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COMMISSION STAFF WORKING DOCUMENT

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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This working document is intended for use by European Commission staff and is for information only. It does not represent an official position of the Commission on this issue, nor does it anticipate such a position.

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.

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

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

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 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

[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.

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.

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):

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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

– 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 affected regions extend all over Europe.

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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.

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].

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

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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)

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).

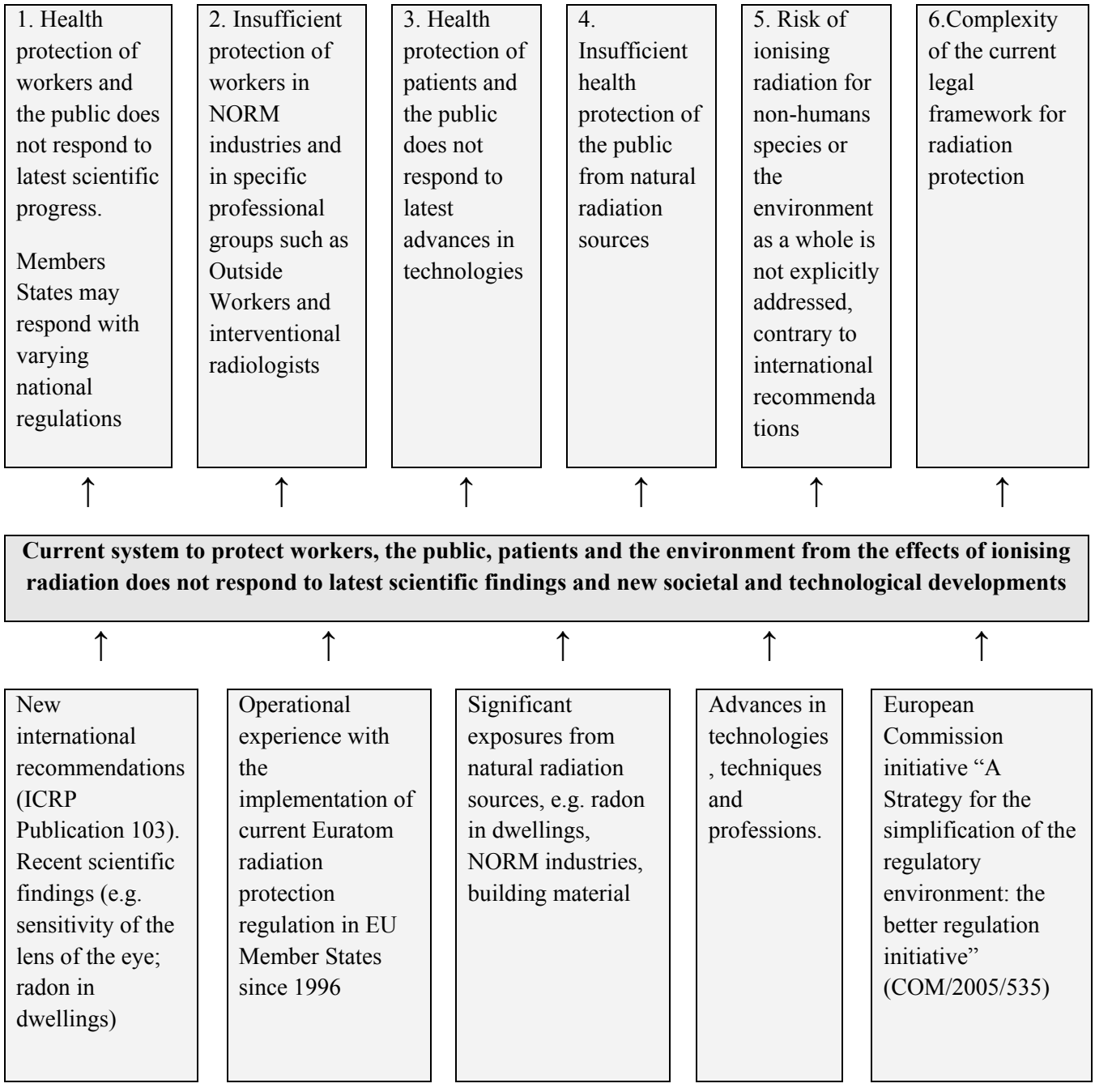
There are two main reasons why referring to or incorporating the International BSS in Community legislation is not feasible. On the one hand, the Euratom Community is bound by the Treaty to establish uniform basic safety standards. Incorporating the International BSS in a community act is difficult. 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 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

[15] EUROSTAT Basic Statistic for 2007

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

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 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].

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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

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

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 maximum reference level of 300 Bq/m^3 rather than 400 Bq/m^3 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

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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

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 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

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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)

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)

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.

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

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

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.

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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)

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 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

[34] EUROSTAT Basic Statistic for 2007

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 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.

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

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

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.