radiation Protection Officer. These proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts. These proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts.

5. **International Conference on Modern Radiotherapy: 'Advances and Challenges in Radiation Protection of the Patients',** organised by the French Nuclear Safety Authority in cooperation with the International Atomic Energy Agency, the World Health Organization and the European Commission from 2 to 4 December 2009 in Versailles[41]. During this conference detailed consideration has been given to the "accidental or unintended exposures" of patients following the several cases of such accidents that occurred in recent years (France, Belgium…).

6. **International Conference on Justification of Medical Exposure in Diagnostic Imaging**, organised jointly by the International Atomic Energy Agency and the European Commission from 2 to 4 September 2009 in Brussels[42]. Despite these initiatives, the approach to and compliance with justification is weak in diagnostic radiology and nuclear medicine. Work within the EU SENTINEL Project and a number of IAEA consultations confirm this. It is also probable that there are significant justification problems in radiological practice in the developing world. In the West, recent studies indicate that >20% of examinations may not be appropriate; this can be as high as 45% in special cases, and up to 75% for specific techniques. This situation should be tackled promptly, particularly as tools are now available to improve it. The sense of urgency about the problem is reinforced by newer high dose activities in radiology, newly available tools for justification and clinical audit, the ongoing revision of the IAEA Basic Safety Standards (BSS), the recasting of the European Directives, and the requirement for an effective regulatory approach in a sensitive area. These developments are happening against a background of worryingly increasing medical radiation doses, and the American College of Radiology (ACR) white paper noting "The rapid growth of CT and certain nuclear medicine studies may result in an increased incidence of radiation-related cancer in the not-too-distant future". These concerns provide additional motivation for dealing with justification. Finally there is a need to align medical justification with contemporary ethical and social thinking.

7. **IAEA RS-G-1.7.** The objective of this Safety Guide is to provide guidance to national authorities, including regulatory bodies, and operating organisations on the application of the concepts of exclusion, exemption and clearance as established in the BSS. The Safety Guide includes specific values of activity concentration for both radionuclides of natural origin and those of artificial origin that may be used for bulk amounts of material for the

[41] main findings from the conference are available on http://www.conference-radiotherapy-asn.com
[42] http://rpop.iaea.org/RPOP/RPoP/Content/PastEvents/justification-medical-exposure.htm

purpose of applying exclusion or exemption. It also elaborates on the possible application of these values to clearance.

8. **International Symposium on Non-Medical Imaging Exposures**, organised by the European Commission on 8 and 9 October 2009 in Dublin. The objective of the symposium was to collect up-to-date information and exchange experiences on non-medical/medico-legal exposures, identify the issues of concern and discuss the ways of addressing them in a revision of the Euratom BSS Directive. The meeting concluded that it is clear that there is a need to retain the level of protection and justification that applies to medical exposures, as defined in the current Medical Exposure Directive. However in doing this it is also necessary to ensure that the over-arching framework is such that all practices are regulated and appropriate levels of control are in place. It was clear that the single most important issue in this area is justification and that this must be applied for every practice and individual exposure. The conclusions supported the exclusion of the medico-legal exposures from the legal definition of medical exposure and grouping them together with other similar cases under the new term 'non-medical imaging exposures', for which a detailed new approach should be proposed in the revised BSS Directive.

B. Summaries of the Reports Published in the Euratom Radiation Protection Series

1. Radiation Protection N° 95 "Reference levels for workplaces processing materials with enhanced levels of naturally occurring radionuclides". The purpose of this Guide is to provide advice on work activities where the processing of NORM is subject to the requirements in Title VII of the BSS Directive 96/29. Since the existence of the radiation risk is incidental to the process undertakings are sometimes not aware of the risk. Therefore, simple means of identifying and categorising such industries are needed so that managements can decide whether more detailed radiological assessments are necessary. The report proposes a graded approach to the regulatory control of workers in NORM industries and suggests dose levels at which the different levels of regulatory control would apply; below 1 mSv per year no regulatory control, between 1-6 mSv per year low level of control, between 6-20 mSv per year high level of control and above 20 mSv exposures should not be accepted. The report also indicates the most significant industries in Europe where processing of NORM can cause increased exposure of workers.

2. Radiation Protection N° 112 "Radiological protection principles concerning natural radioactivity of building materials". The purpose of this publication is to provide guidance for establishing regulatory control of building materials containing enhanced levels of natural radioactivity. The report recommends the establishment of a dose criterion for introducing regulatory control and proposes a methodology for screening material (using an Activity Index formula) to see if the dose criterion is

complied with. The study which formed the basis for the report, see RP 96 Enhanced radioactivity in building materials, also included information about national regulation on natural radioactivity in building materials. In 1997 when the RP 96 was published only five Member States had legislation and the Activity Index formula used to screen material varied between those countries.

3. Radiation Protection N° 122 "Practical use of the concepts of clearance and exemption".

Part I "Guidance on general clearance levels for practices" offers default values for any type of material and any pathway of recycling or disposal (in addition to the specific levels for metals and building rubble, published earlier).

Part II "Application of the concept of exemption and clearance to natural radiation sources". The application of the concepts of exemption and clearance to natural radiation sources is discussed in this study within the overall context of regulatory control of natural radiation sources and in particular as laid down in Title VII of the Basic Safety Standards for work activities. The study discusses how these concepts can be used and which clearance levels would be appropriate. The main conclusions were:

- as a result of the large volumes of material processed and released by NORM industries, the concepts merge and it would be appropriate to have one single set of values both for exemption and clearance;
- although the basic concept and criteria for exemption and clearance for NORM work activities are similar to those for practices, it is not meaningful to define levels on the basis of the individual dose criterion for practices (10μSv per year); instead a dose increment in the order of 300 μSv is appropriate.

4. Radiation Protection N° 130 "Medico-legal exposures, exposures with ionising radiation without medical indication". Proceedings of the International Symposium, organised by the Commission in 2002[43]. According to the Medical Exposure Directive, all individual exposures are supposed to be justified both by the prescriber and by the practitioner, each with respect to their own expertise and area. In cases where a medical doctor is asked by an insurance company, judge, employer etc. to provide advice and/or a conclusion about the physical state of a person, it is likely that X-ray will be indicated to complete the assessment. However, there are situations where the medical doctor is effectively directed to use X-rays by an employer, judge etc. In those cases, the one who orders the X-ray becomes the prescriber.

5. Radiation Protection N° 133 "The Status of the Radiation Protection Expert in the EU Member States and Applicant Countries". This report provides a survey of the present situation of radiation protection experts (RPEs) in the Member States of the European Union and the Applicant Countries (at the time of the survey). Based on the conclusions of the study, some recommendations are made:

[43] http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/130.pdf

- In the context of the single market and the enlargement process, it is recommended to try to achieve harmonisation in the qualifications of the so called "qualified expert" often introduced in national legislations as RPE. This would help promote the achievement of the aims of the Directive on free movement of workers in the European Union and should take due note of the Directive on safety at work.

- Definition, tasks and provisions for recognition of the RPE in the national regulations of EU Member States and Applicant Countries should be compared in detail, in order to expose the obstacles preventing a harmonised implementation of the concept of the “Qualified Expert”.

As a means of achieving this goal, it is recommended to establish a Discussion Platform that could serve as a means for exchange of information on education, training, recognition and registration of RPEs. This Platform may provide a vehicle for moving forward to mutual recognition. The topics mentioned in the recommendations hereunder could be addressed in such a Discussion Platform (see part A.5.).

6. Radiation Protection N° 135 "Effluent and dose control from European Union NORM industries: Assessment of current situation and proposal from a harmonised Community approach". This report identifies relevant NORM industries but from the point of view of discharges. Furthermore, it contains an overview of national regulations in 16 Member States relevant to NORM and proposes a set of screening values based on certain dose criteria for NORM discharges above which a more detailed radiological assessment would be advised. The overview of the national regulations showed that at the time of the publication of the report (2003) most Member States had focused on identification of significant exposures to the workers but that identification of significant exposure to the public from NORM wastes and discharges was still in an early stage. Only nine of the countries had or planned to set up specific discharge controls or assessment procedures for NORM discharges.

7. Radiation Protection N° 154 "European Guidance on Estimating Population Doses from Medical X-Ray Procedures". DG TREN launched in 2004 a study, called **Dose DataMed**, to review the situation in the Member States regarding the doses to the population from medical exposure procedures. The results for 10 European countries participating in the study were published in 2008, demonstrating that there are considerable differences between, and even within, the countries. It was concluded that there is a need for harmonization of the dose data collection among the Member States.

8. Radiation Protection N° 156 "Evaluation of the Implementation of Radiation Protection Measures for Aircrew". The study concluded that current requirements in

Directive 96/29/Euratom lead to a satisfactory protection of aircrew against the dangers arising from cosmic radiation and that there is no area where requirements would be incomplete or where regulations would clearly be missing. It is, however, recommended to incorporate the requirements on protection of aircrew coherently in the title on the protection of workers. These conclusions are made on the base of the collected data on the implementation of the requirements of the BSS Directive 96/29 in various EU Member States and other countries.

9. Radiation Protection Publication N° 157 "Comparative Study of EC and IAEA Guidance on Exemption and Clearance levels". The BSS Directive 96/29 contains general requirements on disposal, recycling and reuse of materials used in practices under regulatory control. According to these requirements material can be released from radiation protection control if they comply with levels of radioactivity set by national competent authorities (clearance levels). The aim of the study is to compare the values in EU Radiation Protection N° 122 and the IAEA document RS-G-1.7 and to provide a basis for deciding whether the IAEA levels could also be used as clearance levels and as a substitution of the level, above which the practices should be notified (exemption levels). After a comprehensive review of the two documents, it is concluded in the report that the IAEA values can be used as general clearance levels, replacing the values recommended by the Commission. It is also justified that the IAEA values can replace the activity concentration values for the exemption of practices from notification and authorisation regime.

10. Radiation Protection Publication N° 166 "Implementation of the Council Directive 90/641/Euratom". According to the final report, the outside workers in European Countries can be estimated to at least 100 000, mainly working for the nuclear industry. Almost all the operators who use outside workers check the medical surveillance and fitness of the outside workers, provide them with specific training and protective equipment; 75% of the operators ensure that radiological data of each worker is recorded into a radiation passport or a network; additionally 50% of the operators set up dose constraints for outside workers. However, the answers provided by outside undertakings (the employers of the outside workers) clearly outline that there is a large variety of situations and there is a need for a harmonisation of both exposure assessment and medical surveillance. The need for a uniform European network or radiation passport is particularly highlighted in this survey.

ANNEX III

Article 31 Group of Experts – Statute and Opinion on the Revision of BSS

A. Statute and Work of the Group of Experts referred to in Article 31 of the Euratom Treaty (Article 31 Group of Experts)

Article 31 Group of Experts is established according to Article 31 from the Euratom Treaty with the task to advise on the elaboration of uniform basic safety standards as described in art.30 from the Treaty. The Group consists of scientific experts, in particular public health experts from Member States, appointed by the Scientific and Technical Committee, set up in compliance with Article 134 of the Treaty. The members of the Group are appointed on a personal basis for a term of five years, renewable. The members of the Group speak on their own behalf and act independently of all external influence. The Treaty requires the European Commission to consult this Group when preparing, revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

When in 2005 the European Commission undertook the revision of the Basic Safety Standards Directives, Art.31 Group of Experts was asked to investigate and deliver an opinion on this issue. This action was triggered by the fact that the International Commission for Radiological Protection (ICRP) has engaged in a process of revising and updating their Recommendations for a System of Radiological Protection which since decades represent the internationally accepted basis for radiological protection. In this context the revision of the BSS was considered as the most important activity of the Group of Experts to be completed before the end of its mandate in May 2010. Therefore, several working parties (WP) were established to identify the items in the BSS directives that may need revision and to look into the impact of the possible changes:

- WP Basic Safety Standards - established at the June 2005 meeting of the Article 31 Group of Experts to monitor the development of the ICRP recommendations, to oversee the work of the topical WPs and ensure that the developments in these WPs are coherent.

- WP Graded Approach to Regulatory Control – this WP was established with the main objective to discuss current concepts of regulatory control with a view to the introduction in BSS of a more elaborated graded approach to regulatory control.

- WP Natural Sources – established in November 2005 to address questions relating to natural radiation exposures. The WP Natural Sources' first priority was to examine how the requirements on natural radiation sources in Title VII of the present Directive could be strengthened and if it was feasible to integrate the regulatory control of so-called NORM industries into the framework of regulatory

control for practices. The second task was to look into the possibility to establish in the BSS Directive requirements related to exposure to radon, taking into account the Commission Recommendation 90/143/Euratom on indoor exposure to radon. The third assignment was to propose a regulatory framework for building materials containing natural radiation sources. For each of these tasks the WP produced comprehensive reports, giving background data on international and Commission standards and guidance, indicating where further guidance and work is necessary and providing proposals for new or modified requirements. The reports have been presented to the Article 31 Group of Experts and agreed upon.

- WP Exemption and Clearance – established in November 2005 with the task to make a review of the existing sets of values for exemption and clearance in the directives, recommendations and international guides. On this basis the WP should advise on possible harmonisation of the values for clearance (choose one set of values) and on harmonisation of the values for exemption and clearance. The conclusions of the WP were expressed in a report submitted to the Article 31 Group of Experts.

- WP on the Recast of Basic Safety Standards – this WP was established in November 2007 to undertake a recast of the BSS directive and four other related directives. According to the mandate WP Recast should focus combining 5 directives into one peace of legislation - BSS Directive (recast). The WP should use the outcomes and the proposals of the other working parties and the results of studies, projects and consultations.

The existing working parties on "Medical exposures" and "Research and Implications on the Health and Safety Standards" (RIHSS) were also involved in the process. WP "Medical exposures" was asked by Article 31 Group of Experts to elaborate on the possible recast of Council Directive 97/43 and BSS Directive and to look into the latest developments in the medical exposures area. RIHSS looked into the scientific basis of the biological effects of radiation, as input both to ICRP and to the revision of the BSS.

After several years of discussions and preparation of the possible revision of BSS Directive and associated directives, Art.31 Group of Experts issued their opinion in February 2010.

B. Main Points from the Opinion of Article 31 Group of Experts on the Revised Basic Safety Standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation

1) A graded approach to the regulatory control of practices needs to be established. It is proposed that the regulatory regime is built on three steps – notification, registration, licensing instead the current 2 levels – notification and authorisation. The Working Party on Graded Approach proposed a list of practices which can be submitted to simple registration instead of licensing.

2) In order to ensure equal protection of the workers in different economic sectors it is proposed to submit the so-called NORM industries[44] to the regulatory control established for the other practices involving radioactivity.

3) With regard to the Commission Recommendation 90/143/Euratom on indoor exposure to radon, which is largely introduced in the Member States, the Working Party on Natural Sources recommended to introduce requirements on the control of radon in workplaces, dwellings and public buildings into the revised BSS Directive.

4) A new regulatory framework should be established for building materials containing naturally occurring radionuclides present in the earth's crust. Member States shall be required to identify building materials of concern. The national authorities should set a reference level of 1 mSv per year for indoor external exposure from building materials. For the identified types of building materials which are liable to exceed the reference level the competent authority shall decide on appropriate measures ranging from registration and general application of relevant building codes, to specific restrictions on the envisaged use of such materials.

5) A revised BSS Directive should propose a set of default activity concentration levels for the clearance of materials from regulated practices involving radiation sources. The levels chosen should be harmonised with international guidance. Based on the findings of the "Comparative Study of EC and IAEA Guidance on Exemption and Clearance levels" (Radiation Protection Series 157) the Working Party on Exemption and Clearance proposed to establish the same set of activity concentration levels for the exemption of practices from regulatory control and for the clearance of materials from regulated practices. Although this will result in lower thresholds above which regulatory control would apply, the study concluded that in practical terms this will not impose additional burden since only a few, if any, practices will be affected.

[44] Industries involving NORM (Naturally Occurring Radioactive Materials)

6) The control of high activity sealed sources (HASS) and orphan sources, now regulated in Council Directive 2003/122/Euratom, is part of the regulatory control regime and covers issues regarding emergency preparedness and response. It is recommended to incorporate the text of Directive 2003/122 into the revised BSS Directive to achieve a more coherent and comprehensive regulation for the control of high activity sealed sources.

7) In view of the development of techniques involving deliberate exposure of individuals for security and other legal purposes like security screening, age determination etc. it is necessary to establish new requirements. The Working Party on Medical Exposures proposed the concept of a regulatory regime for these exposures.

8) In view of new scientific findings regarding enhanced incidence of radiation induced cataracts it is recommended to lower the current organ dose limits for the lens of the eye. This has been supported by reports given at the 2006 Scientific Seminar on New insights in radiation risk and basic safety standards. The proceedings of the 2006 Scientific Seminar are published in the Radiation Protection Publication N° 145 "New Insights in Radiation Risk and Basic Safety Standards".

ANNEX IV

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Energy
D.4 - Radiation Protection

Luxembourg, 9 April 2010
D4/ÅW D(2010)

Summary of the Commission Services' public consultation regarding natural radiation sources in new Euratom BSS

Note to EAN_{NORM}

Consultation and response

A consultation document with the Commission Services' considerations regarding natural radiation sources in the new Euratom Basic Safety Standards Directive (BSS)[45] was launched on the European Commission's website in February 2009. The end date was set to 20 April 2009 although comments kept coming until the end of April. Those have been included as well.

In total forty-seven contributions were received, mostly from industry/industrial organisations or governmental organisations/authorities (around 15 each). A substantial amount of contributions came from individuals (10) and from radiation protection associations or group of experts (5). The contributions from industry were distributed over the following industrial sectors:

- Steel producers

- Zirconium chemicals producers

- Producers of abrasive products

- Building materials industry

- Tiles and bricks industry

- Radon measurement and remediation companies

With regard to the geographical distribution, comments were received from the following countries: Germany(13), UK(5), Spain(4), Italy(4), Belgium(3), Ireland(3), the

[45] The present BSS is the Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of health of workers and the general public against dangers arising from ionizing radiation.

Netherlands(2), Sweden(2) and Finland, Greece, Poland, Austria, Norway, Switzerland, Australia (one each) [46].

A compilation of the comments received was sent to the WP Recast and WP Natural Sources (sub-groups of the Article 31 Group of Experts) for further discussion. It should be noted that the text of the draft BSS has constantly evolved since the Article 31 Group of Experts meeting in November 2008 when the consultation document was approved. Some of the problems raised in the comments were already addressed and solved by the time of the consultation and several issues have been taken care of in the further drafting process during 2009. In February 2010 the Article 31 Group of Experts finalised the draft Euratom BSS and adopted an Opinion on the draft. The Opinion of the Article 31 Group of Experts reflects the broad range of views within the Group of Experts on some issues.

Outcome: In general

The consultation was well received and a large part of the contributors express their appreciation for being invited to comment on ideas this early in the process of revising the Directive. In general the contributions endorsed the goal of the Commission to harmonise, clarify and strengthen the requirements related to natural sources.

The contributors believe the Commission has chosen the right approach when introducing the so-called graded approach to regulatory control but would like to have more information on the regime of notification, registration and licensing. There is also a high demand for guidance and clarification about the rationale for certain issues and about how to implement the requirements in practice. The Commission is planning to further elaborate on principal issues and their implementation in a guidance document which should be published in connection with the adoption of the new Directive. Furthermore there is a demand for clear definitions, e.g. on buildings, dwellings, reuse, recycling, disposal, waste, constructions, natural radiation source and inert material. This has been taken care of and the draft BSS now contain the relevant definitions.

Outcome: Specific topics

The forty-seven contributions contained a number of comments, some detailed, some addressing broader issues. The main concerns are listed below along with comments in italics about how these concerns have been or will be dealt with. Please note that the summary is very brief and does not contain the full reasoning behind neither the comments and concerns nor the outcome shown in italics.

NORM

Positive list

- Some additional industries are suggested.

  Two of them have been added:

  Geothermal energy production, since it has similar radiation protection issues as other types of fluid extraction, e.g. oil and gas extraction.

[46] The sum does not equal forty-seven since some contributions cannot be associated to a specific country.

Mining of ores other than uranium ore. Although exposure to radon is normally the main pathway of exposure in underground workplaces, some mines have problems with high concentrations of Radon-226 in fissure water.

– The positive list is a good thing but after assessment Member States should have the possibility to remove certain industries

This is not explicitly mentioned in the draft BSS, instead it states that all industries on the list needs to be taken into account when Member States make the initial identification of industries which cannot be disregarded from a radiation protection point of view.

Materials of concern

– Need for clarification about pathways when assessing doses

This is an area where the Commission is considering issuing further guidance although earlier Commission guidance such as RP 122 part II is still relevant for identifying pathways.

Mandatory requirement for notification if the industry is recycling residues into building material

– Does not fit with graded approach
– Will be difficult to implement and to control
– Would it not be enough if the building material complies with what is required in the Directive for building materials (index, reference level, etc)?

The mandatory requirement is kept in the draft BSS since recycling of residues into building materials is one of the pathways that may lead to doses to the public exceeding 1 mSv/y and it is therefore necessary to have some form of regulatory control of the industries recycling residues into building materials. The draft BSS contain an annex with of building materials of concern, including a list of the types of residues. The annex indicates which industries would be affected by this requirement.

Exemption values

– Why not use RP 122, part II values (e.g. 0.5 kBq/kg instead of 1 kBq/kg)?

For the sake of harmonisation with international standards the values in the IAEA report RS-G-1.7 have been incorporated, in the same way as for artificial radionuclides. Some of the Article 31 Experts also prefer the RP 122 values and this is reflected in the Opinion.

– Some contributors mention the need for allowing lower values when drinking water may be affected.

This has been introduced in the draft BSS: without explicitly allowing lower levels, the competent authority may impose restrictions wherever drinking water or other pathways of exposure may be affected.

Graded approach

– How to assess doses to workers? Should conventional health and safety equipment be taken into account?

It has been taken care of by referring to "normal working conditions", which implies that compulsory health and safety requirements relevant to the workplace should be taken into account.

– Why notification already when doses to workers are likely to exceed 1 mSv/y? Some of the German contributors mention that they have good regulatory experience of setting the level for notification at 6 mSv/y.

  Why ask for anything more than notification? Licensing or registration requirements would only lead to an unnecessary administrative burden.

  The draft BSS now deal with NORM industries in the same regulatory framework as for other practices. The graded approach applies to all practices and the choice of registration or licensing is based on different criteria, e.g. dose assessment to workers and members of the public. However, for doses to workers in the range 1-6 mSv/y the requirements for occupational exposure to NORM are less demanding.

Mixing

– Mixing NORM with other material should be encouraged. Significant amounts of NORM are recycled and end up mixed with other materials, e.g. in cement and concrete. The term "inert" may also not be appropriate.

  The term "inert material" is no longer used and the text is modified.

Radon

– There is a clear demand for technical guidance, especially with regard to measurement techniques, and for standards and harmonisation on a European level for this.

  According to the website of the International Organization of Standardization (ISO), one of its subcommittees, TC85/SC2, is in the process of developing several ISO standards for Radon-222. With regard to building materials, CEN/TC 351 is presently investigating the possibility of setting a CEN standard for measuring radioactivity concentration (gamma radiation) in building materials.

– There are worries that the action plan will only address radon in dwellings and public buildings. Radon in workplaces needs equal attention.

  The draft BSS are clear about the fact that the national action plan must also address radon in workplaces.

– Some contributors question a threshold for recording doses to workers in NORM industries and question the choice of the value of 400 Bq/m^3.

  This threshold has been removed.

– Modify so that within radon-prone areas all workplaces with a high occupancy are requested to be measured.

  This is reflected in the requirements on the content of the national action plan.

– Modify so MS have the possibility to choose a higher reference level for workplaces with a very low occupancy.

It should be noted that a reference level is not a limit. For such workplaces, where radiation protection measures are optimised, the radon concentrations may very well exceed the reference level.

– Include criteria on level of rooms or workplaces in addition to requirements for measurements in radon-prone areas (upper floors excluded?)

The requirements for measurements at workplaces have been slightly modified. For buildings with public access or dwellings setting specific requirements on types of rooms or workplaces would require a high level of detail. It would be more suitable to discuss such a complex issue in a guidance report.

Building materials

– Clarification needed about whether materials used for infrastructure projects are considered building materials.

The draft BSS contain a definition of building materials.

– Some contributors worry about the proposed requirements causing stigmatization of certain groups of materials, whereas others are concerned that the flexibility, for instance when setting up the list of building materials which need to be considered, would lead to problems in shipping and trading products within EU.

These are valid concerns. However, in order to make informed decisions when constructing buildings, so as to not exceed the appropriate levels of exposure to workers or members of the public and to fulfil Annex 1 of the Council Directive related to construction products (89/106/EEC)[47], the building industry should be made aware of the radioactivity content of the materials a Member State has deemed to be of concern. The flexibility for Member States to establish a reference level for building materials has been removed.

– Some contributors question why the value for exemption proposed by RP 112 (0.3 mSv/y) is replaced by 1 mSv/y.

Based on the prevailing activity concentrations in building material produced in the European Union the Article 31 Group of Experts decided that a level of 1 mSv/y would be more appropriate in a Directive, also in order to avoid problems in trade within the EU.

– Harmonisation or guidance on how to measure radionuclide concentrations and calculate the index would be beneficial, as well as on the concept of "superficial material".

Some information can be found in earlier Commission guidance, such as RP 96 and RP 112, but this is an area where the Commission considers issuing further guidance.

[47] Council Directive 98/106/EEC, Annex 1, states that "…the construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of … the presence of dangerous particles or gases in the air [or] the emission of dangerous radiation…"

ANNEX V

Legislation

enacted under Articles 30 and 31 from Euratom Treaty

Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (BSS Directive 96/29) is the main pillar of the body of secondary legislation on basic safety standards, adopted pursuant to Article 31 of the Euratom Treaty. The following acts are based on art.31 from Euratom Treaty:

1. **Council Directive 97/43/Euratom** of 30 June 1997 on health protection of the individuals against the dangers of ionising radiation in relation to medical exposure, repealing 84/466/Euratom of 3 September 1984 (Medical Directive);

2. **Council Directive 90/641/Euratom** of 4December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (Outside Workers Directive);

3. **Council Directive 2003/122/Euratom** of 22 December 2003 on the control of high-activity sources and orphan sources (HASS Directive);

4. **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 (Public Information Directive);

5. **Council Decision 87/600/Euratom** of 14 December 1987 on Community arrangements for early exchange of information in the event of a radiological emergency;

6. **Council Regulation 87/3954/Euratom** of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency and the related legislative acts - **Commission Regulation 944/89/Euratom** of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency, **Commission Regulation 770/90/Euratom** of 29 March 1990 laying down maximum permitted levels of radioactive

contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency[48];

7. **Council Regulation 93/1493** of 8 June 1993 on shipments of radioactive substances between Member States;

8. **Commission Recommendation 2001/928/Euratom** of 20 December 2001 on the protection of the public against exposure to radon in drinking water supplies;

9. **Council Directive 2006/117** of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel;

10. **Commission Recommendation 90/143** of 21 February 1990 on the protection of the public against indoor exposure to radon;

11. **Council Directive 2009/71/Euratom** of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

[48] These acts are subject to recast - Proposal for a Council Regulation (EURATOM) laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (Recast) COM/2010/0184 final - CNS 2010/0098

ANNEX VI

ESTIMATED CONTRIBUTIONS TO PUBLIC EXPOSURE FROM DIFFERENT SOURCES (in mSv)

(data published in UNSCEAR Report 2008)

Figure I

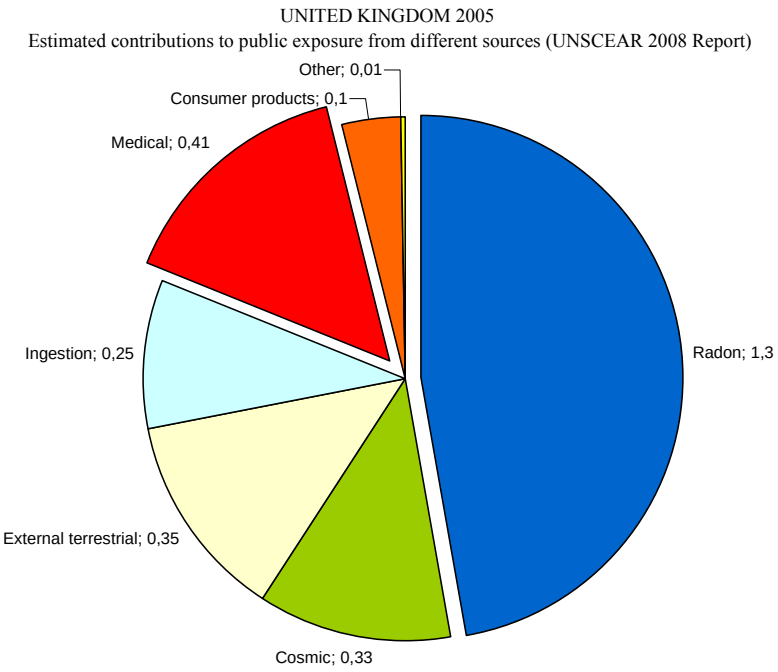


Figure II

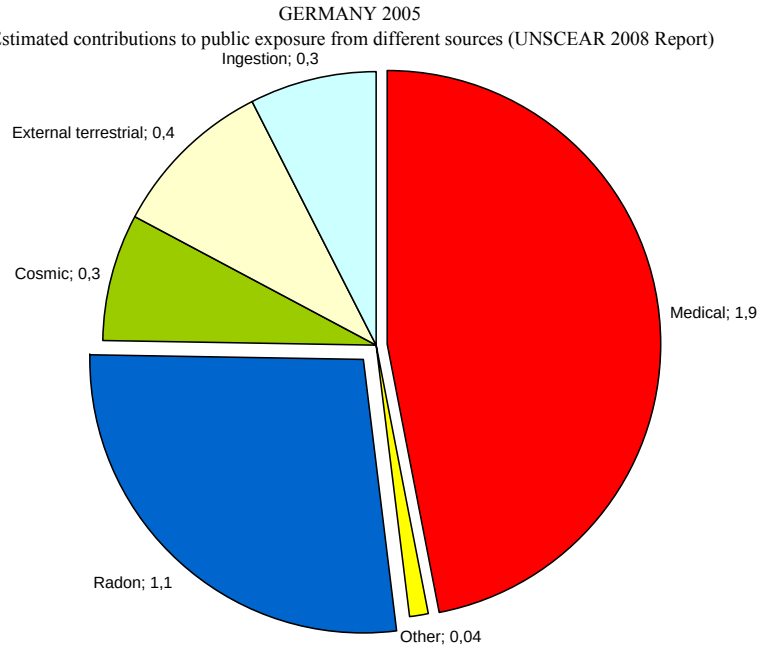

GERMANY 2005
Estimated contributions to public exposure from different sources (UNSCEAR 2008 Report)
Ingestion; 0,3
External terrestrial; 0,4
Cosmic; 0,3
Medical; 1,9
Radon; 1,1
Other; 0,04

Figure III

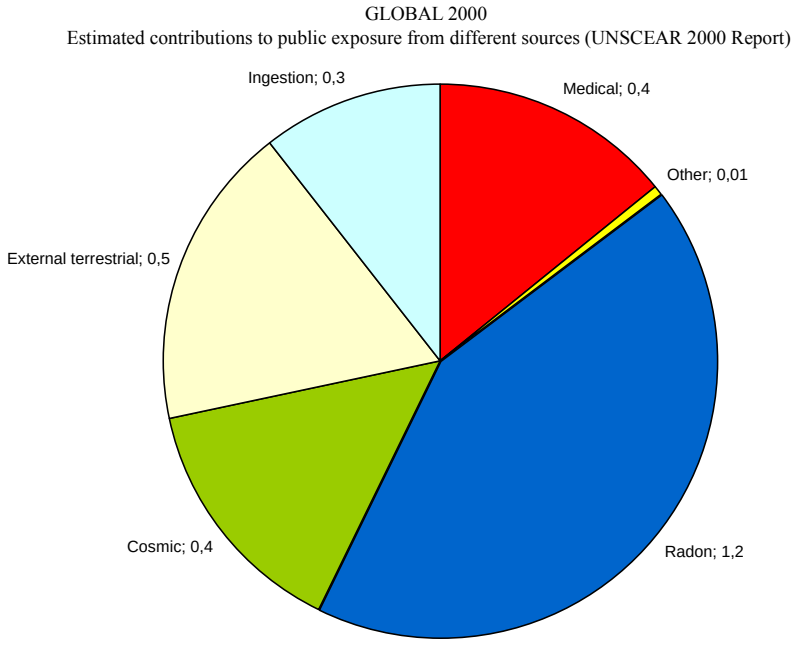
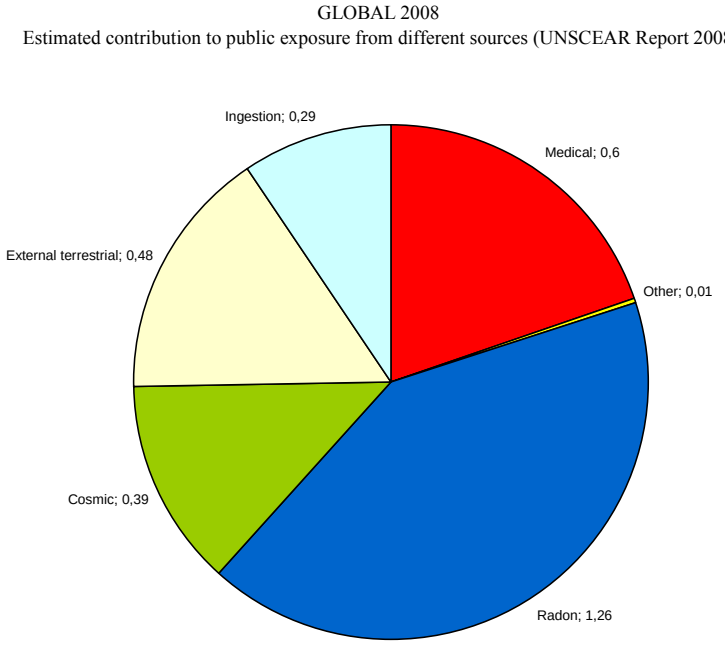

GLOBAL 2000
Estimated contributions to public exposure from different sources (UNSCEAR 2000 Report)
Ingestion; 0,3
Medical; 0,4
Other; 0,01
External terrestrial; 0,5
Cosmic; 0,4
Radon; 1,2

Figure IV

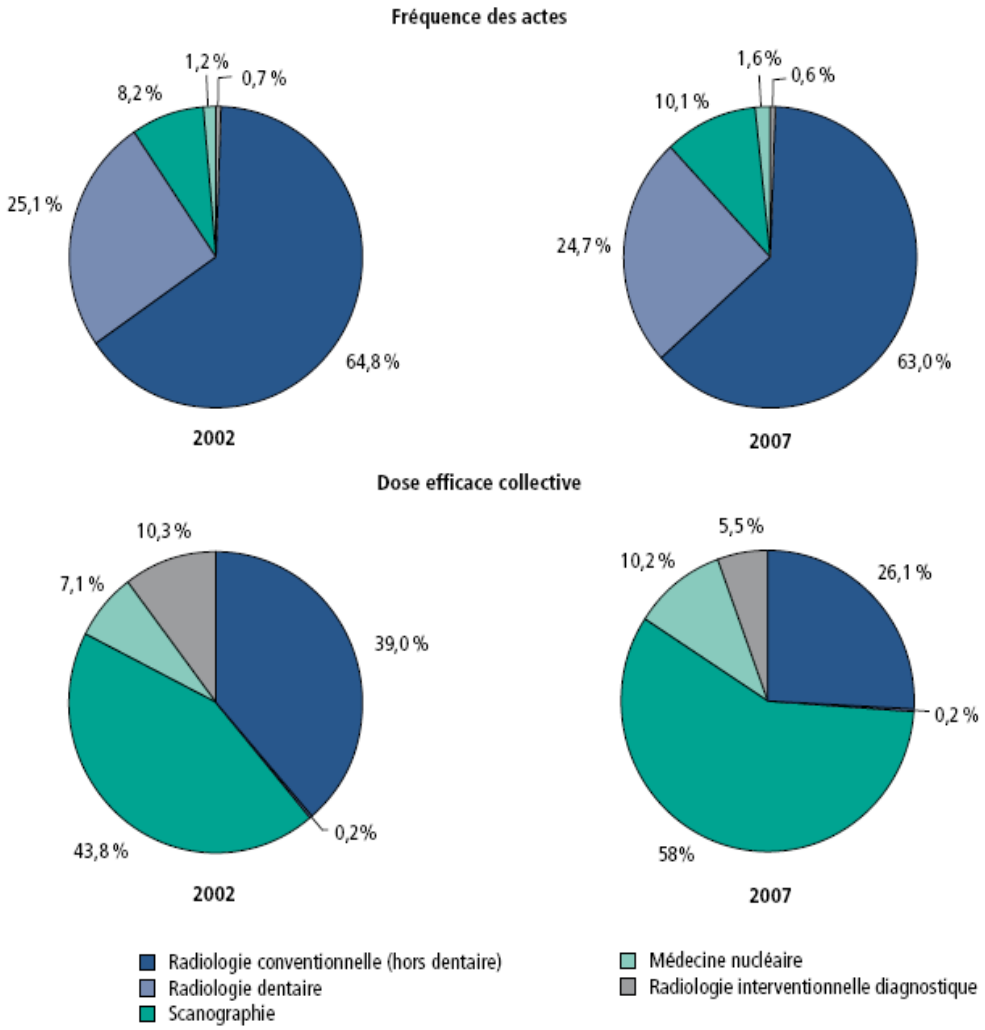


ANNEX VII

EVOLUTION OF THE MEDICAL DIAGNOSTIC EXPOSURE IN FRANCE between 2002 and 2007[49]

	Number of procedures	Number of procedures per capita	Collective effective dose in mSv	Annual dose per capita in mSv
2002	73,6 millions	1,2	50 675 472	0,83
2007	74,6 millions	1,2	82 630 000	1,3

[49] Etard C, Sinno-Tellier S, Aubert B. Exposition de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2007. Saint-Maurice (Fra) : Institut de veille sanitaire, juin 2010, 104 p. Disponible sur : www.invs.sante.fr



The number of performed medical procedures in the period 2002-2007 has increased by only 2%. However the annual dose per capita from these procedures increased by 57% for 5 years. This notable increase is due to the increase of number of procedures in computed tomography and nuclear medicine where the highest dose in diagnostic medicine is delivered. While for 5 years the number of procedures in the conventional radiology is stable, in computed tomography and nuclear medicine significant increase of accordingly 26% and 38% is observed. At the same time the collective effective dose from conventional radiology decreased, while the collective effective dose from computed tomography and nuclear medicine increased by 33 % and in 2007 is 68% from the dose delivered due to medical diagnostic exposure as a whole.

ANNEX VIII (A)

NATURALLY OCCURING RADIOACTIVE MATERIAL

A. Naturally occurring radioactive material and building material

The industrial activities covered by the term "NORM industries" are all related to material extracted from the earth's crust. Either the industries use the material (e.g. production of thorium compounds) or they are involved in the extraction itself (e.g. mining of ores). Table 1 shortlists the types of operations that are likely to warrant regulatory control with the type of material involved and range of dose to workers. It is difficult to forecast the number of enterprises likely to be affected since it depends on the industrial process in each enterprise and on the content of radioactivity in the material being processed. As an example the number of enterprises extracting crude petroleum and natural gas in the EU is 381, the number of enterprises producing lead, zinc and tin is 293 and the number of enterprises mining iron ores is estimated to 40[50].

While the protection of workers in the nuclear industry has been discussed since long, resulting in international consensus on monitoring and registering of doses to workers, this is not the case for exposure to workers in NORM industries. Although many reports were consulted, see Table 2, and the Article 31 Working Party Natural Radiation Sources experts shared their knowledge on approaches and situations in their countries, the collection of data for the impact assessment has been difficult and the data available is often based on estimations rather than actual monitored doses to workers. Furthermore, the NORM sector covers a wide range of industrial activities and there is very little compiled data for the whole sector. The proceedings of the NORM V conference did however provide a summary of the data presented on doses to workers and to members of the public. The results are in line with the doses indicated in Table 1. With regard to estimations of doses from NORM industries to members of the public, the proceedings conclude that members of the public in general receive far less than 0.3 mSv per year.

Data on the number of exposed workers are as previously mentioned scarce. The ESOREX database on occupational exposure does however provide certain information. In 2004 the number of exposed workers in the EU employed in workplaces with enhanced exposure to natural radionuclides was 27 000[51]. One of the objectives of the SMOPIE project (see Table 2) was to provide information on the number of industrial workers exposed to NORM. The project concludes that this information is very scarce but based on the information received and compiled they estimate the number of potentially exposed workers in EU NORM industries to be around 85 000 (2004). The project further concluded that exposure data based on actual workplace monitoring is very scarce. This lack of data reflects the lack of consistent and harmonised requirements

[50] EUROSTAT Basic Statistic for 2007
[51] ESOREX Database

on monitoring of workers and registration of doses in this industrial sector. Far more data should become available once the new Directive is implemented.

The issue of natural radionuclides in building materials was discussed by the Art.31 Working Party Natural Radiation Sources. Based mainly on two reports on activity concentrations in building materials[52] and one study made on Italian building materials[53], the group concluded on a list of materials that Member States should take into account when setting up national lists of materials that would require regulatory control due to their content of radioactivity:

- Natural materials such as alum-shale and materials from natural igneous origin (e.g. granite, basalt and lava)
- Materials incorporating by-products or residues from NORM industries (e.g. fly ash, phosphogypsum and red mud – a residue from Aluminium production)

The Article 31 Group of Experts adopted the list with the some additions (e.g. porphyries and residues from steel production).

To give an indication of amounts, the production of granite (crude or roughly trimmed) in the EU in 2009 was around 4.5 billion kg. The production of porphyry, basalt, quartzite and other monumental or building stone (crude, roughly trimmed, cut) in the EU in 2009 was around 15 billion kg[54].

[52] UNSCEAR Report, 1993, and "Extent of Environmental Contamination by Naturally Occurring Radioactive Material (NORM) and Technical Options for Mitigation", Technical Reports Series No 419, IAEA, 2003

[53] Radioactivity in Building Materials: Experimental Methods, Calculations and an Overview of the Italian Situation, Proceedings "Radon in the Living Environment", Athens, 19-23 April 1999

[54] EUROSTAT PRODCOM Database 2009

ANNEX VIII (B) Types of operation identified, on the basis of worker dose, as likely to require regulatory control[a]

Type of operation	Description of material involved	Worker dose (mSv/a)
Rare earth extraction from monazite	Monazite, Thorium concentrate, Scale, Residue	Average 1 to 8, could approach or exceed dose limit
Production of thorium compounds	Thorium concentrate, Thorium compounds	Typically 6 to 15
Manufacture of thorium-containing products	Thorium compounds, Products	<1 to a significant fraction of dose limit
Processing of niobium/tantalum ore	Ore, Pyrochlore concentrate, Residue, Slag	Could reach a significant fraction of dose limit
Some underground mines and similar workplaces such as water treatment facilities	Ore, Scales from Radium-rich water, Air	<1 to a significant fraction of dose limit[b]
Oil and gas production	Scales during removal from pipes/vessels	<1 to a significant fraction of the dose limit
TiO_2 pigment production	Scales during removal from pipes/vessels	<1 to 6
Thermal phosphorus production	Fume and precipitator dust	0.2 to 5 (average: ~1)
Fused zirconium production	Fume and precipitator dust	0.25 to 3
Production of phosphate fertilizers	Dust and scales	Possible to exceed 1
Metal production: smelters	Dust and dust scales	Possible to exceed 1

[a] Information from IAEA Safety Reports Series No 49, *Assessing the Need for Radiation Protection Measures in Work involving Minerals and Raw Materials* and European Commission Radiation Protection Series No 88.

[b] Measurements in some metal mines indicate an effective dose from gamma radiation and dust of about 0.5 mSv/a per unit U-238 activity concentration (in Bq/g) in the ore. The effective dose from radon is highly variable and difficult to predict, being strongly dependent on ventilation conditions and other factors.

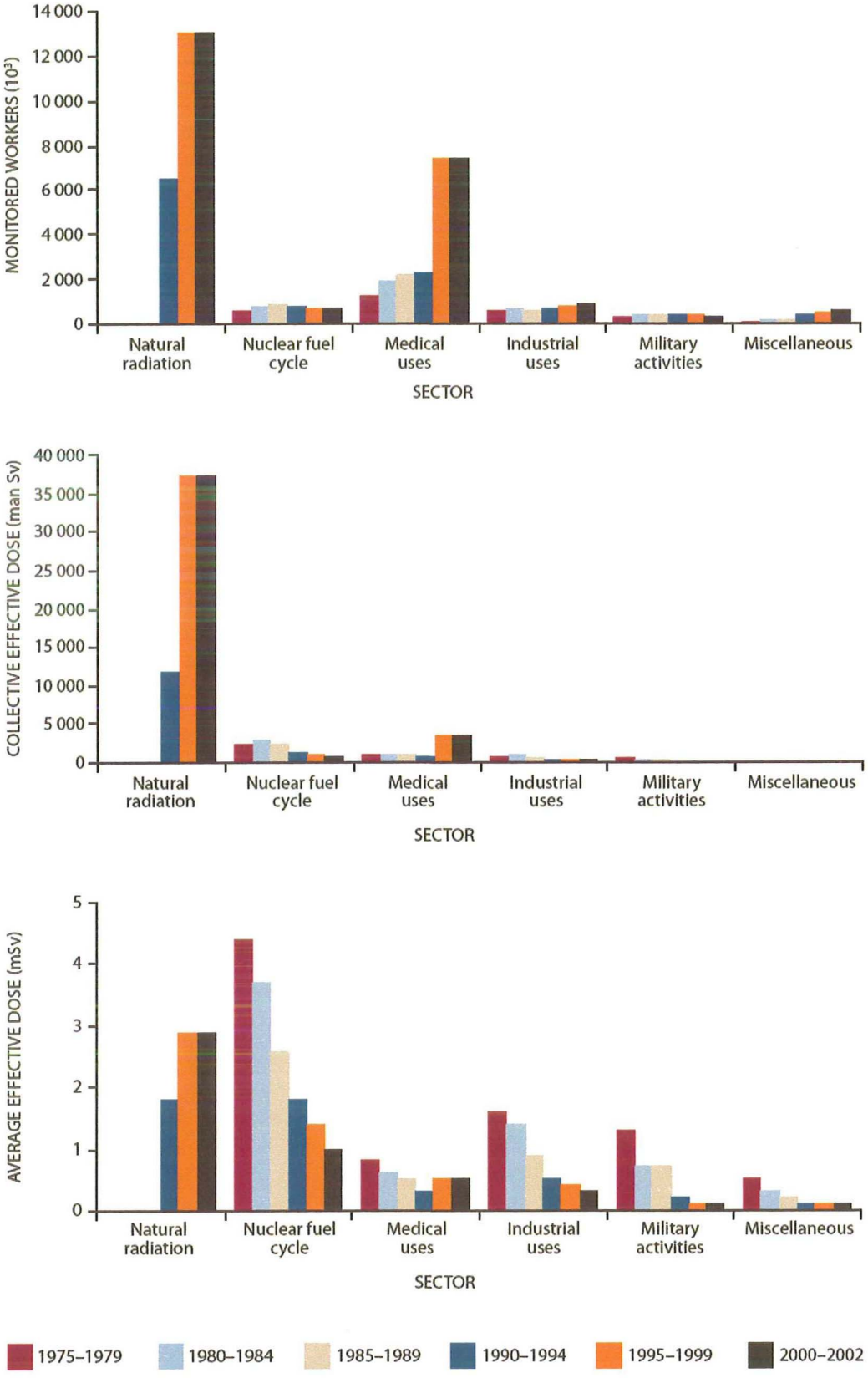
ANNEX VIII (C)

DOCUMENTS EXAMINED FOR THE IMPACT ASSESSMENT REGARDING NORM

Title	Published	Organisation
Approaches for regulating management of large volumes of waste containing natural radionuclides in enhanced concentrations, EUR 16956	1996	European Commission
Current practice of dealing with natural radioactivity from oil and gas production in EU Member States, EUR 17621	1997	European Commission
Recommendations for the implementation of Title VII of the European Basic Safety Standards Directive (BSS) concerning significant increase in exposure due to natural radiation sources, Radiation Protection Series N° 88	1997	European Commission
Establishment of reference levels for regulatory control of workplaces where materials are processed which contain enhanced levels of naturally occurring radionuclides, Radiation Protection Series N° 107	1999	European Commission
Radiological impact due to wastes containing radionuclides from use and treatment of water, EUR 19255	2000	European Commission
Monitoring and surveillance of residues from mining and milling of Uranium and Thorium, Safety Reports Series N°27	2002	IAEA
Radiation Protection and the Management of Radioactive Waste in the Oil and Gas Industry, Safety Reports Series N° 34	2003	IAEA
Occupational radiation protection in the mining and processing of raw material, RS-G-1.6	2004	IAEA
Strategies and Methods for Optimisation of Protection against Internal Exposure of Workers from Industrial Natural Sources, EC project N° FIGM-CT2001-00176 (SMOPIE-project)	2004	NRG, NRPB and CEPN
Summary and recommendations from EAN 9th Workshop, "Occupational exposure to natural radiation"	2005	European ALARA Network

Assessing the need for radiation protection measures in work involving minerals and raw material, Safety Reports Series N° 49	2006	IAEA
Radiation protection and NORM residue management in the Zircon and Zirconium industries, Safety Reports Series N° 51	2007	IAEA
Naturally Occurring Radioactive Material (NORM V), Proceedings from international symposium in Seville, Spain, 19-22 March 2007	2008	IAEA
Sources and effects of ionising radiation, UNSCEAR 2008	2010	United Nations

ANNEX VIII (D) WORLDWIDE TRENDS IN NUMBER OF MONITORED WORKERS AND IN COLLECTIVE EFFECTIVE DOSES AND EFFECTIVE DOSES TO MONITORED WORKERS (UNSCEAR Report 2008)



ANNEX VIII (E)

EXPOSURE TO IONISING RADIATION FOR WORKERS IN NORM INDUSTRIES (case study)

FRANCE, Bilan 2008 de la surveillance de travailleurs exposés aux rayonnements ionisants en France (Institute de Radioprotection et de Sûreté Nucléaire)

Certaines activités industrielles telles que la production de céramiques réfractaires, la combustion de charbon en centrales thermiques ou encore le traitement de minerais d'étain, d'aluminium, etc. mettent en œuvre des matières premières contenant naturellement des radionucléides (chaînes de l'uranium et du thorium). La manipulation et la transformation de ces matières qualifiées de « NORM[29] » ou « TENORM[30] » peuvent entraîner une augmentation notable de l'exposition des travailleurs.

Cette problématique dite des « expositions naturelles renforcées » a été prise en compte pour la première fois au plan réglementaire au travers de dispositions introduites dans le code du travail par le décret 2003-296 et définies plus précisément par l'arrêté du 25 mai 2005 relatif aux activités professionnelles mettant en œuvre des matières premières contenant naturellement des radionucléides non utilisés en raison de leurs propriétés radioactives. Cet arrêté précise la liste des activités ou des catégories d'activités professionnelles concernées et impose notamment aux chefs d'établissements concernés de réaliser une évaluation des doses reçues par les travailleurs.

4.1.1. BILANS DES ETUDES REÇUES

Fin 2008, le nombre de dossiers reçus dans le cadre de l'application de l'arrêté du 25 mai 2005 s'élevait à 79. La figure 28 en présente la répartition selon les catégories d'activités professionnelles visées par les dispositions de l'arrêté.

La figure 29 présente la distribution des doses efficaces individuelles rapportées dans ces dossiers[31].

Environ 17 % des doses efficaces individuelles calculées pour les travailleurs sont supérieures à la limite de 1 mSv/an au-delà de laquelle les travailleurs doivent être considérés comme « professionnellement exposés » au sens du code du travail et faire l'objet d'une surveillance individuelle dosimétrique et médicale. Des postes de travail dans certaines catégories professionnelles visées par l'arrêté du 25 mai 2005 présentent des doses efficaces individuelles pouvant même être supérieures à 20 mSv/an. Ces postes de travail font actuellement l'objet d'une analyse plus approfondie de la part de l'IRSN.

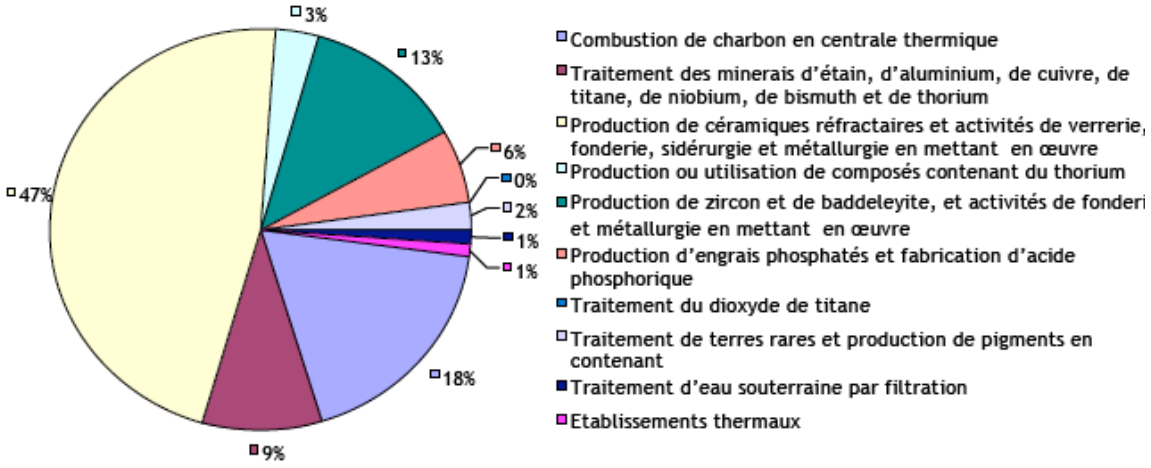


Figure 28 : Répartition des dossiers reçus selon les catégories d'activités professionnelles visées par les dispositions de l'arrêté du 25 mai 2005

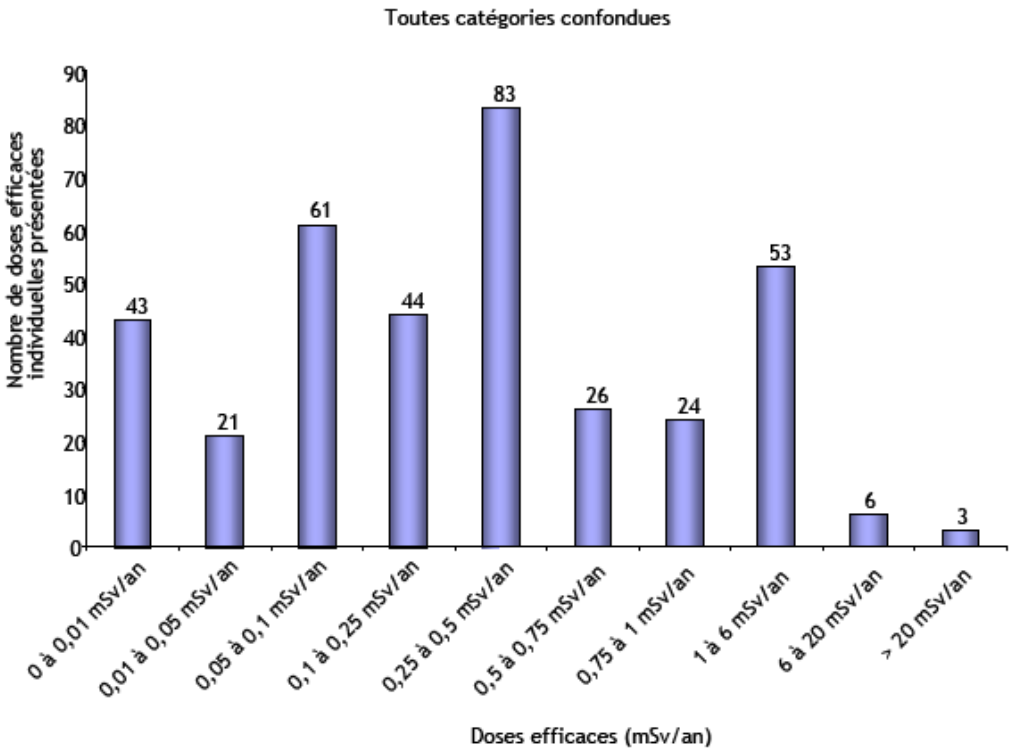
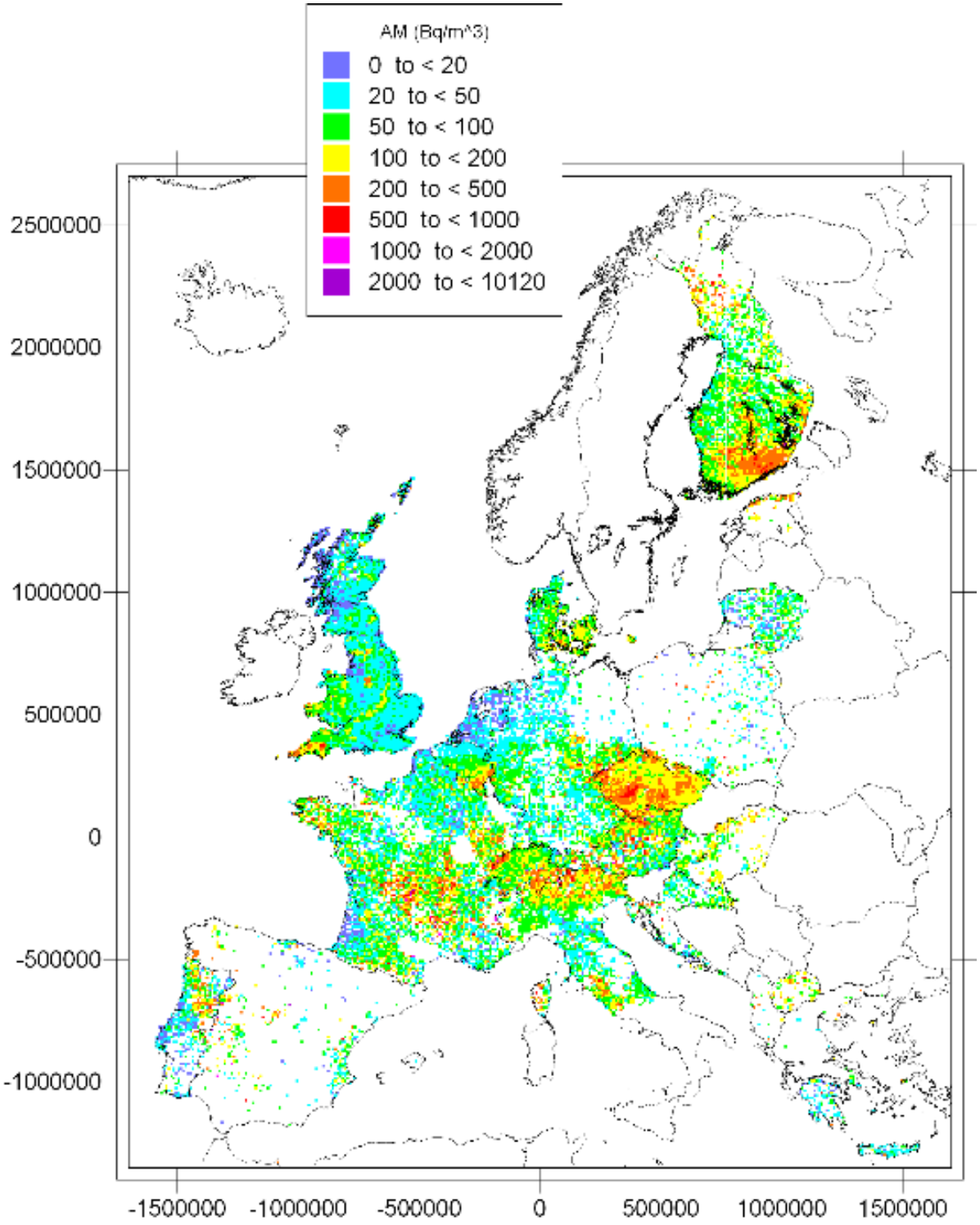


Figure 29 : Distribution des doses efficaces calculées pour les travailleurs

ANNEX IX RADON

(A) Annual Averaged Indoor Radon Concentration



ANNEX IX (B)

Radon in Dwellings

	Finland[55]	**Sweden**[56]	**United Kingdom**[57]
Housing stock	1 700 000	4 500 000	27 000 000
Average radon concentrations	96	108	20
Estimated number of dwellings at or above 200 Bq/m^3	200 000	450 000	100 000
Percentage of dwellings at or above 200 Bq/m^3	12	10	< 1

[55] Recommendations for radon in dwellings in the Nordic countries, 2009, see Nordic radiation protection authorities' websites, e.g. www.ssm.se

[56] Recommendations for radon in dwellings in the Nordic countries, 2009

[57] Radon and Public Health, Report prepared by the Subgroup on Radon Epidemiology of the independent Advisory Group on Ionising Radiation. Advisory Group to Health and Protection Agency, UK, 2009

EUROPEAN COMMISSION

Brussels, 29.9.2011
SEC(2011) 1098 final

2

COMMISSION STAFF WORKING PAPER

IMPACT ASSESMENT

Accompanying the document

COUNCIL DIRECTIVE

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

{COM(2011) 593 final}
{SEC(2011) 1099 final}

ANNEX X

(A) Graded Approach to Regulatory Control

The concept of a graded approach to regulatory control was developed some ten years ago by NEA's Committee on Radiation Protection and Public Health (CRPPH). CRPPH advocated that, in addition to the concept of optimisation of radiation protection, the efficiency of regulatory control could benefit from a similar approach. Hence regulatory authorities would concentrate their supervision on those situations which represent a higher risk of exposure and on those where regulatory intervention is instrumental in reducing overall exposures. The BSS Directive from 1996 already gives indication that as an exception to the rule MS may specify that practices shall not require authorisation in cases where "a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation". This opportunity given by the Directive has been used to little extend, because the requirement is very vague. Given that proper implementation of the graded approach would reduce the administrative burden to the businesses, it is important to clarify and enforce the use of this concept.

In this respect it is necessary to improve the requirements on regulatory control, on the one hand by making the list of practices submitted to authorisation more precise, and on the other hand introducing list of practices that can be submitted to lighter regimes like registration (a two-tier approach replacing the current concept of "prior authorisation" (Article 4 of the BSS). Article 3 of the BSS Directive 96/29 requires all practices to report the conduct of a practice involving ionising radiation or radioactive substances. Practices may be exempted from the requirement to report if certain values, called *exemption levels*, are not exceeded. There are exemption values for the total activity as well as for activity concentrations. These exemption values are laid down in the Directive (on the basis of a European study published in our radiation protection series: RP65) and uniformly transposed in national legislation. The Euratom values were also incorporated in the International Basic Safety Standards of 1996. Later, IAEA adopted a Safety Guide (RS-G-1.7) laying down a different set of radionuclide-specific values (in general lower than those in RP65). As part of the graded approach it is envisaged to make explicit provision for exemption of specific practices, for specific radionuclides, as long as the exemption criteria laid down in the Directive are complied with (essentially that doses should be lower than 1% of the dose limit). The current Directive, again, does not rule out this possibility but it is very vague ("MS's may exempt further practices …").

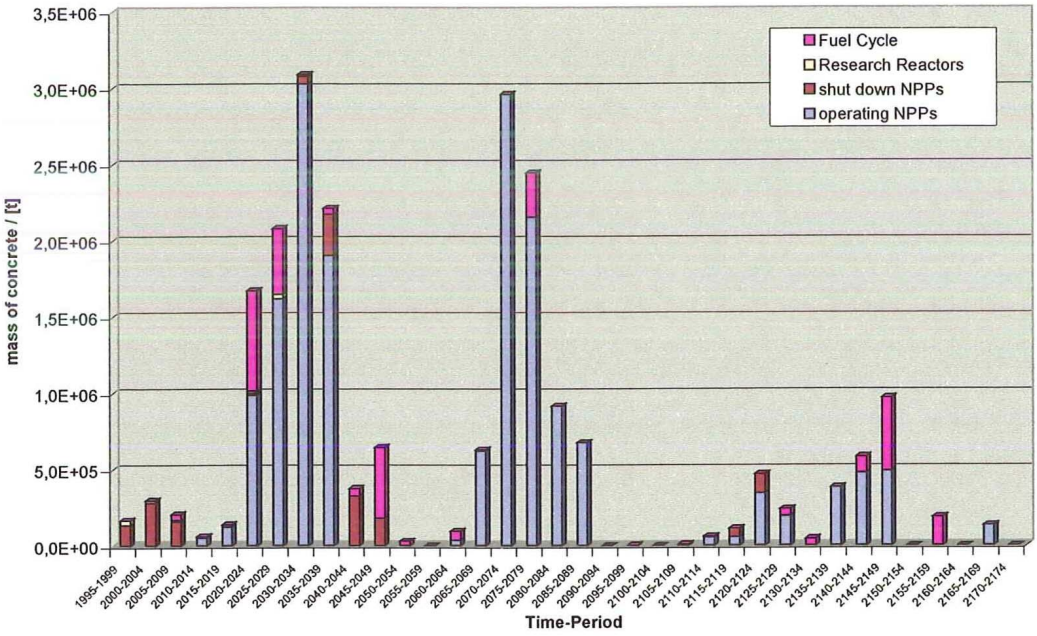
A second important aspect of the "graded approach" relates to the release of materials arising from within a regulated practice. In the absence of any criteria all such materials should be regarded as radioactive waste. Taking into account the huge volume of materials arising from the dismantling of decommissioned nuclear power plants, this would be at a tremendous cost and there would be a shortage of disposal sites. Most of this material has in fact no or very little radioactivity, so it could be cleared from regulatory control. The concept of "clearance", for materials with no or very little contamination, for instance steel or building rubble, is very important in this context. In the current BSS Directive the application of the concept of clearance was left to national authorities, being merely required to take Community guidance into account (as was later published in the Radiation Protection Series). Harmonisation of *clearance levels* for materials resulting from dismantling has therefore become a crucial issue, both within the EU as internationally. In the international guidance (IAEA RS-G_1.7) and draft new

standards it is envisaged to use the same set of values both for clearance and exemption (with the lower numbers taken from RS-G_1.7). This approach could be incorporated in the Euratom BSS as well.

(B) TOTAL EXPECTED MASS OF BUILDING RUBBLE AND STEEL SCRAP

Figure I TOTAL EXPECTED MASS OF BUILDING RUBBLE PER 5a PERIOD FROM ALL PRESENTY EXISTING NUCLEAR FACILITIES IN EUROPE[1]

Figure I



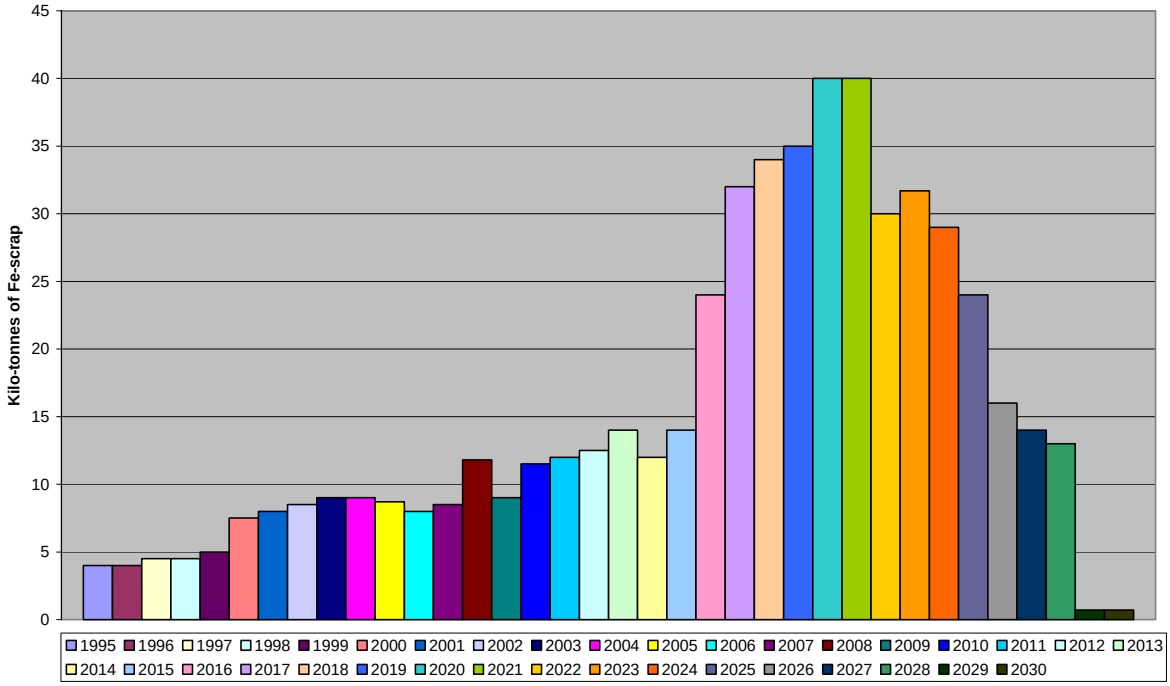
To estimate the total concrete masses arising in Europe and the time of their generation, it is necessary to make generic assumptions. Most of the rubble is produced from the dismantling of nuclear power plants to green field conditions. Because the available data about the concrete masses in power plants is limited, a linear extrapolation of the concrete masses in relation to the power output for smaller and larger units of each type of plant is assumed. The estimation of waste masses in Europe takes into account all types of facilities (nuclear power plants, research reactors and fuel cycle facilities), the number of plants in various countries, the planned operating time, the time for the post-operational period and eventually a safe enclosure and the assumption for the correlation between building masses and electric or thermal power or capacity, respectively. The results of these estimations are presented in figure I. The mass as a function of time shows two distinct peaks in the range between 2020 and 2040 as well as between 2070 and 2090. The first peak is caused by nuclear power plants that will be dismantled soon after their final shut-down, the second peak corresponds to those installations for which a safe enclosure of several decades is foreseen prior to final dismantling. It can be seen that building rubble will also arise in the time after 2100. This corresponds to installations

[1] Radiation Protection Publication 113 "Recommended radiological protection criteria for the clearance of buildings and building rubble from the dismantling of nuclear installations"

mainly in the UK where a long term safe enclosure with an enclosure period of 130 years is envisaged.

It should be noted that this estimation does not include any new nuclear installations that might be built in the future, any nuclear installations in countries that might become member states of the European Union in the future, and any accelerators

Figure II PROJECTED AMOUNT OF CLEARABLE STEEL SCRAP FROM DECOMMISSIONING COMMERCIAL POWER REACTORS IN THE EU (under the assumption that no new reactors are built)[2]



[2] Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations, Radiation Protection N° 89, 1998

ANNEX XI:

Table 1: Possible solutions for each identified problem area (the numbers refer to the subsections in section 2 where the issues are explained)

Problem	**Solution 1**	**Solution 2**	**Analysis**
2.2.1 Scientific progress (ICRP 103)	Amend methodology for dose calculation in BSS and revise dose limits for the lens of the eye		As dose calculation methodology and dose limits are explicitly stipulated in the current BSS Directive, there is from a legal point of view only one solution possible.
2.2.2 Insufficient protection of workers			
- Outside workers	Revise the BSS, impose an annual occupational dose limit and incorporate Outside Workers requirements	Revise BSS and impose an annual occupational dose limit	Both solutions provide uniform level of protection for these workers. Solution 1 would facilitate the clarification of the responsibilities of undertakings and employers.
- Workers in NORM industries	Strengthen the requirements on NORM industries in BSS	Establish guidance on NORM industries	Uniform protection of workers can only be achieved with Solution 1.
2.2.3 Health protection of patients and the public due to technical progress			
- patients	Strengthen requirements on justification and optimisation in MED Directive	Strengthen implementation of current requirements through guidance	Solution 1 and solution 2 should both enhance patient protection, but in certain areas it is expected that only binding legislation is effective.
- non-medical imaging exposures	Include specific requirements in the BSS and amend MED correspondingly	Amend MED Directive and issue guidance on non-medical imaging exposures	Solution 1 allows best protection of the public from these exposures.

2.2.4 Public exposure to natural radiation sources –radon and building materials	Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive(s) on radon and on building materials	Non-legislative measures such as guidance on national action plans for radon, recommendation on building materials	Solution 1.1 provides for best protection from natural radiation and is in line with the simplification objective.
2.2.5 Protection of the environment (non-human species	Legislative measures: 1. Extension of the scope of BSS Directive 2. new Directive on protection of the environment	Non-legislative measures such as guidance on the protection of the environment	Solution 1.1 offers the best coherence with the protection of human health from environmental radioactivity.

ANNEX XII

Working document: Comparison International and Euratom Basic Safety Standards

This document was drafted to give a comprehensive though not exhaustive overview of the differences in approaches and specific requirements in the international standards (draft 3.0) and the revised and recast Euratom Basic Safety Standards (version 24.02.2010, on which the Group of Experts had given an Opinion).

By and large this document is meant to be descriptive, and does not give views on the need for changes in the international standards, except with regard to the overall approach to natural radiation sources.

The Experts have been invited to discuss this document at their meeting on 3 – 4 June 2010 and where appropriate make recommendations either to IAEA or to the Commission. The Commission will forward the recommendations to IAEA and discuss these at the meeting of the BSS-Secretariat (with IAEA and other co-sponsors) Vienna on 25 June 2010.

The Comparison of the draft Standards has been completed to the extent possible with further relevant issues, brought forward by the Experts. This update will continue in order to provide eventually a comprehensive comparison of the different sets of requirements.

1. INTRODUCTION

Throughout the development of the revised international Basic Safety Standards (BSS) and the revised and recast Euratom Basic Safety Standards there has been good cooperation in order to ensure their consistency to the largest possible extent. The Commission has played an active role in the Secretariat of sponsoring organisations of the international standards. Representatives of EU Member States have provided comments to the different Committees of IAEA, especially RASSC. Reports on progress with the international standards have been presented at each meeting of the Group of Experts by IAEA representatives. The Group of Experts has so far never formally given its own views on the international standards. In view of the eventual co-sponsorship of the standards by the Atomic Energy Community it is now the right time to do so, since draft 3.0 has been sent to IAEA Member States for comment and it is envisaged that the final draft will be approved by the Committees by the end of this year. The Experts invite IAEA to consider these comments together with the comments and corrections that have been proposed by the Commission before the deadline for consultation (31.05.2010).

2. GENERAL COMMENTS

To a very large extent the Euratom and international standards are consistent. There are no essential points that are in contradiction. Numerical values are all the same, with the provisional exception of the definition of High Activity Sealed Sources, pending further consideration of the rationale of the two sets of values.

Nevertheless, there are notable differences. These results on the one hand from the constraint to make as little and few changes to the current standards as necessary. This justification of any changes was an essential component of the DPP for the revision of Safety Series 115, and in the spirit of the "recast" of Euratom Directives this applied to the revision of Council Directive 96/29/Euratom as well. Hence many differences which had appeared already in 1996 continue to exist. In addition, while both organisations started from ICRP Publication 103, they have given a slightly different interpretation to the introduction of planned, existing and emergency exposure situations in structuring the requirements. This does not matter too much since the main message of ICRP was that throughout the exposure situations the principles of radiation protection apply very much in the same way. Nevertheless, the allocation of responsibilities and the extent of regulatory control have been addressed in different ways for some situations, especially for exposure to natural radiation sources.

This has also led the Euratom Basic Safety Standards to choose a different structure. While initially both standards were developed along a structure reflecting the three exposure situations, Euratom Standards are now structured along the categories of exposure, occupational, medical and public, within which the differences in management along the exposure situations are reflected. This inversion of the matrix has no implications on content, but makes the comparison of the two standards more difficult.

In order to preserve consistency with the current standards, and for IAEA also with the Safety Fundamentals, the requirements use a different set of definitions. The concept of "facilities and activities" in IAEA is reflected in the definition of "Undertaking" in Euratom BSS. The latter definition incorporates better the concept of legal responsibility for the conduct of activities or the introduction of a radiation source. The term "radiation source" has a very general meaning in the Euratom Standards (including "facilities") and is further differentiated between radiation generators, radioactive sources, natural radiation sources etc.). This allows a more precise formulation of the requirements where the term "source" may be cause of confusion. **IAEA is invited to consider introduction of these definitions and explore whether their use would improve clarity of the text**.

The terminology of the Euratom Standards has been adjusted to the international standards on one important point. The requirements for regulatory control are now structured along the concepts of notification, registration and licensing (as opposed to reporting and prior authorisation in Directive 96/29). The graded approach to regulatory control has been worked out in more detail in the Euratom Standards however, and the differentiation between registration and licensing is more explicit. It should be noted that in principle all requirements in the Euratom BSS apply to Member States or to their competent authorities. It is for national law to transpose the requirements and for the authorities to impose them and ensure their enforcement. The international standards differentiate much more between requirements applying to different responsible parties, e. g. designers, employers, registrants and licensees, often with much more detail than in the Euratom Standards.

These different contexts and approaches have led to many small differences in formulation. The most notable differences with regard to requirements for occupational, public and medical exposure as well as on the protection of the environment are listed in a comprehensive albeit not exhaustive way in the next chapter. The more fundamental differences with regard to the approaches to natural radiation sources are discussed

separately. Finally, there are important differences in the application of the concepts of exemption and clearance, especially for naturally occurring radionuclides. With regard to artificial radionuclides, while both standards have now introduced the values in IAEA RS-G-1.7, the Euratom Standards give less prominence to the continued use of the old exemption values for "moderate amounts of material", and address more explicitly the role of specific clearance levels for specific materials and pathways of disposal. The Euratom approach allows a better optimisation of the management of materials arising e.g. from dismantling of nuclear facilities. **The Group of Experts hopes that these differences will be resolved through a careful redrafting of the international standards**. The Group of Experts also endorses the comments repeatedly made by the Commission, and now re-introduced with regard to draft 3.0, along the lines of this document.

The System of Protection as laid down respectively in Requirement 1 and Schedule III of the international BSS and Title III of the Euratom BSS are broadly the same, with some differences as a result of the different consideration given to planned and existing exposure situations. It should be noted however that in the Euratom BSS it is in general no longer foreseen that doses be integrated over periods longer than 1 year. The dose limits for the lens-of-the-eye are left open, pending ICRP advice, and dose constraints may apply also to organ doses, as a matter of precaution.

3. COMPARISON OF THE DRAFT STANDARDS

3.1. GENERAL

This chapter compares specific requirements in the international standards (Draft 3.0) with those in the Euratom Basic Safety Standards (draft 24.02.2010) with regard to occupational, public and medical exposures as well as with regard to the protection of the environment.

Draft 3.0, in contrast to the Euratom BSS, contains more detailed requirements, which are often addressed directly to the "responsible parties" (government, regulatory body, licensees and registrants, etc. – defined in Para. 2.40 and 2.41). This approach risks unnecessarily restricting implementation of radiation protection to what is "prescribed" while:

- the level of detail does not seem to correspond to the importance of the issue,
- the requirements and described responsibilities, however detailed, are not exhaustive, and
- the proposed rigid distribution of responsibilities does not allow for national differences and sometimes restricts too much the responsibility of a given party.

3.2. OCCUPATIONAL EXPOSURE

3.2.1. DIFFERENCES

IAEA PARAGRAPHS

3.77: workers exposed to radiation from sources not required by or directly related to their work shall receive "the same level of protection" as if they were members of the public.

Euratom: no such requirements, but for the operational protection of workers specific requirements only apply to those who are "exposed workers": … who are liable to receive doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

There was a similar requirement in Directive 96/29; the new Directive has been drafted so as to ensure the same level of protection without re-introducing it; the term "the same level of protection" is indeed ambiguous in legal terms, in particular for existing and emergency exposure situations where in some situations (e.g. radon in workplace) it may be understood to mean that the dose limit for public exposure would apply. **IAEA is invited to consider whether paragraph 3.77 offers any additional protection and otherwise delete it.**

3.115: no person under the age of 18 years is allowed to work in a controlled area unless under supervision and then only for the purpose of training for employment involving exposure to radiation or for students required to use sources in the course of their studies.

Euratom: In the Euratom BSS this is covered by Article 9: persons under 18 years may not be assigned to any work which would result in their being exposed workers, and Article 12.2: the limit for effective dose for apprentices (and students) aged between 16 and 18 years … shall be 6 mSv per year (as for category B workers).

In both cases the exposure of apprentices and students is restricted, either by their access to controlled areas or by the dose.

Schedule III: An effective dose of 20 mSv per year, averaged over five consecutive years.

Euratom: The dose limit for occupational exposure is now simply 20 mSv per year, without averaging. However, a higher effective dose may be authorised in a single year, subject to a maximum effective dose of 50 mSv, …

EURATOM ARTICLES:

Art. 6.2: categorisation of exposed workers (A or B) with an impact on individual monitoring (Art. 64) and medical surveillance (Art. 69 – 72)

IAEA: the international standards do not introduce different categories of workers but in 3.99 individual monitoring shall be undertaken, where appropriate, adequate and feasible, for any worker who is normally employed in a controlled area or who … may receive significant occupational exposure. No distinction is made between

the health surveillance of different categories of workers or different conditions of work.

Title II: Definitions of Radiation Protection Expert and Radiation Protection Officer

These definitions distinguish between the responsibilities of *experts* (give radiation protection advice) and of *officers* (designated by the undertaking to oversee the implementation of the radiation protection arrangements). The capacity to act as an RPE is recognized by the competent authorities. The RPO shall simply be "technically competent". The arrangements for the recognition of the experts (as well as for the medical physics expert) are laid down in Article 16. The responsibilities of the RPE are spelled out in detail in Article 19.

IAEA: Qualified expert. In the international standards this definition relates to the professional qualifications of an individual. In 2.21 (b) there is formal recognition of these experts by the relevant authority for taking up certain responsibilities (footnote 7)

The involvement of qualified experts is mentioned in several paragraphs throughout the text of the international standards.

3.2.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

WORKERS

3.79: recording of any report received from a worker (see 3.82)
Req. 22: Compliance by workers (3.81, 3.82)
3.86 (a): involve workers in optimization of protection and safety

Euratom: it is not appropriate for a Directive to put requirements on workers.

OPERATIONAL GUIDANCE

3.89: delineation of controlled areas
3.91: delineation of supervised areas
3.92 – 3.94: local rules and personal protective equipment

Euratom: it is not appropriate for a Directive to go into so much practical detail.

CONDITIONS OF SERVICE

Req. 27: no substitute for protection and safety
3.113: conditions of service for pregnant or breastfeeding workers

Euratom: these are basic principles of overall occupational health policy which do not need to be recalled specifically for work with ionizing radiation.

3.2.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

NATIONAL DOSE REGISTER

Article 67.1 (d) requires the results of individual monitoring to be submitted to a centralised network. In 67.2 provisions are made for a future European Radiation Passport for outside workers.

In the international standards there are requirements for the establishment of exposure records and for their transmission to workers and other employers registry (Para. 3.102 – 105), but no central. There is no reference to a radiation passport.

NATURAL RADIATION SOURCES

The approach to natural radiation sources in the Euratom standards is quite different from the international standards (see chapter 4 in this document). With regard to occupational exposure the most striking features of the Euratom standards are the following:

> Article 59.2 (second sentence): Where the effective dose to workers is less than or equal to 6 mSv per year the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for protection to be improved or the potential for doses to increase over time or as a result of changes in the process on work instructions.
>
> This requirement is an important element of a graded approach to regulatory control, which is missing in the international standards. **IAEA is invited to consider a similar graded approach for the Regulatory Control of occupational exposure, especially for workers in NORM industries.**
>
> Article 59.3 specifies the assessment and management of the exposure of aircrew to cosmic radiation. In addition, since in the Euratom standards the exposure to aircrew occurs within a planned exposure situation, the requirements for the protection of pregnant aircrew and the child to be born (Article 11.1) are fully applicable.
>
> In the international standards exposure of aircrew is regarded as an existing exposure situation, and the detail of its management is left for Member States to consider. **IAEA is invited to apply similar binding requirements for the protection of aircrew and for the registration of their exposure as in the Euratom Directive; indeed, the operation of airlines calls for international harmonisation.**

3.3. PUBLIC EXPOSURE

3.3.1. DIFFERENCES

IAEA addresses public exposure to consumer products more prominently than in the Euratom standards. See:

3.117: suppliers of consumer products
3.124: responsibilities of suppliers of consumer products
Req. 33: consumer products
3.137: consumer products shall not be made available to members of the public unless exempted or authorised for use by members of the public
3.138: responsibility of the regulatory body
3.139: compliance with the conditions of authorisation (including optimisation of design)
3.140 - 142: labelling and information

Euratom: 1) does not require labelling and information (but this could be part of conditions of use);
2) does not put requirements on the suppliers and designers of the products.

On the other hand the Euratom BSS (Art. 53.2 (b)) require licensing of the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods. The design features and conditions of use will be specified as part of the licence. The introduction of new types of apparatus or products is subject to justification, their use as a consumer product shall explicitly be permitted and a type-approval granted.

Hence the Euratom Standards achieve the same objective but put all responsibility on the licensing authority: the designer or supplier is not responsible for further uses. There is neither an explicit requirement for information of the user or distributor, nor for labelling: it is generally understood that such labelling is contrary to the concept of exempted consumer good, but it can nevertheless be requested by the licensing authority at the time of manufacture or import. Once the consumer good is placed on the market in the EU, no further trade restrictions should apply. However, since national authorities may conclude differently on the justification or type approval, the use of a consumer good may be prohibited or subject to notification; in order to avoid inconsistencies, competent authorities are required to allow for the information provided by other national authorities.

Schedule III (3b): averaging over five years (maximum 5 mSv) has been deleted in the Euratom Directive.

3.3.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

3.123: Impact outside the country

Euratom Treaty provisions under Article 37 allow the Commission to assess such impact; however, in the Joint Convention there is a similar requirement which may be taken up in legislation on waste management.

3.127: Visitors

A Euratom Directive does not require such detail; in addition the phrase "in cooperation with employers" makes this difficult to understand.

3.128: External exposure (details)
3.129: Avoid spread of contamination (implicit in Euratom)
3.130: Details of radioactive waste management (might appear in a specific legislation)
3.135: Access to monitoring data is foreseen in Articles 35 – 36 of the Euratom Treaty.

3.4. MEDICAL EXPOSURE

3.4.1. DIFFERENCES

Roles and responsibilities are distributed differently in the IAEA and the Euratom drafts:

- In draft 3.0 the *government* (Req. 34, Para.3.145-3.147) *and the regulatory body* (Req. 35, Para.3.148, 3.154, 3.163, 3.166, 3.167, etc.) have specific but quite limited responsibilities with respect to medical exposure while in the Euratom BSS the majority of the requirements are addressed to Member States (i.e. government).
- In draft 3.0 a great deal of responsibility is placed on "*registrants and licensees*" (Req. 36, Para.3.149-3.152, 3.160, 3.164, etc.), who shall ensure that "no person receives medical exposure" unless a series of conditions are fulfilled. In the Euratom BSS the requirements directly addressed to "undertakings" are limited to issues like QA and provision of information to patients and there are almost no prohibitive requirements (with the exception of examinations which "can not be justified").

Definitions:

medical exposure: Draft 3.0 mentions asymptomatic individuals in paragraph 3.149: ("whether asymptomatic or not …"). In the Euratom BSS these are grouped with, but are different from, patients. Draft 3.0 also does not refer to the intended benefit to the health or the wellbeing of the exposed person, as in the Euratom BSS. **IAEA is invited to give explicit consideration to asymptomatic individuals and to exposures benefiting to the well-being of the exposed person, in particular to sharpen the definition of non-medical imaging exposures.**

In the Euratom Directive (Article 5 (b)) medical exposures shall be "as low as reasonably achievable, commensurate with the medical purpose". "ALARA" is here to be distinguished from other contexts where economic and social considerations need to be taken into account. **The Experts believe that the mere reference to "commensurate with ..." is not sufficient.**

optimization *of protection and safety* for medical exposure: Draft 3.0 states that it is "management of the radiation dose to the patient commensurate with the medical purpose" without any reference to ALARA as is the case in the Euratom BSS.

radiological medical practitioner: Draft 3.0 defines the responsibilities of the *radiological medical practitioner* more rigidly, especially for justification of

medical exposure for individual patients (Para. 3.155). This is done in a more indirect and flexible way in the Euratom BSS by Art. 82.2 requiring that the exposure is undertaken under the clinical responsibility (including justification) of a radiological practitioner but allowing Member States to define the level of involvement of the practitioner and the referrer in justification process (Art. 82.1).

medical physicist: The role of the *medical physicist* is more specifically and with more detail defined in Draft 3.0 (Para. 3.152, 3.165, 3.166, 3.168, 3.169, etc.). The IAEA definition of medical physicist (MP) differs from the Euratom definition of medical physics expert (MPE) mainly in that the MP is defined by IAEA as "health professional" (i.e. recognized to practice a profession related to health).

medical radiation technologist: Draft 3.0 defines "*medical radiation technologist*", who is included in the list of "other parties who have responsibilities for protection and safety" (Para. 2.41) and is assigned to a number of tasks and responsibilities – Para. 3.161-3.163, 3.168, 3.173, etc. The Euratom BSS have no such definition.

There are the following differences with regard to ***justification***:

- Para. 3.149 (a) effectively prohibits *self-presentation*, which is not explicitly done in Euratom BSS. The same article requires information on the clinical context to be provided.
- Para. 3.149 (b) puts responsibility for justification on the radiological practitioner, in consultation with the referring medical practitioner. The Euratom BSS do not put so much emphasis on the role of the radiological practitioner.
- Para. 3.153 – only *alternative techniques* that do not involve medical exposure shall be taken into account, against the Euratom BSS requirement of taking into account also techniques involving less exposure (Art. 80.1).
- Para. 3.154 – *generic justification* shall be carried out by the health authority in conjunction with the appropriate professional bodies – missing in Euratom BSS.
- Para. 3.155 – there is a requirement that the practitioner shall take into account the *appropriateness* (missing in Euratom BSS) and the *urgency* of the request (required only for pregnant and breastfeeding women in the Euratom BSS – Art. 87.1).
- Para. 3.159 – exposure of *volunteers for biomedical* research is not justified if it doesn't comply with the Helsinki Declaration and the respective guidelines by the CIOMS and the recommendations of ICRP. No such references in Euratom BSS.

In Article 81 on Justification in the Euratom Directive, the requirements are to a large extent written in the passive "shall" style.

Para. 3.146 of draft 3.0 stipulates the government shall ensure that ***diagnostic reference levels*** *(DRLs*) are established against the weaker Euratom BSS requirements that Member States "promote the establishment" of DRLs.

3.4.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

Para. 3.152 (c) requiring that registrants and licensees shall ensure that ***sufficient medical and paramedical personnel*** are available as specified by the health authority does not have correspondence in Euratom BSS.

Para. 3.147 specifies that ***dose constraints*** are established as a result of consultation between the health authority, relevant professional bodies and regulatory body, which is not specified in Euratom BSS. Dose constraints are required only for research *volunteers* undergoing diagnostic investigations (in Euratom BSS this applies to all medical exposures but restricted to cases where there is no direct health benefit to the exposed person).

Para. 3.160 contains ***design considerations*** for the medical radiological equipment and software, which shall comply with the IEC and the ISO standards or to national standards "adopted by the regulatory body". This is out of the scope of the Euratom BSS, since design and pre-marketing phases of medical equipment are regulated under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[3].

Para. 3.165 – requirements for ***calibration***, missing in the Euratom BSS.

Para. 3.166 – detailed requirements for ***clinical dosimetry*** in relation to a "typical patient".

Para. 3.168-170 contains detailed (but not exhaustive and not specific to the type of the procedure) requirements on ***quality assurance***, which are absent from the Euratom BSS:

- Reference to "principles established by the WHO, PAHO and relevant professional bodies".
- QA shall include verification of physical and clinical factors used in patient diagnosis or treatment, records of procedures and results, periodic checks of dosimetry and monitoring equipment, QA audits.

Quite a few paragraphs require ***records and documentation*** for instance on personnel with radiation protection responsibilities (3.148 (c)), on advice by a medical physicist (3.152 (e)), on delegations of responsibility (3.152 (f) and 3.181 (a)), on training records (3.181 (b)), on calibrations and periodic checks of relevant clinical parameters (3.182), on data allowing dose assessment (3.183).

Para. 3.177-179 on ***unintended and accidental medical exposures***:

- 3.177 defines the main causes of unintended and accidental exposures (design flaws and operational failures of equipment and software and human errors) and puts the responsibility for reducing the likelihood of these exposures with the registrants and licensees. This can be too restrictive since design and software flaws are hard to predict and deal with by the licensees alone.
- 3.178 defines a (exhaustive) list of types of unintended and accidental exposures which should be investigated.

[3] The Directive's main purpose is to ensure that medical devices placed on the European market do not compromise the safety and health of patients, users and other individuals. The medical devices must meet the essential requirements for their design and construction, including those for justification of the intended use of the equipment on the basis of risk/benefit weighting and for incorporation of technical features for radiation protection of patients, users and other individuals. This is ensured, inter alia, through a system of harmonized standards issued by the European standardization organizations (CENELEC in this case), pre-market conformity assessment procedures and appropriate supervision by the competent authorities.

3.4.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

unintended and accidental medical exposures: the requirement in Euratom BSS Art. 88 (b) that the QA programme for radiotherapeutic practices shall include a study of risk of accidental or unintended exposures is missing in draft 3.0 (see Para. 3.177-179 above).

While the international standards highlight quality assurance and introduce the concept of "radiological reviews" (Para. 3.180), this does not match the more powerful Euratom concept of "***clinical audit***" (Article 83.4).

Draft 3.0 does not contain a requirement for ***estimating population doses*** from medical exposure procedures, as in Euratom BSS (Art. 89).

3.5. PROTECTION OF THE ENVIRONMENT

Both standards address the protection of the environment but in different ways. In principle, the protection of the environment has a prominent place in draft 3.0. It is part of the objectives of the international standards and is specifically addressed in one of the Fundamental Safety Principles referred to in the first chapter of draft 3.0 (Para.1.7 and 1.26). Whenever draft 3.0 speaks about radiation risks, the risks to ecosystems are included in this term (footnote 6 and Glossary), for instance when setting up legal frameworks and regulatory control (Para.2.13 and 2.14), and making arrangements for the protection of the environment (Para.2.25). However, further on in the draft 3.0 there are only general requirements with regard to the protection of the environment for discharge authorisation (Para.3.122 and 3.131), emergency (Para.3.42, 4.2 and 4.5) and monitoring programmes (Para.2.23), and it is difficult to detect if these requirements are issued to protect the environment itself or it they are set to protect the environment as being a resource to humans (food production, recreation, industrial use). In the first case both Standards have the same set of requirements but the Euratom BSS is more to the point consolidating all requirements for the protection of non-human species in one Title. In the second case the Euratom approach is indeed more elaborate as it includes a separate Title with clear and well-balanced requirements for the radiation protection of non-human species while leaving sufficient flexibility for Member States to adopt these requirements to national situations.

4. DIFFERENT APPROACHES WITH REGARD TO NATURAL RADIATION SOURCES

Both set of standards have a comprehensive approach towards natural radiation sources. The Euratom BSS are more explicit when it comes to actual requirements, mainly for building materials where the international standards basically have only one specific requirement, but also for NORM industries, aircrew and radon. The main difference exists however on a philosophical level – whether to classify the different exposure situations as planned or existing according to ICRP terminology.

4.1. NORM

Although the Euratom BSS are clearer about which specific requirements concern NORM, these industries are essentially regulated in the same way in both standards and the same exemption, clearance or threshold values apply, for the benefit of international harmonisation. The Euratom BSS have explicitly incorporated NORM industries in the framework for practices in a planned exposure situation (Title VI), while the international standards regard them as existing exposure situations while applying the requirements in Section 3, Planned Exposure Situations (Para.3.4). Another difference is that the Euratom BSS use the assessment of doses to workers as a tool for identifying the appropriate level of regulatory control and measures to be taken for the protection of workers (above 6 mSv/y then licensing and full range of requirements in Title VII, between 1-6 mSv/y then registration or licensing and merely requiring undertakings to regularly review exposures) (Art.53), whereas draft 3.0 leaves it to the Member State to decide on which requirements in Section 3 Occupational Exposure (Para.3.68-3.115) should apply. The Euratom BSS also consider doses to members of the public when requiring authorisation for NORM industries (public exposure ≥0.3 mSv/y) (Art.53.3.(f)), while draft 3.0 gives no indication of such a criterion. The Euratom Directive is much more clear about which industries may be of concern by introducing a list of industrial sectors (Annex 8).

4.2. RADON

For radon in dwellings or buildings with public access the approaches are the same in both standards and they both use 300 Bq/m3 as the upper boundary on the reference level for existing buildings. Terminology differs slightly where the Euratom BSS talk about buildings with public access (Art.100) when draft 3.0 uses the term "other buildings with a high occupancy factor of the public" (Para.5.19). Draft 3.0 includes kindergartens, schools and hospitals in that term (footnote 35). The Euratom BSS are more specific about the content of a national action plan for radon (Annex 13) and specify also which types of exposure to radon this plan should include - radon exposures in dwellings, buildings with public access and in workplaces, from all sources of radon: soil, building materials or water (Art.38.1). The IAEA approach is to demand an action plan, if appropriate, for public exposure to indoor radon (Requirement 50). Concerning reference levels there are two further differences: Draft 3.0 does not include a requirement for setting reference levels for new buildings and it does not contain any requirements for setting reference levels for the "other buildings with high occupancy factors of the public".

With regard to radon in workplaces; the basic requirements are the same as well as the upper boundary for the reference level (1000 Bq/m^3). In reality there are no major differences between the standards on this point.

4.3. COSMIC RADIATION

While exposure to aircrew is addressed in both standards, the Euratom BSS offer detailed requirements such as clarifying what kind of measures to take with regard to occupational doses depending on the dose to the aircrew (Art.59.3). Draft 3.0 includes a more general requirement on the possible assessment of doses to aircrew and subsequent requirements for occupational exposure (Para.5.30). With regard to space crew the Euratom BSS treat this as a specially authorised exposure where specific requirements apply (Art.77.3) whereas draft 3.0 requires that a framework for radiation protection applicable to humans in space-based activities is established, when appropriate (Para.5.31). Another difference is that the Euratom Directive regards both types of

exposure as planned exposure situations while draft 3.0 regards them as existing exposure situations.

4.4. BUILDING MATERIALS

With regard to exposure to building materials both standards address this as an existing exposure situation. The Euratom BSS are however much more specific in terms of requirements. While draft 3.0 merely requires that reference levels are set (Para.5.22) that would generally not exceed around 1 mSv/y, the Euratom BSS allocate a whole section of the Directive to new requirements for building materials (Art.101), based on earlier guidelines (RP 112). The aim is to address exposure from building materials in a clear and comprehensive way and enable harmonisation between Member States and smoother trans-boundary movement of these types of material. Another difference is that the Euratom Directive defines the term building materials, deliberately not using the wider term construction material, while the draft 3.0 mentions construction materials without defining the term.

4.5. EXEMPTION AND CLEARANCE

With the introduction of the IAEA RS-G-1.7 values as exemption and clearance levels in the Euratom BSS, the two standards have the same set of values for exemption and clearance. For natural radiation sources the draft 3.0 Schedule I (Para.I-4) gives Member States a large degree of flexibility by stating that exemption should be made on a case by case basis and refers to levels commensurate with natural background levels. On the other hand paragraph 3.4(a) indicates that 1 and 10 Bq/g should be used to detect when an activity should be regulated as a planned exposure situation. This is confusing. For clearance however, draft 3.0 gives the levels 1 and 10 Bq/g. The Euratom BSS also use those values with the difference that they should be used as both exemption and clearance for natural radiation sources. The Euratom approach is more coherent, in particular as it not only sets general criteria for artificial radionuclides but introduces exemption and clearance criteria for natural radionuclides as well (in the order of 0.3 mSv/y or less for members of the public and 1 mSv/y for workers). Furthermore, the Euratom BSS include a comprehensive and cautious use of the clearance criterion for NORM residues, in particular for recycling in building materials and in case of ground water contamination. IAEA is further invited to include relevant isotopes of Uranium and Thorium, Table I-2, for application to clearance of materials arising from the dismantling of nuclear installations such as uranium enrichment or fuel fabrication plants (on the basis of the 10 mSv exemption criterion).

Recommendation: It should be made clear in the international standards what values to use as exemption levels for natural radionuclides. It would also be beneficial to introduce a dose criterion for clearance of natural radionuclides, indicating that if drinking water supplies might be affected this would call for special attention. Basically the whole Schedule I would need to be rewritten. At least the paragraphs in draft 3.0 Schedule I that cause confusion should be deleted, pending on more thorough revision:

- Schedule I Para.I-4
  This paragraph is still very confusing. The restriction to "other than incorporated into consumer products…" is redundant with footnote 42. The intention is probably to provide for exemption of bulk amounts. There is no need for such exemption since the scope of "planned exposure situations" is already defined in

Para.3.4. A case by case assessment in relation to doses to individuals (workers?) of about 1 mSv per year would only apply for the application for instance of requirements for occupational exposure (after assessment of doses when the concentration exceeds the levels defined in Para.3.4, so on a retrospective basis, not for prospective exemption).

- Schedule I Para.I-5 (b)
  It is redundant to include the levels defined in Para.3.4 as clearance levels, since this is the entry point for a planned exposure. In addition, despite footnote 45 this may still easily be misunderstood as applying to building materials or to situations where the residues of NORM industries would contaminate groundwater. There is no clearance criterion (in dose) for natural radionuclides. The criterion in Para.I-4 is more useful in the context of clearance (case-by-case assessment on the basis of a dose criterion which should not exceed 1 mSv per year). However this would require a full restructuring of the requirements or of Schedule I.

5. FURTHER ISSUES IDENTIFIED BY THE ARTICLE 31 EXPERTS

5.1. NON-MEDICAL HUMAN IMAGING EXPOSURE

5.1.1. DIFFERENCES

IAEA PARAGRAPHS

3.61. The government shall ensure that the measures described in para. 3.16 for the justification of practices are applied to any imaging procedure that exposes humans to radiation not intended for diagnostic or therapeutic purposes. The justification process shall consider, inter alia,
(a) Appropriateness of the radiation equipment for the proposed use.
(b) The use of alternative techniques that do not utilize ionizing radiation[4].
(c) The benefits and detriments of implementing the procedure
(d) The benefits and detriments of not implementing the procedure.
(e) Evaluation of various radiation technologies available, including the effectiveness and limitations of the procedures.
(f) Availability of sufficient resources to safely conduct the imaging procedure during the intended period of use.
(g) The impact of any legal or ethical issues which may be raised by the use of the technology

Euratom: Items (a) and (c) to (g) are not considered.
Item (b), referring to alternative techniques, differs from EURATOM item (f) of Annex 16 in as far as IAEA requires the use of alternative techniques that do not utilize ionizing radiation to be considered as part of the justification whereas EURATOM

[4] Such techniques may include manual examination, electrical and magnetic source imaging, ultrasound and sonar, magnetic resonance imaging, microwave imaging, terahertz imaging, infrared imaging and visible imaging

requires that alternative techniques which do not involve exposure to ionising radiation are available where the exposure is routinely carried out for security purposes. This item (b) is believed to be redundant (it applies to justification also in other contexts). The Euratom requirement is in addition to justification.

5.1.2. IAEA REQUIREMENTS WITH NO CORRESPONDING EURATOM TEXT

IAEA PARAGRAPHS

3.18. Human imaging using radiation performed for occupational, legal or health insurance purposes, and undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the justification of such imaging is to be considered, the requirements of paras 3.60 to 3.64 shall apply.

Euratom: no such statement.
However, the list of practices in Annex 16 and the list of the exceptional circumstances mentioned by IAEA (note 19 of para 3.64) are the same.

3.19. Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

Euratom: no such statement

3.66. Registrants and licensees shall ensure that all persons that are about to be exposed to radiation for inspection procedures, are informed about the possibility of choosing an alternative technique that does not use ionizing radiation, where vailable.

Euratom: guarantee that people are informed is not required

5.1.3. EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Art. 49.3: Practices involving the deliberate exposure of humans for non-medical purposes

(e) Informed consent of the individual to be exposed is sought, allowing for cases when the law enforcement bodies may proceed without consent according to national legislation.

IAEA: informed consent is not sought

(d) Relevant requirements of Title VIII, including those for equipment, optimisation, responsibilities and special protection during pregnancy, are

met for procedures implemented by medical staff using medical radiological equipment.

IAEA: special protection during pregnancy is not mentioned

5.2. GENERAL REQUIREMENTS

5.2.1. SCHEDULE III: TABLE III-I. CONVERSION COEFFICIENTS FOR RADON AND THORON PROGENY

Comment: These coefficients are really obsolete: those for radon are taken from ICRP 65 (1993) and were criticised in the 2009 ICRP Radon statement (2009), those for thoron are taken from ICRP 50 (1987) and they were repeatedly declared scientifically incorrect in international literature. ICRP has announced the publication of new dose coefficients.

Euratom: no mention to dose conversion coefficients for radon and thoron. Reference in general is made in article 14 (b)

> "For internal exposure from a radionuclide or from a mixture of radionuclides…ingestion and inhalation dose coefficients in the international basic safety standards published by IAEA shall be used to estimate the effective doses".

In this way Euratom will also adopt these dose conversion coefficients

IAEA is invited to delete Table III–I pending receipt of new dose coefficients from ICRP

SCHEDULE III: DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

For occupational exposure of workers over the age of 18 years, the dose limits are:

…

(b) An equivalent dose to the lens of the eye of 150 mSv in a year;

Euratom: The Experts asked to the Commission to establish a lower value, even if ICRP would not do it, in view of abundant scientific evidence of a higher risk than estimated in the past.

5.2.2. SCHEDULE IV: CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE

TABLE IV-1: GENERIC CRITERIA FOR ACUTE DOSES AT WHICH PROTECTIVE AND OTHER ACTIONS ARE EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES TO AVOID OR MINIMIZE SEVERE DETERMINISTIC HEALTH EFFECTS

Euratom: no generic criteria to prevent severe deterministic effects is made

5.2.3. SCOPE

Art.3: Exclusion ("This Directive shall not apply to …") of radionuclides not usually contained in the human body…

IAEA: Para. 1.31: These Standards shall apply to all situations that are amendable to control (footnote 3 gives some examples of the opposite).

5.3. OTHER EURATOM REQUIREMENTS WITHOUT CORRESPONDENCE IN THE INTERNATIONAL STANDARDS

Metal scrap and orphan sources:

Art. 28.2: Member States shall make arrangements for the establishment of systems aimed at detecting orphan sources in places such as **large metal scrap yards and major metal scrap recycling installations** ...

and

Art. 29: Metal contamination

IAEA: possible melting of a source in metal foundry is not mentioned.

Miscellaneous:

Art. 97 and 98, annex 12A and B: information of the public

IAEA: information of the public is not mentioned

Art. 48: Prohibition of the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import or export of such goods.

IAEA: such practices are not prohibited but only "deemed to be unjustified".

Art. 82.3: The practitioner shall ensure that the patient or legal guardian is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent.

IAEA only information of the patient is required, informed consent is not required.

Natural radiation sources (see also section 4):

Art. 50: Member States shall ensure the identification of NORM industries which cannot be disregarded from the radiation protection point of view, taking the list of industrial sectors in Annex 8 into account

IAEA: No establishment of a list of NORM industries is required

Reading and comparing par. 3.4 and 5.1 (b) it is not clear how agricultural fertilizers and soil amendments should be considered.

A contradiction seems to be present between para 5.22 and 5.23. Drinking water cannot have a reference level of 1 mSv/y, because WHO recommended a reference level of 0.1 mSv/y, moreover a reference level of 1 mSv/y from each of the cited sources is not acceptable.

It is also not clear how building materials should be managed.

ANNEX XIII

CONSULTATION WITH FOREATOM[5]

The last draft version of the Euratom Basic Safety Standards Directive (Council Directive 96/29) was released on 24 February 2010. This draft has taken into account the ICRP recommendations in Publication 103 by structuring the requirements along the concepts of planned, existing and emergency exposure situations.

ENISS (The European Nuclear Installations Safety Standards) has in accordance with its working procedures set up special expert groups on radiation protection and on exemption and clearance in relation to decommissioning, with the mission to follow the revision of the Euratom BSS. As the revision process has advanced in parallel to the revision of the IAEA BSS the same expert groups have worked on the IAEA draft. ENISS welcome the fact that the fundamental requirements in the two documents are very close, while the draft Euratom BSS is much more concise, easier to read and thus should prove easier to be transposed into national regulations. You will find enclosed the industry detailed comments on the draft BSS.

The members of the ENISS Radiation Protection Expert Group have welcomed the opportunities that have been given during the revision process of the Euratom BSS to meet and discuss with you items of special concern. We would therefore very much appreciate a new opportunity to meet you again to discuss in detail the new draft of the BSS.

At present, the Council Directive 96/29 is the basis of all regulations regarding radiation protection in EU Member States and it has been proven effective and sufficient since it came into force. From our experience we thus do not see the necessity of significant changes. This view largely goes in line with ICRP 103, proclaiming in essence "continuity and stability". Therefore some proposed changes in the draft BSS raise our concern and we are not convinced that the envisaged changes in the radiation protection system will enhance worker or public safety and health or offer a better protection of environment.

Optimisation and the use of dose constraints

Optimisation is one of the major guiding principles according to the ICRP system of radiation protection. The radiation protection expert group of ENISS would therefore like to emphasise its importance for radiation protection in general and in particular for the continuing trends of decreasing radiation doses in nearly all industries using ionizing radiation. The concept of dose constraints already introduced by the ICRP long time ago can be viewed as one of the tools that could be used in the optimisation process.

According to the ALARA principle, licensees have for decades optimised radiation protection, starting at the design of the new facility up to the day to day optimisation of protection, including the wide use of experience feedback. Thus it seems appropriate to consider the setting of dose constraints for occupational exposures as a tool used by licensee and employer, under their responsibility, in the optimization process. In this

[5] FORATOM ENISS comments dated 19 November 2010

context, the licensee may use the term constraint for designing the maximum target dose for an operator doing a particular task or the target collective dose for a team doing a particular maintenance task. It could also mean the target dose for workers and subcontractors during a year, based on the planned activities. The definition of the dose constraint is therefore not essential for setting an efficient radiation protection management system resulting in decreasing dose trends. Consequently having too strict definitions or a dependency of some regulatory supervision might act contradictory and lead to a change of a system that has worked very well. Accordingly, ENISS proposes that the general frame of optimisation should be addressed more clearly in the BSS, along with the establishment of dose constraints.

Radiation protection officers and experts

In the current draft, the role of the "qualified expert" in the Council Directive 96/29/Euratom has been split between two functions: the radiation protection expert and the radiation protection officer. ENISS does not see any reason behind such a change. In addition, almost all the responsibilities are given to the radiation protection expert. A better balance must be achieved between the tasks requiring an expertise and the practical implementation of protection carried out by the radiation protection officer.

In addition the current version of the BSS gives most of the responsibility for the occupational exposure to the undertaking. This is a shift from current practice in many Member States where the responsibility for the protection of workers lies mainly with the employer. We suggest, whenever possible, to leave the flexibility and let national regulations assign the responsibilities between undertaking and the employer.

Exemption and clearance

The ENISS special expert group on exemption and clearance has through a questionnaire collected data of current practices of clearance in the different EU Member States using nuclear energy and Switzerland. The responses showed that the strategies in the respective countries were to large extent based on the current recommendations of the European Commission. In the Draft EURATOM Basic Safety Standards Directive the clearance levels endorsed for the sake of international harmonization are coming from the IAEA recommendations (RS-G-1.7) and not from the respective EU guidance documents that have been issued on general clearance levels for any type of material [RP 122 part 1]. The EC guidance on clearance levels – the general clearance levels (see above) as well as clearance levels for metals [RP 89], for buildings and building rubble [RP 113] – has received a lot of positive attention internationally and it is commonly assumed that they are scientifically even better founded than the IAEA guidance levels. Concomitantly, several European Member States, with large decommissioning projects ahead, have recently issued new regulations on clearance based on the current EC guidance. The EU members of ENISS therefore proposes that the BSS Directive should contain the general clearance levels from EU recommendation RP 122/1 instead of IAEA exemption levels from RS-G-1.7 and directly incorporate the levels from EU recommendations RP 89 and 113, in order to harmonise the clearance levels in the EU Member States (see appendix to the ENISS comments on the draft BSS).

Protection of the environment

In the draft Euratom BSS requirements for the protection of the environment have been laid down. However, neither the underlying principles for the suggested actions nor any definitions on the environment are stated. In addition, there are large numbers of open scientific and technical questions still to be solved in this field which makes the suggested detailed requirements doubtful. ENISS would be opposed to enlarge the regulatory and surveillance efforts and waste human and monetary resources without being sure of improving radiation protection of the environment.

ANNEX XIV

Comparison of options 2 to 6

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Economic					
Functioning of the internal market	(+) competitiveness of NORM industries due to harmonised regulation	(+) competitiveness of NORM industries due to harmonised regulation	(+) 1. competitiveness of NORM industries due to harmonised regulation 2. harmonised labelling and control of building materials	(+) competitiveness of NORM industries due to harmonised regulation	(+) 1. competitiveness of NORM industries due to harmonised regulation 2. harmonised labelling and control of building materials
Administrative burden on businesses	(+) reduction of dismantling costs by better application of the concept of clearance	(+) reduction of dismantling costs by better application of the concept of clearance	(+) reduction of dismantling costs by better application of the concept of clearance (-) cost for monitoring and labelling of building materials	(+) reduction of dismantling costs by better application of the concept of clearance (-) monitoring and assessment of environmental impact	(+) reduction of dismantling costs by better application of the concept of clearance (-) 1. cost for monitoring and labelling of building materials 2. monitoring and assessment of environmental impact
Regulatory authorities	(-) transposition into national law	(+) overall coherent set of legislation	(-) New requirements, extended scope	(-) New requirements, extended scope	(+) overall coherent set of legislation (--) New requirements, extended scope

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Environment					
Protection of the environment	(+) regulating residues and effluents from NORM	(+) regulating residues and effluents from NORM	(+) regulating residues and effluents from NORM	(++) 1. regulating residues and effluents from NORM	(++) 1. regulating residues and effluents from NORM

	industries	industries	industries	industries 2. better demonstration and understanding of protection of non-human species	industries 2. better demonstration and understanding of protection of non-human species

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Social and Health					
Health and safety at work	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(++) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye 3. Better Protection of Outside Worker through clearer assignment of responsibilities to the undertaking and the employer	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(+) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye	(++) 1. Equal treatment of workers in all industrial sectors. 2. Reduction of the dose-limit for the lens of the eye 3. Better Protection of Outside Worker through clearer assignment of responsibilities to the undertaking and the employer
Mobility of workers and experts	(+) Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers 2. Radiation passport for outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers	(+) 1. Harmonisation of dose limits eases mobility of outside workers 2. Radiation passport for outside workers
Protection of patients	(+) Better justification of medical examinations and corresponding reduction in number of exposures	(+) Better justification of medical examinations and corresponding reduction in number of exposures			(+) Better justification of medical examinations and corresponding reduction in number of exposures
Protection of the public	(+) Regulation of non-medical	(+) Regulation of non-medical	(++) 1. Regulation of non-	(+) Regulation of non-medical	(++) 1. Regulation of non-

	imaging exposures	imaging exposures Guidance on radon and protection of non-human species	medical imaging exposures 2. Reduction of lung cancer incidence through binding requirements on radon in dwellings	imaging exposures	medical imaging exposures 2. Reduction of lung cancer incidence through binding requirements on radon in dwellings

Impact	Option 2	Option 3	Option 4	Option 5	Option 6
Coherence and clarity of legislation	(+) 1. Clearer requirements 2. Graded approach to regulatory control	(++) 1. Clearer requirements 2. Graded approach to regulatory control 3. Simplification and integration of five Euratom Directives	(+) 1. Clearer requirements 2. Graded approach to regulatory control 3. Commission recommendation indoor radon incorporated in Directive	(+) 1. Clearer requirements 2. Graded approach to regulatory control 3. Coherent approach to protection of man and the environment for authorisation of effluent discharges	(++) 1. Clearer requirements 2. Graded approach to regulatory control 3. Simplification and integration of five Euratom Directives 4. Comprehensive framework for all exposure situations 5. Commission recommendation indoor radon incorporated in Directive 6. Coherent approach to protection of man and the environment for authorisation of effluent discharges
International coherence	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(+) 1. Exemption and clearance levels, 2. Overall approach and definitions	(++) 1. Exemption and clearance levels, 2. Overall approach and definitions

	3. Requirements for authorisation of practices	3. Requirements for authorisation of practices 4. Harmonisation of categorisation of sealed sources	3. Requirements for authorisation of practices 4. Protection against indoor radon exposure in the same way as international standards	3. Requirements for authorisation of practices 4. Protection of the environment covered in the same way as in the international standards	3. Requirements for authorisation of practices 4. Harmonisation of categorisation of sealed sources 5.Full range of exposure situations and categories of exposure, including environmental exposures, covered in the same way as in the international standards
Overall impact	+	++	++	+	+++