Opinion of the Group of Experts established under Article 31 of the Euratom treaty

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.

24 February 2010

1. The European Commission has undertaken the simplification of Community legislation in the area of radiation protection and has proposed the consolidation into a single text of the following Directives:

- 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,
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.
- 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.
- Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas.
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

2. The latter four Directives cover different specific aspects complementary to the overall Basic Safety Standards. While definitions have evolved over time and have been adjusted to the specific scope, and while many requirements fit in the original context but cannot be extended for general application of the Standards, the consolidation proceeded through a recast rather than codification of the original texts.

3. Other important components of binding Community legislation have not been included in the recast. The Directive on the shipment of radioactive waste which has recently been updated (2006/117/Euratom) has a rather administrative character which does not quite fit in a recast with actual radiation protection requirements. The very recent Council Directive 2009/71/Euratom on a framework for nuclear safety supplements the Basic Safety Standards, but was not considered for a recast at the present stage. A recast of Directives with other legal instruments, e.g. the Council Decision 87/600/Euratom establishing arrangements for the early exchange of information in the event of a radiological emergency, or the Regulations on foodstuffs (EC Regulations on post-Chernobyl import of contaminated food and the codified Euratom Regulations in case of a future accident), is not possible since Decisions and Regulations apply directly, without transposition in national law. The Group of Experts had given a favourable Opinion on a draft Euratom Directive on the monitoring of drinking water supplies for radioactive substances, which could have been incorporated in the recast, but the Group was informed that this development now proceeds under a joint legal basis (EC, Euratom) that precludes a recast with Euratom Directives.

4. The Group of Experts emphasises that the current Basic Safety Standards Directive 96/29/Euratom offers appropriate levels of protection to workers and to members of the public. The basic principles of radiation protection (justification, optimisation and dose limitation), which also have been incorporated in the fundamental safety principles published in the IAEA Safety Standards in 2006 and cosponsored by Euratom, shall be maintained. The initial review of the BSS nevertheless led to the conclusion that requirements on natural radiation sources needed to be harmonised and strengthened, and that requirements on exemption and clearance needed to be updated and incorporated in a graded approach to regulatory control. The Group of Experts thus proceeded, in close cooperation with the Commission, with Working Parties assessing these specific issues in parallel to a Working Party that was first looking into the development of the ICRP recommendations, followed by an actual drafting group once the other WP's had completed their review and the ICRP recommendations were published. The work resulted in the revised and recast draft Euratom Directive laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation, version 24 February 2010 which is the basis for this Opinion of the Group of Experts.

5. The Group of Experts has taken the opportunity of the recast to take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in Publication 103 (2007), and to update certain requirements of the current legislation in the light of new scientific evidence and operational experience. Allowance for the ICRP recommendations, in particular the distinction between three exposure situations: planned, emergency and existing exposure situations, has required thorough re-structuring of the Standards. Nevertheless the Experts have kept existing requirements without modifications to the largest possible extent. Minor adjustments have been made for the sake of coherence, so as to reflect the spirit of the recast process and not to cause an unnecessary burden to Member States when transposing the Directive into national legislation.

6. Currently, radon in dwellings is excluded from the scope of Directive 96/29/Euratom and is covered by the Commission Recommendation 90/143/Euratom. Recent epidemiological findings from residential studies demonstrate a lung cancer risk from indoor radon exposure at levels of the order of 100 Bq m^{-3}. The Group of Experts notes that the recast Directive now incorporates the Commission Recommendation 90/143/Euratom in binding requirements while leaving enough flexibility for implementation. The Group of Experts is aware that ICRP is currently re-considering its earlier guidance on the dose conversion factors relating to concentrations of radon gas and its progeny in the decay chain. The ICRP Main Commission has issued a statement in November 2009 now proposing a maximum value for the reference level in dwellings of 300 Bq m^{-3}, in line also with the WHO handbook on indoor radon published in 2009. The new Directive has incorporated this value for existing dwellings. The Group of Experts is of the opinion that the value for the lower reference level proposed by WHO, 100 Bq m^{-3}, is suitable as a long-term goal but that currently the value of 200 Bq m^{-3} for new dwellings should be maintained. The Experts further note that if the dose conversion factor would be doubled this might enhance the current difficulties to comply with the dose limit in uranium mines, and that a longer transposition time may be needed to allow such practices to adjust to this situation.

7. A maximum value for the reference level for radon in workplaces has been set at 1000 Bq m^{-3}, in line with the ICRP Statement and with the current draft of the international standards. The Experts observe that, with the possible doubling of the dose conversion factor, a radon concentration of 1000 Bq m^{-3} would correspond to around 10 mSv per year, which is

a high threshold for managing radon at work as planned occupational exposure and well above 6 mSv per year, used in the definition of Category A workers.

8. The Group of Experts notes that, along the lines of ICRP Publication 103, the protection against natural radiation sources has now been fully integrated, rather than laid down in a specific title as in Directive 96/29/Euratom. Industries processing materials containing naturally occurring radionuclides are now dealt with in the same regulatory framework as other practices. The explicit consideration of types of industries and the graded approach to regulatory control of occupational exposures has been introduced for radiation protection in these industries. The Group of Experts recommends that further guidance be issued for the implementation of these new requirements by regulatory authorities and by the industries.

9. In addition to the control of radon in workplaces, dwellings and buildings with public access, the Directive now also incorporates requirements on radioactivity in building materials. The Group of Experts emphasises this new feature which allows a coherent approach to all radiation sources, and reflects earlier guidance published in Radiation Protection 112. This publication recommended a dose criterion in the range of 0.3 mSv per year – 1 mSv per year, however a review of prevailing activity concentrations in EU building materials was the basis for introducing 1 mSv per year in the Directive. The Experts note that the requirements are drafted in such a way as to cause no problems with the free circulation of building materials and have no reason to believe that the requirements will cause an excessive burden to the building industry or to regulatory bodies.

10. The requirements for aircrew, now regarded as a planned exposure situation, in Directive 96/29/Euratom have been maintained. The scope of the Directive now also includes the operation of spacecraft, and the exposure of space-crew can be managed as a specially authorised exposure.

11. Drafting of the revised Directive has proceeded to a large extent in parallel to and in close coordination with the similar revision of the international Basic Safety Standards, so as to strive for the harmonisation of Euratom and international (IAEA) standards. The Group of Experts had no sufficient basis to conclude whether for this purpose, amongst others, the definition of High Activity Sealed Sources should be adjusted to the Code of Conduct on the Safety and Security of Radioactive Sources of IAEA. In the context of a recast the Group of Experts feel that it is appropriate to keep the activity values laid down in Council Directive 2003/122/Euratom. The Experts nevertheless invite the Commission to investigate the technical basis of the values and the operational implications before making the amendment for the sake of the political and practical benefit of international harmonisation. The two sets of values are appended to the Opinion.

12. The Directive has developed the concept of a graded approach to regulatory control, so that it is commensurate with the risk and with the effectiveness of such controls. In line with the international standards the Directive has introduced a system of regulation based on the concepts of notification, registration and licensing. The Directive identifies which type of practices shall be subject to each level what general conditions need to be fulfilled and what are the requirements laid down upon registration or as part of a specific licence. The Group of Experts welcomes the graded approach and the harmonisation of national authorisation regimes pursued by the classification of a broader range of practices, but invites the Commission and Member States to further test this classification in the light of current national systems.

13. For the sake of aligning to the international Basic Safety Standards the default values included in the Directive for exemption and clearance of materials with very low activity concentration are those laid down in IAEA RS-G-1.7 rather than those in earlier guidance of the Experts (Radiation Protection 122). Nevertheless, several Experts consider that the Community guidance has a better scientific basis, in particular the exemption values for naturally occurring radionuclides, and they are concerned with the increase of some of the values. The Group of Experts endorses the prudent approach laid down in the Euratom Directive where it is established unambiguously that the values in RS-G-1.7 for naturally occurring radionuclides do not apply to the recycling of residues into building material or to situations where there is a specific risk such as groundwater contamination.

14. The Group of Experts notes that as part of the graded approach to regulatory control there is now explicit provision for higher exemption and clearance levels laid down at national level for specific materials and practices. The Group of Experts recommends that, whenever the exempt activity concentration values laid down in Directive 96/29/Euratom, on the basis of Radiation Protection 65, are preserved in national legislation, that these values be used only for moderate amounts of material, as defined in legislation or as specified by the competent authority.

15. The default values of activity concentration for exemption and for clearance are now identical and these values define the borderline of regulatory control and hence give substance to the qualitative definition of "radioactive substance", still referring to "activity concentrations which cannot be disregarded as far as radiation protection is concerned". The Group of Experts observes that it is not possible to have a more clear-cut definition that would apply to all exposure situations. The Group of Experts also notes that the Directive now introduces a very general definition of "radioactive waste" to distinguish the disposal of waste from the discharges of radioactive effluent, but observes that the term "radioactive waste" should not be used to designate solid materials below clearance levels.

16. Directive 96/29/Euratom already introduced the concept of type approval of apparatus and consumer goods as part of the graded approach to regulatory control. The new Directive elaborates on the requirements on justification of the introduction of such new products and on the conditions for type approval. The Directive also requires national competent authorities to allow for the type approval granted in another Member State so as to avoid duplication of assessments and to avoid problems with free circulation of such goods in the European Union. The Group of Experts emphasises this development and recommends that the Commission assesses its impact and develops the appropriate tools and procedures for sharing this information between Member States.

17. The Directive maintains the principle of Justification in radiation protection, and the implementation of this principle remains a national responsibility. The Directive still prohibits the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics. In addition, the activation of material is now explicitly regarded as a form of "deliberate addition". The Group of Experts underlines that it is not the practice of irradiation which is prohibited as such: for instance, the irradiation of diamonds to enhance their ornamental value may be justified if carried out in such a way that any radioactive substances have decayed prior to the placing on the market of the diamonds. The Experts also note that watches, incorporating e.g. Tritium to illuminate the dial, are generally not regarded as "personal ornaments".

18. The subject matter and general purpose of the Basic Safety Standards is the health protection of the population and workers against the dangers of ionising radiation; this includes the protection of the human environment as a pathway from environmental sources to the exposure of man. In line with ICRP Publication 103 it is now felt that this should be complemented where appropriate with specific consideration of the exposure of biota in the environment as a whole. The extension of the scope of the Basic Safety Standards Directive enables a better integration of the Euratom legislation with overall environmental legislation adopted under EC Treaty provisions, as well as the observance of international agreements. While Chapter 3, *Health & Safety*, of the Euratom Treaty only relates to the health protection of workers and members of the public, the policies for the protection of man and the environment should be coherent. For instance, environmental criteria as well as dose constraints should be considered for the authorisation of discharges of radioactive effluent. Therefore, requirements on the protection of the environment have been incorporated in the Directive at this stage.

19. The Group of Experts supports this development and notes the recent publication by ICRP (Publication 108) of guidance on the definition of reference animals and plants, and on the assessment of the impact of radiation on non-human species. The application of the principles of radiation protection to non-human species and ecosystems needs to be further developed. The Experts also feel that the protection of the environment should not warrant a high level of regulatory control, and that the means for the demonstration of compliance should be proportionate to the expected relevance of the issue, in line with the graded approach. Also in view of the limited experience with this new issue, the Experts invite the Commission to leave enough time for transposition of these requirements in national law, pending the results of further research and international guidance of ICRP.

20. With regard to the management of emergency exposure situations, the former approach based on intervention levels has been replaced by a more comprehensive system comprising
- threat analysis;
- overall emergency management system;
- emergency response plans for identified threats;
- pre-planned strategies for the management of each postulated event.

21. In line with ICRP Publication 103 each strategy should aim at keeping doses below a reference level, optimising the available protective actions rather than justifying each action on the basis of intervention levels. The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.

22. The Directive also highlights the requirements for cooperation between Member States in emergency planning and response. The Directive further addresses thoroughly the information, training and protection of emergency workers, within the overall framework of occupational exposure.

23. The Directive confirms the main elements of the system of protection: justification of practices, optimisation of protection and limitation of individual doses. This is not essentially different from the current BSS. Greater emphasis is given to the application of optimisation (ALARA) in all exposure situations and categories of exposure. Optimisation strategies may

still make use of the concept of collective dose. Additional text has been incorporated on the more prominent use of the concept of "dose constraint" and on "reference levels".

24. The current dose limits for practices are kept, but the annual dose limit for occupational exposure is now 20 mSv per year in order to achieve a more harmonised approach within Europe. There should be no need for averaging over 5 years, except in special circumstances specified in national legislation.

25. On grounds of the precautionary principle, the Directive expands the optimisation principle to be applied also to organ doses, where appropriate, to keep doses as low as reasonably achievable. In this connection, the Group of Experts draws attention to the conclusion of the EU Scientific Seminar in 2008 on emerging evidence for radiation induced circulatory diseases which indicated that epidemiological evidence is accumulating in favour of an increased risk in circulatory diseases for cumulative doses higher than 0.5 Gy low-LET radiation.

26. In view of the conclusion of the EU Scientific Seminar in 2006 on the issue of radiation induced cataract and the further review of scientific literature performed by the Group, the Group of Experts recommends to lower the dose limits to the lens of the eye. The Group of Experts notes that ICRP will issue guidance on this matter and recommends that the Commission takes this guidance into account. Furthermore, the Directive requires the set-up of adequate systems for individual monitoring of (significant) doses to the lens of the eye.

27. The Directive defines the roles and responsibilities of services and experts who should be involved in ensuring that technical and practical aspects of radiation protection are managed with a high level of competence. The Directive defines the role of the Radiation Protection Expert (previously Qualified Expert) and of the Medical Physics Expert and introduces the function of a Radiation Protection Officer, operating within the undertaking and reporting directly to the management.

28. The requirements for information, training and education are strengthened and addressed in a specific title in order to highlight the importance of education and training in radiation protection. In the medical area, education and training should also raise the awareness of the medical profession, in particular with a view to risk communication with patients.

29. With regard to occupational exposure, the Directive has kept most requirements without modification, except for some restructuring to distinguish between the responsibilities of the undertaking and of the employer, as was necessary for the incorporation of the Outside Workers Directive. The Directive maintains the classification of controlled and supervised areas and the categories of workers. The specific arrangements for outside workers are extended to cover also supervised areas. With regard to the register of data related to individual dose records in a centralised national network, in particular with regard to the free circulation of outside workers, the Group of Experts urges the Commission and Member States to develop a European Radiation Passport.

30. The so-called "medico-legal" exposures introduced in the Medical Directive (97/43/Euratom) have now been clearly identified as non-medical imaging exposures (deliberate exposure of individuals for other than medical purposes), and have been put under appropriate regulatory control. The need for justification of such practices, in three stages as for medical exposures, and for establishing associated conditions, has been worked out,

including the differentiation between procedures implemented by medical staff using medical equipment and procedures implemented by non-medical staff using non-medical equipments (e.g. security screening). While, in general, the annual dose limit and corresponding constraints for public exposure should apply, exceptions should be allowed for some specific non-medical exposure procedures carried out in a medical environment (e.g. drug search within the body). Some experts expressed concerns about the proliferation of security screening equipment using ionising radiation and the related health impact.

31. The category of medical exposure has been redefined to include exposure of patients or asymptomatic individuals intended to benefit their health or well-being, in addition to the exposure of comforters and carers as well as volunteers in bio-medical research. The title on medical exposures remains essentially unmodified, but gives new emphasis to the need for justification of the exposure of asymptomatic individuals, to information provided for patients, and on interventional radiology procedures, diagnostic reference levels and dose-indicating devices. A new feature is the detailed consideration of accidental or unintended exposures and the role of the quality assurance programme, including risk analysis in radiotherapy, to avoid such incidents.

32. The section on public exposure is almost exactly copied from Title VIII of Directive 96/29/Euratom. However, the Directive now gives more precise indications for the establishment of discharge authorisations and on the monitoring of discharges, with reference to Commission Recommendation 2004/2/Euratom.

33. As a result of the rules of the recast procedure the current draft of the new Basic Safety Standards has not introduced any requirements that had not been part, possibly in a different way, of the earlier Directives. In particular, no major changes have been made to the most recent Directive on High Activity Sealed Sources and orphan sources (2003/122/Euratom), except for the broadening of some of the requirements to any sealed sources, where this is considered to be good practice. The HASS Directive introduced new safety, security and enforcement aspects, some of which have now been applied to all radiation sources. On the other hand, the Experts note that there are still problems with orphan sources which might be resolved more efficiently for example along the lines of the so-called "Spanish Protocol", and that there have been important cases of contaminated metal being imported from third countries. The Group of Experts feels that it is timely to strengthen the requirements on orphan sources in Directive 2003/122/Euratom, and to introduce a requirement on the notification of incidents with orphan sources or the contamination of metal. The Group of Experts recommends pursuing further international efforts in this area to meet the conclusions of the Conference held in Tarragona in February 2009, and, striving for world-wide consensus on further legislative initiatives in particular with regard to the restriction of trade of metal and scrap metal, that these be incorporated in the recast Directive at a later stage.

34. The Group of Experts notes that at this stage ICRP has not yet published new dose coefficients for the intake of radionuclides by inhalation or ingestion by both occupationally exposed persons and members of the public. While it may take more than two or three years for all such values to be available, the Group of Experts recommends making reference to the same set of values in the international standards to the extent that IAEA also follows ICRP recommendations on dose coefficients.

35. The Group of Experts draws the attention of the Commission to the need to maintain the provisions of Article 54 in Council Directive 96/29/Euratom in order to allow Member States to reflect possible new scientific evidence after the adoption of the Directive.

36. As a whole, the Group of Experts concludes that the recast achieved its objectives and that it will allow more coherent and more comprehensive radiation protection across all exposure situations and categories of exposure.

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Annex: Activity values defining high activity sealed sources

Radionuclide	*Activity level (TBq)*	
	Directive 2003/122/Euratom	*IAEA Code of Conduct – Category 3 sources* [c]
Am-241	1E-01[b]	6E-02
Am-241/Be	*Not given*	6E-02
Cf-252	5E-04	2E-02
Cm-244	*Not given*	5E-02
Co-60	4E-03	3E-02
Cs-137	2E-02[a]	1E-01
Gd-153	1E-01	1E+00
I-125	2E-01	2E-01
Ir-192	1E-02	8E-02
Kr-85	1E-01	3E+01
Pm-147	4E-01	4E+01
Pu-238	1E-01[a]	6E-02
Pu-239b/Be	*Not given*	6E-02
Ra-226	2E-03[b]	4E-02
Se-75	3E-02	2E-01
Sr-90 (Y-90)	3E-03[a]	1E+00
Tm-170	3E-02	2E+01
Yb-169	*Not given*	3E-01
Au-198	*Not given*	2E-01
Cd-109	*Not given*	2E+01
Co-57	*Not given*	7E-01
Fe-55	4E-01	8E+02
Ge-68	*Not given*	7E-01
Ni-63	*Not given*	6E+01
Pd-103	4E-01[a]	9E+01
Po-210	*Not given*	6E-02
Ru-106 (Rh-106)	*Not given*	3E-01
Tl-204	1E-01	2E+01

(a) The activity level includes contributions from daughter nuclides with half-lives less than 10 days.
(b) Includes neutron sources with beryllium.
(c) Sources for which the activity exceeds the D-values specified in "Dangerous quantities of radioactive material (D-values), EPR-D-Values 2006, IAEA Vienna (2006)