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

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[(1)]. The Directives have been revised several times, most recently by Council Directive 96/29/Euratom[(2)] which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom[(3)], Council Directive 89/618/Euratom[(4)], Council Directive 90/641/Euratom[(5)] and Council Directive 2003/122/Euratom[(6)] cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does

not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of the Euratom Treaty, should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in ICRP Publication 103[(7)], and should be revised in the light of new scientific evidence and operational experience.

(7) The provisions of this Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. Taking into account this new framework, this Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.

(8) The definition of the term "undertaking" in this Directive, and its use in the context of the protection of the health of workers against ionising radiation, is without prejudice to the legal systems and the allocation of responsibilities to the employer introduced in national legislation transposing Council Directive 89/391/EEC[(8)].

(9) Calculation of doses from measureable quantities should rely on scientifically established values and relationships. Recommendations for such dose coefficients have been published and updated by ICRP, taking scientific progress into account. A collection of dose coefficients based on its earlier recommendations in ICRP Publication 60[(9)], is available as ICRP Publication 119[(10)]. However, in ICRP Publication 103, a new methodology was introduced by ICRP to calculate doses based on the latest knowledge on radiation risks, and this should, where possible, be taken into account in this Directive.

(10) For external exposure, values and relationships have been published following the new methodology in ICRP Publication 116[(11)]. These data, as well as the well-established operational quantities, should be used for the purpose of this Directive.

(11) For internal exposure, while ICRP has consolidated in ICRP Publication 119 all earlier publications (on the basis of ICRP Publication 60) on dose coefficients, updates of this publication will be provided and the coefficients that are tabulated in it will be superseded by values based on the radiation and tissue weighting factors and phantoms laid down in ICRP Publication 103. The Commission will invite the group of experts referred to in Article 31 of the Euratom Treaty to continue to monitor scientific developments and the Commission will make recommendations on any updated values, relationships and coefficients, including those for exposure to radon, taking relevant opinions of the group of experts into account.

(12) Article 30 of the Euratom Treaty provides that the "basic standards" are meant to include "maximum permissible doses compatible with adequate safety". This Directive should lay down uniform dose limits for this purpose.

(13) The current annual effective dose limits for occupational and public exposure should be maintained. However, there should be no further need for averaging over five years, except in special circumstances specified in national legislation.

(14) New scientific information on tissue reactions calls for the optimisation principle to be applied to equivalent doses as well, where appropriate, in order to keep doses as low as reasonably achievable. This Directive should also follow new ICRP guidance on the limit for equivalent dose for the lens of the eye in occupational exposure.

(15) Industries processing naturally-occurring radioactive material extracted from the earth's crust subject workers and, if material is released into the environment, members of the public to increased exposure.

(16) Protection against natural radiation sources, rather than being addressed separately in a specific title, should be fully integrated within the overall requirements. In particular, industries processing materials containing naturally-occurring radionuclides should be managed within the same regulatory framework as other practices.

(17) It is appropriate for this Directive to establish reference levels for indoor radon concentrations and for indoor gamma radiation emitted from building materials, and to introduce requirements on the recycling of residues from industries processing naturally-occurring radioactive materials into building materials.

(18) Regulation (EU) No. 305/2011[(12)] lays down harmonised conditions for the marketing of construction products.

(19) Building materials emitting gamma radiation should be within the scope of this Directive but should also be regarded as construction products as defined in Regulation (EU) No 305/2011, in the sense that that Regulation applies to construction works emitting dangerous substances or dangerous radiation.

(20) This Directive should be without prejudice to the provisions of Regulation (EU) No 305/2011 on the declaration of performance, the establishment of harmonised standards or the means and conditions for making available the declaration of performance or with regard to CE marking.

(21) Regulation (EU) No 305/2011 requires information to be made available when products are placed on the market. This does not affect the right of Member States to specify in national legislation requirements for additional information they deem necessary to ensure radiation protection.

(22) Recent epidemiological findings from residential studies demonstrate a statistically significant increase of lung cancer risk from prolonged exposure to indoor radon at levels of the order of 100 Bq m^{-3}. The new concept of exposure situations allows the provisions of Commission Recommendation 90/143/Euratom[(13)] to be incorporated into

the binding requirements of the Basic Safety Standards while leaving enough flexibility for implementation.

(23) National action plans are needed for addressing long-term risks from radon exposure. It is recognized that the combination of smoking and high radon exposure presents a substantially higher individual lung cancer risk than either factor individually and that smoking amplifies the risk from radon exposure at the population level. It is important that Member States address both of these health hazards.

(24) Where, due to national prevailing circumstances, a Member State establishes a reference level for indoor radon concentrations in workplaces that is higher than 300 Bq m^{-3}, the Member State should submit the information to the Commission.

(25) Where radon enters from the ground into indoor workplaces, this should be considered to be an existing exposure situation since the presence of radon is largely independent of the human activities carried out within the workplace. Such exposures may be significant in certain areas or specific types of workplaces to be identified by Member States, and appropriate radon and exposure reduction measures should be taken if the national reference level is exceeded. Where levels continue to remain above the national reference level, these human activities carried out within the workplace should not be regarded as practices. However, Member States should ensure that these workplaces are notified and that, in cases where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value, they are managed as a planned exposure situation and that dose limits apply, and determine which operational protection requirements need be applied.

(26) The exposure of air crew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and, if dose limits are exceeded, be managed as a specially authorised exposure.

(27) The contamination of the environment may pose a threat to human health. The Community's secondary legislation so far has regarded such contamination only as a pathway of exposure to members of the public directly affected by radioactive effluent discharged to the environment. While the state of the environment can impact long-term human health, this calls for a policy protecting the environment against the harmful effects of ionising radiation. For the purpose of long-term human health protection, environmental criteria based on internationally recognised scientific data (such as published by EC, ICRP, United Nations Scientific Committee on the Effects of Atomic Radiation, International Atomic Energy Agency (IAEA)) should be taken into account.

(28) In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, this Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices. It should be noted that according to the World Health Organisation the concept of health is understood to cover the physical, mental and social well-being of an individual and not merely the absence of disease or infirmity.

(29) A high level of competence and a clear definition of responsibilities and tasks among all professionals involved in medical exposure is fundamental to ensure adequate protection of patients undergoing medical radiodiagnostic and radiotherapeutic procedures. This applies to medical doctors, dentists and other health professionals entitled to take clinical responsibility for individual medical exposures, to medical physicists and to other professionals carrying out practical aspects of medical radiological procedures, such as radiographers and technicians in radiodiagnostic medicine, nuclear medicine and radiotherapy.

(30) Accidental and unintended medical exposures are a source of continuing concern. Whereas for medical devices post-market surveillance is required under Council Directive 93/42/EEC[(14)], it is the role of the competent authority in radiation protection to address the prevention of accidental and unintended medical exposure and the follow-up in case of their occurrence. In this respect, the role of quality assurance programmes, including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

(31) In veterinary practice the use of ionising radiation for imaging is growing, often with second-hand equipment from the medical sector. Especially in the case of larger animals, or in the administration of radiopharmaceuticals to animals, there is a substantial risk of high occupational exposures and of exposure of accompanying persons. This calls for the provision of adequate information and the education of veterinarians and their staff.

(32) The so-called "medico-legal" exposures introduced in Directive 97/43/Euratom have now been clearly identified as the deliberate exposure of individuals for other than medical purposes, or "non-medical imaging exposures". Such practices need to be placed under appropriate regulatory control and should be justified in a similar way as for medical exposures. However, a different approach is needed on the one hand for procedures using medical radiological equipment and on the other hand for procedures not using such equipment. In general, the annual dose limits and corresponding constraints for public exposure should apply.

(33) Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices.

(34) The application of radiation protection principles in relation to consumer products requires the regulatory control of practices to start at the stage of design and manufacture of products or at the time of import of such products. Therefore, the manufacture or import of consumer products should be regulated and specific procedures should be introduced, so as to allow the timely justification of the intended use of the consumer products, as well as to allow checking that this use can be exempted from regulatory control. While such assessment should continue to be carried out in the Member State in which those practices are conducted, Member States should inform each other, so as to allow them to request relevant information from the undertakings in question and to make their own assessment.

(35) The deliberate addition of radioactive substances to certain categories of consumer products should remain prohibited, but it needs to be made clear that this also applies to the activation of such products by irradiation, without prejudice to existing legislation such as Directive 1999/2/EC of the European Parliament and of the Council[(15)].

(36) Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.

(37) There is a benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from authorised practices. After a comprehensive review, it has been concluded that the values recommended in IAEA publication Application of the Concepts of Exclusion, Exemption and Clearance[(16)] can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122[(17)].

(38) Member States should be able to grant specific exemption from authorisation for certain practices involving activities above the exemption values.

(39) Specific clearance levels, as well as corresponding Community guidance[(18)], remain important tools for the management of large volumes of materials arising from the dismantling of authorised facilities.

(40) Member States should ensure that outside workers receive the same protection as exposed workers employed by an undertaking performing practices with radiation sources. The specific arrangements for outside workers in Directive 90/641/Euratom should be extended to also cover work in supervised areas.

(41) With regard to the management of emergency exposure situations, the current approach based on intervention levels should be replaced by a more comprehensive system comprising an assessment of potential emergency exposure situations, an overall emergency management system, emergency response plans, and pre-planned strategies for the management of each postulated event.

(42) The introduction of reference levels in emergency and existing exposure situations allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.

(43) The efficient management of an emergency with cross-border consequences calls for enhanced cooperation between Member States in emergency planning and response.

(44) While urgent information exchange between Member States and the Commission in the event of an emergency is established through Council Decision 87/600/Euratom[(19)], there is a need to put in place arrangements for information exchange beyond the scope of this Decision to allow cooperation with all other Member States and with third countries which may be involved or are likely to be affected.

(45) The IAEA together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation have revised the International Basic Safety Standards in the light of the ICRP's new Publication 103, and the Commission has informed the IAEA of its decision of 6 August 2012 to co-sponsor that document on behalf of the European Atomic Energy Community.

(46) The roles and responsibilities of the national services and experts involved in ensuring that the technical and practical aspects of radiation protection are managed with a high level of competence need to be clarified. This Directive should clearly distinguish between the different roles and responsibilities of the services and experts without precluding that national frameworks allow the grouping of responsibilities or allow the assignment of responsibilities for specific technical and practical tasks in radiation protection to specified experts.

(47) Commission Recommendation 2004/2/Euratom[(20)] introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities, for transmission of the data to the Commission under Article 36 of the Euratom Treaty.

(48) Member States should have in place precise requirements for the issuing of discharge authorisations and the monitoring of discharges. The reporting of data to the competent authority on discharges from nuclear power plants and reprocessing facilities should be based on standardised information.

(49) Under Article 35 of the Euratom Treaty Member States shall ensure that an appropriate programme to monitor the level of radioactivity in the environment is in place. Under Article 36 of the Euratom Treaty Member States shall report the results of such monitoring to the Commission. Reporting requirements under Article 36 of the Euratom Treaty have been explained in Commission Recommendation 2000/473/Euratom[(21)].

(50) Council Regulation (EU) No 333/2011[(22)] establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste[(23)]. Measures need to be taken to prevent the accidental melting of orphan sources as well as to ensure compliance of metals released from nuclear installations, for instance during their dismantling, with clearance criteria.

(51) Changes need to be made to Directive 2003/122/Euratom to broaden some of the requirements to include any radioactive source. Unresolved problems with orphan sources remain, and there have been significant cases of contaminated metal being imported from third countries. A requirement should therefore be introduced for the notification of incidents with orphan sources or the contamination of metal. It is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA.

(52) Pursuant to Article 106a(3) of the Euratom Treaty, the legislation adopted on the basis of the provisions of the Treaty on European Union and of the Treaty on the Functioning

of the European Union should not derogate from the provisions of this Directive, and consequently the justification and optimisation principles should apply notably for medical devices and construction products covered by CE marking.

(53) In accordance with the Joint Political declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the transmission of such documents is justified.

(54) Directive 96/29/Euratom and the complementary Directives 89/618/Euratom, 90/641/Euratom, 97/43/Euratom and 2003/122/Euratom should be repealed,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 11, 20.2.1959, p. 221.

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

(**3**) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

(**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 (OJ L 357, 7.12.1989, p. 31).

(**5**) Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (OJ L 349, 13.12.1990, p. 21).

(**6**) Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJ L 346, 31.12.2003, p. 57).

(**7**) The 2007 Recommendations of the International Commission on Radiological Protection.

(**8**) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

(**9**) 1990 Recommendations of the International Commission on Radiological Protection.

(**10**) Compendium of Dose Coefficients based on ICRP Publication 60, 2012.

(**11**) Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures, 2010.

(**12**) Regulation (EU) No. 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

(**13**) Commission Recommendation 90/143/Euratom of 21 February 1990 on the protection of members of the public against indoor exposure to radon (OJ L 80, 27.3.1990, p. 26).

(**14**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(**15**) Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (OJ L 66, 13.3.1999, p. 16).

(**16**) IAEA 2004 Safety Standards Series RS-G-1.7, Application of the Concepts of Exclusion, Exemption and Clearance.

(**17**) Radiation Protection 122: Practical use of the Concepts of the Clearance and Exemption

(**18**) Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations, Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations, Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption.

(**19**) Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (OJ L 371, 30.12.1987, p. 76).

(**20**) Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation (OJ L 2, 6.1.2004, p. 36).

(**21**) OJ L 191, 27.7.2000, p. 37.

(**22**) Council Regulation (EU) No 333/2011 of 31 March 2011 establishing the criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council (OJ L 94, 8.4.2011, p. 2).

(**23**) OJ L 312, 22.11.2008, p. 3.