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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.11.2008  
COM(2008) 790 final

2008/0231 (CNS)

Proposal for a

**COUNCIL DIRECTIVE (Euratom)**

**setting up a Community framework for nuclear safety**

{SEC(2008) 2892}  
{SEC(2008) 2893}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### 1.1. Grounds for and objectives of the proposal

The present draft Directive setting up a Community framework on Nuclear Safety aims at re-starting the process of establishing a common EU framework on nuclear safety, by updating and replacing the Commission proposal for a Council (Euratom) Directive setting out basic obligations and general principles on the safety of nuclear installations<sup>1</sup>, included in the initial Nuclear Safety Package.

The renewed interest in nuclear power expressed by a number of Member States, with the perspective of numerous life extensions and construction of new plants, makes the timing of this revised proposal particularly appropriate. It is evident that the effects of radiological incidents do not stop at borders, with potential consequences both for the health of workers and citizens, but also wide ranging economic implications for the energy generating industry. Enacting in binding Community legislation internationally endorsed nuclear safety principles would ensure an additional level of guarantee for the public in the EU at large, by providing legal certainty.

In this framework, the revised legislative proposal builds on: a) the technical work of the Western European Nuclear Regulators Association (WENRA) completed in 2006 for existing nuclear installations, with the participation of all European nuclear safety regulators; b) the principle that only strong and independent regulators can ensure the continued safe operation of the nuclear power plants in the EU; c) enshrining in the Community legislation the principles of the main international instruments available, namely the Convention on Nuclear Safety (CNS)<sup>2</sup>, concluded under the auspices of the International Atomic Energy Agency (IAEA), and the safety work carried out by the IAEA<sup>3</sup>.

Its basic approach is that a set of common principles in the field of nuclear safety, already included in the CNS, are regulated at Community level, supplemented with additional safety requirements for new nuclear power reactors, which Member States are encouraged to develop in line with the principle of continuous improvement of safety, on the basis of the safety levels developed by WENRA and in close collaboration with the European High Level Group on Nuclear Safety and Waste Management (HLG). Based on the ten principles for the regulation of nuclear safety adopted by it, the group will become the focal point for cooperation between the regulatory bodies charged with the safety of nuclear installations in the Member States and will contribute to the development of the EU nuclear safety framework.

The general objective of the proposal is to achieve, maintain and continuously improve nuclear safety in the Community and to enhance the role of the regulatory bodies. Its scope of application is the design, siting, construction, maintenance, operation and decommissioning of nuclear installations, for which consideration of safety is required under the legislative and

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<sup>1</sup> COM(2003)32 final and COM(2004)526 final

<sup>2</sup> INFCIRC/449

<sup>3</sup> IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No. SF-1 (2006)

regulatory framework of the Member State concerned. The right of each Member State to decide to use nuclear energy or not is recognised and fully respected.

By means of this Community nuclear safety framework, several operational objectives are envisaged to be achieved, namely enhancing the role of national regulators, prime responsibility of the licence holder for safety under the control of the regulatory body, reinforcing the independence of the regulatory body, ensuring a high level of transparency on issues related to the safety of nuclear installations, implementation of management systems, regular safety supervision, availability of nuclear safety expertise, priority to safety.

## **1.2. General context**

At present, the interest in nuclear energy is undergoing a revival phase, due to a number of driving factors.

The EU is the largest nuclear electricity generator in the world, having a mature nuclear industry, spanning the entire fuel cycle with its own technological base and highly skilled workforce. Nuclear energy is currently the main low-carbon source in many EU Member States, providing more than a third of the EU electricity, and it has proven to be a stable, reliable source, relatively shielded from price fluctuations when compared to the oil and gas markets. Continued use of nuclear energy therefore would contribute to the EU energy supply security as well as to the limitation of CO<sub>2</sub> emissions, but it is also still confronted with a number of outstanding issues that need to be resolved. Nuclear energy plays an important role in the EU energy mix, supported by a firm commitment in research and promotion of technological developments, aimed at further enhancing its safety and security.

The continuous improvement of the safety of nuclear installations is a prerequisite for the acceptance of nuclear energy. Building on the existing work carried out under the auspices of the IAEA and bringing it within the Community framework would add value to the national approaches. Interlinking the national systems and the Community system will guarantee the maintenance of a high level of safety for nuclear installations in the EU and will enhance the transparency of the EU regulatory mechanisms. In a long-term perspective, this shall result in an improved public confidence in the EU decision-making process on nuclear safety matters and bring legal certainty.

## **1.3. Existing Community instruments advocating for nuclear safety harmonization at EU level**

With the development of the European nuclear industry, convergence at Community level became necessary in order to support the Member States in their efforts to harmonise safety practices. The Council Resolution of 22 July 1975 on the technological problems of nuclear safety<sup>4</sup> recognised that it was the Commission's responsibility to act as a catalyst in initiatives taken at international level in the field of nuclear safety. This Resolution, while *"taking into account the prerogatives and responsibilities assumed by national authorities"*, makes reference to the alignment of safety requirements in the context of a desirable harmonised approach at Community level.

Against this background, a second Council Resolution was adopted in 1992<sup>5</sup>, in which the Council reaffirmed the intentions of the 1975 Resolution and invited Member States to continue and intensify concerted efforts towards harmonization of safety issues.

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<sup>4</sup> OJ No C 185 of 14 August 1975, p. 1.

<sup>5</sup> OJ No C 172 of 8 July 1992, p. 2.

In addition, the support for the elaboration of Community nuclear safety legislation has been constantly reflected over the years in the Council Conclusions<sup>6</sup> and in the European Parliament Reports<sup>7</sup>. However, binding Community legislation in the area of nuclear safety has not been adopted until present.

#### **1.4. Consistency of the proposal with other policies and objectives of the Union**

The intrinsic link between radiation protection and nuclear safety was recognised by the European Court of Justice in its ruling in the Case C-29/99, according to which “*it is not appropriate, in order to define the Community’s competencies, to draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation*”. The Court has also confirmed that the Commission has competence to make recommendations for harmonising the measures required by Articles 18 and 19 of the CNS concerning the design, construction and operation of nuclear installations which can be the subject of the provisions which the Member States lay down to ensure compliance with the basic standards. The development of a Community approach in the field of nuclear safety would contribute to the full achievement of the objectives of the community acquis in the area of radiation protection, namely protecting the workers and the general public against the dangers of ionising radiation without unduly limiting the beneficial uses of the practices giving rise to radiation exposure.

#### **1.5. Initial Nuclear Safety Package**

On 30 January 2003, after receiving the opinion of the Group of Experts set up by Article 31 of the Euratom Treaty, the Commission adopted two proposals of Directives dealing respectively with the safety of nuclear facilities and the management of spent fuel and radioactive waste<sup>8</sup>.

After the European Economic and Social Committee gave its opinion on 26 March 2003, both proposals were forwarded to the Council. In accordance with the procedure in Article 31 of the Euratom Treaty, the Council requested the opinion of the European Parliament, which adopted opinions on the proposals in its plenary session on 13 January 2004.

At the same time, both proposals were discussed in the Council, under the Italian and Irish Presidencies. As a majority allowing the adoption or the rejection of both proposals was not possible to be obtained, it was agreed that Council conclusions would be worked out by consensus. Draft Conclusions on nuclear safety and on the safety of the management of spent nuclear fuel and radioactive waste were adopted by the Council in June 2004<sup>9</sup>, leading to the creation of the Council Working Party on Nuclear Safety (WPNS). A detailed presentation of the procedural aspects related with the initial Nuclear Safety Package is included in the Impact Assessment Report<sup>10</sup> accompanying the present initiative.

The existing proposal of a Directive dealing with the safety of nuclear facilities will be withdrawn and replaced by the new proposal.

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<sup>6</sup> Council Conclusions on nuclear safety and on the safety of the management of spent nuclear fuel and radioactive waste (10823/04); Council Conclusions on Nuclear Safety and Safe management of spent nuclear fuel and radioactive waste (8784/07)

<sup>7</sup> Maldeikis report on the 50 years of the Euratom Treaty (A6-0129/2007) and Reul report on conventional energies (A6-0348/2007)

<sup>8</sup> COM(2003) 32 final

<sup>9</sup> 10823/04

<sup>10</sup> SEC(2008) 2892.

## **2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **2.1. Stakeholders consultations on the necessity of a Community nuclear safety legislative framework**

The current revised legislative proposal is the result of an extensive and continuous consultation process, initiated in 2004 during the Irish Presidency. The WPNS, the HLG and the European Nuclear Energy Forum continued work on this issue.

Throughout the elaboration process of the initial Nuclear Safety Package, a wide consultation with the stakeholders on the opportunity of setting up a nuclear safety legislative framework was carried out at the initiative of the Commission, supplementing the consultations resulting from the legislative procedure provided for in the Euratom Treaty (the opinions of the Group of experts set up by Article 31 of the Treaty and of the European Economic and Social Committee). Consultations were also undertaken with international organizations, such as the IAEA and the OECD Nuclear Energy Agency (NEA). The Commission took also advantage of its participation in various international meetings to present its plans for EU regulation in the field of nuclear safety.

The European Nuclear Energy Forum, established in 2007 and involving key decision-makers and organizations from national and EU levels, has already contributed to enhancing a better understanding on common approaches that are required in the further development of the safety of nuclear installations. The Conclusions of the Prague and Bratislava 2008 Forum meetings emphasised the Forum's strong support for the adoption of EU legislation on nuclear safety, based on "*common fundamental safety principles for nuclear installations*".

In addition, the technical background supporting the basic principles proposed in the current draft revised Directive was provided by the outcome of the activity of the different expert groups dealing with nuclear safety matters. Several different levels and types of activities have been developed at EU level, with the involvement of expert groups comprising representatives of the safety authorities of the Member States, which have actively contributed to the harmonisation of nuclear safety practices.

### **2.2. Overview of the expert groups in the field of the harmonization of nuclear safety approaches at EU level**

#### **2.2.1. Nuclear Regulators' Working Group (NRWG) and Reactor Safety Working Group (RSWG)**

In order to pursue the objectives of the 1975 Council Resolution on the technological problems of nuclear safety, the Commission set up two expert groups dealing with nuclear installation safety. The NRWG, which met last in June 2005, includes representatives of nuclear regulatory authorities from EU Member States and Candidate States of Central and Eastern Europe. The RSWG, which included all the EU regulatory bodies and industry, was discontinued in 1998.

#### **2.2.2. CONCERTation on European Regulatory Tasks (CONCERT)**

The CONCERT Group, formed in 1992, was a forum that brought together EU, Central and Eastern European Countries and Newly Independent States nuclear regulators to share experience and to enhance the progress of assistance and co-operation programmes in general. The group held its last meeting in 2005.

### 2.2.3. WENRA

Special emphasis should be put on the activity carried on by WENRA, an organisation comprising the Heads and senior staff members of nuclear regulatory authorities from 17 European Countries.

In order to harmonise safety approaches, two working groups were launched with the mandate to analyse the current situation and the different safety approaches, compare individual national regulatory approaches with the IAEA Safety Standards, identify differences and propose a way forward to possibly eliminate the differences without impairing the final resulting level of safety.

In January 2006, reports on safety reference levels were published and subsequently revised in 2007 and 2008<sup>11</sup>. WENRA members have defined many common safety reference levels for power reactors with a view to align national requirements by the year 2010. Any Community initiative in the field of nuclear safety should take advantage of the technical progresses achieved within WENRA. Moreover, the WENRA reports on the harmonization of safety approaches for nuclear power reactors were assessed by the WPNS which concluded that "*WENRA methodology is a systematic, documented and logical approach to harmonisation*".

### 2.2.4. WPNS

Following the 2004 Council Conclusions on nuclear safety and safe management of spent fuel and radioactive waste, which call for an "*extensive consultation*" with stakeholders, a wide ranging consultation process was initiated, aiming to identify new instrument(s) that can contribute more effectively to further improving nuclear safety and the safety of the management of spent fuel and radioactive waste, in the framework of the Euratom Treaty and in line with the principles of better law making. As a result, the WPNS was established<sup>12</sup>.

The final WPNS Report<sup>13</sup>, comprising overall conclusions and recommendations, was approved by the Council on 13 December 2006. The detailed methodology, organisation of work and data collection, detailed results from data collection and analysis, and justification for the conclusions and recommendations are presented in the reports produced by the three established subgroups<sup>14</sup>. 70 experts from Member States and the Commission participated at the work of the WPNS. The conclusions of these Reports offer a sound technical background for the approach envisaged by the current draft Directive setting up a Community framework for Nuclear Safety.

### 2.2.5. HLG

In 10 January 2007, the Commission adopted a draft Nuclear Illustrative Programme that proposed the establishment of a High Level Group on nuclear safety, waste management and decommissioning. Subsequently, this proposal has been endorsed and supported by all the highest EU fora (as reflected in the Conclusions of the Brussels European Council from March 2007<sup>15</sup>, the Council Conclusions of May 2007 on Nuclear Safety and Safe

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<sup>11</sup> <http://www.wenra.org>

<sup>12</sup> WPNS has been activated by the Working Party on Atomic Questions (WPAQ) as a consequence of the Council conclusions on Nuclear Safety and Safe management of spent fuel and radioactive waste (10823/04)

<sup>13</sup> 15475/2/06 REV2

<sup>14</sup> 15475/2/06 REV 2 ADD 1, 15475/2/06 REV 2 ADD 2, 15475/2/06 REV 2 ADD 3

<sup>15</sup> 7224/1/07 REV 1

Management of Spent Nuclear Fuel and Radioactive Waste<sup>16</sup> and in the 2007 European Parliament Report on 50 years of European nuclear energy policy<sup>17</sup>).

The HLG was formalised by the Commission Decision 2007/530/Euratom<sup>18</sup> in July 2007. The Decision mandates the HLG to assist the EU institutions in progressively developing common understanding and eventually additional European rules in the fields of the safety of nuclear installations and the safety of the management of spent fuel and radioactive waste.

The HLG comprises the Heads of the national regulatory or nuclear safety authorities of the 27 Member States. By setting up the HLG, the technical work of WENRA will be widened in a more formal framework, in association with representatives of the EU non nuclear energy countries.

The proposed draft Directive includes specific provisions on the actions to be implemented by the HLG, which will have a key role by supporting the definition of instruments to maintain and further improve nuclear safety throughout the Community. For this purpose, upon the adoption by the Council of the current Directive, the initial mandate of the Group, as set up in the Commission Decision 2007/530/Euratom will be amended by the Commission, in order to properly reflect its responsibilities in connection with the implementation of the Directive.

### 2.3. Impact Assessment

The accompanying Impact Assessment updates the Impact Assessment related to the previous nuclear safety proposal included in the Nuclear Safety Package<sup>19</sup>, and it is based on the technical conclusions and recommendations identified in the WPNS Reports, as well as on the obligations and requirements set up in the CNS and on the principles of the IAEA Safety Fundamentals.

The Impact Assessment analyses **four policy options**: *Policy option 0* consists in keeping the current situation unchanged; *Policy option 1* envisages the elaboration of Community legislation establishing common safety standards for existing nuclear installations; *Policy option 2* consists in the enacting Community legislation that sets up only a common framework aiming at achieving and maintaining a high uniform level of nuclear safety throughout the Community by recalling widely recognised nuclear safety principles, the subsequent implementing measures being elaborated by the HLG; *Policy option 3* is built upon a set of internationally-recognised nuclear safety principles (approach proposed by Policy option 2), supplemented with additional safety requirements for new nuclear power reactors, which Member States are encouraged to develop in line with the principle of continuous improvement of safety, on the basis of the safety levels developed by WENRA and in close collaboration with the HLG. As a result, the assessment of the options showed that the most efficient solution for setting up a Community nuclear safety common approach is the one envisaged by Policy option 3. The Impact Assessment Report is accessible on.....

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<sup>16</sup> 8784/07

<sup>17</sup> A6-0129/2007

<sup>18</sup> O.J. L 195, 27/07/2007 P. 0044 - 0046

<sup>19</sup> COM 2003/32

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **3.1. Summary of the proposed action**

The present proposal aims at re-starting the process of establishing a common EU framework on nuclear safety with the objective of achieving and maintaining a high comparable level of nuclear safety throughout the Community, by replacing the corresponding initial proposal included in the Nuclear Safety Package. The proposal is anchored on the provisions of the CNS, which sets up a precise legal framework representing the foundation of a harmonised nuclear safety system and to which Euratom and all the EU Member States are Contracting Parties.

#### **3.2. Legal basis**

The legal basis for this proposal is Article 31 of the Euratom Treaty, in connection with Article 32 thereof. Article 31 defines the procedure for the adoption of the basic safety standards provided for in Article 30 for the protection of the health of workers and the general public against the dangers arising from ionising radiation. Article 32 explicitly states that the basic standards might be supplemented in accordance with the procedure laid down in Article 31.

#### **3.3. Subsidiarity and proportionality**

Nuclear energy plays an important role in the transition to a low carbon economy and reduces EU external supply dependency. The choice to include nuclear energy in the energy mix lies with the Member States. The role of the European Union is to ensure that this source of energy is developed while meeting the highest level of safety.

All the EU Member States are Contracting Parties to the CNS, which constitutes an internationally recognised common platform for nuclear safety development. The EU Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the EU. However, because of the different historical backgrounds, legal frameworks, type and number of reactors and different approaches to regulation, common rules in the field of nuclear safety to be applied across the Community have not been yet established.

The approach of the current proposal allows Member States to fully exploit the subsidiarity principle as it creates a legislative framework for nuclear safety without being prescriptive as regards details. Moreover, the draft Directive aims to reinforce the role and the independence of the national regulatory bodies thereby building on their competencies, as well as the role of the national bodies in the implementation of the agreed measures. By means of the Directive, the principle of national responsibility for the safety of nuclear installations is fully adhered to, as for the safety of new nuclear power reactors, Member States are encouraged to develop additional safety requirements, in line with the continuous improvement of safety on the basis of the safety levels developed by WENRA and in close collaboration with the HLG. In addition, Member States retain the right to impose at national level more stringent safety measures than those provided for in the draft Directive.

### **4. MAIN PROVISIONS OF THE PROPOSAL**

#### **4.1. Responsibility and framework for the safety of nuclear installations (Article 3)**

The article on responsibility for the safety of nuclear installations reflects one of the fundamental principles of nuclear safety, also enshrined in Article 9 of the CNS: the prime

responsibility for the safety of nuclear installations, throughout their lifetime, rests with the holder of the license under the control of the regulatory body. Furthermore, the safety measures and controls to be implemented in a nuclear installation shall be decided only by the regulatory body and realised by the licence holder.

The second paragraph requires Member States to establish and maintain a legislative and regulatory framework for nuclear safety. This provision is already adhered to by all Member States and should not pose any difficulty for implementation.

#### **4.2. Regulatory bodies (Article 4)**

The text reinforces the role and the independence of the national regulatory bodies, building on their competencies. In order to facilitate autonomous decisions giving priority to nuclear safety, the effective independence of the regulatory body from all organizations tasked to promote, operate nuclear installations or justify societal benefits, as well as its freedom from undue influence must be ensured. A similar provision already exists in the CNS (Article 8 paragraph 2). The regulatory body, provided with adequate authority, competence and financial and human resources to fulfil its responsibilities and duties, will be entrusted with the supervision and regulation of the safety of nuclear installations, as well as with ensuring of the implementation of safety requirements, conditions and regulations.

The regulatory body will have the responsibility of granting licences and monitoring their application on siting, design, construction, commissioning, operation or decommissioning of nuclear installations.

The regulatory body will have the duty to ensure that licence holder have staff in sufficient numbers and level of qualification to run the installations.

In order to continuously improve the regulatory infrastructure, the regulatory body and the national regulatory structure will be subject to periodic international peer reviews.

In the framework of this provision, the national regulatory bodies and the regulatory systems will be subject to regular international peer review missions by the IAEA International Regulatory Review Service (IRRS) missions, and subscribe to prepare at least a self assessment every ten years.

#### **4.3. Transparency (Article 5)**

The provisions of Article 5 respond to the necessity ensure access to reliable information and to allow the public to participate to a transparent decision-making process.

#### **4.4. Safety requirements and regulations for nuclear installations (Article 6)**

Article 6 reiterates and reinforces Member States' obligation to respect the IAEA safety fundamentals<sup>20</sup> as well as to observe the internationally agreed obligations and requirements of the CNS.

In addition, as regards the safety of new nuclear power reactors, Member States are encouraged to develop additional safety requirements, in line with the continuous improvement of safety on the basis of the safety levels developed by WENRA, and in close collaboration with the HLG.

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<sup>20</sup> IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No. SF-1 (2006).

In this context, it should be underlined that, once the Council has agreed on the text of the Directive, the Commission will adapt accordingly the mandate of the HLG as established by its founding Commission Decision.

#### **4.5. Obligations of licence holders (Article 7)**

This article sums up the obligations of licence holders for fulfilling the requirements set up in Article 6 and emphasises their duties to establish and implement management systems and possess adequate financial and human resources for nuclear safety.

#### **4.6. Supervision (Article 8)**

The nuclear safety assessments, investigations, control and enforcement actions of the regulatory body must be carried out throughout the whole lifetime of installations, including during decommissioning. This is another commonly agreed principle. In order to strengthen the powers of European regulators, the present Directive provides for extended regulatory powers in the interest of safety. In case of serious or repeated safety rules breaches, the regulatory body shall have the power to withdraw the operating licence and order the suspension of operations of any plant if it deems that safety is not fully guaranteed. The obligation of the assessment and verification of safety is also set up in Article 14 of the CNS.

#### **4.7. Nuclear safety expertise (Article 9)**

The availability of nuclear safety experts is an extremely important issue which comes up at every international meeting concerned with nuclear safety. The past decades have not trained enough specialists, so that there is also the problem of aging of safety personnel and inspectors, of which many are approaching retirement. This is an area where the Community can assist with encouraging trans-national cooperation and training. The obligation to ensure the availability of sufficient and qualified staff is also recognised in Article 11 paragraph 2 of the CNS.

#### **4.8. Priority to safety (Article 10)**

In line with the principle of priority of safety, Member States have the possibility to impose at national level more stringent safety measures than those provided for in the draft Directive.

### **5. CONCLUSION**

The Council is, therefore, requested to:

approve the attached proposal for a Council Directive (Euratom) setting up a Community framework for Nuclear Safety.

Proposal for a

**COUNCIL DIRECTIVE (Euratom)**

**setting up a Community framework for nuclear safety**

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 Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States<sup>21</sup>,

Having regard to the opinion of the European Parliament<sup>22</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>23</sup>,

Whereas:

- (1) Article 2(b) of the Treaty stipulates that the Community is to establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied.
- (2) Article 30 of the Treaty provides that basic standards are to be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionising radiations.
- (3) For that purpose 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<sup>24</sup> establishes the basic safety standards. The provisions of that Directive were supplemented by more specific legislation.
- (4) 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<sup>25</sup> established a framework for notification and provision of information to be used by the Member States in order to protect the general public in case of a radiological emergency. Council Directive 89/618/Euratom of 27 November 1989 on informing the

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<sup>21</sup> OJ C [...], [...], p. [...]

<sup>22</sup> OJ C [...], [...], p. [...]

<sup>23</sup> OJ C [...], [...], p. [...]

<sup>24</sup> OJ L 159, 29.6.1996, p. 1.

<sup>25</sup> OJ L 371, 30.12.1987, p. 76.

general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency<sup>26</sup> imposed obligations on the Member States to inform the general public in the event of a radiological emergency.

- (5) Although the system of radiation protection established by the existing basic safety standards, taking into account the current scientific knowledge, ensures a high level of protection for the health of the population, it should be further supplemented to ensure that a high level of safety of nuclear installations is maintained, developed and continuously improved. Keeping up a high level of safety from design to decommissioning is a *sine qua non* condition in order to fully attain the objectives of health protection set out in Article 2(b) of the Treaty. For this purpose effective defences against radiological risks should be maintained and accidents which could have radiological consequences should be prevented.
- (6) While each Member State is free to decide on its energy mix, after a period of reflection, interest in the construction of new plants has grown and some Member States decided to licence new plants. Furthermore, requests for nuclear power plant life extensions are expected to be presented by licence holders in the years to come.
- (7) For this purpose best practices should be developed to guide the regulatory bodies in their decisions on the lifetime extension of nuclear installations.
- (8) The Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the Community.
- (9) The continuous improvement of nuclear safety requires that the management systems established and the licence holders ensure the high level of safety for the general public.
- (10) Fundamentals and requirements set by the International Atomic Energy Agency (IAEA) constitute a framework of practices on which national safety requirements should be based. Member States have made considerable contributions to the improvement of those fundamentals and requirements.
- (11) The national safety authorities of the Member States having nuclear power plants on their territory have worked together in the context of Western European Nuclear Regulators' Association (WENRA) and have defined many common safety reference levels for power reactors with a view to align national requirements by the year 2010.
- (12) Despite existing harmonisation, the nuclear safety procedures and practices still vary from one Member State to another. At present, the diversity of measures does not ensure that the health protection requirements of Article 2(b) of the Treaty are applied in the most coherent way in the Community. The European Atomic Energy Community by joining the Convention on Nuclear Safety, which entered into force on 24 October 1996, committed itself to observing an internationally recognised high level of nuclear safety<sup>27</sup>. In order for the Community to ensure that the principles of

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<sup>26</sup> OJ L 357, 7.12.1989, p. 31.

<sup>27</sup> The Interinstitutional Agreement on inter-institutional co-operation in the framework of international Conventions to which the European Atomic Energy Community and its Member States are parties applies in this context.

this Convention are given effect at Community level and that uniform safety standards as required by Article 2(b) of the Treaty are applied, the basic standards for radiation protection should be supplemented by common safety principles.

- (13) The provision of information to the public in an accurate and timely manner about important nuclear safety matters should be based on high level of transparency on issues relating to the safety of nuclear installations.
- (14) National responsibility of Member States for the safety of nuclear installations is the fundamental principle on which nuclear safety regulation has been developed on the international level, as endorsed by the Convention on Nuclear Safety. This principle of national responsibility as well as the principle of prime responsibility for the safety of a nuclear installation which rests with the licence holder under the control of its national regulatory body should be enhanced by this Directive.
- (15) In order to ensure the effective implementation of safety requirements for nuclear installations, Member States should establish regulatory bodies as independent authorities. Regulatory bodies should be provided with adequate competence and resources in order to be able to discharge their duties.
- (16) In order to ensure an effective implementation of this Directive, Member States should report to the Commission at regular intervals. Intervals of three years are appropriate in the light of the requirements of the Convention on Nuclear Safety.
- (17) In order to continuously improve nuclear safety the Commission, if appropriate, may present proposals for adoption by the Council.
- (18) The European High Level Group on Nuclear Safety and Waste Management was created<sup>28</sup> to contribute to the achievement of the Community objectives in the field of nuclear safety. For this purpose it should support the development of instruments that are necessary to maintain and continuously improve nuclear safety and that should be applied to the design, siting, construction, maintenance, operation and decommissioning of nuclear installations, for which compliance with safety requirements is required under the legislative and regulatory framework of the Member State concerned.
- (19) The regulatory bodies charged with the safety of nuclear installations in the Member States should mainly cooperate through the European High Level Group on Nuclear Safety and Waste Management which has developed ten principles for the regulation of nuclear safety. The European High Level Group on Nuclear Safety and Waste Management should contribute to the Community nuclear safety framework with the aim of continuously improving it.

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<sup>28</sup> O.J. L 195, 27/07/2007 P. 0044 - 0046

HAS ADOPTED THIS DIRECTIVE:

*Article 1*  
*Objective and scope*

1. This Directive aims at achieving, maintaining and continuously improving nuclear safety in the Community and to enhance the role of the national regulatory bodies.
2. It shall apply to the design, siting, construction, maintenance, operation and decommissioning of nuclear installations, for which consideration of safety is required under the legislative and regulatory framework of the Member State concerned.
3. This Directive is without prejudice to the Council Directive 96/29/Euratom.
4. This Directive is without prejudice to the right of each Member State to decide whether to operate its own civil nuclear programme or not .

*Article 2*  
*Definitions*

For the purposes of this Directive the following definitions shall apply:

- (1) "nuclear installation" means a nuclear fuel fabrication plant, research reactor (including subcritical and critical assemblies), nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;
- (2) "nuclear safety" means the achievement of proper operating conditions through measures taken with a view to the prevention of accidents or mitigation of accident consequences, resulting in protection of workers, general public and the air, water and soil from undue radiation hazards arising from nuclear installations;
- (3) "radioactive material" means any material containing one or more radionuclides the activity or concentration thereof cannot be disregarded as far as radiation protection is concerned;
- (4) "decommissioning" means administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a nuclear installation, except for a repository or for certain nuclear facilities used for the disposal of residues from the mining and processing of radioactive material, which are closed and not decommissioned;
- (5) "radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen by the Member State, and which is controlled as radioactive waste by a regulatory body under the legislative and regulatory framework of a Member State;
- (6) "spent fuel" means nuclear fuel that has been irradiated in and permanently removed from a reactor core; spent fuel may either be considered as usable resource that can be reprocessed or be destined for final disposal with no further use foreseen and treated as radioactive waste;

(7) “ionising radiation” means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometer or less or a frequency of  $3 \times 10^{15}$  Hertz or more capable of producing ions directly or indirectly;

(8) ”regulatory body” means any body or bodies authorised by the Member State to grant in that Member State licences and to supervise the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;

(9) "licence" means any authorisation granted by the regulatory body to the applicant to confer the responsibility for the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;

(10) “new power reactors” mean nuclear power reactors licensed to operate after the entry into force of this Directive.

### *Article 3*

#### *Responsibility and framework for the safety of nuclear installations*

1. The prime responsibility for the safety of nuclear installations shall rest with the holder of the license under the control of the regulatory body. The safety measures and controls to be implemented in a nuclear installation shall be decided only by the regulatory body and applied by the licence holder.

The licence holder shall have the prime responsibility for safety throughout the lifetime of the nuclear installations until its release from regulatory control. This responsibility of the licence holder cannot be delegated.

2. Member States shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations. This shall include national safety requirements, a system of licensing and control of nuclear installations and the prohibition of their operation without a licence and a system of regulatory supervision including the necessary enforcement.

### *Article 4*

#### *Regulatory bodies*

1. Member States shall ensure that the regulatory body is effectively independent of all organisations whose task is to promote, operate nuclear installations or justify societal benefits and free from any influence that may affect the safety.

2. The regulatory body shall be provided with adequate authority, competence and financial and human resources to fulfil its responsibilities and discharge its duties. It shall supervise and regulate the safety of nuclear installations and ensure the implementation of safety requirements, condition and safety regulations.

3. The regulatory body shall grant licenses and monitor their application on siting, design, construction, commissioning, operation or decommissioning of nuclear installations.

4. Regulatory bodies shall ensure that licence holders have at their disposal appropriate staff in terms of numbers and qualifications.

5. At least every ten years the regulatory body shall submit itself and the national regulatory system to an international peer review aimed at continuously improving the regulatory infrastructure.

*Article 5*  
*Transparency*

Member States shall inform the public about the procedures and the results of the surveillance activities on nuclear safety. They shall also ensure that the regulatory bodies effectively inform the public in the fields of their competence. Access to information shall be ensured, in accordance with relevant national and international obligations.

*Article 6*  
*Safety requirements and regulations for nuclear installations*

1. Member States shall respect the IAEA safety fundamentals (IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No. SF-1 (2006)). They shall observe the obligations and requirements incorporated in the Convention on Nuclear safety (IAEA INFCIRC 449 of 5 July 1994).

They shall in particular ensure that the applicable principles laid down in the IAEA safety fundamentals are implemented to ensure a high level of safety in nuclear installations, including *inter alia* effective arrangements against potential radiological hazards, accident prevention and response, ageing management, long term management of all produced radioactive materials and information of the population and the authorities of neighbouring States.

2. As regards the safety of new nuclear power reactors Member States shall aim to develop additional safety requirements, in line with the continuous improvement of safety on the basis of the safety levels developed by the Western European Nuclear Regulators' Association (WENRA) and in close collaboration with the European High Level Group on Nuclear Safety and Waste Management.

*Article 7*  
*Obligations of licence holders*

1. Licence holders shall design, construct, operate and decommission their nuclear installations in accordance with the provisions set out in Article 6(1) and (2).

2. Licence holders shall establish and implement management systems which shall be regularly verified by the regulatory body.

3. Licence holders shall allocate adequate financial and human resources to fulfil their obligations.

*Article 8*  
*Supervision*

1. Nuclear safety assessments, investigations, controls and, where necessary, enforcement actions shall be carried out by the regulatory body in nuclear installations throughout their lifetime, including during decommissioning.
2. The regulatory body shall have the power to withdraw the operating licence in case of serious or repeated safety rules breaches in the nuclear installation.
3. The regulatory body shall have the power to order the suspension of operations of any nuclear plant if it deems that safety is not fully guaranteed.

*Article 9*  
*Nuclear safety expertise*

Appropriate education and training opportunities for continuous theoretical and practical training in nuclear safety shall be made available by Member States separately and through trans-national cooperation.

*Article 10*  
*Priority to safety*

Member States may lay down more stringent safety measures than those laid down in this Directive.

*Article 11*  
*Reporting*

Member States shall submit a report to the Commission on the implementation of this Directive by [three years after the entry into force] at the latest, and every three years thereafter. On the basis of the first report, the Commission shall present a report to the Council on progress made with the implementation of this Directive, accompanied, if appropriate, by legislative proposals.

*Article 12*  
*Transposition*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [two years after the date referred to in Article 13] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 13*  
*Entry into force*

This Directive shall enter into force the twentieth day after its publication in the Official Journal of the European Union.

*Article 14*  
*Addressees*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Council*  
*The President*