

COUNCIL OF THE EUROPEAN UNION

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ATO 45

NOTE

from:	General Secretariat of the Council
to:	Delegations
No. Cion prop.:	15030/13 ATO 119
Subject:	Proposal for a Council Directive amending Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations

Delegations will find attached proposal for amending Directive 2009/71/EURATOM.

10410/14 GB/st DG E

Proposal for a

COUNCIL DIRECTIVE

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

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:

- Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards
 for protection against the dangers arising from exposure to ionising radiation¹ establishes
 uniform basic safety standards for the protection of health of individuals subject to
 occupational, medical and public exposures against the dangers arising from ionising
 radiation.
- 2. Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations² 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 Safety³, as well as the Safety Fundamentals⁴ established by the International Atomic Energy Agency ('IAEA').

OJ L 13, 17.1.2014, p. 1.

OJ L 172, 2.7.2009. p. 18.

³ OJ L 318, 11.12.1999, p. 20.

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

- 3. Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste¹ imposes obligations on the Member States to establish and maintain a national framework for spent fuel and radioactive waste management.
- 4. The Council Conclusions of 8 May 2007 on nuclear safety and safe management of spent nuclear fuel and radioactive waste² 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".
- 5. 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 the European Council's conclusions of March 2011³, the national competent regulatory authorities, together with the Commission in the framework of the European Nuclear Safety Regulators Group (ENSREG), carried out Community wide comprehensive risk and safety assessments of nuclear power plants ('stress tests'). The results identified a number of improvements which could be implemented in nuclear safety approaches and industry practices in the participating countries⁴.
- 6. Moreover, the European Council also called the Commission to review, as appropriate, 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.

OJ L 199, 2.8.2011. p. 48.

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

European Council, EUCO 10/1/11.

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

- 7. A strong competent regulatory authority with effective independence in regulatory decision making is a fundamental requirement of the European nuclear safety regulatory framework. It is of utmost importance that the competent regulatory authority has the ability to exercise its powers impartially, transparently and free from undue influence in its regulatory decision making to ensure a high level of nuclear safety. Regulatory decisions and enforcement actions should be based on objective safety-related technical considerations and should be established without any undue external influence that might compromise safety, such as undue influence associated with changing political, economic or societal conditions. The provisions of Directive 2009/71/Euratom on functional separation of competent regulatory authorities have been strengthened to ensure the regulatory authorities' effective independence from undue influence in their regulatory decision making and to guarantee that they are provided with the appropriate means and competencies to properly carry out the responsibilities assigned 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 should be however without prejudice to close cooperation, as appropriate, with other relevant national authorities or to general policy guidelines issued by the government.
- 8. The regulatory decision making process should take into account competences and expertise, which may be provided by technical support organization. This expertise should be based on state-of-the-art scientific and technical knowledge, including from operational experience and safety-related research, on knowledge management, and on adequate technical resources.
- 9. In accordance with Part 1 of the IAEA General Safety Requirements, the role of the Member States in establishing the framework for nuclear safety, and the role of the regulator in implementing that framework, should both be respected.
- 10. 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 competent regulatory authority with advice or services.

- 11. The consequences of a nuclear accident can go beyond national borders, therefore close cooperation, coordination and information exchange between regulatory authorities of Member States in the vicinity of a nuclear installation, irrespective of whether those Member States operate nuclear installations or not, should 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.
- 12. 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 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.
- 13. 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 general public have been made more specific as to which type of information should be provided. In addition, the general public should be given opportunities to participate in the relevant phases of the decision making process relating to nuclear installations in accordance with the national framework, taking into account the different national systems. Decisions on licensing remain the responsibility of national competent authorities.
- 14. 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 emergency 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 2013/59/Euratom includes requirements on Member States to inform the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, and to provide at regular intervals updated information to the population likely to be affected in the event of a such an emergency.

OJ L 371, 30.12.1987, p. 76.

- 15. During the 6th Review Meeting, the Contracting Parties to the Convention on Nuclear Safety reiterated their commitment to the findings of the 2nd Extraordinary Meeting which took place after the Fukushima accident. In particular, they stressed that "nuclear power plants should be designed, constructed and operated with the objectives of preventing accidents and, should an accident occur, mitigating its effects and avoiding off-site contamination, and that regulatory authorites should ensure that these objectives should be applied in order to identify and implement appropriate safety improvements at existing plants".
- 16. In view of the technical progress achieved by the IAEA, and the Western European Nuclear Regulators Association ('WENRA') and responding to the lessons learnt from the stress tests and the Fukushima nuclear accident investigations, Directive 2009/71/Euratom has been amended to include a high level Community nuclear safety objective covering all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning). In particular this objective calls for significant safety enhancements in the design of new reactors for which the state of the art knowledge and technology should be used, taking into account the latest international safety requirements.
- 17. These objectives should notably be reached through nuclear safety assessments, which fall under the scope of this directive. They should be carried out by the license holders under the control of the national competent regulatory authority and may be used for the assessment of the risk of a major accident, as covered by Directive 2011/92/EU, as amended¹, provided that the requirements of this directive are met.

OJ L 26, 28.01.2012, p.1

- 18. The concept of defence-in-depth is fundamental to the safety of nuclear installations and the basis for implementing high level nuclear safety objectives. Application of the defence-indepth principles, as recognised in international standards and guidance and by WENRA, ensures that safety activities are subject to, as far as reasonably practicable, independent layers of provisions, so that should a failure occur, it would be detected, compensated or corrected by appropriate measures. The effectiveness of each of the different layers is an essential element of defence-in-depth to prevent accidents and mitigate the consequences if they occur. Defence in depth is generally structured in five levels. Should one level fail, the subsequent level comes into play. The objective of the first level of protection is the prevention of abnormal operation and system failures. If the first level fails, abnormal operation is controlled or failures are detected by the second level of protection. Should the second level fail, the third level ensures that safety functions are further performed by activating specific safety systems and other safety features. Should the third level fail, the fourth level limits accident progression through accident management, so as to prevent or mitigate severe accident conditions with external releases of radioactive materials. The last objective (fifth level of protection) is the mitigation of the radiological consequences of significant external releases through the off-site emergency response.
- 19. Together with defence-in-depth, an effective nuclear safety culture is regarded as a fundamental factor in achieving a high level of nuclear safety and continuous improvement to nuclear safety. Indicators for an effective nuclear safety culture include, in particular: the commitment at all levels of staff and management within an organisation to nuclear safety and its continuous improvement; the promotion of the ability of staff at all levels to question the delivery of relevant safety principles and practices to continuously improve nuclear safety; the ability of staff to report in a timely manner on safety issues; the identification of the lessons learnt from operational experience; and the systematic reporting of any deviation from normal operating conditions or arrangement relevant to accident management that have the potential to impact on nuclear safety. Important elements which help to achieve a strong nuclear safety culture include, in particular, effective management systems, appropriate education and training and arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience and effective resolution of issues that have been raised.

- 20. Where 'reasonably practicable' is used in this Directive it should be applied in accordance with established definitions, in particular the WENRA and IAEA definitions.
- 21. 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 limits the effects of a reactor core damage to within the containment, i.e. the applicant has to prove that a large or unauthorised radioactive release outside the containment is extremely unlikely, and that applicant can demonstrate a high degree of confidence that such a release will not occur.
- 22. More specific arrangements for accident management and on-site emergency response should be requested to address the prevention and mitigation of accidents. These should be in accordance and without prejudice to the relevant provisions of the Council Directive 2013/59/Euratom. The licence holder should provide for procedures, guidelines and arrangements that address accidents including severe accidents, that could occur in all operational modes, including full power, shutdown and transitional states, ensuring consistency and continuity between all such procedures and arrangements, and ensuring that they are exercised, reviewed and updated. These arrangements should also provide for sufficient staff, equipment and other necessary resources. An organisational structure with clear allocation of responsibilities, and coordination amongst response bodies should be provided.
- 23. 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.

24. Cooperation on Nuclear Safety between Members States is well established and can give an added value in terms of nuclear safety, transparency and openness towards stakeholders at the European and international level.

Member states, through their competent regulatory authorities making relevant use of ENSREG, building on the expertise of the Western Nuclear Regulatory Association (WENRA), should every six years define a methodology, Terms of Reference and a time frame for Peer Reviews on a common specific technical topic related to nuclear safety of their nuclear installations. The common specific technical topic to be considered should be identified among the WENRA safety reference levels or on the basis of operating experience feed-back, incidents and accidents, technological and scientific developments. Member States should perform a national self-assessment and make arrangements for common peer reviews by other Member States' competent regulatory authorities of their national self-assessment. Reports on the findings of these peer reviews should be produced. Taking into account the results of these peer review reports Member States should establish national action plans for addressing any relevant findings and their own national assessment. The peer review reports should also form the basis of any summary report of the outcome of the EU wide topical peer review exercise prepared collectively by the competent regulatory authorities of the Member States. The summary report will not aim to rank the safety of nuclear installations but rather focus on the process and the technical findings of the topical peer review so that the knowledge gained from the exercise can be shared.

In order to further comfort the spirit of reciprocal trust which should prevail in peer reviews, it would be appropriate for the Commission, whenever practicable, to inform Member States when it intends to use the results of peer review reports in its policy documents.

- 25. The obligations of the Member States to report on the implementation of this Directive and the obligation of the Commission to draw up a report on the basis of the national reports provide an opportunity to take stock of and evaluate the various aspects of the implementation of this Directive as well as its effectiveness. A number of relevant reporting obligations, such as the Convention on Nuclear Safety reports, exist at international level, the results of which might be used for the evaluation of the implementation of this Directive. Moreover, additional reporting requirements are established under this Directive in relation to the findings of the topical peer reviews of nuclear installations. Consequently, with a view to simplifying the legislation and reducing the administrative burden, the reporting obligation for the Member States has been made less onerous both as regards the frequency of reporting and the content of the reports.
- 26. In line with graded approach, the implementation of the provisions 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 potential magnitude and nature of risks posed by the nuclear installations they plan or operate. In particular, the graded approach 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.
- 27. 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. The 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.
- 28. 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.

- 29. 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 transmission of such documents is justified.
- 30. 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) 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.";
 - (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 2013/59/Euratom."

- (3) Article 3 is amended as follows:
 - (a) paragraph 1(a) is replaced by the following:
 - "(a). a nuclear power plant, enrichment plant, nuclear fuel fabrication plant, reprocessing plant, research reactor facility, spent fuel storage facility; and";
 - (b) the following paragraphs 6 to 11 are added:
 - "6. 'Accident' means any unintended event, the consequences or potential consequences of which are significant from the point of view of radiation protection or nuclear safety;
 - 7. 'incident' means any unintended event, the consequences or potential consequences of which are not negligible from the point of view of radiation protection or nuclear safety;
 - 8. 'abnormal operations' means an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions;
 - 9. 'design basis' means the range of conditions and events taken explicitly into account in the design, including upgrade, of a nuclear installation, according to established criteria, so that the installation can withstand them without exceeding authorised limits by the planned operation of safety systems;
 - 10. 'design basis accident' means accident conditions against which a nuclear installation is designed according to established design criteria, and for which the damage to the fuel, where applicable, and the release of radioactive material are kept within authorised limits;
 - 11. 'severe conditions' means conditions that are more severe than conditions related to design basis accidents; such conditions may be caused by multiple failures, such as the complete loss of all trains of a safety system, or by an extremely unlikely event."
- (4) In Chapter 2, the following title is inserted after the heading '**OBLIGATIONS**':

"SECTION 1

General obligations".

- (5) Article 4, paragraph 1 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. The national framework shall provide in particular for:
 - (a) the allocation of responsibilities and coordination between relevant state bodies;
 - (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;
 - (c) a system of licensing and prohibition of operation of nuclear installations without a licence;
 - (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;
 - (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.".
- (6) In Article 5, paragraphs 2 and 3 are replaced by the following:
 - "2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:
 - (a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organization, when carrying out its regulatory tasks;

- (b) takes regulatory decisions, founded on robust and transparent nuclear safety-related requirements;
- (c) is given dedicated, and appropriate budget allocations to allow the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget;
- (d) employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;
- (e) establishes procedures for the prevention and resolution of any conflicts of interest;
- (f) provides nuclear safety-related information without clearance from any other body or organization, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international obligations.
- 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). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks:
- (a) to propose, define or participate in the definition of national nuclear safety requirements;
- (b) to require that the licence holder complies and demonstrates compliance with national nuclear safety requirements and the terms of the relevant licence;
- (c) to verify this compliance through regulatory assessments and inspections;
- (d) to propose or carry out effective and proportionate enforcement actions.".

(7) Articles 6, 7 and 8 are replaced by the following:

"Article 6

Licence holders

Member States shall ensure that the national framework requires that:

1. the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;

2. when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;

3. licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner;

4. the assessments referred to in paragraph 3 shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including verification of the application of defence-in-depth provisions;

5. licence holders establish and implement management systems which give due priority to nuclear safety;

6. licence holders provide for appropriate on–site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences. These procedures shall in particular:

- (i) be consistent with other operational procedures and periodically exercised to verify their practicability;
- (ii) address accidents and severe accidents that could occur at all operational modes and those that simultaneously involve or affect several units;
- (iii) provide arrangements to receive external assistance;
- (iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;
- 7. licence holders provide for and maintain financial and human resources with appropriate qualifications and competencies, necessary to fulfil their obligations with respect to nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competencies to fulfil their obligations.

Article 7

Expertise and skills in nuclear safety

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

Article 8

Transparency

- 1.Member States shall ensure that necessary information in relation to nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. This obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:
 - information on normal operating conditions of nuclear installations to workers and the general public, and
 - prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.
 - 2. Information shall be made available to the public in accordance with relevant legislation and international obligations, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international obligations.
 - 3. Member States shall, without prejudice to Article 5(2), ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.
 - 4. Member States shall ensure that the general public shall be given the appropriate opportunities to participate effectively in the decision making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international obligations."

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

"SECTION 2

Specific obligations

Article 8a

Nuclear safety objective for nuclear installations

- 1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:
- early radioactive releases that would require off site emergency measures but with insufficient time to implement them;
- large radioactive releases that would require protective measures that could not be limited in area or time.
- 2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:
- a) applies to nuclear installations for which a construction licence is granted for the first time after the entry into force of this directive;
- b) is used as a reference for timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

Article 8b

Implementation of the nuclear safety objective for nuclear installations

- 1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:
- (i) the impact of extreme external natural and unintended man-made hazards is minimised;
- (ii) abnormal operation and failures are prevented;
- (iii) abnormal operation is controlled and failures are detected;
- (iv) accidents within the design basis are controlled;
- (v) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;
- (vi) organizational structures according to Article 8d(1) are in place.
- 2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. These measures include in particular:
- (i) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(5);
- (ii) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;
- (iii) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority; and,
- (iv) arrangements for education and training, in accordance with Article 7.

Article 8c

Initial assessment and periodic safety reviews

Member States shall ensure that the national framework requires that:

- a) any grant of a licence to
- (i) construct a nuclear installation, or
- (ii) operate a nuclear installation,

is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a of this Directive;

b) the licence holder under the regulatory control of the competent regulatory authority, reassesses systematically and regularly, at least every ten years, the safety of the nuclear installation as laid down in Article 6(3). This safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.

Article 8d

On-site emergency preparedness and response

- 1. Without prejudice to the provisions of the Council Directive 2013/59/Euratom, Member States shall ensure that the national framework organizational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the license holder and with competent authorities and organisations taking into account all phases of an emergency.
- 2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom."

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

"CHAPTER 2a

PEER REVIEWS AND REPORTING

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 such peer review shall be reported to the Member States and the Commission, when available.
- 2. Member States shall ensure that, on a coordinated basis:
- (a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;
- (b) all other Member States and the Commission as observer are invited to peer review the national assessment referred to in paragraph (a);
- (c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;
- (d) relevant reports are published on the above mentioned process and its main outcome when results are available.
- 3. Member States shall ensure that arrangements are in place to allow the first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.
- 4. In case of an accident leading to situations that would require off-site emergency measures or protective measures for the general public, the Member State concerned shall ensure that an international peer review is invited without undue delay.".

- (10) Article 9 is amended as follows:
 - (a) paragraph 1 is replaced by the following:
 - "1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and then by 22 July 2020.";
 - (b) paragraph 3 is deleted:
- (11) 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 and 8d of this Directive shall not apply to Member States without nuclear installations, 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.

^{*} OJ please insert the date: three years after the entry into force of this directive.

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