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Subject:	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

Delegations will find attached Commission document SWD(2012) 137 final VOLUME 2.

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EUROPEAN COMMISSION

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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

{COM(2012) 242 final}
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ANNEX I

Organisations in Radiation Protection

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

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

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

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

International Radiation Protection Association (IRPA) is an international non-profit organisation that enlists individuals as members who are also members of an affiliated national or regional Associate Society. Today, there are 46 associated societies around the world with membership of nearly all professionals with operational responsibilities in

radiation protection. The primary purpose of IRPA is to provide a medium whereby those engaged in radiation protection activities in all countries may communicate more readily with each other and through this process advance radiation protection in many parts of the world. This includes relevant aspects of such branches of knowledge as science, medicine, engineering, technology and law, to provide for the protection of man and his environment from the hazards caused by radiation, and thereby to facilitate the safe use of medical, scientific, and industrial radiological practices for the benefit of mankind.

International Atomic Energy Agency (IAEA) is an independent international organisation, related to the United Nations system, which seeks to promote the peaceful use of nuclear energy. The IAEA was established as an autonomous organisation on 29 July 1957 with headquarters in Vienna, Austria. Today, IAEA has 151 member states. The IAEA serves as an intergovernmental forum for scientific and technical cooperation in the peaceful use of nuclear technology and nuclear power worldwide. The programs of the IAEA encourage the development of the peaceful applications of nuclear technology, provide international safeguards against misuse of nuclear technology and nuclear materials, and promote nuclear safety (including radiation protection) and nuclear security standards and their implementation. A big part of the IAEA´s statutory mandate is the establishment, and promotion, of advisory international standards and guides. The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionising radiation. They are issued in the IAEA Safety Standards Series, and cover nuclear safety, radiation protection, radioactive waste management, the transport of radioactive materials, the safety of nuclear fuel cycle facilities and quality assurance. The main document in radiation protection is Safety Standard 115 "International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources", edition 2003. These Standards, co-sponsored by FAO[1], ILO[2], OECD/NEA[3], PAHO[4] and WHO[5], are based on assessments of the biological effects of radiation made by the United Nations Scientific Committee on the Effects of Atomic Radiation, and on the recommendations of the International Commission on Radiological Protection and the International Nuclear Safety Advisory Group. In 2006 IAEA together with the cosponsors undertook revision of Safety Standard 115. This is ongoing activity also driven by the new ICRP Recommendations 103, published in 2007.

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

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

[1] Food and Agriculture Organisation of United Nations
[2] International Labour Organisation
[3] Organisation for Economic Cooperation and Development, Nuclear Energy Agency
[4] Pan American Health Organisation
[5] World Health Organisation

ANNEX II

Projects, Studies, Scientific Radiation Protection Publications

A. Summaries of the scientific publications, projects and studies

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

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

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

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

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

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

2. **European Study on Occupational Radiation Exposure** (ESOREX)**.** The ESOREX was established in 1997 to collect information on how individual monitoring is structured in MS and how data are recorded and reported. The project consisted of surveys on radiation monitoring and exposure of workers for the period from 1995 to 2005. The data collected have allowed statistical evaluation of occupational radiation exposure in different work sectors. The analysis of different years allowed the evaluation of changes and trends after the implementation of the BSS Directive 96/29.

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

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

- To allow free movement of outside workers within Europe it is necessary to establish a harmonised dose limit for occupational exposure. It is therefore recommended to abandon the current dose limit of 100 mSv averaged over 5 years (with a yearly maximum of 50 mSv) and to introduce a single year dose limit of 20 mSv.

- The establishment of a national dose registry allows tracking the doses of exposed workers nationally, in particular the doses of outside workers.

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

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

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

proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts. These proposals aim to establish harmonised environment for the recognition of these specialist and to contribute to the free movement of these experts.

5. **International Conference on Modern Radiotherapy: 'Advances and Challenges in Radiation Protection of the Patients',** organised by the French Nuclear Safety Authority in cooperation with the International Atomic Energy Agency, the World Health Organization and the European Commission from 2 to 4 December 2009 in Versailles[6]. During this conference detailed consideration has been given to the "accidental or unintended exposures" of patients following the several cases of such accidents that occurred in recent years (France, Belgium…).

6. **International Conference on Justification of Medical Exposure in Diagnostic Imaging**, organised jointly by the International Atomic Energy Agency and the European Commission from 2 to 4 September 2009 in Brussels[7]. Despite these initiatives, the approach to and compliance with justification is weak in diagnostic radiology and nuclear medicine. Work within the EU SENTINEL Project and a number of IAEA consultations confirm this. It is also probable that there are significant justification problems in radiological practice in the developing world. In the West, recent studies indicate that >20% of examinations may not be appropriate; this can be as high as 45% in special cases, and up to 75% for specific techniques. This situation should be tackled promptly, particularly as tools are now available to improve it. The sense of urgency about the problem is reinforced by newer high dose activities in radiology, newly available tools for justification and clinical audit, the ongoing revision of the IAEA Basic Safety Standards (BSS), the recasting of the European Directives, and the requirement for an effective regulatory approach in a sensitive area. These developments are happening against a background of worryingly increasing medical radiation doses, and the American College of Radiology (ACR) white paper noting "The rapid growth of CT and certain nuclear medicine studies may result in an increased incidence of radiation-related cancer in the not-too-distant future". These concerns provide additional motivation for dealing with justification. Finally there is a need to align medical justification with contemporary ethical and social thinking.

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

8. **International Symposium on Non-Medical Imaging Exposures**, organised by the European Commission on 8 and 9 October 2009 in Dublin. The objective of the symposium was to collect up-to-date information and exchange experiences on non-medical/medico-legal exposures, identify the issues of concern and discuss the ways of addressing them in a revision of the Euratom BSS Directive. The meeting concluded that it is clear that there is a need to retain the level of protection and justification that applies to medical exposures, as defined in the current Medical Exposure Directive. However in

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

doing this it is also necessary to ensure that the over-arching framework is such that all practices are regulated and appropriate levels of control are in place. It was clear that the single most important issue in this area is justification and that this must be applied for every practice and individual exposure. The conclusions supported the exclusion of the medico-legal exposures from the legal definition of medical exposure and grouping them together with other similar cases under the new term 'non-medical imaging exposures', for which a detailed new approach should be proposed in the revised BSS Directive.

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

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

2. Radiation Protection N° 112 "Radiological protection principles concerning natural radioactivity of building materials". The purpose of this publication is to provide guidance for establishing regulatory control of building materials containing enhanced levels of natural radioactivity. The report recommends the establishment of a dose criterion for introducing regulatory control and proposes a methodology for screening material (using an Activity Index formula) to see if the dose criterion is complied with. The study which formed the basis for the report, see RP 96 Enhanced radioactivity in building materials, also included information about national regulation on natural radioactivity in building materials. In 1997 when the RP 96 was published only five Member States had legislation and the Activity Index formula used to screen material varied between those countries.

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

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

Part II "Application of the concept of exemption and clearance to natural radiation sources". The application of the concepts of exemption and clearance to natural radiation

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

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

4. Radiation Protection N° 130 "Medico-legal exposures, exposures with ionising radiation without medical indication". Proceedings of the International Symposium, organised by the Commission in 2002[8]. According to the Medical Exposure Directive, all individual exposures are supposed to be justified both by the prescriber and by the practitioner, each with respect to their own expertise and area. In cases where a medical doctor is asked by an insurance company, judge, employer etc. to provide advice and/or a conclusion about the physical state of a person, it is likely that X-ray will be indicated to complete the assessment. However, there are situations where the medical doctor is effectively directed to use X-rays by an employer, judge etc. In those cases, the one who orders the X-ray becomes the prescriber.

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

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

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

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

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

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

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

8. Radiation Protection N° 156 "Evaluation of the Implementation of Radiation Protection Measures for Aircrew". The study concluded that current requirements in Directive 96/29/Euratom lead to a satisfactory protection of aircrew against the dangers arising from cosmic radiation and that there is no area where requirements would be incomplete or where regulations would clearly be missing. It is, however, recommended to incorporate the requirements on protection of aircrew coherently in the title on the protection of workers. These conclusions are made on the base of the collected data on the implementation of the requirements of the BSS Directive 96/29 in various EU Member States and other countries.

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

10. Radiation Protection Publication N° 166 "Implementation of the Council Directive 90/641/Euratom". According to the final report, the outside workers in European Countries can be estimated to at least 100 000, mainly working for the nuclear

industry. Almost all the operators who use outside workers check the medical surveillance and fitness of the outside workers, provide them with specific training and protective equipment; 75% of the operators ensure that radiological data of each worker is recorded into a radiation passport or a network; additionally 50% of the operators set up dose constraints for outside workers. However, the answers provided by outside undertakings (the employers of the outside workers) clearly outline that there is a large variety of situations and there is a need for a harmonisation of both exposure assessment and medical surveillance. The need for a uniform European network or radiation passport is particularly highlighted in this survey.

ANNEX III

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

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

Article 31 Group of Experts is established according to Article 31 from the Euratom Treaty with the task to advise on the elaboration of uniform basic safety standards as described in art.30 from the Treaty. The Group consists of scientific experts, in particular public health experts from Member States, appointed by the Scientific and Technical Committee, set up in compliance with Article 134 of the Treaty. The members of the Group are appointed on a personal basis for a term of five years, renewable. The members of the Group speak on their own behalf and act independently of all external influence. The Treaty requires the European Commission to consult this Group when preparing, revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.
When in 2005 the European Commission undertook the revision of the Basic Safety Standards Directives, Art.31 Group of Experts was asked to investigate and deliver an opinion on this issue. This action was triggered by the fact that the International Commission for Radiological Protection (ICRP) has engaged in a process of revising and updating their Recommendations for a System of Radiological Protection which since decades represent the internationally accepted basis for radiological protection. In this context the revision of the BSS was considered as the most important activity of the Group of Experts to be completed before the end of its mandate in May 2010. Therefore, several working parties (WP) were established to identify the items in the BSS directives that may need revision and to look into the impact of the possible changes:

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

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

- WP Natural Sources – established in November 2005 to address questions relating to natural radiation exposures. The WP Natural Sources' first priority was to examine how the requirements on natural radiation sources in Title VII of the present Directive could be strengthened and if it was feasible to integrate the regulatory control of so-called NORM industries into the framework of regulatory control for practices. The second task was to look into the possibility to establish in the BSS Directive requirements related to exposure to radon, taking into account the Commission Recommendation 90/143/Euratom on indoor exposure to radon. The third assignment was to propose a regulatory framework for building materials containing natural radiation sources. For each of these tasks the

WP produced comprehensive reports, giving background data on international and Commission standards and guidance, indicating where further guidance and work is necessary and providing proposals for new or modified requirements. The reports have been presented to the Article 31 Group of Experts and agreed upon.

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

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

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

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

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

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

2) In order to ensure equal protection of the workers in different economic sectors it is proposed to submit the so-called NORM industries[9] to the regulatory control established for the other practices involving radioactivity.

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

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

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

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

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

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

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

ANNEX IV

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Energy
D.4 - Radiation Protection

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

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

Note to EAN_{NORM}

Consultation and response

A consultation document with the Commission Services' considerations regarding natural radiation sources in the new Euratom Basic Safety Standards Directive (BSS)[10] was launched on the European Commission's website in February 2009. The end date was set to 20 April 2009 although comments kept coming until the end of April. Those have been included as well.

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

- Steel producers
- Zirconium chemicals producers
- Producers of abrasive products
- Building materials industry
- Tiles and bricks industry
- Radon measurement and remediation companies

With regard to the geographical distribution, comments were received from the following countries: Germany(13), UK(5), Spain(4), Italy(4), Belgium(3), Ireland(3), the Netherlands(2), Sweden(2) and Finland, Greece, Poland, Austria, Norway, Switzerland, Australia (one each) [11].

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

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

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

Outcome: In general

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

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

Outcome: Specific topics

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

NORM

Positive list

- Some additional industries are suggested.
  Two of them have been added:
  Geothermal energy production, since it has similar radiation protection issues as other types of fluid extraction, e.g. oil and gas extraction.
  Mining of ores other than uranium ore. Although exposure to radon is normally the main pathway of exposure in underground workplaces, some mines have problems with high concentrations of Radon-226 in fissure water.
- The positive list is a good thing but after assessment Member States should have the possibility to remove certain industries
  This is not explicitly mentioned in the draft BSS, instead it states that all industries on the list needs to be taken into account when Member States make the initial identification of industries which cannot be disregarded from a radiation protection point of view.

Materials of concern

- Need for clarification about pathways when assessing doses
  This is an area where the Commission is considering issuing further guidance although earlier Commission guidance such as RP 122 part II is still relevant for identifying pathways.

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

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

The mandatory requirement is kept in the draft BSS since recycling of residues into building materials is one of the pathways that may lead to doses to the public exceeding 1 mSv/y and it is therefore necessary to have some form of regulatory

control of the industries recycling residues into building materials. The draft BSS contain an annex with of building materials of concern, including a list of the types of residues. The annex indicates which industries would be affected by this requirement.

Exemption values

- Why not use RP 122, part II values (e.g. 0.5 kBq/kg instead of 1 kBq/kg)?
  For the sake of harmonisation with international standards the values in the IAEA report RS-G-1.7 have been incorporated, in the same way as for artificial radionuclides. Some of the Article 31 Experts also prefer the RP 122 values and this is reflected in the Opinion.
- Some contributors mention the need for allowing lower values when drinking water may be affected.
  This has been introduced in the draft BSS: without explicitly allowing lower levels, the competent authority may impose restrictions wherever drinking water or other pathways of exposure may be affected.

Graded approach

- How to assess doses to workers? Should conventional health and safety equipment be taken into account?
  It has been taken care of by referring to "normal working conditions", which implies that compulsory health and safety requirements relevant to the workplace should be taken into account.
- Why notification already when doses to workers are likely to exceed 1 mSv/y? Some of the German contributors mention that they have good regulatory experience of setting the level for notification at 6 mSv/y.
  Why ask for anything more than notification? Licensing or registration requirements would only lead to an unnecessary administrative burden.
  The draft BSS now deal with NORM industries in the same regulatory framework as for other practices. The graded approach applies to all practices and the choice of registration or licensing is based on different criteria, e.g. dose assessment to workers and members of the public. However, for doses to workers in the range 1-6 mSv/y the requirements for occupational exposure to NORM are less demanding.

Mixing

- Mixing NORM with other material should be encouraged. Significant amounts of NORM are recycled and end up mixed with other materials, e.g. in cement and concrete. The term "inert" may also not be appropriate.
  The term "inert material" is no longer used and the text is modified.

Radon

- There is a clear demand for technical guidance, especially with regard to measurement techniques, and for standards and harmonisation on a European level for this.
  According to the website of the International Organization of Standardization (ISO), one of its subcommittees, TC85/SC2, is in the process of developing several ISO standards for Radon-222. With regard to building materials, CEN/TC 351 is presently investigating the possibility of setting a CEN standard for measuring radioactivity concentration (gamma radiation) in building materials.
- There are worries that the action plan will only address radon in dwellings and public buildings. Radon in workplaces needs equal attention.
  The draft BSS are clear about the fact that the national action plan must also address radon in workplaces.

- Some contributors question a threshold for recording doses to workers in NORM industries and question the choice of the value of 400 Bq/m^3.
  This threshold has been removed.
- Modify so that within radon-prone areas all workplaces with a high occupancy are requested to be measured.
  This is reflected in the requirements on the content of the national action plan.
- Modify so MS have the possibility to choose a higher reference level for workplaces with a very low occupancy.
  It should be noted that a reference level is not a limit. For such workplaces, where radiation protection measures are optimised, the radon concentrations may very well exceed the reference level.
- Include criteria on level of rooms or workplaces in addition to requirements for measurements in radon-prone areas (upper floors excluded?)
  The requirements for measurements at workplaces have been slightly modified. For buildings with public access or dwellings setting specific requirements on types of rooms or workplaces would require a high level of detail. It would be more suitable to discuss such a complex issue in a guidance report.

Building materials

- Clarification needed about whether materials used for infrastructure projects are considered building materials.
  The draft BSS contain a definition of building materials.
- Some contributors worry about the proposed requirements causing stigmatization of certain groups of materials, whereas others are concerned that the flexibility, for instance when setting up the list of building materials which need to be considered, would lead to problems in shipping and trading products within EU.
  These are valid concerns. However, in order to make informed decisions when constructing buildings, so as to not exceed the appropriate levels of exposure to workers or members of the public and to fulfil Annex 1 of the Council Directive related to construction products (89/106/EEC)[12], the building industry should be made aware of the radioactivity content of the materials a Member State has deemed to be of concern. The flexibility for Member States to establish a reference level for building materials has been removed.
- Some contributors question why the value for exemption proposed by RP 112 (0.3 mSv/y) is replaced by 1 mSv/y.
  Based on the prevailing activity concentrations in building material produced in the European Union the Article 31 Group of Experts decided that a level of 1 mSv/y would be more appropriate in a Directive, also in order to avoid problems in trade within the EU.
- Harmonisation or guidance on how to measure radionuclide concentrations and calculate the index would be beneficial, as well as on the concept of "superficial material".
  Some information can be found in earlier Commission guidance, such as RP 96 and RP 112, but this is an area where the Commission considers issuing further guidance.

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

ANNEX V

Legislation
enacted under Articles 30 and 31 from Euratom Treaty

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

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

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

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

4. **Council Directive 89/618/Euratom** of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (Public Information Directive);

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

6. **Council Regulation 87/3954/Euratom** of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency and the related legislative acts - **Commission Regulation 944/89/Euratom** of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency, **Commission Regulation 770/90/Euratom** of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency[13];

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

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

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

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

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

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

ANNEX VI

ESTIMATED CONTRIBUTIONS TO PUBLIC EXPOSURE FROM DIFFERENT SOURCES (in mSv)
(data published in UNSCEAR Report 2008)

Figure I

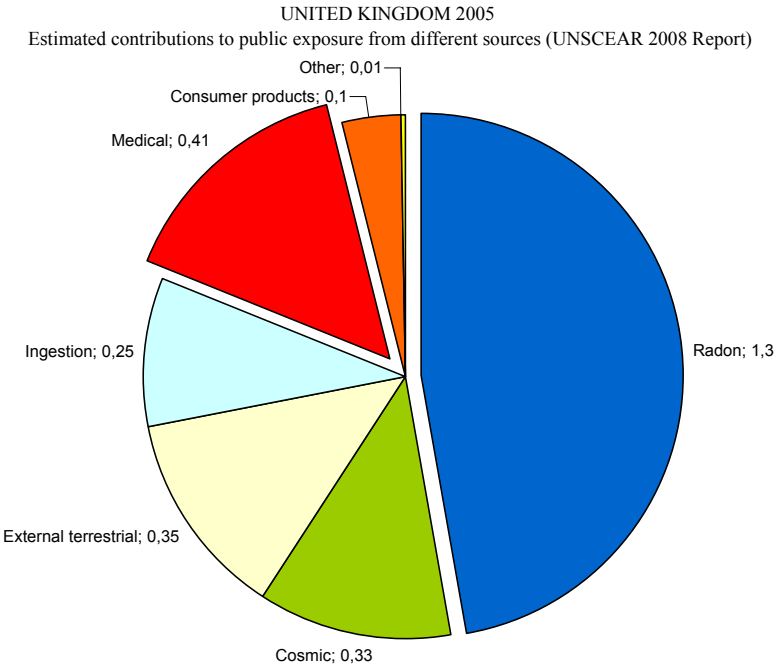


Figure II

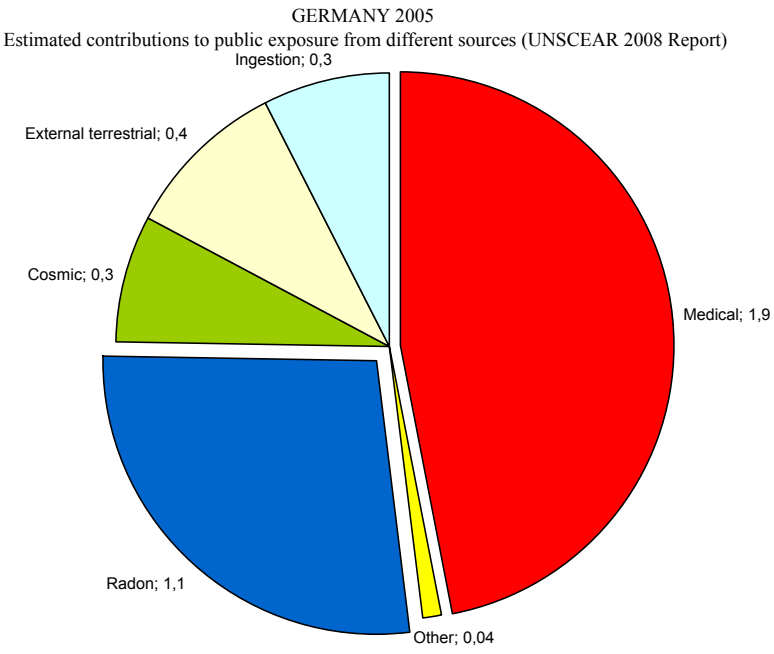


Figure III

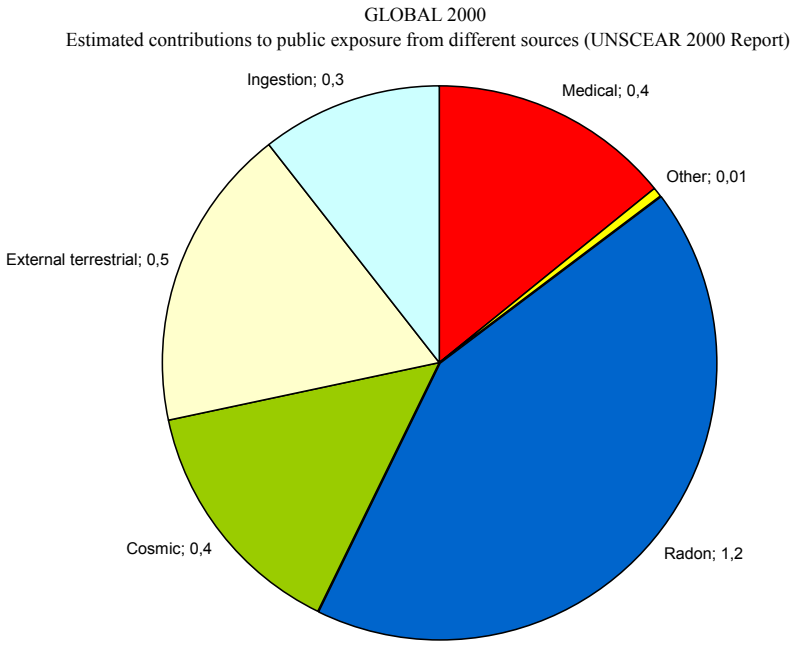
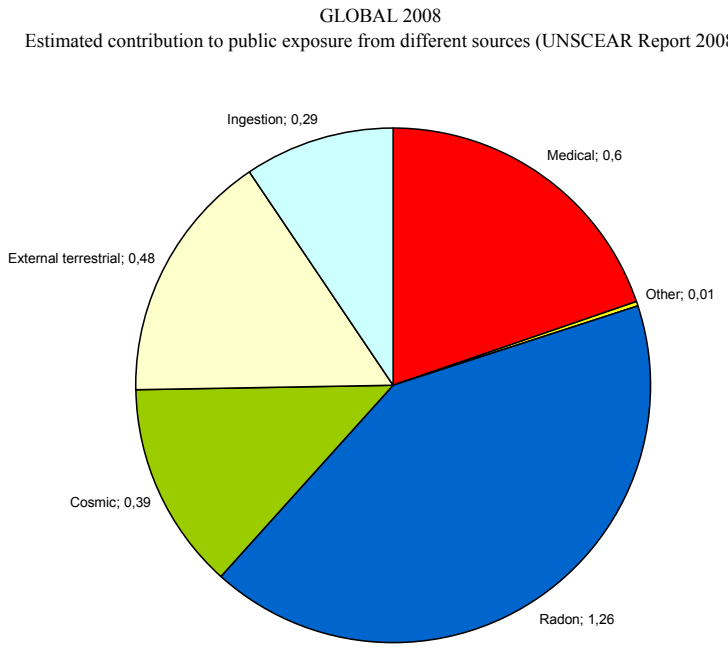


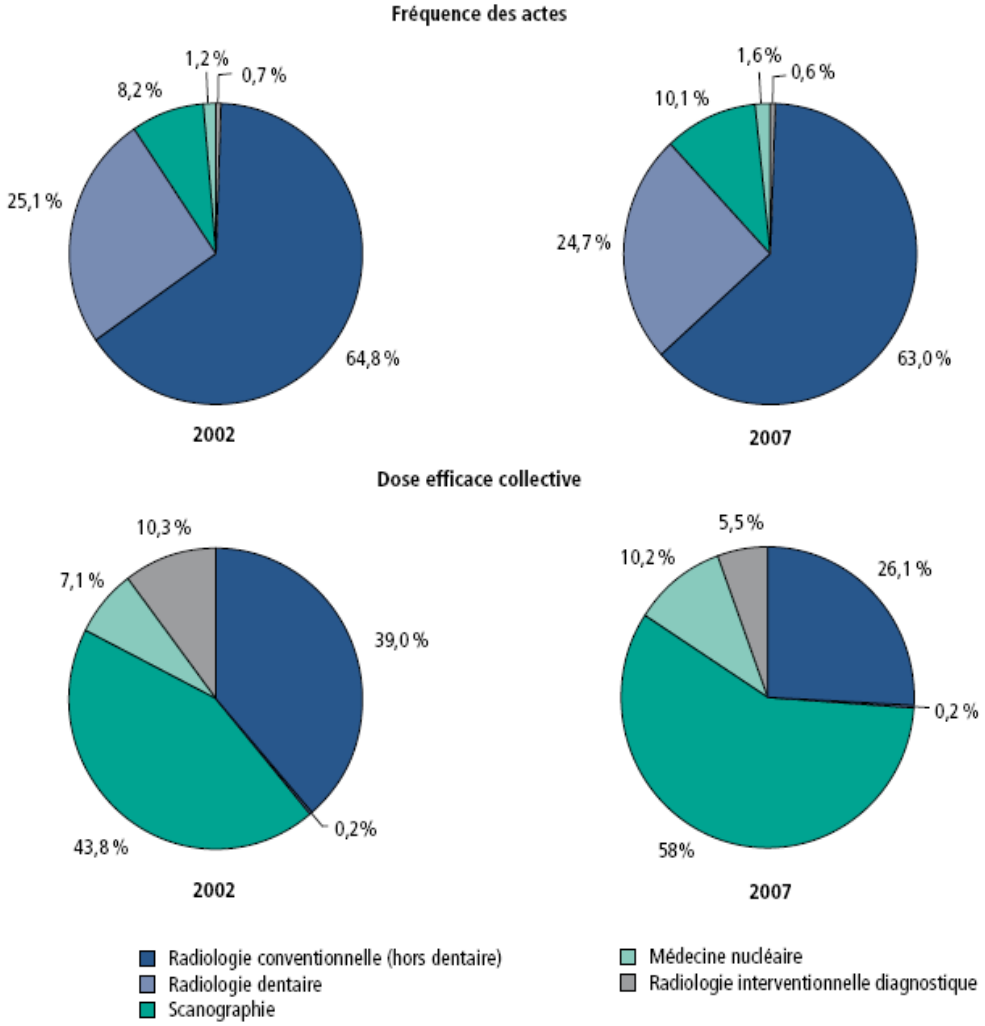
Figure IV



ANNEX VII

EVOLUTION OF THE MEDICAL DIAGNOSTIC EXPOSURE IN FRANCE between 2002 and 2007[14]

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



The number of performed medical procedures in the period 2002-2007 has increased by only 2%. However the annual dose per capita from these procedures increased by 57% for 5 years. This notable increase is due to the increase of number of procedures in computed tomography and nuclear medicine where the highest dose in diagnostic medicine is delivered. While for 5 years the number of procedures in the conventional radiology is stable, in computed tomography and nuclear medicine

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

significant increase of accordingly 26% and 38% is observed. At the same time the collective effective dose from conventional radiology decreased, while the collective effective dose from computed tomography and nuclear medicine increased by 33 % and in 2007 is 68% from the dose delivered due to medical diagnostic exposure as a whole.

ANNEX VIII (A)

NATURALLY OCCURING RADIOACTIVE MATERIAL

A. Naturally occurring radioactive material and building material

The industrial activities covered by the term "NORM industries" are all related to material extracted from the earth's crust. Either the industries use the material (e.g. production of thorium compounds) or they are involved in the extraction itself (e.g. mining of ores). Table 1 shortlists the types of operations that are likely to warrant regulatory control with the type of material involved and range of dose to workers. It is difficult to forecast the number of enterprises likely to be affected since it depends on the industrial process in each enterprise and on the content of radioactivity in the material being processed. As an example the number of enterprises extracting crude petroleum and natural gas in the EU is 381, the number of enterprises producing lead, zinc and tin is 293 and the number of enterprises mining iron ores is estimated to 40[15].

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

Data on the number of exposed workers are as previously mentioned scarce. The ESOREX database on occupational exposure does however provide certain information. In 2004 the number of exposed workers in the EU employed in workplaces with enhanced exposure to natural radionuclides was 27 000[16]. One of the objectives of the SMOPIE project (see Table 2) was to provide information on the number of industrial workers exposed to NORM. The project concludes that this information is very scarce but based on the information received and compiled they estimate the number of potentially exposed workers in EU NORM industries to be around 85 000 (2004). The project further concluded that exposure data based on actual workplace monitoring is very scarce. This lack of data reflects the lack of consistent and harmonised requirements on monitoring of workers and registration of doses in this industrial sector. Far more data should become available once the new Directive is implemented.

The issue of natural radionuclides in building materials was discussed by the Art.31 Working Party Natural Radiation Sources. Based mainly on two reports on activity

[15] EUROSTAT Basic Statistic for 2007
[16] ESOREX Database

concentrations in building materials[17] and one study made on Italian building materials[18], the group concluded on a list of materials that Member States should take into account when setting up national lists of materials that would require regulatory control due to their content of radioactivity:

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

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

To give an indication of amounts, the production of granite (crude or roughly trimmed) in the EU in 2009 was around 4.5 billion kg. The production of porphyry, basalt, quartzite and other monumental or building stone (crude, roughly trimmed, cut) in the EU in 2009 was around 15 billion kg[19].

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

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

[19] EUROSTAT PRODCOM Database 2009

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

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

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

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

ANNEX VIII (C)

DOCUMENTS EXAMINED FOR THE IMPACT ASSESSMENT REGARDING NORM

Title	Published	Organisation
Approaches for regulating management of large volumes of waste containing natural radionuclides in enhanced concentrations, EUR 16956	1996	European Commission
Current practice of dealing with natural radioactivity from oil and gas production in EU Member States, EUR 17621	1997	European Commission
Recommendations for the implementation of Title VII of the European Basic Safety Standards Directive (BSS) concerning significant increase in exposure due to natural radiation sources, Radiation Protection Series N° 88	1997	European Commission
Establishment of reference levels for regulatory control of workplaces where materials are processed which contain enhanced levels of naturally occurring radionuclides, Radiation Protection Series N° 107	1999	European Commission
Radiological impact due to wastes containing radionuclides from use and treatment of water, EUR 19255	2000	European Commission
Monitoring and surveillance of residues from mining and milling of Uranium and Thorium, Safety Reports Series N°27	2002	IAEA
Radiation Protection and the Management of Radioactive Waste in the Oil and Gas Industry, Safety Reports Series N° 34	2003	IAEA
Occupational radiation protection in the mining and processing of raw material, RS-G-1.6	2004	IAEA
Strategies and Methods for Optimisation of Protection against Internal Exposure of Workers from Industrial Natural Sources, EC project N° FIGM-CT2001-00176 (SMOPIE-project)	2004	NRG, NRPB and CEPN
Summary and recommendations from EAN 9th Workshop, "Occupational exposure to natural radiation"	2005	European ALARA Network
Assessing the need for radiation protection measures in work involving minerals and raw material, Safety Reports Series N° 49	2006	IAEA
Radiation protection and NORM residue management in the Zircon and Zirconium industries, Safety Reports Series N° 51	2007	IAEA
Naturally Occurring Radioactive Material (NORM V), Proceedings from international symposium in Seville, Spain, 19-22 March 2007	2008	IAEA

Sources and effects of ionising radiation, UNSCEAR 2008	2010	United Nations