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Draft proposal for a
COUNCIL DIRECTIVE
amending Directive 2009/71/EURATOM establishing a Community framework for the
nuclear safety of nuclear installations

Draft presented under Article 31 Euratom Treaty for the opinion of the European
Economic and Social Committee

{SWD(2013) 199 final}
{SWD(2013) 200 final}
{SWD(2013) 201 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. General context

The accident at the Fukushima Daiichi nuclear power plant (NPP) in 2011 resulted in significant environmental, economic and social damage, and raised concerns about possible health effects in the affected population in Japan. Although triggered by an earthquake and tsunami of an immense magnitude, investigations of the causes of the accident reveal a range of foreseeable factors which combined to produce a catastrophic outcome. The analysis of the Fukushima nuclear accident reveals quite substantial and recurring technical issues as well as persistent institutional failures similar to the ones from the post-accident evaluations of the Three Mile Island and Chernobyl nuclear accidents decades ago. This latest nuclear accident once again undermined public confidence in the safety of nuclear power; and particularly so at a time when the use of nuclear power is being debated as a possible option to meet global energy demands in a sustainable manner.

The Fukushima nuclear accident renewed attention on the paramount importance of ensuring the most robust levels of nuclear safety in the EU and worldwide.

Nuclear energy currently generates close to 30% of all electricity in the EU and about two-thirds of its low-carbon electricity. The EU has 132 operating reactors, representing about one-third of the 437 operating nuclear power reactors in the world. Many of the EU NPPs were constructed already three to four decades ago, and are based on designs and safety provisions that were continuously updated since then.

Nuclear safety is of the utmost importance to the EU and its people. The effects of nuclear accidents do not stop at national borders and can entail potential harmful consequences for the health of workers and citizens but also wide-ranging economic implications. It is therefore essential for society and the economy to reduce the risk of a nuclear accident in an EU Member State by applying high nuclear safety standards and guaranteeing a high quality of regulatory oversight.

In the aftermath of the Fukushima nuclear accident, the EU response to the events was immediate.

Based upon a mandate from the European Council at its meeting of 24-25 March 2011¹, the European Commission, together with the European Nuclear Safety Regulators Group (ENSREG), launched EU-wide comprehensive risk & safety assessments of nuclear power plants ('Stress Tests'). The Stress Tests were defined as a targeted reassessment of the safety margins of NPPs in the light of the events in Fukushima related to extreme natural events challenging the plants safety functions. All fourteen EU Member States that operate nuclear power plants² plus Lithuania³ participated in these assessments. Switzerland, Ukraine and

¹ European Council Conclusions EUCO 10/1/11

² Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Netherlands, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom

³ The Ignalina NPP is being decommissioned

Croatia participated fully in the EU Stress Tests and the peer review process, while other neighbouring countries (e.g. Turkey, Belarus and Armenia) that agreed to use the same methodology, are working within different timetables. Stress Tests were started in 2011 by self-assessments carried out by nuclear operators and the preparation of national reports by national regulators. Preliminary findings were presented in a Commission Communication on an Interim Stress Tests Report⁴ in November 2011 and an extensive EU-wide peer review process was carried out from January to April 2012. An overview report was produced by the ENSREG Peer Review Board⁵ and endorsed by ENSREG. In addition, ENSREG also agreed on an Action Plan⁶ to follow up the implementation of the peer review recommendations. In October 2012, the Commission issued a Communication on the Final Stress Tests Report⁷. Currently, in line with the requirements of the ENSREG Action Plan, National Action Plans⁸ associated with post-Fukushima lessons learned and Stress Test peer review recommendations have been prepared and were reviewed in terms of contents and status of implementation in the framework of a Workshop in April 2013. The Summary Report of the Workshop is intended to be presented at the 2013 Second ENSREG Conference on Nuclear Safety in Europe⁹. Furthermore in the process of ensuring a proper follow-up of the Stress Tests, the Commission will elaborate, in close cooperation with ENSREG, a consolidated report on the status of the implementation of the Stress Tests recommendations, envisaged to be issued in June 2014 and transmitted to the European Council.

In the legislative domain, the European Commission received a clear mandate from the European Council in March 2011 "to review the existing legal and regulatory framework for the safety of nuclear installations" and propose any improvements that may be necessary.

The European Parliament has also encouraged a legislative review. In the 2011 Resolution on energy infrastructure priorities for 2020 and beyond¹⁰, it stated that "future legislative initiatives to set up a common framework for nuclear safety are essential in order to continuously improve safety standards in Europe". Furthermore, in the 2011 Resolution on the Commission Work Programme 2012¹¹, the Parliament called for "an urgent revision of the Nuclear Safety Directive with a view to its strengthening, namely by taking into account the results of the Stress Tests implemented in the aftermath of the Fukushima accident". More recently, in the 2013 Resolution on Stress Tests¹², it called on the revision to be "ambitious in nature", including major improvements in areas such as "safety procedures and frameworks – in particular through the definition and implementation of binding nuclear safety standards that reflect state-of-the-art practices in the EU in technical, regulatory and operational respects – as well as in the role and resources of the nuclear regulatory authorities and, in particular, should boost the latter's independence, openness and transparency, while also strengthening monitoring and peer review".

⁴ COM 784 final

⁵ Peer review Report – Stress Tests performed on European nuclear power plants www.ensreg.eu

⁶ ENSREG Action Plan regarding the follow-up of the peer-review of the stress tests performed on European nuclear power plants

⁷ COM (2012) 571, 04.10.2012

⁸ 17 National Action Plans are available on the ENSREG website www.ensreg.eu

⁹ <http://www.ensreg.eu/ensreg-conferences>

¹⁰ P7_TA(2011)0318

¹¹ P7_TA(2011)0327

¹² P7_TA(2013)0089

The European Economic and Social Committee expressed in the 2012 Opinion on the Commission Communication on a Final Stress Tests Report¹³ its support for the "Commission's intention to undertake an ambitious revision of the Nuclear Safety Directive".

In response to the mandate from the European Council and the calls from the other EU institutions and bodies, the Commission engaged in a comprehensive process of analysis and opinion gathering, to identify the appropriate areas and mechanisms for legislative intervention. This process included an open on-line public consultation (December 2011 – February 2012), complemented by an extensive dialogue with the stakeholders.

The 2011 and 2012 Stress Tests Communications contain indications on the potential areas of legislative improvement. In this context, with reference to the existing Council Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations¹⁴ (hereinafter referred to as "Nuclear Safety Directive"), the latter Communication highlights the areas of safety procedures and frameworks, role and means of nuclear regulatory authorities, openness and transparency, monitoring and verification.

Moreover, the Commission services developed in the course of 2012 an Impact Assessment, based on a wide range of information sources and taking into account the post-Fukushima EU and international developments in the nuclear domain.

On this basis, a draft proposal for a Directive amending the Nuclear Safety Directive has been developed, benefiting from the input and expertise of the Euratom Treaty Article 31 Group of scientific experts, as well as an extensive consultation process with the high-level representatives of the national nuclear regulatory authorities reunited in ENSREG.

1.2. Grounds and objectives of the proposal

The current Nuclear Safety Directive has been a key advancement. However, in the spirit of nuclear safety's philosophy of continuous improvement, and thus with the intention to take account *inter alia* of the lessons learned from the Fukushima nuclear accident and of the outcomes of the subsequent Stress Tests, it was necessary to reconsider the sufficiency of the existing provisions.

The Fukushima nuclear accident has shown that well-known lessons learned from accidents decades ago have not been taken up voluntarily by parts of the industry and not been sufficiently enforced by regulators, even in a nation – Japan – that was assumed to have particularly high standards of industrial and nuclear safety. The technical and organisational issues arising from the analysis of this accident are therefore relevant for wider consideration.

In Europe, the Stress Tests have confirmed that there are continued differences between Member States in ensuring comprehensive and transparent identification and management of key safety issues. Moreover, the Stress Tests clearly showed the benefits of cooperation and coordination mechanisms between all parties having responsibilities for nuclear safety, such as peer reviews.

¹³ TEN/498

¹⁴ OJ L 172, 2.7.2009

In addition, in the course of the public meetings held in the framework of the Stress Tests, demands have emerged to extend the assessment to emergency preparedness and response arrangements.

The Commission considers it therefore appropriate to amend, strengthen and supplement the Nuclear Safety Directive, by combining technical improvements with wider safety issues such as governance, transparency and on-site emergency preparedness and response.

The proposed amendments aim at enhancing the regulatory framework for nuclear safety in the EU, in particular by:

- Strengthening the role and effective independence of the national regulatory authorities;
- Enhancing transparency on nuclear safety matters;
- Strengthening existing principles, and introducing new general nuclear safety objectives and requirements, addressing specific technical issues across the entire lifecycle of nuclear installations, particularly NPPs;
- Reinforcing monitoring and exchange of experiences, by establishing a European system of peer reviews;
- Establishing a mechanism for developing EU-wide harmonised nuclear safety guidelines.

1.3. Existing EU legislation in the nuclear safety area

Following the recognition by the Court of Justice of the EU in the Case 29/99¹⁵ of the intrinsic link between radiation protection and nuclear safety and, thus, of the competence of the Euratom Community to legislate in the area of nuclear safety, the Nuclear Safety Directive is the first EU-wide topical legally binding instrument¹⁶. The Directive sets up a legally binding framework based upon recognised principles and obligations of the main international instruments available, namely the Convention on Nuclear Safety¹⁷ and the Safety Fundamentals¹⁸ established by the International Atomic Energy Agency (IAEA).

1.4. Consistency with other policy areas

The Euratom nuclear safety legislation, due to the fact that it ultimately aims at ensuring the protection of the workers and the general public against the dangers of ionising radiation, is mainly linked to the Euratom radiation protection corpus of legislation, whose main pillar is the Basic Safety Standards Directive¹⁹. It is not possible to achieve the protection of workers and the general public from the dangers of ionising radiation without controlling the potentially harmful sources of that radiation.

¹⁵ Judgment of the Court of Justice of 10 December 2002 [2002] ECR I-11221

¹⁶ Only two legally non-binding Council Resolutions of 22 July 1975 and 18 June 1992 on the technological problems of nuclear safety existed beforehand

¹⁷ INFCIRC/449 of 5 July 1994

¹⁸ IAEA Safety Standard Series no SF-1 (2006)

¹⁹ Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation

Nuclear safety is also of paramount importance for the overall prevention, preparedness for and response to disasters in the Member States. The nuclear safety directive is thus closely linked to the Union Civil Protection Mechanism²⁰ which provides the framework for the EU cooperation in this area, including the response to radiological emergencies inside and outside the Union.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

2.1. Consultation of interested parties

In the period following the Fukushima nuclear accident, the Commission has engaged in an extensive and transparent dialogue process with the various stakeholders and the public, which included launching an open consultation via the Internet, in line with the Commission's minimum consultation standards²¹.

In response to the on-line public consultation seeking views on areas of reinforcing the existing Euratom nuclear safety legislative framework, contributions were received from nuclear regulatory authorities, other public authorities, companies, non-governmental organisations, as well as individuals. This consultation offers insights into a large range of stakeholder opinions. The broad outcome shows that more than 90% of respondents agree on the importance of a Euratom nuclear safety framework, setting up common rules for EU Member States, whilst 76% agree with the need to reinforce the existing safety legislative framework.

The Commission also received both written and meeting-based contributions from various stakeholders, e.g. nuclear regulatory authorities, other public authorities, individual companies, industry associations and non-governmental organisations. In addition, the Commission has organised with ENSREG conferences and public debates involving a wide range of stakeholders, including non-governmental organisations, on the process, the intermediate and final results of the Stress Tests²².

The European social partners from the Electricity Sectoral Social Dialogue Committee industry have also been consulted. In their response, the social partners underline the role of a Euratom nuclear safety legislative framework in setting up common rules for Member States.

A special role was given to ENSREG, which represents a unique focal point of expertise, as it reunites high-level representatives of the national competent nuclear regulatory authorities from all the EU Member States, nuclear and non-nuclear alike. A detailed contribution of ENSREG was received and taken into account.

²⁰ Commission proposal for a Decision of the European Parliament and of the Council on a Union Civil Protection Mechanism (COM/2011/934 final), intending *inter alia* to replace Council Decision 2007/779 of 8 November 2007 establishing a Community Civil Protection Mechanism (recast).

²¹ COM(2002) 704 final

²² For instance, the first ENSREG Conference on 28-29 June 2011, a Stakeholders Conference on Peer Reviews on 17 January 2012, a Public Debate on Stress Tests and Peer Review Results on 8 May 2012. The second ENSREG Conference is scheduled for June 2013.

Finally, as part of the procedure laid out in the Euratom Treaty, the Commission consulted the Article 31 Group of scientific experts. In their opinion, the experts welcomed the Commission proposal for amending the Nuclear Safety Directive and make several suggestions for enhancing the link with radiation protection legislation.

2.2. Impact Assessment

In 2012, an Impact Assessment was developed. The document analyses the challenges of ensuring sufficient levels of nuclear safety in the EU. It defines the general and specific objectives for enhancing the prevention and mitigation of nuclear accidents. A number of policy options are proposed and analysed, ranging from maintaining the current situation to more profound reforms. Each option has been assessed for its estimated safety, economic, environmental and social impacts.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal Basis

Any legislative amendment should build upon and enhance the approach of the current Nuclear Safety Directive. The legal basis remains thus Articles 31 and 32 of the Euratom Treaty.

3.2. Subsidiarity and proportionality

The proposal aims at strengthening even further the role and independence of the competent regulatory authorities, as it is clear that only strong regulators endowed with all the necessary powers and independence guarantees can oversee and ensure the safe operation of nuclear installations in the EU. Close cooperation and information-sharing between regulators, taking into account the potential cross-border impacts of a nuclear accident, is encouraged.

Given the wide consequences of a nuclear accident and particularly the public need for information in such a case, an EU-wide approach on transparency issues is essential. This can ensure that, irrespective of state borders, the public is properly informed on all relevant nuclear safety matters. The existing provisions of the Directive are amended in this sense.

In Europe, the Stress Tests have confirmed that there are not only continued differences between the EU Member States in ensuring comprehensive and transparent identification and management of key safety issues, but that also gaps remain. Therefore, the Nuclear Safety Directive is strengthened to include a set of shared objectives aiming at harmonising the EU approach to nuclear safety. Moreover, the experience from the Fukushima nuclear accident and the valuable insights coming from the Stress Tests have clearly shown that exchange of information and peer-reviews are an essential element to ensure the effective and continuous implementation of any safety regime.

In accordance with the proportionality principle, the proposed legislative action does not go beyond what is necessary to achieve the objectives. Furthermore, taking into account the different situations in the Member States, a flexible and proportionate approach as regards the level of applicability is defined. A mechanism of joint development by the Member States of

EU-wide technical guidelines is defined with special regard to the principle of proportionality, by using the knowledge and practical experience of the regulatory experts.

The applicability and the extent of the provisions of the proposal vary according to the type of nuclear installation. Therefore, when implementing these provisions, Member States should follow a proportionate approach, taking account of the risks from the specific types of nuclear installations.

3.3. Legal elements of the proposal

The proposal introduces new or strengthens the existing provisions of the Nuclear Safety Directive with the overall aim of continuously improving nuclear safety and its regulation at EU level. Specific information on the main proposed amendments of the Nuclear Safety Directive is presented below.

Objectives

Article 1 is complemented with a new objective aiming at ensuring the avoidance of radioactive releases during all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning).

Definitions

In Article 3, new definitions are introduced corresponding to terms used in the new provisions, such as "accident", "abnormal event", "design basis", "design basis accident", "beyond design basis accident", "periodic safety review". These definitions are aligned with the international terminology, such as the IAEA Safety Glossary.

Legislative, regulatory and organisational framework

Article 4 is amended in order to further clarify the main elements of the national framework. For instance, it is specified that the national safety requirements mentioned in Article 4(1)(a) should cover all stages of the lifecycle of nuclear installations.

Competent regulatory authority (effective independence, regulatory role)

The Nuclear Safety Directive contains only minimal provisions underlying the independence of the national competent regulatory authority in Article 5(2). These provisions are strengthened in line with latest international guidance²³, by defining strong and effective benchmark criteria and requirements to guarantee the effective independence of regulators. New requirements include ensuring effective independence in decision-making, own appropriate budget allocations and autonomy in implementation, clear requirements for the appointment and dismissal of staff, avoidance and resolution of conflicts of interests, and staffing levels with the necessary qualifications, experience and expertise.

The Nuclear Safety Directive enumerates in a general manner the main competencies of the competent regulatory authority in Article 5(2). Through the amendment, these provisions are further detailed to ensure that regulators possess the appropriate powers to carry out a strong

²³ e.g. Governmental, Legal and Regulatory Framework for Safety - General safety requirements - IAEA safety standards series no. GSR part 1

regulatory oversight. For this purpose, the core task of the competent regulatory authority to define national nuclear safety requirements is added to the existing catalogue of regulatory competencies.

Transparency

The existing provisions of Article 8 of the Nuclear Safety Directive are limited to generic requirements on public information. Moreover, this Article does not impose any obligation on the licence holder, who has the prime responsibility for nuclear safety. To fill these gaps, in the proposed amendment, the existing provisions are extended and specified. Thus, both the competent regulatory authority and the licence holder are required to develop a transparency strategy, which covers information provision under normal operating conditions of nuclear installations as well as communication in case of accident or abnormal event conditions. The role of the public is fully acknowledged through the requirement that it effectively participates in the licensing process of nuclear installations. Recently organised exchanges with experts²⁴ in the field have confirmed that the public has a very important role to play by being involved effectively in the decision-making procedures and that their views should be considered, taking into account the provisions of the Aarhus Convention²⁵.

Nuclear Safety Objectives

The current Nuclear Safety Directive does not include specific requirements for the different stages of the lifecycle of nuclear installations. Therefore, for example the type of risks related to the issues identified in the analysis of the Fukushima accident and the subsequent Stress Tests are not sufficiently identified and addressed by the provisions of the current Directive, e.g.:

- The need to evaluate the appropriateness of the siting of nuclear installations based on considerations on how to prevent, where possible, and minimise the impact from external hazards;
- The need to continuously re-assess the probability of such hazards and their impacts in the course of periodic safety reviews and perform a corresponding design basis review for each nuclear installation, including for the purpose of possible lifetime extension;
- The need to base risk assessments, including those for external events, on methods reflecting progress in scientific development and thus enable effective continuous improvement of safety.

In line with the principle of continuous improvement of nuclear safety the amendment introduces general safety objectives for nuclear installations (Article 8a) which reflect the progress achieved at the level of WENRA in developing safety objectives for new NPPs.

²⁴ Series of international workshops between 2009-2013 with the participation of DG ENER, DG ENV from the Commission side and National Association of Committees and Commission of Information - French "Local Commissions of Information" (CLIs) and their national federation (ANCCLI)

²⁵ Convention on access to information, public participation in decision-making and access to justice in environmental matters, ratified on 17 February 2005 by Council Decision 2005/370/EC

For achieving these high level safety objectives, more detailed provisions are laid down for different life-cycle phases of nuclear installations (Article 8b).

In addition, in order to support their consistent implementation, methodological requirements concerning the siting, design, construction, commissioning, operation and decommissioning of nuclear installations, are laid out in Article 8c.

This approach provides flexibility to the national frameworks, by assigning high level objectives that have to be fulfilled by national legislation in line with the principle of continuous improvement of nuclear safety. For example, this leaves to Member States the choice of selecting among the available engineering solutions to upgrade their nuclear installations when addressing safety issues based on lessons learned from severe accidents, such as the need to allow safe depressurizing of a reactor containment in case of an accident (e.g. by means of containment filtered venting).

On-site emergency preparedness and response

The amendment includes provisions regarding on-site emergency preparedness and response as the current Directive does not provide for such measures. The new provisions include indications on the planning and organisational measures that should be provided by the licence holder (Article 8d). As an example of new requirements, the amendment prescribes that an on-site emergency response centre is required for a nuclear installation, sufficiently protected against the effects from external events and severe accidents, including radiological ones, and equipped with the necessary material to mitigate the effects of severe accidents.

Peer Reviews

The existing provisions of the Nuclear Safety Directive of Article 9(3) include a requirement for periodic self-assessment of the Member States national framework and competent regulators authorities, combined with the obligation to invite an international peer review on relevant segments. This concept remains unchanged in the proposal, in Article 8e(1).

The amendment introduces new provisions on self-assessments and peer-reviews of nuclear installations based on nuclear safety topics selected by the Member States jointly and in close coordination with the Commission across the entire lifecycle of nuclear installations (example could be the above-mentioned containment depressurisation in case of severe accident in order to avoid hydrogen explosion). Should Member States fail to jointly select at least a topic, the European Commission should select the topics to be subject to the peer reviews. Further, each Member State has to define a methodology for the implementation of the technical recommendations from the peer review process. Should the Commission identify substantial deviations or delays in the implementation of the technical recommendations from the peer review process, the Commission should invite the competent regulatory authorities of Member States not concerned to organise and carry out a verification mission to get a full picture of the situation and inform the Member State concerned about possible measures to remedy any identified shortcomings.

In case of an accident with off-site consequences, a special peer review should be arranged.

This new compulsory and regular mechanism of EU peer reviews (Article 8e(2) to (5)) aims at verifying the level of technical compliance with the safety objectives in each Member State.

These new provisions setting out the peer-review mechanism are without prejudice to the rules governing the infringement procedure in case a Member State fails to fulfil an obligation under the Treaties, as laid out in Articles 258, 259 and 260 of the Treaty on the Functioning of the European Union (TFEU).

Proportionate implementation of the amended Directive

The amendment acknowledges that the applicability and the extent of the provisions of the amended Directive vary according to the type of nuclear installation. Therefore, when implementing these provisions, Member States should follow a proportionate approach, taking account of the risks posed by the specific types of nuclear installations they plan or operate.

Reporting on practical implementation of the amended directive

The provisions of the Nuclear Safety Directive on reporting are not changed by this proposal, leaving the date for the first reporting on 22 July 2014 at which the Member States are expected to submit a report on the implementation of the existing provisions of the Directive. At the time of the second reporting on the implementation however, by 22 July 2017, the Member States should report on the implementation of the Nuclear Safety Directive as amended by this proposal.

4. BUDGETARY IMPLICATION

The proposal has no budgetary implications for the EU budget.

5. EXPLANATORY DOCUMENTS

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 Commission considers the transmission of such documents to be justified for the following reasons:

- **The complexity of the transposition of the amended Nuclear Safety Directive at national level**

The existing provisions of the Nuclear Safety Directive are significantly strengthened by this proposal which also introduces new substantial provisions in several areas. The complexity of transposition of the amended directive is therefore determined by the fact that it covers many different issues, including requirements on national framework for nuclear safety of nuclear installations, role and independence of national regulatory authorities, obligations of the licence holders, skills in nuclear safety, transparency on nuclear safety matters, technical objectives and requirements on nuclear safety of nuclear installations, on-site emergency preparedness and response and provisions on national assessments of nuclear installations and

related topical peer-reviews. Moreover, the directive places requirements on different Member States' bodies as well as private actors.

The different obligations inherent to the amended directive are therefore likely to lead to a complex transposition at national level. The existing provisions of the Nuclear Safety Directive have already been transposed in general by several national transposition measures per Member State, the number is however exceeding 15 transposition measures in some cases. The number of notified transposition measures can be legitimately expected to rise with the new provisions brought to the existing directive by this proposal. Furthermore, due to the specificity of nuclear safety, various transposition measures are used and notified to the Commission, ranging from laws, government decrees and ministerial orders to instructions and decisions of national nuclear regulatory authorities.

The need for explanatory documents explaining the relationship between the provisions of the amended Nuclear Safety Directive and the corresponding parts of national transposition measures seems to be obvious under these circumstances.

- **Pre-existing national legislation**

In some Member States, some legislation is already in place in the area of amendments brought by this proposal. The transposition of the amended Directive is therefore likely to result in a combination of amendments to existing national legislation and adoption of new legislation. In such a situation, the explanatory documents would be necessary to obtain a clear and comprehensive picture of the transposition.

- **Framework directive**

The proposed amendments do not fundamentally change the 'framework' character of the Nuclear Safety Directive. The amended directive continues to include general principles and requirements.

It is important for the Commission and its monitoring of transposition and implementation to know which national provisions transpose the general principles and requirements that the amended directive lays down. For instance, the proposal introduces general safety objectives and requirements for all types of nuclear installations. Given the very broad scope of these new safety objectives and requirements, it is of utmost importance for the Commission but also the public to be able to ascertain how they are transposed at national level.

PROPORTIONALITY PRINCIPLE

The requirement to provide explanatory documents can create an additional administrative burden on the Member States. This burden is however not disproportionate considering the objectives of the amended Nuclear Safety Directive and the complexity of its subject matter. It is furthermore necessary for the Commission to allow effective verification of correct transposition. There are no less burdensome measures to allow efficient verification, considering the likely complexity of transposition at national level which may result in new or amended legislation. It is also to be mentioned that a relevant number of Member States have already been notifying useful explanatory documents to the Commission on their transposition of the existing Euratom legislation such as the existing Nuclear Safety Directive or other pieces of legislation.

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THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European 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,

Having regard to the opinion of the European Parliament,

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

Whereas:

- (1) Article 2(b) of the Treaty establishing the European Atomic Energy Community ('Euratom Treaty') provides for the establishment of uniform safety standards to protect the health of workers and of the general public.
- (2) Article 30 of the Euratom Treaty provides for the establishment of basic standards within the European Atomic Energy Community ('Community') for the protection of the health of workers and the general public against the dangers arising from ionizing radiations.
- (3) 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 ionizing radiation¹ establishes the basic safety standards. This Directive establishes requirements for a system of radiation protection including the justification and optimisation of radiation exposures and dose-limitation for public and occupational exposure. It specifies requirements for the control of radiation exposures to the public and to workers under both normal operations and emergency situations. The provisions of Directive 96/29/Euratom have been supplemented by more specific legislation.

¹ OJ L 159, 29.6.1996, p. 1.

- (4) The Court of Justice of the European Union has recognised in its case-law² that the Community shares competences, together with its Member States, in fields covered by the Convention on Nuclear Safety³.
- (5) Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations⁴ imposes obligations on the Member States to establish and maintain a national framework for nuclear safety. That Directive reflects the provisions of the main international instruments in the field, namely the Convention on Nuclear Safety⁵ and the Safety Fundamentals⁶ established by the International Atomic Energy Agency ('IAEA'). The deadline for Member States to bring into force and notify the Commission the laws, regulations and administrative procedures to comply with, Directive 2009/71/Euratom expired on 22 July 2011.
- (6) Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste⁷ imposes obligations on the Member States to establish and maintain a national framework for spent fuel and radioactive waste management.
- (7) Council Conclusions of 8 May 2007 on nuclear safety and safe management of spent nuclear fuel and radioactive waste⁸ highlighted that “nuclear safety is a national responsibility exercised where appropriate in an EU-framework. Decisions concerning safety actions and the supervision of nuclear installations remain solely with the operators and national authorities”.
- (8) Following up on the Council’s invitation to set up a High Level Group at EU level, as recorded in its above mentioned Conclusions of 8 May 2007, the European Nuclear Safety Regulators Group (ENSREG) was established by Commission Decision 2007/530/Euratom of 17 July 2007 on establishing the European High Level Group on Nuclear Safety and Waste Management⁹ to contribute to the achievement of the Community objectives in the field of nuclear safety.
- (9) The Fukushima nuclear accident in Japan in 2011 renewed attention worldwide on the measures needed to minimise risk and ensure the most robust levels of nuclear safety. Based on a mandate from the European Council in March 2011¹⁰, the Commission, together with the European Nuclear Safety Regulator Group ('ENSREG'), carried out Union wide comprehensive risk and safety assessments of nuclear power plants ('stress

² C-187/87 (1988 ECR p. 5013), C-376/90 (1992 ECR I-6153) and C-29/99 (2002 ECR I-11221).

³ OJ L 172, 6.5.2004, p. 7.

⁴ OJ L 172, 2.7.2009, p. 18.

⁵ OJ L 318, 11.12.1999, p. 20.

⁶ IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No SF-1 (2006).

⁷ OJ L 199, 2.8.2011, p. 48.

⁸ Adopted by the Coreper on 25 April 2007 (doc. Ref. 8784/07) and the Economic and Financial Affairs Council on 8 May 2007.

⁹ OJ L 195, 27.7.2007, p. 44.

¹⁰ European Council, EUCO 10/1/11.

tests'). The results identified a number of improvements which could be implemented in nuclear safety approaches and industry practices in the participating countries¹¹.

- (10) Moreover, the European Council also mandated the Commission to review the existing legal and regulatory framework for the safety of nuclear installations and propose any improvements that may be necessary. The European Council also stressed that the highest standards for nuclear safety should be implemented and continuously improved in the EU.
- (11) The Commission included initial views on potential areas of legislative improvement in its Communication on the Interim Report on the Comprehensive Risk and Safety Assessments ("stress tests") of Nuclear Power Plants in the European Union¹² of 24 November 2011.
- (12) In line with its general principles of consultation and dialogue, the Commission also conducted an on-line public consultation, between December 2011 and February 2012, seeking views on areas of reinforcing the Community nuclear safety framework.
- (13) The Commission identified a number of areas for revising the current Directive 2009/71/Euratom, as outlined in its 4 October 2012 *Communication from the Commission to the Council and the European Parliament on the comprehensive risk and safety assessments ("stress-tests") of nuclear power plants in the EU and related activities*¹³.
- (14) In identifying the relevant areas for improvement, the Commission took into account technical progress achieved at European and international level, the experience and results gained from the stress tests, the findings of the various reports into the Fukushima nuclear accident, the views expressed in the public consultation on areas of reinforcing the Community legislative framework, the views expressed by different stakeholders including national competent regulatory authorities, industry and civil society, and the results of the preliminary assessment of the transposing measures of the Member States.
- (15) A strong and independent competent regulatory authority is a fundamental condition of the European nuclear safety regulatory framework. Its independence and the exercise of its powers impartially and transparently are crucial factors to ensure a high level of nuclear safety. Objective regulatory decisions and enforcement actions should be established without any undue external influence that might compromise safety, such as pressures associated with changing political, economic or societal conditions, or pressures from government departments or any other public or private entities. The negative consequences of the lack of independence were evident in the Fukushima accident. The provisions of Directive 2009/71/Euratom on functional separation of competent regulatory authorities should be strengthened to ensure the regulatory authorities' effective independence and to guarantee that they are provided with the appropriate means and competencies to properly carry out the responsibilities assigned

¹¹ ENSREG Peer review Report – Stress Tests performed on European nuclear power plants, 25 April 2012.

¹² COM(2011) 784 final.

¹³ COM(2012) 571 final.

to them. In particular, the regulatory authority should have sufficient legal powers, sufficient staffing and sufficient financial resources for the proper discharge of its assigned responsibilities. The strengthened requirements aiming at ensuring independence in carrying out the regulatory tasks should be however without prejudice to close cooperation, as appropriate, with other relevant national authorities or to general policy guidelines issued by the government not related to the regulatory powers and duties.

- (16) The independence of the regulatory authority's decision making further depends on the competence of its staff. Therefore the regulatory authority should employ staff with the necessary qualifications, experience and expertise to be able to undertake its functions and responsibilities. Given the specialised nature of the nuclear industry and the limited availability of persons with the required expertise and competence, resulting in the possible rotation of persons with executive responsibility between the nuclear industry and the regulators, special attention should be given to avoiding conflicts of interest. Moreover, arrangements should be made to ensure that there is no conflict of interest for those organisations that provide the regulatory body with advice or services.
- (17) When undertaking infrastructure projects that could affect the nuclear safety of nuclear installations, the appropriate national mechanisms of consultation with national regulatory authorities and the public should be in place and full account should be taken of the opinions expressed by them.
- (18) Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment¹⁴ is relevant for nuclear installations. This Directive provides that the Member States must ensure that, before development consent is given, projects likely to have significant effects on the environment by virtue, *inter alia*, of their nature, size or location are made subject to an assessment of the environmental effects. In this regard, it is a tool for ensuring that environmental considerations are integrated in the licensing process of nuclear installations.
- (19) Any assessment under this Directive is without prejudice to any relevant environmental assessment.
- (20) For nuclear installations for which the obligation to carry out assessments of the effects on the environment arises simultaneously from this Directive and other Union legislation, Member States may provide for coordinated or joint procedures fulfilling the requirements of the relevant Union legislation.
- (21) The consequences of a nuclear accident can go beyond national borders, therefore close cooperation, coordination and information exchange between regulatory authorities of neighbouring countries or of countries in the same region, irrespective of whether they operate nuclear installations or not, need to be encouraged. In this respect, Member States should ensure that appropriate arrangements are in place to facilitate such cooperation on nuclear safety matters with cross-border impacts, including with third countries. Synergies should be sought with the Union Civil

¹⁴ OJ L 26, 28.01.2012, p.1 - codified version of Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment, as amended.

Protection Mechanism¹⁵ which provides an EU framework for cooperation between the Member States in the field of civil protection in improving the effectiveness of systems for preventing, preparing for and responding to natural and man-made disasters.

- (22) In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, all parties should ensure that all staff (including sub-contractors), having responsibilities relating to the nuclear safety of nuclear installations and to the on-site emergency preparedness and response arrangements, undergo a continuous learning process. This can be achieved through the establishment of training programmes and training plans, procedures for periodic review and updating of the training programmes as well as appropriate budgetary provisions for training.
- (23) Another key lesson learned from the Fukushima nuclear accident is the importance of enhancing transparency on nuclear safety matters. Transparency is also an important means to promote independence in regulatory decision making. Therefore, the current provisions of Directive 2009/71/Euratom on the information to be provided to the public should be more specific as to which type of information should be provided, as a minimum by the competent regulatory authority and by the licence holder, and within which time frames. To this purpose, for example, the type of information that should be provided, as a minimum by the competent regulatory authority and by the licence holder as part of their wider transparency strategies, should be identified. Information should be released in a timely manner, particularly in case of abnormal events and accidents. Results of periodic safety reviews and international peer reviews should also be made public.
- (24) The requirements of this Directive on transparency are complementary to those of the existing Euratom legislation. Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency¹⁶ imposes obligations on Member States to notify and provide information to the Commission and to other Member States in case of a radiological emergency on its territory, whilst Council Directive 89/618 Euratom of 27 November 1989¹⁷ includes requirements on Member States to inform the public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, and to provide advance and continuing information to the population likely to be affected in the event of a such an emergency. However, in addition to the information to be provided in such an event, Member States should under this Directive arrange for appropriate transparency provisions, with prompt and regularly updated release of information to ensure that workers and the general public are kept informed about all nuclear safety related events, including abnormal events or accident conditions. Moreover, the public should be given opportunities to participate effectively in the licencing process of nuclear installations and the competent regulatory authority should provide any safety-related information independently, without need for prior consent from any other public or private entity.

¹⁵ Commission proposal for a Decision of the European Parliament and of the Council on a Union Civil Protection Mechanism (COM/2011/934 final).

¹⁶ OJ L 371, 30.12.1987, p. 76.

¹⁷ OJ L 357, 7.12.1989, p.31.

- (25) The Directive 2009/71/Euratom sets up a legally binding Community framework underlying a nuclear safety legislative, administrative and organisational system. It does not include specific requirements for nuclear installations. In view of the technical progress achieved by the IAEA, and the Western European Nuclear Regulators Association ('WENRA') and other sources of expertise, including the lessons learned from the stress tests and the Fukushima nuclear accident investigations, Directive 2009/71/Euratom should be amended to include Community nuclear safety objectives covering all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning).
- (26) Risk-informed methods examine the probability of each event in an event sequence likely to lead or contribute to an accident as well as its possible consequences. The answers can be used to provide insights into the strengths and weaknesses of the design and operation of a nuclear installation and can thus guide requirements and regulatory attention to the issues where the largest benefit for the safety of a nuclear installation can be obtained. Having invested over the last decades considerable resources in developing Probabilistic Safety Assessments for nuclear installations, particularly for nuclear power plants and research reactors, licence holders and competent regulatory authorities worldwide are now in a position to use the insights derived to enhance the safety of nuclear installations on a risk-informed basis while operating them in the most efficient manner.
- (27) Ageing of the safety related structures, systems and components of a nuclear installation, and especially embrittlement of components which are difficult to replace in practice, such as reactor pressure vessels, puts a natural limit to its acceptable continued operation. From both a safety and an economical point of view, the limit of operational lifetime is typically 40 years after the start of commercial operation therefore Member States should ensure that possible lifetime extension of existing nuclear power plants does not expose the workers and the public to additional risks. To this end, Directive 2009/71/Euratom should be amended to include new Community wide safety objectives to be complied with by the regulatory authorities and the licence holders in case of a lifetime extension of existing nuclear power plants.
- (28) For new reactor design, there is a clear expectation to address in the original design what was beyond design for previous generations of reactors. Design extension conditions are accident conditions that are not considered for design basis accidents, but are considered in the design process of the installation in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits. Design extension conditions could include severe accident conditions.
- (29) Application of the concept of defence-in-depth in organisational, behavioural, or design activities related to a nuclear installation, ensures that safety related activities are subject to independent layers of provisions, such that if a failure were to occur, it would be detected and compensated by appropriate measures. The independent effectiveness of each of the different layers is an essential element of defence in depth to prevent accidents and mitigate the consequences if they do occur.
- (30) After the nuclear accidents at Three Mile Island and Chernobyl, the Fukushima nuclear accident highlighted once again the critical importance of the containment

function, which is the last barrier to protect people and the environment against radioactive releases resulting from an accident. Therefore the applicant for a licence for the construction of a new power or research reactor should demonstrate that the design practically limits the effects of a reactor core damage to within the containment, i.e. he has to prove that a radioactive release outside the containment is physically impossible or can be considered extremely unlikely with a high degree of confidence for such release to occur.

- (31) Directive 2009/71/Euratom does not include measures regarding on-site emergency preparedness and response, which, as the Fukushima nuclear accident highlighted, are crucial to mitigate the consequences of a nuclear accident. Council Directive 96/29/Euratom foresees that, in case of radiological emergencies, it is necessary to organise appropriate intervention to stop or reduce the emission of radionuclides, and to assess and record the consequences of the emergency and the effectiveness of the intervention. Measures should also be in place for the protection and monitoring of the environment and population. However, more specific provisions regarding on-site emergency preparedness and response are needed in order to assess situations that might require on-site protective measures, to have an organisational structure and coordination among response bodies, and to ensure that sufficient resources are available to apply those appropriate protective measures even in extreme cases.
- (32) The stress tests demonstrated the key role of enhanced cooperation and coordination mechanisms between all parties having responsibilities for nuclear safety. The peer-reviews have proved to be a good means of building confidence, with the aim of developing and exchanging experience and ensuring the common application of high nuclear safety standards. The scope of the provisions of Directive 2009/71/Euratom is however limited only to self-assessments and international peer-reviews of Member States' legislative, regulatory and organisational infrastructure and therefore the Directive should be widened to include peer reviews of nuclear installations.
- (33) This Directive introduces new provisions on self-assessments and peer-reviews of nuclear installations based on selected nuclear safety topics covering their entire lifecycle. At an international level, there is already confirmed experience with conducting such peer-reviews on nuclear power plants. At the EU level, the experience from the stress tests process shows the value of a coordinated exercise to assess and review the safety of EU nuclear power plants. A similar mechanism, based on cooperation between the Member States' regulatory authorities and the Commission, should be applied here. Therefore, competent regulatory authorities coordinating in the context of expert groups such as ENSREG, could contribute with their expertise to identifying the relevant safety topics and in carrying out these peer reviews. If Member States fail to jointly select at least one topic the Commission should select one or more topics to be subject to the peer reviews. Participation of other stakeholders, such as Technical Support Organisations, international observers or non-governmental Organisations could bring added value to the peer reviews.
- (34) In order to guarantee the rigour and the objectivity of the peer reviews, Member States should provide access to all necessary information, subject to the required security clearance procedures, to staff and to the nuclear installation concerned.

- (35) An appropriate follow-up mechanism should be established to ensure that the outcome of these peer-reviews is properly implemented. Peer reviews should help improve the safety of individual nuclear installations as well as help formulate generic technical safety recommendations and guidelines valid across the Union.
- (36) In case the Commission identifies substantial deviations or delays in the implementation of the technical recommendations from the peer review process, the Commission should invite the competent regulatory authorities of Member States not concerned to organise and carry out a verification mission with the aim of getting a full picture of the situation and informing the Member State concerned about possible measures to remedy any identified shortcomings.
- (37) The provisions setting out the peer-review mechanism of this Directive are without prejudice to the rules governing the procedure in case a Member State fails to fulfil an obligation under the Treaties, as laid out in Articles 258, 259 and 260 of the Treaty on the Functioning of the European Union (TFEU).
- (38) The periodicity of the peer reviews and the reporting under this Directive should be aligned with the review and reporting cycles of the Convention on Nuclear Safety.
- (39) In line with the principle of proportionality, the applicability of the provisions of Chapter 2, Section 2 "Specific Obligations" of this Directive depends on the type of nuclear installations on the territory of a Member State. Therefore, when implementing these provisions in national law, Member States should take account of the risks posed by the specific types of nuclear installations they plan or operate. In particular, the proportionality principle will concern those Member States that keep only a small inventory of nuclear and radioactive materials, e.g. linked to the operation of smaller research reactor facilities, which in case of a severe accident would not engender consequences comparable to those generated by nuclear power plants.
- (40) The provisions of this Directive which are intrinsically linked to the existence of nuclear installations, namely those concerning the licence holder's obligations, the new specific requirements for nuclear installations and the provisions concerning the on-site emergency preparedness and response are not applicable to Member States without nuclear installations as defined by this Directive. These Member States need not transpose and implement the requirement to impose penalties on those who do not comply with this Directive. The other provisions of this Directive should be transposed and implemented in a proportionate manner in accordance with national circumstances and taking into account the fact that these Member States do not have nuclear installations, whilst ensuring that nuclear safety receives appropriate attention by the government or by the competent authorities.
- (41) According to Directive 2009/71/Euratom, the Member States have to establish and maintain a national legislative, regulatory and organisational framework ('national framework') for nuclear safety of nuclear installations. The determination on how the provisions of the national framework are adopted and through which instrument they are applied rests with the competence of the Member States.
- (42) 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 provisions of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(43) Directive 2009/71/Euratom should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2009/71/Euratom is amended as follows:

(1) The heading of Chapter 1 is replaced by the following:

"OBJECTIVES, SCOPE OF APPLICATION AND DEFINITIONS".

(2) In Article 1, the following point (c) is added:

"(c) to ensure that Member States shall provide for appropriate national arrangements so that nuclear installations are designed, sited, constructed, commissioned, operated or decommissioned so as to avoid unauthorised radioactive releases."

(3) Article 2 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. This Directive shall apply to any civilian nuclear installation subject to a licence as defined in Article 3(4) at all stages covered by this licence.";

(b) paragraph 3 is replaced by the following:

"3. This Directive supplements the basic standards referred to in Article 30 of the Treaty as regards the nuclear safety of nuclear installations and is without prejudice to the existing Community legislation for the protection of the health of the workers and the general public against the dangers arising from ionising radiation, and in particular Directive 96/29/Euratom."

(4) In Article 3, the following paragraphs 6 to 17 are added:

"6. 'defence-in-depth' means a hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between a radiation source or radioactive material and workers, members of the public or the air, the water and the soil, in operational states and, for some barriers, in accident conditions;

7. 'abnormal event' means any unintended occurrence the consequences, or potential consequences of which are not negligible from the point of view of protection or nuclear safety;
8. 'accident' means any unplanned event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or nuclear safety;
9. 'early releases' means situations that would require off-site emergency measures but with insufficient time to implement them;
10. 'large releases' means situations that would require protective measures for the public that could not be limited in area or time;
11. 'practically eliminating' means that it is physically impossible or it can be considered extremely unlikely with a high degree of confidence for a condition to occur;
12. 'reasonably achievable' means that, in addition to meeting the requirements of good practice in engineering, further safety or risk reduction measures for the design, commissioning, operation or decommissioning of a nuclear installation should be sought and that these measures should be implemented unless it can be demonstrated that they are grossly disproportionate with regard to the safety benefit they would confer;
13. 'design basis' means the range of conditions and events taken explicitly into account in the design of an installation, according to established criteria, so that the installation can withstand them without exceeding authorised limits by the planned operation of safety systems;
14. 'design basis accident' means accident conditions against which an installation is designed according to established criteria, and for which the damage to the fuel and the release of radioactive material are kept within authorised limits;
15. 'beyond design basis accident' means an accident which is possible, but was not fully considered in the design because it was judged to be too unlikely;
16. 'design extension analysis' means a set of design extension conditions derived on the basis of engineering judgement, deterministic assessments and probabilistic assessments for the purpose of further improving the safety of the nuclear power plant by enhancing the plant's capabilities to withstand, without unacceptable radiological consequences, accidents that are either more severe than design basis accidents or that involve additional failures. These design extension conditions are used to identify the additional accident scenarios to be addressed in the design and to plan practicable provisions for the prevention of such accidents or the mitigation of their consequences if they do occur.
17. 'periodic safety review' means a systematic reassessment of the safety of an existing installation carried out at regular intervals to deal with the cumulative effects of ageing, modifications, operating experience, technical developments and siting

aspects and aimed at ensuring a high level of safety throughout the service life of the installation."

- (5) In Chapter 2, the following title is inserted after the heading '**OBLIGATIONS**':

"SECTION 1

General obligations".

- (6) Article 4, paragraph 1 is amended as follows:

- (a) the introductory part is replaced by the following:

"1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (hereinafter referred to as the 'national framework') for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall provide in particular for:";

- (b) point (a) is replaced by the following:

"(a) national nuclear safety arrangements, covering all stages of the lifecycle of nuclear installations referred to in Article 3(4);";

- (c) point (b) is replaced by the following:

"(b) a system of licensing and prohibition of operation of nuclear installations without a licence;";

- (d) point (c) is replaced by the following:

"(c) a system of nuclear safety supervision;".

- (7) In Article 5, paragraphs 2 and 3 are replaced by the following:

"2. Member States shall guarantee the effective independence of the competent regulatory authority from undue influence in its decision making, in particular when carrying out the regulatory tasks set out in paragraph 3, ensuring that safety is not subordinated to political, economic or societal interests. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

(a) is functionally separate from any other public or private entity concerned with the promotion or utilisation of nuclear energy or electricity production;

(b) does not seek or take instructions from any other public or private entity concerned with the promotion or utilisation of nuclear energy or electricity production, when carrying out its regulatory tasks;

(c) takes regulatory decisions, founded on objective and verifiable safety-related criteria;

(d) has its own appropriate budget allocations, with autonomy in the implementation of the allocated budget. The financing mechanism and the budget allocation process shall be clearly defined in the national framework;

(e) employs an appropriate number of staff with the necessary qualifications, experience and expertise;

(f) establishes procedures and criteria for the appointment and dismissal of staff, and for the prevention and resolution of any conflicts of interest;

(g) provides safety-related information without review or clearance from any other public or private entity in accordance with Article 8(2).

3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. For this purpose, Member States shall ensure that the national framework provides for the following main regulatory tasks:

(a) to define national nuclear safety requirements;

(b) to require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;

(c) to require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6 and Articles 8a to 8d;

(d) to verify this compliance through regulatory assessments and inspections;

(e) to carry out enforcement actions, including suspending the operation of a nuclear installation in accordance with the conditions defined by the national framework referred to in Article 4(1)."

(8) Article 6 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Member States shall ensure that the national framework requires that the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.";

(b) paragraph 2 is replaced by the following:

"2. Member States shall ensure that the national framework requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.";

(c) paragraph 3 is replaced by the following:

"3. The assessments referred to in paragraph 2 shall include verification that, based on a comprehensive safety assessment, measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including verification of the sufficiency of defence-in-depth provisions and the licence holders' organisational measures of protection that would have to fail before workers and the general public would be significantly affected by ionising radiations.";

(d) paragraph 4 is replaced by the following:

"4. Member States shall ensure that the national framework requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.";

(e) the following paragraph 4a is inserted:

"4a. Member States shall ensure that the national framework requires that when applying for a licence, the applicant is required to submit a detailed demonstration of safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard presented. It shall be reviewed and assessed by the competent regulatory authority in accordance with clearly defined procedures.";

(f) paragraph 5 is replaced by the following:

"5. Member States shall ensure that the national framework requires licence holders to provide for and maintain adequate financial and human resources, with appropriate qualifications, expertise and skills, to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4a of this Article and Articles 8a to 8d of this Directive. These obligations also extend to subcontracted workers.".

(9) Articles 7 and 8 are replaced by the following:

"Article 7

Expertise and skills in nuclear safety

Member States shall ensure that the national framework requires all parties to make arrangements for education, training and exercise for their staff having responsibilities relating to the nuclear safety of nuclear installations and to on-site emergency preparedness and response arrangements, in order to build up, maintain and to further develop up-to-date and mutually recognised expertise and skills in nuclear safety.

Article 8

Transparency

1. Member States shall ensure that up to date and timely information in relation to nuclear safety of nuclear installations and related risks is made available to workers and the general public, with specific consideration to those living in the vicinity of a nuclear installation.

The obligation established in the first subparagraph includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, develop, publish and implement a transparency strategy covering, inter alia, information on normal operating conditions of nuclear installations, non-mandatory consultation activities with the workers and the general public and communication in case of abnormal events and accidents.

2. Information shall be made available to the public in accordance with applicable Union and national legislation and international obligations, provided that this does not jeopardise other overriding interests, such as security, recognised in national legislation or international obligations.

3. Member States shall ensure that the public shall be given early and effective opportunities to participate in the licensing process of nuclear installations, in accordance with relevant Union and national legislation and international obligations."

(10) The following Section 2 is inserted after Article 8:

"SECTION 2

Specific obligations

Article 8a

Safety objective for nuclear installations

1. Member States shall ensure that the national framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of avoiding potential radioactive releases by:

- (a) practically eliminating the occurrence of all accident sequences which would lead to early or large releases;
- (b) for accidents that have not been practically eliminated, implementing design measures so that only limited protective measures in area and time are needed for the public and that sufficient time is available to implement these measures, and that the frequency of such accidents is minimised.

2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1 applies to existing nuclear installations to the extent reasonably achievable.

Article 8b

Implementation of the safety objective for nuclear installations

In order to achieve the safety objective set out in Article 8a, Member States shall ensure that the national framework requires that nuclear installations are:

- (a) sited so that due consideration is provided to avoid, where possible, external natural and man-made hazards and minimise their impact;
- (b) designed, constructed, commissioned, operated and decommissioned based on the defence-in-depth concept so that:
 - (i) radiation doses to workers and the general public do not exceed prescribed limits and are kept as low as reasonably achievable;
 - (ii) the occurrence of abnormal events is minimised;
 - (iii) the potential for escalation to accident situations is reduced by enhancing the nuclear installations' capability to effectively manage and control abnormal events;
 - (iv) harmful consequences of abnormal events and design basis accidents, should they occur, are mitigated to ensure that they induce no off-site radiological impact, or only minor radiological impact;
 - (v) external natural and man-made hazards are avoided, where possible, and their impact is minimised.

Article 8c

Methodology for siting, design, construction, commissioning, operation and decommissioning of nuclear installations

1. Member States shall ensure that the national framework requires that the licence holder, under the supervision of the competent regulatory authority:
 - (a) regularly evaluates the radiological impact of a nuclear installation on workers, the general public and air, water and soil, in both normal operating and in both operating and accident conditions;
 - (b) defines, documents and re-assesses regularly and at least every ten years, the design basis of nuclear installations through a periodic safety review, and supplements it by a design extension analysis, to ensure that all reasonably practicable improvement measures are implemented;
 - (c) ensures that the design extension analysis covers all accidents, events and combination of events, including internal and external natural or man-made hazards and severe accidents, leading to conditions not included in the design basis accidents;
 - (d) establishes and implements strategies to mitigate both design basis and beyond-design basis accidents;
 - (e) implements Severe Accident Management Guidelines for all nuclear power plants and, if appropriate, other nuclear installations, covering all operational conditions, accidents in the spent fuel pools and long-duration events;

- (f) carries out a specific safety review for nuclear installations which the competent regulatory authority considers to be close to the limit of their operating lifetime as originally foreseen, and for which an extension of the lifetime is requested.

2. Member States shall ensure that the national framework requires that the granting or the review of a licence to construct and/or operate a nuclear installation should be based upon an appropriate site- and installation-specific safety assessment.

3. Member States shall ensure that the national framework requires, for nuclear power plants and, if applicable, for research reactor facilities, for which a construction licence is sought for the first time, that the competent regulatory authority obliges the applicant to demonstrate that the design practically limits the effects of a reactor core damage to within the containment.

Article 8d

On-site emergency preparedness and response

Member States shall ensure that the national framework requires that the licence holder, under the supervision of the competent regulatory authority:

- (a) prepares and regularly updates an on-site emergency plan which shall:
 - (i) be based on an assessment of events and situations that may require protective measures on-site or off-site;
 - (ii) be co-ordinated with all other bodies involved and shall draw on lessons learned from the feedback of experience from severe events, should they occur;
 - (iii) address in particular events that could impact multiple units of a nuclear installation;
- (b) establishes the necessary organisational structure for clear allocation of responsibilities and ensures the availability of necessary resources and assets;
- (c) puts in place arrangements for co-ordinating on-site activities and co-operating with authorities and agencies responsible for emergency response throughout all phases of an emergency, that should be regularly exercised;
- (d) provides for preparedness measures for the workers on-site with regard to potential abnormal events and accidents;
- (e) provides arrangements for cross-border and international cooperation, including pre-defined arrangements for receiving on-site external assistance, if needed;
- (f) arranges for an on-site emergency response centre, sufficiently protected against natural hazards and radioactivity to ensure its habitability;

- (g) takes protective measures in case of an emergency in order to mitigate any consequences for human health and for air, water and soil."

(11) The following Chapter 2a is inserted after Chapter 2:

"CHAPTER 2a

PEER REVIEWS AND GUIDELINES

Article 8e

Peer Reviews

1. Member States shall at least every ten years arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of any peer review shall be reported to the Member States and the Commission, when available.

2. Member States, with the support of the competent regulatory authorities, shall periodically arrange, and at least every six years, a system of topical peer reviews and agree on a time-frame and the modalities for implementation. For this purpose Member States shall:

- (a) jointly and in close coordination with the Commission select one or more specific topics related to the nuclear safety of nuclear installations. Should Member States fail to jointly select at least a topic within the time frame specified in this paragraph, the Commission shall select the topics to be the subject of the peer reviews;
- (b) based on these topics, perform in close collaboration with licence holders, national assessments and publish the results;
- (c) jointly define a methodology, arrange and carry out a peer review of the results of the national assessments referred to in point (b), to which the Commission is invited to participate;
- (d) publish the results of the peer reviews referred to in point (c).

3. Each Member State subject to the peer review referred to in paragraph 2 shall arrange for the planning and mode of implementation on its territory of relevant technical recommendations resulting from the peer-review process and shall inform the Commission thereof.

4. Should the Commission identify substantial deviations or delays in the implementation of the technical recommendations resulting from the peer review process, the Commission shall invite the competent regulatory authorities of Member States not concerned to organise and carry out a verification mission to get a full picture of the situation and inform the Member State concerned about possible measures to remedy any identified shortcomings.

5. In case of an accident which leads to an early or large release or an abnormal event leading to situations that would require off-site emergency measures or protecting measures for the public, the Member State concerned shall invite within six months a peer review of the installation concerned in accordance with paragraph 2, and to which the Commission shall be invited to participate.

Article 8f

Guidelines for the improvement of nuclear safety

Based on the results of the peer reviews performed in accordance with Article 8e(2) and the resulting technical recommendations, in line with the principles of transparency and continuous improvement of nuclear safety, Member States shall, with the support of the competent regulatory authorities, jointly develop and establish guidelines on the specific topics referred to in Article 8e(2)(a).".

- (12) The following title is inserted after Chapter 2a:

"CHAPTER 2b

GENERAL PROVISIONS".

- (13) In Article 9, paragraph 3 is deleted.

- (14) The following Article 9a is inserted after Article 9:

"Article 9a **Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [*insert date –this date must correspond to the deadline for transposition set out in article 2 of this proposal*] at the latest and shall notify it without delay of any subsequent amendment affecting them.".

- (15) In Article 10, the following paragraph 1a is inserted after paragraph 1:

"1a. The obligations of transposition and implementation of Articles 6, 8a, 8b, 8c, 8d and 9a of this Directive shall not apply to Cyprus, Ireland, Luxembourg and Malta, unless they decide to develop any activity related to nuclear installations subject to a licence under their jurisdiction.".

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*deadline for transposition to be inserted in the course of the legislative process*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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.

2. 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 and of any subsequent amendments to those provisions.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President