VERSION 28.12.12

Council Directive …. *(no.)* of …. *(date)*

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 Articles 31 and 32 thereof,

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

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

Having regard to the opinion of the European Parliament,

Whereas:

[*text of recitals to be developed]*

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

OBJECTIVES, SCOPE OF APPLICATION AND DEFINITIONS

Article 1
Objectives

The objectives of this Directive are:

(a) to establish a Community framework in order to maintain and promote the continuous improvement of nuclear safety and its regulation;

(b) to ensure that Member States shall provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionizing radiations from nuclear installations.

Article 2
Scope

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.

2. This Directive does not prevent Member States from taking more stringent safety measures in the subject-matter covered by this Directive, in compliance with Community law.

3. This Directive supplements the basic standards referred to in Article 30 of the Euratom 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 ionizing radiation, in particular the Directive 96/29/Euratom.

Article 3
Definitions

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

1) 'nuclear installation' means:

(a) an enrichment plant, nuclear fuel fabrication plant, nuclear power plant, reprocessing plant, research reactor facility, spent fuel storage facility; and

(b) storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations listed under point (a);

2) 'nuclear safety' means the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionizing radiations from nuclear installations;

3) 'competent regulatory authority' means an authority or a system of authorities designated in a Member State in line with Article 5(1) or, respectively, with Article 5(2), in the field of nuclear safety of nuclear installations;

4) 'licence' means any legal document granted under the jurisdiction of a Member State to confer responsibility for the siting, design, construction, commissioning and operation or decommissioning of a nuclear installation;

5) 'licence holder' means a legal or natural person having overall responsibility for a nuclear installation as specified in a licence.

6) 'accident' means any unintended 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 safety;

7) '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;

8) '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;

9) '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;

10) '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.

CHAPTER II

OBLIGATIONS

SECTION 1

GENERAL OBLIGATIONS

Article 4
Legislative, regulatory and organisational framework

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:

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

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

   (c) a system of nuclear safety supervision;

   (d) enforcement actions, including effective, proportionate and dissuasive sanctions on licence holders not complying with their obligations under the national framework, such as suspension of operation and modification or revocation of a licence.

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

Article 5
Competent regulatory authority

1. Member States shall establish and maintain at national level a single competent regulatory authority in the field of nuclear safety of nuclear installations.

2. The requirement of paragraph 1 shall be without prejudice to the right of Member States with a federal or decentralised structure to establish and maintain other competent regulatory authorities at regional level.

3. Member States shall guarantee the effective independence of the competent regulatory authority, for carrying out the regulatory tasks laid out in paragraphs 4 to 6, assuring that safety judgements are not subordinated to political, economic or societal interests. For this purpose, Member States shall ensure that:

(a) the competent regulatory authority is legally distinct and functionally separate from any other public or private entity;

(b) the competent regulatory authority has its own appropriate budget allocations, with autonomy in the implementation of the allocated budget. The financing mechanism shall be clearly defined in the national framework;

(c) the competent regulatory authority takes autonomous regulatory decisions, founded on objective and verifiable safety-related criteria, based on science, proven technology and relevant experience. These decisions shall follow clear and transparent decision-making procedures and methodologies and shall be accompanied by a comprehensive explanation of the reasons underpinning them;

(d) the personnel of the competent regulatory authority acts independently and does not seek or take direct instructions from any other public or private entity when carrying out the regulatory tasks. The competent regulatory authority shall be able to provide extensive safety-related information without review or clearance from any other public or private entity. Procedures for preventing and duly resolving any conflicts of interests shall be put in place;

(e) the persons with executive responsibility in the competent regulatory authority are appointed for a fixed term, according to clearly defined procedures and requirements for appointment. They may be relieved from office during their term only if they do not comply with the requirements of independence set out in this Article or have been guilty of misconduct under national law. An appropriate cooling-off period for posts with a potential conflict of interest shall be defined;

(f) the competent regulatory authority shall comprise a sufficient number of personnel with the necessary qualifications, experience and expertise;

(g) the competent regulatory authority sets out a systematic programme for professional reviews and audits of regulatory performance.

4. 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. This includes the following main regulatory tasks:

(a) to define national nuclear safety requirements;

(b) to review and assess submissions on safety, both prior to licensing and periodically during operation as required;

(c) to provide for issuing, amending, suspending or revoking licences;

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

(e) to require demonstration of this compliance, including the requirements under paragraphs 2 to 6 of Article 6;

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

(g) to carry out enforcement actions, including effective, proportionate and dissuasive sanctions on licence holders not complying with their obligations under the national framework. Possible actions shall include, in particular, suspension of operation and modification or revocation of a licence in accordance with conditions defined by the national framework referred to in Article 4(1).

5. Member States shall ensure that, in order to fulfil its main regulatory tasks referred to in paragraph 4, the competent regulatory authority shall:

(a) establish a process for dealing with applications, such as applications for the issuing of a licence, accepting a notification or the granting of an exemption, or for removal from regulatory control;

(b) establish a process for changing licence conditions;

(c) provide guidance to the licence holder on developing and presenting installation-specific safety assessments or any other required safety-related information;

(d) ensure that operating experience is appropriately analysed and that lessons learned are disseminated;

(e) ensure that appropriate records related to safety are retained and retrievable;

(f) confirm periodically the competence of personnel responsible for the safe operation of a nuclear installation, both at the level of the licence holder and at the level of the competent regulatory authority;

(g) confirm that safety is managed adequately by the licence holder.

6. Member States shall ensure that the competent regulatory authority is consulted and gives an opinion on infrastructure projects that could affect the nuclear safety of nuclear installations.

7. Member States shall establish procedures for review and appeal against regulatory decisions in line with national law.

8. Member States shall ensure that appropriate arrangements are in place to facilitate the cooperation between the competent regulatory authority and counterpart authorities from other Member States or neighbouring countries, on nuclear safety matters with cross-border impacts.

Article 6
Licence holders

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

2. Member States shall ensure that the national framework in place 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.

3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the sufficiency of physical barriers and licence holder's organisational measures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.

4. Member States shall ensure that the national framework in place 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.

5. Member States shall ensure that, when applying for a licence, the applicant is required to submit a detailed demonstration of safety, which

shall be reviewed and assessed by the competent regulatory authority in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented.

6. Member States shall ensure that the national framework in place 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 5.

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 and to on-site emergency preparedness and response arrangements, in order to obtain, maintain and to further develop up-to-date expertise and skills in nuclear safety.

Article 8
Information to the public

1. Member States shall ensure that information in relation to the nuclear safety of nuclear installations is made available to the workers and the general public. This obligation includes that, particularly during accident conditions, both the competent regulatory authority and the licence holder ensure in a coordinated way the early and continuous release of reliable information in the fields of their competence.

2. For fulfilling the requirement of paragraph 1, Member States shall ensure that the competent regulatory authority develops and implements appropriate procedures and easily accessible communication mechanisms in order to:

(a) disclose information in a timely manner, with the necessary input from the licence holder, in particular on nuclear safety relevant events and their classification based on international reporting schemes;

(b) make available the regulations and guides upon which its regulatory decisions are based;

(c) provide regularly updated information on its activity, in particular on its regulatory decisions, the explanation of the reasons underpinning them, as well as information on how these decisions have practically been implemented by the licence holder;

(d) provide information on the outcomes of international peer-reviews.

3. For fulfilling the requirement of paragraph 1, Member States shall ensure that the licence holder also:

(a) discloses safety relevant information in a timely manner;

(b) provides regularly updated information on its activity, in particular on results of periodic safety reviews and on outcomes of international peer-reviews.

4. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, *inter alia*, security, recognised in national legislation or international obligations.

5. Member States shall ensure that the public is given the appropriate opportunities to participate effectively in the decision-making process regarding the planning and location of nuclear installations.

SECTION 2

SPECIFIC OBLIGATIONS

Article 9
Siting of nuclear installations

1. Member States shall ensure that appropriate and continuously updated procedures, following progress in scientific development, are established by the competent regulatory authority and are adequately implemented by the licence holder in order to:

(a) evaluate all relevant site-related hazards likely to affect the safety of a nuclear installation during its lifetime. This evaluation shall explicitly include analysis of hazards from extreme natural phenomena, of hazards related to possible accidents from nearby industrial or transport activities as well as of common cause vulnerabilities and dependencies due to effects of multiple units of a nuclear installation at a particular site;

(b) evaluate the likely safety impact of a proposed nuclear installation on workers, general public and the air, water and soil, in both normal operating and in severe accident conditions;

(c) consult interested Member States and their public on the appropriateness and completeness of the procedures chosen for the purposes described under (a) and (b).

2. Member States shall ensure that the competent regulatory authority requires that the applicant or the licence holder carries out before licensing and continuously updates, at least as part of the periodic safety review, a comprehensive risk-informed assessment of the exposure and vulnerability of a nuclear installation to the hazards mentioned in paragraph 1.

Article 10
Design and construction of nuclear installations

1. Member States shall ensure that nuclear installations are designed, constructed and continuously kept in a safe condition, by ensuring that:

(a) a consistent design basis is defined, documented during the entire operating lifetime, regularly reviewed and possibly redefined in order to reflect the actual capabilities of the nuclear installation, as well as the actual hazard conditions of its siting and surroundings, which could reasonably cause hazards and threats to the its safety;

(b) the design basis has as its main objective the prevention or, if this fails, the mitigation of harmful consequences resulting from anticipated operational occurrences and design basis accident conditions;

(c) the design basis development covers installation-specific internal and site-specific natural and man-made external hazards, or credible combinations therefrom, that could lead to anticipated operational disturbances or design basis accident conditions;

(d) the design basis is complemented by installation-specific sets of nuclear safety criteria. Their role is to demonstrate in a risk-informed manner that the design is sufficiently capable to prevent, or if prevention fails, to sufficiently mitigate harmful radioactive releases. In this way, it is ensured that potential radiation doses to the public and the site personnel do not exceed prescribed limits and are as low as reasonably achievable. These criteria shall be hierarchical, from the level of the entire installation to the various levels of preventive and mitigative systems, structures and components, functions and management strategies;

(e) progress in scientific development is taken into account, integrating insights from operating history of similar types of nuclear installations. In this process of continuous improvement, reasonable conservatism and safety margins of the actual design basis of a nuclear installation needs to

be demonstrated by re-evaluating it against relevant sets of internal and external hazards at a high frequency, and at least via the periodic safety review process. This may require a re-definition of the sets of relevant internal and external hazards, prescribed radiation dose limits and other nuclear safety criteria.

2. Member States shall ensure that the competent regulatory authority establishes an adequate regulatory framework including safety enhancement rules to cope with beyond-design basis accidents. Such rules shall aim at developing the most adequate features or actions to prevent a severe accident or mitigate its consequences, including hardware modifications, procedure changes and program improvements. The related decision making process shall use risk as a safety measure, taking into account economic and societal factors to screen out alternatives that are not considered efficient enough with regard to fulfilling the nuclear safety criteria.

3. Member States shall ensure that, for nuclear power plants and, if applicable, for research reactor facilities, for which a new construction licence is sought, the competent regulatory authority requires that the applicant successfully demonstrates that the actual design limits the effects of a reactor core damage to within the containment. This demonstration shall be independent of the probabilities of occurrence of extreme site-specific initiating events and installation-specific severe accident sequences, and take into account the uncertainties of the assessment. If this cannot be demonstrated against the applicable nuclear safety criteria, adequate design upgrading measures may need to be developed and implemented. Such a demonstration of sufficient safety shall also be applied to the fuel stored in the spent fuel pool to the same extent as for the reactor core.

Article 11
Operation of nuclear installations

1. Member States shall ensure that:

(a) the granting of a licence to operate a nuclear installation is based upon an appropriate site- and installation-specific safety assessment and a commissioning programme demonstrating that the nuclear installation, as constructed, is consistent with design and nuclear safety requirements;

(b) operational limits and conditions derived from the installation-specific safety assessment, from tests and from operational experience are defined and revised as necessary for identifying safe boundaries for operation;

(c) operation, maintenance, inspection and testing of a nuclear installation are conducted in accordance with approved procedures;

(d) procedures are established for responding to anticipated operational occurrences and to both design-basis and beyond-design-basis accidents;

(e) Severe Accident Management Guidelines (SAMGs) for all nuclear power plants and, if appropriate, for other nuclear installations, covering all operational conditions, accidents in the spent fuel pools and long-duration events, are adopted, monitored and periodically updated by the competent regulatory authority. These SAMGs shall be implemented by licence holders and also be used for the training of staff. To the extent that the application of the SAMGs requires specific information on the status of nuclear installation parameters, appropriately qualified additional instrumentation may need to be installed into operating nuclear installations;

(f) necessary engineering and technical support in all nuclear safety-related fields is available throughout the lifetime of a nuclear installation;

(g) nuclear safety-relevant events are reported in a timely manner by the licence holder to the competent regulatory authority;

(h) programmes to collect and analyse operating experience are established and appropriate actions are taken on the basis of the results. For this purpose, relevant operating experience as reported by international bodies and other relevant bodies shall be taken into account.

2. Member States shall ensure that the licence holder, under the supervision of the competent regulatory authority, carries out periodic safety reviews as often as appropriate, but at least every ten years, and in case of changes with a potentially significant risk increasing effect on the nuclear installation.

3. Member States shall ensure that, for nuclear power plants considered by the competent regulatory authority to be close to their originally foreseen limit of operating lifetime and for which the lifetime extension is requested, the licence holder, under the supervision of the competent regulatory authority, carries out a specific safety review for that extension. This review shall be based on the scope and methodology of a periodic safety review, having the specific objectives to determine:

(a) the extent to which the nuclear installation conforms to best available standards and practices;
(b) the extent to which the licencing basis will remain valid over the proposed extended operating lifetime;
(c) the adequacy of the arrangements that are in place to maintain nuclear safety for the extended operating lifetime, and
(d) the improvements to be implemented to adequately address the safety issues that have been identified.

This specific safety review shall be accompanied by an independent international peer review in order to demonstrate that the proposed operating lifetime extension does not expose the workers and the public to greater risks than the ones assessed during the latest periodic safety review.

The decision of the competent regulatory authority to grant a licence to extend the operating lifetime of a nuclear installation shall be based on the results of the specific safety review and on those of the independent international peer review.

Article 12
On-site emergency preparedness and response

1. Member States shall ensure:

(a) the periodic re-evaluation by both the competent regulatory authority and the licence holder of site-specific emergency preparedness and response measures put in place in relation to management of severe accident conditions, including the availability of staff, of necessary equipment at each site and of other resources. This periodic re-evaluation shall be carried out as often as appropriate, but at least in the course of the periodic safety reviews;

(b) that SAMGs, large fire and explosion response strategies, and other emergency preparedness and response plans are effectively integrated to ensure that nuclear installations are capable of an effective response to events that could impact also multiple units of a nuclear installation at a particular site.

2. Member States shall ensure that licence holders arrange for an on-site emergency response centre, sufficiently protected against natural hazards and radioactivity to ensure its habitability, and equipped with suitable emergency response equipment.

Article 13
Community nuclear safety criteria

In order to ensure a consistent implementation of the provisions of this Directive, the Commission shall establish Recommendations laying down harmonised Community nuclear safety criteria. A group of experts drawn from the Member States shall be set up to advise and assist the Commission in developing these criteria.

CHAPTER III

MONITORING, REPORTING AND VERIFICATION

Article 14
Monitoring

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 shall at least every ten years arrange for periodic self-assessments of the design and operational safety performance of each nuclear power plant and invite an international peer review 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.

3. In case of an unplanned release of radioactivity not contained within the nuclear installation, the Member State concerned shall invite an international peer review of the installation within six months.

4. Following the international peer reviews referred to in paragraphs 1, 2 and 3, the Member State concerned shall elaborate a plan of measures for the implementation and follow-up of the recommendations of the international peer reviews and notify it to the Commission.

5. Within six months of the date of the receiving the notification referred to in paragraph 4, the Commission may request clarifications and express its opinion on the plan of measures.

6. Within six months of receiving the Commission's reaction, Member States shall provide the requested clarifications and inform the Commission on any revision of the plan of measures.

Article 15
Reporting

1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by xxxx, and every

three years thereafter, taking advantage of the review and reporting cycles under the Convention on Nuclear Safety.

2. On the basis of the Member States' reports, the Commission shall submit a report to the Council and the European Parliament on progress made with the implementation of this Directive.

Article 16
Verification

1. Should the outcome of a peer review, carried out under Article 14 in a Member State, together with the report received under Article 15 from that Member State, raise concerns about the full and effective implementation of any of obligations specified by this Directive, the Commission shall carry out a verification mission to get a full picture of the situation.

2. Prior to the verification mission, the Commission shall inform the Member State concerned of the verification, specifying the subject-matter, the purpose, the date on which it is to begin and the names of the team members.

3. The Commission shall transmit the verification reports to the Member State concerned which, within three months of receipt, shall indicate the measures taken to remedy any identified shortcoming.

CHAPTER IV

FINAL PROVISIONS

Article 17
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 the date specified in Article 18 at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 18
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by XXX at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. The obligations for transposition and implementation of Articles…….. of this Directive shall not apply to Cyprus, Ireland, Luxembourg and Malta, for as long as they do not have nuclear installations subject to a licence on their territory.

3. 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 19
Entry into force

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

Article 20
Addressees

This Directive is addressed to the Member States.