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- having regard to Rules 51 and 83(7) of its Rules of Procedure,
  - having regard to the report of the Committee on International Trade and the opinion of the Committee on Foreign Affairs (A6-0085/2006),
1. Approves the conclusion of the agreement;
  2. Instructs its President to forward its position to the Council and the Commission, and the governments and parliaments of the Member States and of Turkmenistan.

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### **Community framework for nuclear safety \***

P6\_TA(2009)0254

**European Parliament legislative resolution of 22 April 2009 on the proposal for a Council directive (Euratom) setting up a Community framework for nuclear safety (COM(2008)0790 – C6-0026/2009 – 2008/0231(CNS))**

(2010/C 184 E/59)

(Consultation procedure)

*The European Parliament,*

- having regard to the Commission proposal to the Council (COM(2008)0790),
  - having regard to Articles 31 and 32 of the Euratom Treaty, pursuant to which the Council consulted Parliament (C6-0026/2009),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Rules 51 and 35 of its Rules of Procedure,
  - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on the Environment, Public Health and Food Safety (A6-0236/2009),
1. Approves the Commission proposal as amended;
  2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 119, second paragraph, of the Euratom Treaty and to ensure that the legal requirements foreseen by the Euratom Treaty for the adoption of this proposal have been respected, notably the consultation of the group of experts in accordance with Article 31 of the Euratom Treaty;
  3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
  4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;
  5. Instructs its President to forward its position to the Council and Commission.

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TEXT PROPOSED BY THE COMMISSION

AMENDMENT

**Amendment 1**  
**Proposal for a directive**  
**Recital 6**

(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.**

(6) Each Member State is free to decide on its energy mix.

**Amendment 2**  
**Proposal for a directive**  
**Recital 7**

(7) For this purpose best practices should be developed to guide the regulatory bodies in their decisions on the lifetime extension of nuclear installations.

(7) **Nuclear security is a matter of Community interest, which should be taken into consideration in the event of decisions on licensing new plants and/or extending the lifetime of nuclear installations.** For this purpose best practices should be developed to guide the regulatory bodies **and Member States when deciding whether or not to licence new plants as well as** in their decisions on the lifetime extension of nuclear installations.

**Amendment 3**  
**Proposal for a directive**  
**Recital 9**

(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.

(9) The continuous improvement of nuclear safety requires that the management systems established and the licence holders **and waste managers** ensure the **highest possible** level of safety for the general public.

**Amendment 4**  
**Proposal for a directive**  
**Recital 10**

(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.

(10) Fundamentals, requirements **and guidelines** set by the International Atomic Energy Agency (IAEA) constitute **a set of rules and** a framework of practices on which national safety requirements should be based. Member States have made considerable contributions to the improvement of those fundamentals, requirements **and guidelines. Those rules should reflect best international practice as regards safety requirements and therefore constitute a good basis for Community legislation. They cannot be introduced into Community law by simple reference to the IAEA Safety Standards Series No. SF-1 (2006) in this Directive. An Annex containing the Fundamental Safety Principles should therefore be added to this Directive.**

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**Amendment 5**  
**Proposal for a directive**  
**Recital 13**

(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.

(13) The provision of information to **nuclear industry workers and** 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.

**Amendment 6**  
**Proposal for a directive**  
**Recital 13 a (new)**

**(13a) In order to ensure access to information, public participation and transparency, Member States should take all the appropriate measures to implement the obligations laid down in international conventions that already provide for the necessary requirements in national, international, or trans-boundary contexts, such as the Convention on access to information, public participation in decision-making and access to justice in environmental matters (Aarhus Convention, 25 June 1998) <sup>(1)</sup>.**

<sup>(1)</sup> OJ L 124, 17.5.2005, p. 1; OJ L 164, 16.6.2006, p. 17 and Regulation (EC) 1367/2006, OJ L 264, 25.9.2006, p. 13.

**Amendment 7**  
**Proposal for a directive**  
**Recital 15**

(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.

(15) In order to ensure the effective **regulation** of nuclear installations, Member States should establish regulatory bodies as authorities **independent from interests that could unduly affect decisions on nuclear safety issues**. Regulatory bodies should be provided with adequate competence and resources in order to be able to discharge their duties.

**Amendment 8**  
**Proposal for a directive**  
**Recital 19**

(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.

(19) The regulatory bodies charged with the **supervision** of **the** nuclear installations in the Member States should mainly cooperate through the European High Level Group on Nuclear Safety and Waste Management. **The High Level Group** has developed ten principles for the regulation of nuclear safety **which are important in the context of this Directive**. 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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**Amendment 9****Proposal for a directive  
Article 1 – paragraph 1**

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.

1. This Directive aims at **creating a Community framework for nuclear safety in the European Union. It sets out a foundation for legislation and regulatory arrangements in the Member States concerning nuclear safety and aims at** achieving, maintaining and continuously improving nuclear safety in the Community and to enhance the role of the national regulatory bodies.

**Amendment 11****Proposal for a directive  
Article 1 – paragraph 2**

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.

2. It shall apply to the design, siting, construction, maintenance, **commissioning**, operation and decommissioning of nuclear installations **and to work carried out by subcontractors used by operators**, for which consideration of safety **shall be** required under the legislative and regulatory framework of the Member State concerned.

**Amendment 12****Proposal for a directive  
Article 2 – point 1**

(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;

(1) 'nuclear installation' means a nuclear fuel fabrication plant, research reactor (including subcritical and critical assemblies), nuclear power plant, spent fuel **and radioactive waste** storage facility, enrichment plant or reprocessing facility, **including facilities for handling and treatment of radioactive substances generated during the operation of an installation**;

**Amendment 13****Proposal for a directive  
Article 2 – point 3**

(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;

(3) 'radioactive **substance**' means any material containing one or more radionuclides the activity or concentration thereof cannot be disregarded as far as radiation protection is concerned;

**Amendment 14****Proposal for a directive  
Article 2 – point 8**

(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**;

(8) 'regulatory body' means **an authority or a system of authorities designated by a Member State as having the legal authority to conduct the regulatory process, including the issue of authorisations, and thereby the regulation of nuclear, radiation, radioactive waste and transport safety**;

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**Amendment 15****Proposal for a directive  
Article 2 – point 9**

(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;

(9) ‘licence’ means any authorisation granted by **a government or a national authority approved by that government** to the applicant to confer the responsibility for the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;

**Amendment 16****Proposal for a directive  
Article 2 – point 10**

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

(10) ‘new power reactors’ mean nuclear power reactors licensed **for construction** after the entry into force of this Directive.

**Amendment 17****Proposal for a directive  
Article 3 – title**

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

**Legal** framework for the safety of nuclear installations

**Amendment 18****Proposal for a directive  
Article 3 – paragraph 1**

**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.**

*deleted*

**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.**

**Amendment 19****Proposal for a directive  
Article 3 – paragraph 2**

**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.**

**1. Member States shall establish and maintain a legislative and regulatory framework, based on EU and international best available practices, 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, through suspension, modification or revocation of licences including the necessary enforcement.**

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**Amendment 20****Proposal for a directive  
Article 3 – paragraph 2 a (new)**

*2a. Member States shall ensure that legislation is put in place to provide for withdrawal of the operating licence of a nuclear installation in cases of serious breaches of the conditions of a licence.*

**Amendment 21****Proposal for a directive  
Article 3 – paragraph 2 b (new)**

*2b. Member States shall ensure that all organisations engaged in activities directly related to nuclear installations shall establish policies that give due priority to nuclear safety.*

**Amendment 22****Proposal for a directive  
Article 3 – paragraph 2 c (new)**

*2c. Member States shall ensure that at least every 10 years the regulatory body and the national regulatory system is submitted to an international peer review aimed at continuously improving the regulatory infrastructure.*

*Member States shall notify the results of the international peer review to the Commission.*

**Amendment 23****Proposal for a directive  
Article 3 – paragraph 2 d (new)**

*2d. Member States may lay down more stringent safety measures than those laid down in this Directive.*

**Amendment 24****Proposal for a directive  
Article 4 – title**

Regulatory bodies

*Designation and responsibilities of the regulatory bodies***Amendment 25****Proposal for a directive  
Article 4 – paragraph – -1 (new)**

*-1. Member States shall designate a national regulatory body responsible for regulating, supervising and assessing the safety of nuclear installations.*

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**Amendment 26****Proposal for a directive****Article 4 – paragraph 1**

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.

1. Member States shall ensure *the effective independence of* the regulatory body. *For this purpose, Member States shall ensure that, when carrying out the tasks conferred upon it by this Directive:*

(a) *the regulatory body is legally distinct and functionally independent from any other public or private entity, and, in particular from those* whose task is to promote, operate nuclear installations or justify societal benefits, and free from any influence that may affect safety;

(b) *that the staff of the regulatory body and the persons responsible for its management act independently from any market interest and shall not seek or take instructions from any government or other public or private entity, when carrying out its regulatory duties.*

*This requirement shall be without prejudice to close cooperation, as appropriate, with other relevant national authorities.*

**Amendment 27****Proposal for a directive****Article 4 – paragraph 2**

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*.

2. *Member States shall ensure that* the regulatory body *has* adequate authority, competence and financial and human resources to fulfil its responsibilities and discharge its duties. *The regulatory body* shall supervise and regulate the safety of nuclear installations and ensure *that* the *applicable* safety requirements *and licensing conditions are met*.

**Amendment 28****Proposal for a directive****Article 4 – paragraph 3**

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

**Amendment 29****Proposal for a directive****Article 4 – paragraph 3 a (new)**

3a. *Member States shall ensure that the regulatory body carries out nuclear safety assessments, investigations and controls and, where necessary, enforcement actions in nuclear installations throughout their lifetime, including during decommissioning.*

**Amendment 30****Proposal for a directive****Article 4 – paragraph 3 b (new)**

3b. *Member States shall ensure that the regulatory body is empowered to order the suspension of operations of any nuclear installations in cases where safety is not guaranteed.*

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**Amendment 31****Proposal for a directive  
Article 4 – paragraph 4**

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

**Amendment 32****Proposal for a directive  
Article 4 – paragraph 5**

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.* *deleted*

**Amendment 33****Proposal for a directive  
Article 4 – paragraph 5 a (new)**

*5a. Regulatory bodies of the Member States shall exchange best regulatory practice and develop a common understanding of internationally accepted nuclear safety requirements.*

**Amendment 34****Proposal for a directive  
Article 5**

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.

Member States shall inform the public *and the Commission* about the procedures and the results of the surveillance activities on nuclear safety *and shall inform the public immediately in the event of any incident*. 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.

**Amendment 35****Proposal for a directive  
Article 6 – paragraph 1 – subparagraph 1**

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).

1. *For the siting, design, construction, operation and decommissioning of nuclear facilities*, Member States shall *apply those parts of* the IAEA safety fundamentals (IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No. SF-1 (2006)), *which are relevant to the creation of a Community framework for nuclear safety, as specified in the Annex*. They shall *apply* the obligations and requirements incorporated in the Convention on Nuclear Safety <sup>(1)</sup>.

<sup>(1)</sup> OJ L 318, 11.12.1999, p. 20 and OJ L 172, 6.5.2004, p. 7.



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**Amendment 36****Proposal for a directive****Article 6 – paragraph 1 – subparagraph 2**

*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.*

*deleted*

**Amendment 37****Proposal for a directive****Article 6 – paragraph 2**

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.*

2. *For the licensing of construction* of new nuclear power reactors Member States shall aim to develop additional safety requirements, *reflecting* the continuous improvement of *the operating experience of existing reactors, insight gained from safety analyses for operating plants, state of the art methodologies and technology and results of safety research.*

**Amendment 38****Proposal for a directive****Article 6 – paragraph 2 a (new)**

2a. *The Commission shall ensure that all third countries that wish to enter or are in the process of negotiating their accession to the EU comply, as a minimum, with the standards set out in this Directive and the principles in the Annex, as set by the IAEA.*

**Amendment 39****Proposal for a directive****Article 7 – title**

**Obligations** of licence holders

**Responsibilities** of licence holders

**Amendment 40****Proposal for a directive****Article 7 – paragraph – -1 (new)**

-1. *Member States shall ensure that the prime responsibility for the safety of nuclear installations, throughout the lifetime of the nuclear installations, shall rest with the holder of the licence. This responsibility of the licence holder cannot be delegated.*

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**Amendment 41****Proposal for a directive  
Article 7 – paragraph 1**

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)**.

1. **Member States shall ensure that** licence holders **are responsible for the design, construction, operation and decommissioning of** their nuclear installations in accordance with the provisions set out in **Article 6**.

**Amendment 42****Proposal for a directive  
Article 7 – paragraph 2**

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

2. **Member States shall ensure that** licence holders establish and implement management systems which **are** regularly verified by the regulatory body.

**Amendment 44****Proposal for a directive  
Article 7 – paragraph 3 a (new)**

3a. **Member States shall ensure that the regulatory body assess regularly the sufficiency and qualifications of the staff of the licence holder, as a prerequisite for ensuring nuclear safety, on the basis of a report presented by the licence holder on the evaluation of employment issues such as health and safety and the safety culture, qualifications and training, numbers of staff employed and use of subcontractors.**

**Amendment 45****Proposal for a directive  
Article 7 – paragraph 3 b (new)**

3b. **The relevant regulatory authorities shall, every three years, present to the Commission and the European social partners a report on nuclear safety and safety culture. The Commission, in consultation with the European social partners, may propose improvements to ensure nuclear safety including health protection at the highest possible level in the EU.**

**Amendment 46****Proposal for a directive  
Article 8 – paragraph 1**

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.**

*deleted*

**Amendment 47****Proposal for a directive  
Article 8 – paragraph 2**

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.**

*deleted*

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**Amendment 48****Proposal for a directive  
Article 8 – paragraph 3**

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.* *deleted*

**Amendment 49****Proposal for a directive  
Article 9**

*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.

*In order to build adequate national human resources and preserve nuclear knowledge, Member States shall ensure that* education and training opportunities for **basic and** continuous theoretical and practical training in nuclear safety, **including exchange programmes, are** made available by Member States and, **if necessary,** through *transnational* cooperation.

**Amendment 50****Proposal for a directive  
Article 10****Article 10****Priority to safety**

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

*deleted***Amendment 51****Proposal for a directive  
Article 11**

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.

Member States shall report to the Commission on the implementation of this Directive **at the same time and frequency as for their national reports under review meetings of the Convention of the Nuclear Safety.** On the basis of **this** report, the Commission shall present a report to **the European Parliament and** the Council on progress made with the implementation of this Directive, accompanied, if appropriate, by legislative proposals.

**Amendment 52****Proposal for a directive  
Article 12 – paragraph 1**

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.**

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.

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**Amendment 53**  
**Proposal for a directive**  
**Annex (new)**

*Annex*

**SAFETY OBJECTIVE**

*The fundamental safety objective is to protect workers and the general public from harmful effects of ionising radiation, which may be caused by nuclear installations.*

*1. To ensure the protection of workers and the general public, nuclear installations shall be operated so as to achieve the highest standards of safety that can reasonably be achieved taking into account economic and social factors.*

*In addition to the measures concerning health protection, laid down in the Euratom Basic Standards (Directive 96/29/Euratom), the following measures shall be taken:*

- restriction of the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source and*
- mitigation of the consequences of such events if they were to occur.2. The fundamental safety objective shall be taken into account for all nuclear installations and for all stages over the lifetime of the nuclear installation.*

**SAFETY PRINCIPLES**

**Principle 1: Responsibility for safety**

*Each Member State shall ensure that the prime responsibility for the safety of a nuclear installation rests with the holder of the relevant licence and shall take the appropriate steps to ensure that all such licence holders meet their responsibility.*

*1.1 Each Member State shall ensure that the licence holder has implemented provisions for:*

- establishing and maintaining the necessary competences;*
- providing adequate training and information;*
- establishing procedures and arrangements to maintain safety under all conditions;*
- verifying appropriate design and the adequate quality of nuclear installations;*
- ensuring the safe control of all radioactive material that is used, produced or stored;*

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- *ensuring the safe control of all radioactive waste that is generated*

*to fulfil the responsibility for the safety of a nuclear installation.*

*These responsibilities shall be fulfilled in accordance with applicable safety objectives and requirements as established or approved by the regulatory body, and their fulfilment shall be ensured through the implementation of a management system.*

#### *Principle 2: Leadership and management for safety*

*Effective leadership and management for safety must be established and sustained in all organisations concerned with nuclear safety.*

*2.1 Leadership in safety matters shall be demonstrated at the highest levels in an organisation. An effective management system shall be implemented and maintained, integrating all elements of management so that requirements for safety are established and applied coherently with other requirements, including those relating to human performance, quality and security, and so that safety is not compromised by other requirements or demands.*

*The management system also shall ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.*

*2.2 A safety culture that governs the attitudes and behaviour in relation to safety of all organisations and individuals concerned shall be integrated into the management system. Safety culture includes:*

- *individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;*
- *accountability of organisations and of individuals at all levels for safety;*
- *measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety.*

*2.3 The management system shall recognise the entire range of interactions of individuals at all levels with technology and with organisations. To prevent safety, significant human, and organisational failures, human factors shall be taken into account and good performance and good practices shall be supported.*

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**Principle 3: Assessment of Safety**

*Comprehensive and systematic safety assessments shall be carried out before the construction and commissioning of a nuclear installation and throughout its lifetime. A graded approach shall be used taking in account the magnitude of the potential risks arising from the nuclear installation.*

3.1 The regulatory body shall require an assessment on nuclear safety for all nuclear installations, consistent with a graded approach. This safety assessment shall involve the systematic analysis of normal operation and its effects, of the ways in which failures might occur and of the consequences of such failures. The safety assessments shall cover the safety measures necessary to control the hazard, and the design and engineered safety features shall be assessed to demonstrate that they fulfil the safety functions required of them. Where control measures or operator actions are called on to maintain safety, an initial safety assessment shall be carried out to demonstrate that the arrangements made are robust and that they can be relied on. An authorisation for a nuclear installation shall only be granted by a Member State once it has been demonstrated to the satisfaction of the regulatory body that the safety measures proposed by the licence holder are adequate.

3.2 The required safety assessment shall be repeated in whole or in part as necessary later in the conduct of operations in order to take into account changed circumstances (such as the application of new standards or scientific and technological developments), the feedback of operating experience, modifications and the effects of ageing. For operations that continue over long periods of time, assessments shall be reviewed and repeated as necessary. Continuation of such operations shall be subject to these reassessments demonstrating that the safety measures remain adequate.

3.3 Within the required safety assessment precursors to accidents (an initiating event that could lead to accident conditions) shall be identified and analysed, and measures shall be taken to prevent the occurrence of accidents.

3.4 To further enhance safety, processes shall be put in place for the feedback and analysis of operating experience in own and other facilities, including initiating events, accident precursors, 'near misses', accidents and unauthorised acts, so that lessons may be learned, shared and acted upon.

**Principle 4: Optimisation of safety**

Member States shall ensure that nuclear installations are optimised to provide the highest level of safety that can reasonably practicable be achieved without unduly limiting their operation.

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**4.1** *The optimisation of safety shall require judgements to be made about the relative significance of various factors, including:*

- the likelihood of the occurrence of foreseeable events and the resulting consequences;*
- the magnitude and distribution of radiation doses received;*
- economic, social and environmental factors arising from the radiation risks.*

*The optimisation of safety also means using good practices and common sense as far as is practical in day to day activities.*

**Principle 5: Prevention and mitigation**

*Member States shall ensure that all practical efforts are made to prevent and mitigate nuclear incidents and accidents in its nuclear installations.*

**5.1** *Each Member State shall ensure, that the licence holders engage all practical efforts*

- to prevent the occurrence of abnormal conditions or incidents that could lead to a loss of control;*
- to prevent the escalation of any such abnormal conditions or incidents that do occur; and*
- to mitigate any harmful consequences of an accident.*

*by implementing ‘defence in depth’.*

**5.2** *The application of the defence in depth concept shall ensure that no single technical, human or organisational failure could lead to harmful effects, and that the combinations of failures that could give rise to significant harmful effects are of very low probability.*

**5.3** *Defence in depth shall be implemented through the combination of a number of consecutive and independent levels of protection that would all have to fail before harmful effects could be caused to workers or the general public. The levels of defence in depth shall include:*

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- 
- *an adequate site selection*
  - *an adequate design of the nuclear installation, consisting of:*
    - High quality of design and construction*
    - High reliability of components and equipment*
    - Control, limiting and protection systems and surveillance features;*
  - *an adequate organisation with:*
    - An effective management system with a strong management commitment to safety culture*
    - Comprehensive operational procedures and practices*
    - Comprehensive accident management procedures*
    - Emergency preparedness arrangements.*
- Principle 6: Emergency preparedness and response*
- Members States shall ensure that arrangements are made for emergency preparedness and response for nuclear installations accidents according to Directive 96/29/Euratom.*
-