

ANNEX

EUROPEAN ATOMIC ENERGY COMMUNITY

REPORT

**On the implementation of the obligations under the
Convention on Nuclear Safety**

**7th Review meeting
of the Contracting Parties to the
Convention on Nuclear Safety (CNS)
Vienna, 27 March-7 April 2017**

(presented by the European Commission)

Executive Summary

Nuclear safety is of the utmost importance for the European Atomic Energy Community (hereinafter referred to as “Euratom”). Over the past few years, major steps have been taken at European Union (EU) level to improve nuclear safety in an evolving context for nuclear energy. Therefore, several key initiatives taken since the last Review Meeting are reported in the present document.

The improvement of the legal framework

Two major Euratom directives have been revised: the Basic Safety Standards Directive in December 2013 and the Nuclear Safety Directive in July 2014.

To start with the latter, the review of the Euratom legal framework for nuclear safety, also called for by Heads of State and Government in reaction to the Fukushima accident, led to a Commission proposal for substantial amendments to Directive 2009/71/Euratom (the "Nuclear Safety Directive"). The amendment of Directive 2009/71 was adopted by the Council on 8 July 2014¹. It takes into account the lessons learned from the nuclear stress tests as well as the safety requirements of the Western European Nuclear Regulators Association (WENRA)² and the IAEA³. The amended Nuclear Safety Directive is to be transposed into national law by 15 August 2017.

The amendments:

- strengthen the independence of national regulatory authorities;
- set up a European system of peer reviews on specific safety issues every six years so-called topical peer reviews (the first one to begin in 2017);
- increase transparency on nuclear safety matters by informing and involving the public;
- promote an effective nuclear safety culture; and

¹ Directive 2014/87/Euratom

² Association comprised of the nuclear regulatory bodies from 18 countries in Europe. It serves as a network of chief nuclear safety regulators exchanging experience and discussing significant safety issues (<http://www.wenra.org/>).

³ The International Atomic Energy Agency.

- introduce high-level EU-wide safety objectives to prevent accidents and avoid radioactive releases.

At the Diplomatic Conference in February 2015, all the attending Contracting Parties of the CNS, including the 28 EU Member States and Euratom, agreed upon a text for a Declaration containing a set of principles and implementation mechanisms to improve and enhance the safety of nuclear power plants. These principles, already enacted in legally binding legislation in the EU, aim to prevent nuclear accidents and, should an accident occur, mitigate their consequences on the population, and include the safety objective of avoiding long-term off site contamination.

Thus, as regards such safety objectives for nuclear installations, 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 accidents⁴. It applies to nuclear installations for which a construction licence has been granted for the first time after 14 August 2014. Furthermore, the safety objective is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations. Based on WENRA's proposal, the European Nuclear Safety Regulators' Group (ENSREG)⁵ will prepare technical guidelines to support the Commission in ensuring an appropriate implementation of the nuclear safety objective for nuclear installations.

The Directive provides for regular safety reassessments of nuclear installations, to be carried out by the licence holder under the supervision of the competent regulatory authority, to identify further safety improvements, taking into account, inter alia, ageing issues. As regards the European system of peer reviews on specific safety issues to be organised every six years, the topic chosen for the first review to begin in 2017 is the ageing management of nuclear power plants as well as of research reactors of a capacity of 1 MWth and above.

⁴ Article 8a (1) of Council Directive 2009/71/Euratom.

⁵ Independent expert advisory group to the Commission created in 2007 following a decision of the European Commission. It is made up of the national nuclear safety, radioactive waste safety or radiation protection regulatory authorities from all EU Member States, as well as of representatives of the European Commission. ENSREG helps to establish the conditions for continuous improvement and to reach a common understanding in the areas of nuclear safety and radioactive waste management (<http://www.ensreg.eu/>).

It is important to mention that the Nuclear Safety Directive defines nuclear installations in a broader context than the Nuclear Safety Convention, as it includes also research reactors and nuclear fuel cycle facilities (except for off-site waste management facilities).

In November 2015 the Report from the European Commission to the Council and the European Parliament on the Implementation of Council Directive 2009/71/Euratom⁶ was published. This report was based on the Member States' national reports, which demonstrated how Member States had addressed the objectives of the directive and illustrated the approaches taken at national level. On the basis of this report, it could be concluded that there was, in general, a good level of compliance with the 2009 Nuclear Safety Directive, although there was still room for improvement⁷.

The newly revised Basic Safety Standards (BSS) Directive⁸ was adopted by the Council on 5 December 2013 and published on 17 January 2014. It entered into force on 6 February 2014. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018. The new Directive sets out, in a single coherent document, basic safety standards for the protection against the dangers arising from ionising radiation which take account of the status of science and technology, cover all relevant radiation sources, including natural radiation sources, integrate protection of workers, members of the public, patients, cover all exposure situations, planned, existing, emergency, and harmonise numerical values with international standards.

In the area of emergency preparedness, the basic safety standards were complemented with Council Directive 89/618/Euratom⁹ on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency and Council Decision 87/600/Euratom¹⁰ on arrangements for the early exchange of information between competent authorities and the Commission in the event of a radiological emergency

⁶ COM(2015) 573 final.

⁷ https://ec.europa.eu/priorities/publications/nuclear-safety-directive-implementation-report_en

⁸ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L13, 17.1.2014, p. 1 - 73).

⁹ Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, OJ L 357, 07.12.1989 p. 31.

¹⁰ 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, OJ L 371 of 30.12.1987, p. 76

(ECURIE). It should be noted that the provisions of Council Directive 89/618/Euratom are now included in Directive 2013/59/Euratom.

In the context of emergency preparedness and response, the global system for radiological monitoring, currently being developed by the IAEA with support from the Commission, IRMIS, is based on the very successful European Radiological Data Exchange Platform (EURDEP), developed and maintained during the last 20 years by the European Commission. EURDEP continues to be the tool that EU Member States and 10 other countries use for the exchange of radiological monitoring data in nearly real time. Likewise, the Union Civil Protection Mechanism has continued to contribute to reinforcing Europe's preparedness to natural and man-made disasters, including nuclear or radiological emergencies.

To ensure a timely and adequate transposition of both the amended Nuclear Safety Directive and the revised BSS Directive, the Commission is interacting with the Member States in the pre-transposition phases, including the organisation of workshops.

The follow-up of the nuclear power reactors stress tests

Following the 2011 Fukushima nuclear accident, the European Council asked the Commission and ENSREG to reassess the EU's nuclear power reactors. The reassessment and improvement of the safety of nuclear power plants in the EU has experienced significant progress: many nuclear operators have almost completed implementation and others have clear schedules to complete actions during 2016, while some have rescheduled specific actions until later than 2020. The Commission assessed the progress in collaboration with ENSREG a first time in April 2013 and a second time in April 2015, and will continue to follow the implementation of the measures in EU Member States. Following the assessment of April 2015, ENSREG considered that the rate of safety upgrade implementation should be strengthened to target agreed implementation deadlines, taking into account other safety priorities and quality requirements¹¹.

The building of the Energy Union

¹¹ http://www.ensreg.eu/sites/default/files/attachments/hlg_p2015-31_146_ensreg_statement_nacp_final.pdf

The Commission's Strategy for a European Energy Union¹², which was adopted in February 2015, builds on five mutually reinforcing dimensions:

- energy security, solidarity and trust;
- the internal energy market;
- energy efficiency as a contribution to the moderation of energy demand;
- decarbonisation of the economy and
- research, innovation and competitiveness.

Nuclear energy is part of the energy mix of half of the EU Member States. The Energy Union Strategy and the European Energy Security Strategy¹³ stressed that Member States need to apply the highest standards of safety, security, waste management and non-proliferation as well as to diversify nuclear fuel supplies.

Currently, 14 Member States have operating nuclear power plants (Belgium, Bulgaria, Czech Republic, Germany, Spain, Finland, France, Hungary, the Netherlands, Romania, Sweden, Slovenia, Slovakia and the United Kingdom), with 2 more Member States with nuclear power plants in a shut-down situation (not operating), i.e. Italy and Lithuania. One of these Member States (Germany) has announced a plan to decommission all of their nuclear power plants. Two other Member States have indicated their interest to enter (or re-enter) into nuclear energy (Lithuania and Poland).

In the Member States using nuclear energy, we are moving from a phase of mainly operation of existing power plants built 30 to 40 years ago, to a phase of replacing or extending aging capacity, as well as dismantling. Such changes bring forward a number of challenges which the Member States choosing nuclear energy will have to face while continuously improving nuclear safety.

In April 2016, as announced in the roadmap for accompanying the Energy Union Strategy, the Commission has published a Nuclear Illustrative Programme, the so-called PINC¹⁴. The PINC provides an overview of Member States' plans in terms of investments in the EU for all the

¹² COM(2015)80 - <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2015:80:FIN>.

¹³ COM(2014)330

steps of the nuclear lifecycle and gives an indication on the future role of nuclear energy in achieving the EU's energy and climate objectives. As nuclear safety remains the Commission's absolute priority, the PINC specifically includes investments related to post-Fukushima safety upgrades and those related to the long term operation of existing nuclear power plants. In addition, with the EU nuclear industry moving into a new phase characterised by increased activities in the back-end of the lifecycle, it will contribute to an informed debate on the associated investment needs and the management of nuclear liabilities.

The nuclear power park in the EU is ageing and should individual EU Member States opt to maintain or introduce nuclear energy in their energy mix, significant investments will be needed for the replacement or for the long term operation (and related safety improvements) of existing nuclear plants, for the decommissioning of closed facilities and for the long-term storage of nuclear waste.

Continuing outreach and research activities

In order to contribute to an improvement of the nuclear safety situation in Central and Eastern European Countries (CEEC) and New Independent States (NIS), the EU used the nuclear safety component of two major instruments: PHARE and TACIS. From the beginning of 2007 the assistance/cooperation under these instruments continued under, respectively, the Instrument for Pre-Accession Assistance and the Instrument for Nuclear Safety Cooperation. Since 2014, such assistance to all third countries is exclusively funded under the new Instrument for Nuclear Safety Cooperation 2014 – 2020. After TACIS, the INSC enlarged the geographical scope of the nuclear safety and nuclear safeguards cooperation to ‘third countries’ (i.e., non EU countries); the current Instrument has a budget of EUR 225.321.000 for the period 2014-2020.

As mentioned above, the Commission Communication on an Energy Union underlines that the European Union must ensure that Member States use the highest standards of nuclear safety, security, waste management and non-proliferation. One of the means to achieve this objective is research. The current main instrument to support nuclear research at European level is the Euratom Research and Training Programme 2014-2018 (hereinafter "Euratom Research Programme").

¹⁴ <https://ec.europa.eu/energy/en/news/commission-presents-nuclear-illustrative-programme>

The Euratom Research Programme complementing the Horizon 2020 Framework Programme for Research and Innovation was adopted in December 2013. Its main objective is to pursue nuclear research and training activities with an emphasis on continuous improvement of nuclear safety, security and radiation protection, notably to potentially contribute to the long-term decarbonisation of the energy system in a safe, efficient and secure way. The Programme is implemented through "direct actions", carried out by the European Commission's Joint Research Centre (JRC) and through "indirect actions", carried out by consortia of industry, academia, and Research and Development organisations, funded by the Commission.

The JRC continued contributing to the EU research needed for improved nuclear safety, security and waste management, standardisation, education and training, as well as providing transnational access for all EU Member States to its nuclear research infrastructures. As regards nuclear reactor safety, during the reporting period, the JRC provided technical skills on behalf of Commission for the follow-up of the post-Fukushima "stress tests" at European Nuclear Power Plants (NPPs). In addition, JRC research on nuclear power plant safety focussed on: NPP operational events and feedback of operating experience; severe accident modelling and analysis; long-term safe operation of existing plants with a view to improving residual lifetime assessment techniques; post irradiation examinations and modelling of fuels at high burn-up; properties and behaviour of nuclear fuel under normal, transient and accident conditions; generation of nuclear data and determination of structural and fuel material properties of sustainable advanced reactor designs, and of accident tolerant fuels.

Likewise, the JRC maintained and further improved the Commission tools for exchange of information in case of nuclear emergency and on radiological monitoring and measurements relating to radioactivity in the environment, including updating and maintaining the related database and reporting system. Other research aspects focus on the enhancement of preparedness for nuclear or radiological incidents through benchmarking of environmental dispersion models and development of severe accident modelling, radiological source term evaluation and accident management of nuclear power plants.

The current Research and Training Programme of the European Atomic Energy Community will need to be extended to cover a two year period (2019 and 2020) in order to align its duration with the 7 years of the EU Horizon 2020 Programme covering all other aspects of EU research except nuclear energy.

Finally, as part of the existing programmes the Commission continued the decommissioning support and the Euratom loans.

The situation of Euratom and the EU and as regards the Convention

Neither the EU nor Euratom own nuclear installations¹⁵ as defined by the Convention. All nuclear power plants on the territories of the EU Member States are regulated by the national regulatory authorities in accordance with their respective national laws and in conformity with the legal framework of the Community.

Euratom acceded to the Convention in 1999, as a regional organisation, and the Convention entered into force for Euratom on 30 April 2000; since then, Euratom actively participates in all review meetings.

All 28 EU Member States have signed and ratified the Convention and are now Contracting Parties.

Euratom possesses competences, shared with its Member States, as regards the legislative and regulatory framework (Article 7), assessment and verification of safety (Article 14), radiation protection (Article 15), emergency preparedness (Article 16), siting of nuclear installations (Article 17) and design, construction and operation of nuclear installations (Article 18 and 19). Euratom reports upon these articles and also, in addition on a voluntary basis, upon Articles 8 to 12.

The Euratom Treaty and the legal acts adopted on its basis ("Euratom law") entertain a *lex specialis* relationship with the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU) and prevail over conflicting rules set out by the latter two Treaties. Legislation adopted under the TFEU and legal acts adopted under the Euratom Treaty are legally binding upon Member States. They have primacy over national law. Moreover, Directives, which in principle need to be transposed into national law, may be, subject to certain conditions, directly applicable within the legal systems of the different Member States. To ensure a better understanding and easier peer review, the present report

¹⁵ The only nuclear reactor owned by Euratom still in operation is the High Flux Reactor (HFR) located at Commission's Joint Research Centre in Petten, the Netherlands. It is operated by the Nuclear Consultancy and Research Group (NRG) and it is regulated by the Dutch regulatory authority. Since 2005, the Netherlands includes the HFR in its CNS national review report. For these reasons the present Euratom report entails no information on this reactor.

contains a revised and updated introduction about the legal framework of the EU and Euratom, explaining the legal instruments, the legislative procedures, the joint institutional framework, the general and special obligations of Member States and the enforcement mechanisms.

Since the Member States are responsible for implementing EU and Euratom law, the Euratom report only informs about the current legal framework, European initiatives and programmes, but not about the practical implementation in the 28 Member States. This information is to be found in the respective national reports.

The present Euratom report is a stand-alone report, based on the last report for the 6th Review Meeting. It has been revised, updated and restructured to be in line with the revised Guidelines regarding National Reports. New information is in bold italics.

The report ends with a series of annexes, including the Declaration of Competences, the last Rapporteur's report and a list of Euratom legal acts.

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SECTION I

INTRODUCTION

1. BACKGROUND

European Union (EU) energy policy plays a key role in the promotion of a more resource efficient, sustainable, low carbon, secure, and competitive Europe in the framework of the Europe 2020 new strategy for jobs and growth. In this context, as one of seven flagship initiatives, the Commission put forward the energy-relevant "Resource efficient Europe" initiative, to help decouple economic growth from the use of resources, support the shift towards a low carbon economy, increase the use of renewable energy sources, modernise our transport sector and promote energy efficiency.

The Commission's Strategy for a European Energy Union¹⁶, which was adopted in February 2015, builds on five mutually reinforcing dimensions: energy security, solidarity and trust: the internal energy market; energy efficiency as a contribution to the moderation of energy demand; decarbonisation of the economy and research, innovation and competitiveness.

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 currently 129 operating nuclear power reactors, representing about one-third of the operating nuclear power reactors in the world. Many of the EU nuclear power plants (NPPs) were constructed already three to four decades ago, and are based on designs and safety provisions that were continuously updated since then.

As 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, nuclear safety is of the utmost importance to the EU and its citizens.

2. OVERVIEW OF THE EURATOM NUCLEAR PROGRAMME

The Euratom Community neither owns nor operates any nuclear installations as defined in Article 2(1) of the Convention. Such nuclear installations exist only in the territories of the Member States, to which the Euratom Treaty applies.

Despite the fact that the Convention applies to nuclear power reactors only, meaning research reactors are not formally covered by the Convention (see Art. 2), some Contracting Parties agreed to include them in their reporting during the last CNS peer review conference. The only nuclear reactor owned by Euratom, which is still effectively in operation, is the High Flux Reactor (hereinafter: HFR) of the Commission's Joint Research Centre (hereinafter

¹⁶ COM(2015)80 - <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2015:80:FIN>.

referred to as: 'JRC')¹⁷ in Petten, Netherlands. The HFR research reactor is formally owned by the JRC on behalf of the Euratom Community, but it is operated by Nuclear Consultancy and Research Group (NRG), a subsidiary of the Energy Research Centre of the Netherlands (ECN). It is regulated by the Dutch regulatory authority. For these reasons the present Euratom report entails no information on research reactors. In the past, the JRC held the licence, but the IAEA recommended the transfer of the licence to the operator NRG. As a result, the operating licence was transferred from JRC to NRG.

3. THE EUROPEAN ATOMIC ENERGY COMMUNITY'S (EURATOM) ACCESSION TO THE CONVENTION ON NUCLEAR SAFETY

The European Union is neither a federal state, nor an intergovernmental organisation. The EU is, in fact, unique because it constitutes a new legal order in international law. For reasons of mutual social and economic benefit, its Member States have set up common institutions to which they delegate some of their sovereignty so that decisions on specific matters of joint interest can be taken at European level.

Like the EU, the European Atomic Energy Community (hereinafter referred to as "Euratom") is an international organisation endowed with international legal personality. While membership and organisation of Euratom are fully integrated with the European Union, Euratom is a separate legal entity bearing rights and duties on the international plane.

As a regional organisation as referred to in Article 30 (4) of the Convention on Nuclear Safety (hereinafter: the Convention), Euratom acceded to the Convention after the Decision of the Commission of 16 November 1999¹⁸, adopted on the basis of Article 101 of the Euratom Treaty, following a Decision of the Council of 7 December 1998. The instruments of accession were deposited with the Director General of the International Atomic Energy Agency on 31 January 2000. Thus, for Euratom, the Convention entered into force on 30 April 2000 in accordance with Article 31(2) of the Convention.

The following States are Members of the EU and thus Members of Euratom: The Republic of Austria, the Kingdom of Belgium, the Republic of Bulgaria, the Republic of Croatia, the Republic of Cyprus, the Czech Republic, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, the Hellenic Republic, the Republic of Hungary, Ireland, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Poland, the Portuguese Republic, Romania, the Slovak Republic, the Republic of Slovenia, the Kingdom of Spain, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland. All the 28 EU Member States have signed and ratified the Convention on Nuclear Safety and are now Contracting Parties.

¹⁷ For more information on the JRC please see below Section III, Chapter 1.3 "The Joint Research Centre (JRC) of the Commission", p.38 and Chapter 3.1.2 "Specific Programme for research and training activities implemented by direct actions and carried out by the Commission's Joint Research Centre (JRC)", p. 46.

¹⁸ Commission Decision 1999/819/Euratom of 16 November 1999 concerning the accession to the 1994 Convention on Nuclear Safety by the European Atomic Energy Community (EURATOM), OJ L 318, 11.12.1999, p. 2

4. STATEMENT OF THE COMMITMENT OF THE CONTRACTING PARTY TO THE CONVENTION ON NUCLEAR SAFETY

According to the Convention, regional organisations must – in matters within their competence – "on their own behalf, exercise the rights and fulfil the responsibilities, which the Convention attributes to States Parties" (Article 30(4) ii of the Convention). The participation of Euratom in the CNS Review Meetings is therefore limited to the fields for which a Community competence was declared by the Declaration under Article 30(4)iii of the Convention (see Annex 1).

On the basis of Article 2(b) and the relevant Articles of Title II, Chapter 3, entitled "Health and Safety" of the Euratom Treaty in connection with the Decision of the Court of Justice of the European Communities of 10th December 2002¹⁹ the Community (Euratom) possesses competences, shared with the abovementioned Member States, in the fields of:

- Legislative and regulatory framework, covered by Article 7,
- Assessment and verification of safety, covered by Article 14,
- Radiation protection, covered by Article 15,
- Emergency preparedness, covered by Article 16 paragraph 1, 2 and 3,
- Siting of nuclear installations covered by Article 17,
- Design and construction of nuclear installations, covered by Article 18 and
- Operation of nuclear installations, covered by Article 19 of the Convention.

In conclusion, only the Articles 1 to 5, Article 7 and Articles 14 to 35 of the Convention apply to Euratom. This fact was and is duly reflected in the past²⁰ and present Euratom Reports presented by the Commission.

As the Nuclear Safety Directive covers additional Articles of the Convention, Euratom reports under Articles 8 to 12 on a voluntary basis.

5. EXPLANATION OF THE PREPARATION, STRUCTURE AND MAIN FEATURES OF THE EURATOM REPORT

Euratom submits the present report for peer review at the *seventh* Review Meeting of the Convention at the International Atomic Energy Agency (IAEA) *to be held from 27 March to 7 April 2017. Since the Member States are responsible for implementing and applying Euratom legal acts, the Euratom report only informs about the current legal framework,*

¹⁹ Judgment of the Court of 10 December 2002, *Commission of the European Communities v Council of the European Union*, C-29/99, ECLI:EU:C:2002:734, 102-103.

European initiatives and programmes, but not on the practical implementation of the legal acts in question in the 28 Member States. This information is found in the respective national reports.

This report is based on the last report for the 6th Review Meeting. It has been revised, updated and restructured in line with the new Guidelines regarding National Reports under the Convention on Nuclear Safety²¹. It is a full report without references to previous reports to allow easy reading. New information has been highlighted, as recommended, in bold italics font. For a better follow-up of the 6th review meeting the last 'Rapporteur's Oral Report' for Euratom has been annexed to the present report.

The Euratom report starts with an introduction on the general policy, the accession and declaration of competences, followed by a summary to highlight the follow-up from the 6th Review Meeting. Finally, the Article by Article Review should demonstrate how Euratom, as a regional organisation, contributes to meeting the main objective of the Convention: to achieve and maintain a high level of nuclear safety worldwide by enhancing Community measures and international cooperation. It also shows how the Community meets the obligations of the applicable articles established by the Convention.

Through Council Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations²² adopted in 2009 and its subsequent 2014 amendment, Euratom introduces a number of new regulatory requirements for nuclear safety aspects which had not been addressed before. As this Directive deals with several aspects touched upon by Articles 8-12 of the Convention, the present Report provides selected information relating to said Articles of the Convention, even though it does so on a voluntary basis. In addition, the present Report covers Article 7 and Articles 14 to 19 of the Convention which are mentioned in the relevant Euratom Declaration under Article 30(4)iii of the Convention (deposited with the Director General of the IAEA on 11th May 2004).

²⁰ EURATOM Report on the implementation of the obligations of the Convention on Nuclear Safety (COM(2001) 568 final) and EURATOM Report on the implementation of the obligations under the Convention on Nuclear Safety, Brussels, 13.10.2004, C(2004) 374.

²¹ INFCIRC/572/Rev.4 of 28 January 2013.

²² OJ L 172, 02/07/2009, p.18.

SECTION II SUMMARY

1. THE EURATOM COMMUNITY'S EFFORTS IN ACHIEVING THE OBJECTIVES OF THE CONVENTION

The European Atomic Energy Community (Euratom) has been active in the field of nuclear safety for over 50 years, through the action of its institutions, in particular the Commission and the Council, at different levels. The commitment of Euratom and its Member States to a high level of nuclear safety and to the safe management of spent fuel and radioactive waste is reflected, in particular, in the existing Euratom legislative framework adopted under the Euratom Treaty as well as in the relevant Council Resolutions and conclusions of the European Council.

In the Council Resolution of 22 July 1975 on the technological problems of nuclear safety²³, the European Council considered that the technological problems relating to nuclear safety, in view of their environmental and health implications, called for appropriate action at Community level which would take into account the prerogatives and responsibilities assumed by national authorities. It recognised that it was the Commission's responsibility to act as a catalyst in initiatives taken at international level with regard to nuclear safety. As a result of this resolution, the Commission set up several expert groups dealing with nuclear safety matters. These groups, in which representatives of the safety authorities of the Member States participate, have actively contributed to the harmonisation of nuclear safety practices.

The Council Resolution of 18 June 1992 on the technological problems of nuclear safety²⁴ encouraged the continuation of the process of consultation and co-operation established by the resolution of 1975, and recommended its extension to third countries, notably to the Central and Eastern European Countries (hereinafter: CEEC) and the New independent States comprising the Republics of the former Soviet Union as a result of its break-up (hereinafter: NIS). It further requested the Member States and the Commission to adopt as the fundamental and priority objective of Community cooperation in the nuclear field, in particular with the other European countries, especially those of Central and Eastern Europe and the Republics of the former Soviet Union, that of bringing their nuclear installations up to safety levels equivalent to those in practice in the Community and to facilitate the implementation of the safety criteria and requirements already recognized throughout the Community. Following this Resolution, participation in the different expert groups was extended to representatives of the CEECs and the NIS.

The Cologne European Council in June 1999 asked the Commission to ensure that high safety standards are applied in Central and Eastern Europe. Following on from this request, the

²³ OJ C-185 of 14.08.1975, p. 1.

²⁴ OJ C-172 of 08.07.1992, p. 2.

safety of nuclear installations in the candidate countries²⁵ was evaluated by the Commission and the Council in 2001, making it possible to arrive at a European perspective with regard to nuclear safety agreed by the then fifteen Member States and the Commission.

The Laeken European Council in December 2001 marked the transition from reflection conducted in the perspective of enlargement to that of a global political vision at the level of the enlarged EU. One of the conclusions of this meeting was that *"the European Council undertakes to maintain a high level of nuclear safety in the Union. It stresses the need to monitor the security and safety of nuclear power stations. It calls for regular reports from Member States' atomic energy experts, who will maintain close contacts with the Commission"*.

The Brussels European Council of 8/9 March 2007 confirmed that it is for each and every Member State to decide whether or not to rely on nuclear energy and stressed, that this has to be done while further improving nuclear safety and the management of radioactive waste.²⁶

To this effect the Council envisages the creation of a high-level group on nuclear safety and waste management and suggested that broad discussion takes place among all relevant stakeholders on the opportunities and risks of nuclear energy.

On 8 May 2007 the Council adopted Conclusions on Nuclear Safety and Safe Management of Spent Nuclear Fuel and Radioactive Waste on the basis of the Presidency Conclusions of the Brussels European Council of 8/9 March 2007 in Brussels²⁷. In these conclusions the Council recalled that nuclear safety is a national responsibility exercised where appropriate in an EU-framework and that decisions concerning safety actions and the supervision of nuclear installations would remain solely with the operators and national authorities. Community added value had been recognized in building common views on nuclear safety issues, and Council resolutions have paved the way for co-operation between Member States and the Commission. Finally the Council endorsed the Commission proposal²⁸ concerning the establishment of a High Level Group on Nuclear Safety and Waste Management. The group was later renamed ENSREG, the European Nuclear Safety Regulators Group. ENSREG's central mission is to strive for the continuous improvement in nuclear safety and radioactive waste and spent fuel management and their regulation, and to promote openness and transparency in those areas. ENSREG has divided its activities in four basic areas: Safety of nuclear installations, Radioactive waste and spent fuel management, Openness and transparency, and, recently, International cooperation.

²⁵ The fifth EU Enlargement comprised the largest number of countries ever admitted at one time: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia acceded to the EU on 1st May 2004, Romania and Bulgaria joined in on 1st January 2007.

²⁶ Council of the European Union, Brussels, 8-9 March 2007: Presidency Conclusions (9 March 2007: Brussels), Council Document No 7224/07 of 2 May 2007, REV 1, CONCL 1.

²⁷ Council Conclusions on Nuclear Safety and Safe Management of Spent Nuclear Fuel and Radioactive Waste, 2798th ECONOMIC and FINANCIAL AFFAIRS Council meeting, Brussels 8 May 2007.

²⁸ Communication from the Commission to the European Council and the European Parliament: "An Energy Policy for Europe", COM(2007) 1 final of 10.01.2007; SEC(2007)12.

2. PREVIOUS SAFETY ISSUES

During the last review meeting²⁹, a number of challenges were identified in the Rapporteur's report for Euratom and suggestions were made.

With regard to challenges put forward, this mainly included the need to build on the experience of the stress tests to further promote harmonisation of safety approaches in Europe through cooperation on specific subjects including peer reviews; the continuation of the dialogue with the International Atomic Energy Agency (IAEA) and the World Association of Nuclear Operators (WANO) to ensure that the addition of such new peer review activities does not duplicate peer review activities from the other organisations; and the completion of the legislative follow-up activities related to the implementation of lessons learned from the Fukushima accident.

In order to tackle these challenges, it was suggested that Euratom would provide an update on the new, targeted Euratom peer review process during the 7th CNS Review Meeting, and discuss their resource impact; and would provide an update on legislative activities related to the implementation of lessons learned from the Fukushima accident.

In addition, the fact that Euratom is exploring a recurring peer review process that is based upon the stress tests and includes design issues was presented as a good initiative. The new nuclear decommissioning assistance programs and the new instrument for international nuclear safety cooperation were also presented as good initiatives.

3. SIGNIFICANT CHANGES AND DEVELOPMENTS SINCE THE PREVIOUS EURATOM REPORT

3.1. Comprehensive risk and safety assessments ("stress tests") of nuclear power plants in the European Union overview

3.1.1. Background

In the Conclusions of its meeting of 24-25 March 2011, the European Council, comprising the Heads of State or Government of the EU Member States, stated that the safety of all EU nuclear plants should be reviewed on the basis of a comprehensive and transparent risk and safety assessment.

The mandate from the European Council also comprised the invitation for EU neighbouring countries to take part in the process.

The Commission and the European Nuclear Safety Regulators' Group (ENSREG)³⁰, which comprises the Euratom Member States' national nuclear safety or regulatory authorities

²⁹ See "Rapporteur's Report for EURATOM of 25 March 2014 in the 6th Review Meeting under the Convention on Nuclear Safety", attached as annex 2.

³⁰ The role of ENSREG is to advise and assist the Commission, at its own initiative or at the initiative of the Commission, to progressively develop a common understanding and furthering common approaches in priority

responsible for nuclear safety, were invited to reassess the safety margins of the EU nuclear power plants in light of the Fukushima events.

All "Stress Tests" reports, including the licensee reports, have been made available on the ENSREG website³¹.

3.1.2. Main findings from the Stress Tests

While the assessments found that the safety standards of nuclear power plants in Europe were generally high, further improvements were recommended.

In the framework of the stress tests, EU-wide issues were identified through topical reviews. The peer review Board report identified three main areas for further improvement for the safety of nuclear power plants as described below:

- *Developing European guidance by Western European Nuclear Regulators Association (WENRA), involving the best available expertise from Europe, on the assessment of natural hazards, including earthquake, flooding and extreme weather conditions, and safety margins beyond the design basis and cliff-edge effects, to increase consistency between Member States;*
- *Using Periodic Safety Reviews (PSRs), as often as appropriate but at least every 10 years, to maintain and improve the safety and robustness of nuclear power plants;*
- *Implementation of recognised measures to protect containment integrity as the last barrier to protect the people and the environment against radioactive releases resulting from a nuclear accident;*

3.1.3. EU Stress Tests follow-up phases

As a follow up to the stress tests, national action plans (NACPs) were prepared by all participating countries, which set forth actions to improve nuclear safety as well as the schedule for their implementation. The majority of these actions were expected to be implemented by 2015-18, the latest foreseen date for completion being 2020.

These NACPs were reviewed during a National Action Plan Workshop organised by ENSREG in 2013. The NACPs were revised during late 2014 and reviewed during a 2nd NACPs Workshop in the Spring of 2015. The second workshop focused in particular on evaluating progress of implementation, including any additional measures undertaken and changes made to the original schedule. Special attention was devoted to the technical reasons for the changes proposed as well as to the review of studies and analyses identified and completed since the 2013 Workshop.

Following the 2nd NACP workshop, ENSREG:

- *Endorsed the summary report of the workshop which was made public on the ENSREG website;*

domains related to the safety of nuclear installations, the safety of the management of spent fuel and radioactive waste and transparency.

³¹ <http://www.ensreg.eu/node/3889>.

- *Commended the importance of promoting the sharing of practices, experiences and challenges across European countries, with the aim of continuously improving safety;*
- *Recognised the strong and continuous commitment of all participating nuclear operators and regulatory authorities towards the full implementation of all improvement actions identified in their respective NAcPs and;*
- *Recognised that an important number of actions listed on the NAcPs had been completed under the oversight of the national safety regulatory authorities.*
- *Noted that the status of implementation differs compared to the original deadlines presented in the 1st National Action Plan summary report³² where major modifications were to be implemented by 2015-2018, and at the latest by 2020. While many nuclear operators had almost completed implementation, and others had clear schedules to complete actions by 2016 some had rescheduled specific actions for later than 2020;*
- *Considered that the rate of safety upgrade implementation should be strengthened to target agreed implementation deadlines, taking into account other safety priorities and quality requirements;*
- *Recommended that a status report from each participating country on the implementation of the NAcPs be updated and published periodically to ensure a transparent monitoring with the aim of publishing a report on the implementation in 2017.*

3.1.4. *Voluntary participation of third countries in the Stress Test process*

As an outcome of the meeting of 23 June 2011 with Commissioner Oettinger, Deputy Ministers of Energy and senior representatives of the Ministries of Energy and national authorities responsible for nuclear energy of the Republic of Armenia, Republic of Belarus, Republic of Croatia, Russian Federation, Swiss Confederation, Republic of Turkey, Ukraine confirmed their willingness to undertake the Stress Tests including a peer-review. The need for a consistent approach towards nuclear safety by all countries making use of nuclear energy was reinforced by shared vision that highlights the potential cross-border nature of nuclear accidents;

Two countries Switzerland and Ukraine directly participated to the full process of the Stress Tests with the other EU countries in 2012 and to the National Action Plan peer reviews in 2013 and 2015.

Since then, the exercise has also been completed in Armenia.

Euratom is dedicated to further promotion of the international nuclear safety standards in third countries, as well as the prompt accomplishment of the Stress Tests including a peer-review in third countries.

³² <http://www.ensreg.eu/node/1343>

3.2. Revision of the legal and regulatory Euratom framework for the nuclear safety of nuclear installations

Following the entry into force of Nuclear Safety Directive (Directive 2009/71/Euratom), the Member States had until 22 July 2011 to bring into force their laws, regulations and administrative provisions ensuring compliance with the Directive.

Under Article 9(2) of Directive 2009/71/EURATOM, EU Member States were required to submit a report to the Commission on the implementation of that Directive for the first time by 22 July 2014, and on the basis of the Member States' reports, the Commission was required to submit a report to the Council or the European Union and the European Parliament on progress made with the implementation of the Directive.

Having reviewed these national reports, the Commission concluded, in its report³³, that there is, in general, a good level of compliance with the 2009 Nuclear Safety Directive. The Directive has proven to be an effective instrument in improving nuclear safety, as most Member States reported that they had upgraded their legal system in order to transpose it into national law.

The basic aim of the Directive being to ensure appropriate national arrangements to achieve a high level of safety, in general, the national reports demonstrate that these arrangements are in place in the EU as regards the legal framework and regulatory authority. However, in some cases it is not certain that such authorities are adequately staffed and funded. Cooperation among Member States should be encouraged in order to ensure an effective use of existing resources, for instance in the case of Long Term Operation of nuclear power plants or licencing procedures for new builds. Such cooperation would be particularly beneficial for smaller competent regulatory authorities.

International benchmarking has been widely used: by the end of 2015, international counterparts will have reviewed the legal and organisational framework of all Member States operating nuclear power plants, through IAEA Integrated Regulatory Review Service missions. Full-scope missions should be preferred to limited ones.

Safety arrangements imposed on nuclear installations (under the supervision of regulatory authorities), including development of expertise and skills, are largely in place. Wherever appropriate, nuclear plant licence holders tend to establish strong synergies with national or international research and training organisations dedicated to the improvement of reactor safety regulation, technology and culture.

However, although most of the Member States reported having national provisions as regards the human and financial resources of the licence holders, it should be clarified whether the regulatory authority has the ability to assess the adequacy of such resources,

³³ Report from the Commission to the Council and the European Parliament 'Implementation of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations', COM(2015) 573 final, 18.11.2015.

especially financial ones, and whether these obligations are effectively implemented and enforced.

As confirmed through the nuclear stress tests and the initial check of Member States' transposition of the Directive, there are differences from country to country over the identification and management of safety issues. This is partly due to the fact that the 2009 Directive only contained broad principles, leaving some leeway to Member States as regards their implementation.

The review of the Euratom legal framework for nuclear safety, also called for by Heads of State and Government in March 2011, led to a Commission proposal for substantial amendments to Directive 2009/71/Euratom. The proposals took account of the lessons learned from the nuclear stress tests as well as the safety requirements of the Western European Nuclear Regulators Association (WENRA) and of the standards of the IAEA.

The European Parliament also encouraged a legislative review. In its 2013 Resolution on Stress Tests, it pointed out that "an overall nuclear safety and security policy [...] should also guarantee the existence of strong and independent regulators", it called on the upcoming 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". The European Economic and Social Committee also expressed its support for the "Commission's intention to undertake an ambitious revision of the Nuclear safety Directive".

The European Economic and Social Committee (EESC) gave its opinion on the Commission's draft proposal under Article 31 of the Euratom Treaty. It commended the prompt action taken by the Commission in bringing forward the proposal for amending the Nuclear Safety Directive, and expressed satisfaction that several issues highlighted in its previous opinions on nuclear safety had been addressed in the proposal, including the clarification of regulatory responsibilities, competence and capacity, the enhanced independence of national regulators, and action on on-site emergency preparedness and response. The Committee also commended the strengthened approach to overall transparency.

Following discussions in the Council, the amended Nuclear Safety Directive (Directive 2014/87/Euratom) was adopted on 8 July 2014. The Directive promotes an effective nuclear safety culture and introduces high-level EU-wide safety objectives that aims to reduce the risks of a nuclear accident, and, should an accident occur, to limit its consequences by avoiding radioactive releases, in line with the set of principles and implementation mechanisms to improve and enhance the safety of nuclear power plants as enshrined in the Vienna Declaration on Nuclear Safety adopted in 2015.

These objectives address the safety of the entire lifecycle of nuclear installations, i.e. siting, design, construction, commissioning, operation and decommissioning, as well as on-site emergency preparedness and response. Moreover, the Directive provides for regular safety

reassessments of nuclear installations, to be carried out by the licence holder under the supervision of the competent regulatory authority, to identify further safety improvements, taking into account, inter alia, ageing issues.

Under the amended Nuclear Safety Directive, the independence of the national regulatory authorities is strengthened, requiring that they be provided with the appropriate means and competences 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 the responsibilities assigned to it.

Member States are required to define every six years, through their competent regulatory authorities and making relevant use of ENSREG, a methodology, terms of reference and a time frame for peer reviews on a common specific technical topic related to the nuclear safety of their nuclear installations. 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. In view of plans for long term operation of some nuclear power plants in the EU, the subject of "ageing management" has been chosen as the specific topic of the national assessment and peer review which shall start in 2017.

Member States are also required to arrange for periodic self-assessments of their national framework and competent regulatory authorities at least every ten years and to request an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety.

Finally, the amended Directive enhances transparency on nuclear safety matters, by making the provisions on the information to be provided to the general public more specific.

The amended Directive entered into force on 14 August 2014. EU Member States have until August 2017 to transpose it into national legislation.

To ensure a timely and adequate transposition of the amended Nuclear Safety Directive, the Commission is interacting with the Member States in the pre-transposition phases, including the organisation of discussion workshops.

The next national reports on the implementation of the Directive are due to be sent to the Commission by 22 July 2020. By that time, the Commission will have received and analysed Member States' national provisions transposing the amended Nuclear Safety Directive.

3.3. Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (Revised 2013 Basic Safety Standards Directive)

Following international recommendations (International Commission on Radiological Protection ICRP Publication 103, 2007) *and in the context of lessons learned from the Fukushima accident as regards emergency preparedness and response*, the Commission worked out a Proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. The proposal was tabled on 30 May 2012 and, it was then submitted to the European Parliament for consultation

and to the Council for adoption. *The Directive was adopted on 5 December 2013. It was published on 17 January 2014 and entered into force on 6 February 2014. Member States are required to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018.*

With the publication of the new basic safety standards Directive, the European Union modernises and consolidates the European radiation protection legislation. The new Directive offers in a single coherent document basic safety standards for the protection against the dangers arising from ionising radiation which take account of the status of science and technology, cover all relevant radiation sources, including natural radiation sources, integrate protection of workers, members of the public, and patients, cover all exposure situations, planned, existing, emergency, and harmonise numerical values with international standards.

The new Basic Safety Standards (BSS) Directive provides for:

- *Better protection of the public, in particular with regard to radon in dwellings, exposure from activities involving Naturally Occurring Radioactive Material (NORM), exposure from building materials, exposure from existing exposure situations, exposure from emergency situations, and deliberate exposure for non-medical purposes;*
- *Better protection of workers, in particular for medical staff, workplaces with indoor radon, workplaces with NORM, and emergency workers;*
- *Better protection of patients, in particular with a view to put more emphasis on the justification of medical exposures, to strive for enhanced safety culture in the medical area, and with measures aiming at a minimisation of probability and magnitude of accidental or unintended exposures;*
- *Strengthened requirements on emergency preparedness and response, especially with a view to the lessons learned from the Fukushima accident.*

The transposition and implementation of this comprehensive piece of legislation will constitute a major challenge for national legislators and regulators in the coming years. The Commission has elaborated and is currently pursuing a strategy to monitor and facilitate the transposition of the Directive into Member States' national legislation and to support its implementation, mainly by means of organising a series of workshops with the participation of Member States. This will allow, even at an early stage, the detection of issues, an exchange of first experiences, and the identification of good practices. Later in the process, when Member States will already have drafted legislation, the latter will be analysed with a view to assessing its compliance with the BSS Directive.

3.4. Adoption of the "Euratom Drinking Water Directive"

In addition to the new Basic Safety Standards Directive, a Directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water was adopted in 2013 ("Euratom Drinking Water Directive"). In view of the importance for human health of the quality of water intended for human consumption, the EU laid down quality standards at Community level and provided

for the monitoring of compliance with those standards, with the aim of enhancing radiation protection legislation.

In particular, the Directive sets out parametric values, frequencies and methods for monitoring radioactive substances in drinking water. Its transposition by Member States was due by 28 November 2015. The final transposing measures have been communicated to the Commission and the Commission assessment is currently in progress.

3.5. Revision of the existing legislation establishing maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other radiological emergency.

Following the nuclear accidents of Chernobyl in 1986 and of Fukushima in 2011, specific EU Regulations on import conditions into the EU of agricultural products, food and feed have been put in place. On the basis of the experience gained the Commission proposed to the Council in 2014 a revision of the existing legislation establishing maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other radiological emergency. In January 2014 the Commission adopted its final proposal for a Council Regulation, after having received the opinion of the Article 31 Group of Experts and of the European Economic and Social Committee. After having reached technical agreement in the WPAQ of Council at the end of 2014, the opinion of the European Parliament was received on 9 July 2015. Council Regulation (Euratom) 2016/52 was then adopted on 15 January 2016.

3.6. Instruments for improving the level of nuclear safety in third countries

The 1986 Chernobyl and the 2011 Fukushima Daichii accidents highlighted the catastrophic consequences of nuclear power with a deficient design associated with a poor safety culture and an inadequate operational safety and regulatory framework. In order to contribute to an improvement of the nuclear safety situation in Central and Eastern European Countries (CEEC) and New Independent States (NIS), the EU used the nuclear safety component of two major instruments: PHARE and TACIS. From the beginning of 2007 the assistance/cooperation under these instruments continued under, respectively, the Instrument for Pre-Accession Assistance and the Instrument for Nuclear Safety Cooperation. Since 2014, such assistance to all third countries is exclusively funded under the new Instrument for Nuclear Safety Cooperation 2014 – 2020.

3.6.1. Instrument for Nuclear Safety Co-operation (INSC)³⁴

After TACIS, the INSC enlarged the geographical scope of the nuclear safety and nuclear safeguards cooperation to ‘third countries’ (i.e., non EU countries); the current Instrument has a budget of EUR 225 million for the period 2014-2020. The three programme priority areas are: i) the promotion of a nuclear safety culture by supporting the regulatory authorities and their technical support organisations, ii) the safe management of nuclear

³⁴ Council Regulation (Euratom) No 300/2007 of 19 February 2007 establishing an Instrument for Nuclear Safety Cooperation, OJ L81, 22.03.2007, p.1.

waste and spent fuel, including remediation of former legacy sites and iii) establishment of an efficient nuclear material safeguards system.

The geographical priority of the programme is among the Accession Countries and the neighbourhood of the EU where most of the funding is concentrated. Cooperation nevertheless continues across the globe; here regional approaches are favoured. The instrument supports, inter alia, significant initiatives in Ukraine, Belarus, Armenia and Turkey, and further afield in Central, East and South-East Asia, Africa and Latin America. More recently, the INSC has also become the EU vehicle for the civil nuclear safety cooperation with Iran pursuant to the nuclear deal reached in 2015.

Over the last years, collaboration under the INSC with the IAEA has also been stepped up with the objective of further developing nuclear safety culture and the required expertise at global level and to support adherence to international Conventions and Treaties as well as to avoid duplication of activities in the cooperation programmes carried out for the third countries.

It is noted that nuclear security issues, e.g. the tackling of illicit trafficking, may also be funded through other EU instruments such as the Instrument contributing to Stability and Peace³⁵.

3.6.2. Instrument for Pre-Accession Assistance (IPA³⁶)

In the Western Balkans, current potential candidates and candidate countries for accession to the EU (Albania, Bosnia and Herzegovina, the Former Yugoslav Republic of Macedonia, Kosovo*, Montenegro and Serbia) received very limited support for nuclear activities until 2006 through PHARE and the CARDS programme (Community Assistance for Reconstruction, Development and Stability in the Balkans).

Since 1 January 2007, a more substantial support has been provided through IPA to the Western Balkan countries. Between 2007 and 2011, some 45 nuclear projects were programmed for these countries for a total amount of about 33 million Euros. The main activities of the IPA horizontal programme on nuclear safety and radiation protection covered the repatriation of spent fuel from Serbia to the Russian Federation, management of radioactive waste, radiation protection, actions to prevent illicit trafficking of nuclear materials and radiation sources, monitoring of the radioactivity in the environment and enhancement of the technical capacity of newly created nuclear regulatory bodies. Several IPA projects were implemented under joint management with the IAEA³⁷.

3.7. Cooperation with International Organisations

³⁵ For more information see http://ec.europa.eu/europeaid/how/finance/ifs_en.htm_en.

³⁶ Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA), OJ L 210 31/03/2007, p. 82.

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/99, as well as the opinion of the International Court of Justice on Kosovo's declaration of independence.

³⁷ For more information see at:

http://europa.eu/legislation_summaries/enlargement/ongoing_enlargement/e50020_en.htm.

The IAEA and Euratom have been developing extensive scientific and technological cooperation for many years. An existing cooperation agreement between the IAEA and EURATOM, in force since 1 January 1976, provides a formal basis for the collaboration of the two organisations.

In May 2008, both organisations signed a Joint Statement where they agreed to examine concrete steps to significantly reinforce the quality and intensity of their cooperation. The IAEA and the European Commission currently cooperate in various areas and their cooperation has grown significantly over the last few years.

Based on the 1976 Cooperation Agreement and the 2008 "Joint Statement", the European Commission and the IAEA signed in 2013 a Memorandum of Understanding on nuclear safety, including expert peer reviews and emergency preparedness and response, allowing further synergies and avoiding duplication of efforts.

3.8. Experts Groups of the Commission

3.8.1. High-level Group on Nuclear Safety and Waste Management (ENSREG)

Following the endorsement of the Commission proposal³⁸ by the European Council of 8-9 March 2007, the Conclusions of the 2798th meeting of the Council of the European Union (Economic and Financial Affairs) of 8 May 2007 and the European Parliament resolution on Assessing Euratom — 50 years of European nuclear energy policy (10 May 2007), the Commission adopted a Decision establishing a "European High Level Group for Nuclear Safety and Waste Management (High Level Group)"³⁹ on 17 July 2007. The High Level Group is based on the work carried out by European Union Member States and the Commission in the "Working Party on Nuclear Safety (WPNS)" during 2005 and 2006 which aimed at improving the nuclear safety within the European Union. Later the Group was renamed the European Nuclear Safety Regulators' Group (ENSREG). It brings together the senior representatives from the national nuclear regulatory or safety authorities of all EU Member States having competence in the areas covered, and a representative of the Commission. Its mandate is to develop common approaches in the domains of the safety of nuclear installations and the safety of the management of spent fuel and radioactive waste and to advise the Commission on possible Community legal acts in these fields

ENSREG's central mission is to strive for the continuous improvement in nuclear safety and radioactive waste and spent fuel management and their regulation, and to promote openness and transparency in those areas. The ENSREG Work Programme 2014-16⁴⁰ was agreed at the 26th Meeting of ENSREG and building on the achievements of the 2012-13 work programme focuses on:

- *seeking continuous improvement in nuclear safety arrangements through:*

³⁸ The Nuclear Illustrative Programme 2007 put forward a proposal to set up an EU High Level Group on Nuclear Safety and Waste Management; Communication from the Commission to the Council and the European Parliament of 4 October 2007, COM(2007) 565 final, p. 22, not published in the Official Journal; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0565:FIN:EN:PDF>.

³⁹ OJ L 195/44 of 27.07.2007

⁴⁰ [http://www.ensreg.eu/sites/default/files/HLG_p\(2014-27\)_135%20ENSREG%20Workprogramme%202014-16%20final.pdf](http://www.ensreg.eu/sites/default/files/HLG_p(2014-27)_135%20ENSREG%20Workprogramme%202014-16%20final.pdf)

- *continuing to follow up on the indicative program for the conduct of IRRS-Missions in EU-Member States (MS)*
- *conducting technical discussion regarding reporting according to Art. 9(1) of the Nuclear Safety Directive*
- *conducting a second workshop to peer review the updated National Action Plans (NACPs) in 2015*
- *seeking continuous improvement in radioactive waste management, spent fuel and decommissioning arrangements through:*
 - *finalising the guidelines for reporting under Art. 14(1) of the Waste Directive and reviewing the guidelines for MS National Reports*
 - *continuing to follow up on interaction with IAEA regarding Peer Review services also for peer reviews under the Waste Directive*
 - *organising a workshop on European approaches to responsible and safe management of spent fuel and radioactive waste*
- *seeking enhanced openness and transparency by:*
 - *reviewing and assessing the progress achieved by European Nuclear Regulators in transparency issues*
 - *maintaining a comprehensive ENSREG website*
 - *organising an ENSREG led European Conference, accessible to all stakeholders, dedicated to furthering the central mission of ENSREG for continuous improvement.*
- *In the context of international cooperation developing and promoting a common understanding and continuous improvement in the fields of nuclear safety, spent fuel management and radioactive waste management worldwide through:*
 - *providing ENSREG with the ability to advise the European Commission in the areas of nuclear safety and radiation protection (where related to radioactive material management) within the Instrument for Nuclear Safety Co-operation (INSC) (and Instrument for Pre-accession Assistance (IPA))*
 - *evaluating the needs for nuclear regulatory safety cooperation and defining overall and country-specific strategies for nuclear safety cooperation*
 - *identifying preliminary proposals for nuclear regulatory safety cooperation activities and coordinating nuclear regulatory safety cooperation*

As a result of discussions within ENSREG concerning priorities and the effectiveness of ENSREG and working group practices, ENSREG tasked a "reflection group" to review the work programme format and produce a new work programme for 2016-19⁴¹.

The new work programme aims to provide greater clarity on the key tasks to be achieved by ENSREG and when and how they will be completed- enabling greater oversight by the plenary and increased transparency of the work of ENSREG. The new work programme is shaped by recent European legislative changes, in particular Council Directive

⁴¹ <http://www.ensreg.eu/document/ensreg-work-programme-2016-2019>

2014/87/EURATOM (the amended Nuclear Safety Directive) and Council Directive 2011/70/EURATOM (the Spent Fuel and Radioactive Waste Directive) and focuses on preparing the implementation of this legislation.

In 2013 and 2015, ENSREG submitted to the Commission two Activity Reports^{42 43}, presenting the activities undertaken by the Group, its discussions and recommendations covering nuclear safety, waste management and transparency aspects.

ENSREG's first conference took place in 2011 and dealt mainly with the work done by ENSREG, its achievements and perspectives. The second ENSREG conference in 2013 had focused largely on the accident at Fukushima and the lessons learnt from it. This year's event sought to build on and move forward from those experiences to promote the continuous improvement of nuclear safety.

ENSREG held its third conference in Brussels on 29 and 30 June 2015. An objective of the conference was to promote greater International outreach through presentations from Argentina, China, South Korea and the USA. Building on the previous conferences in 2011 and 2013, this year's event focused on promoting continuous improvement in nuclear safety and reinforced the common goal of securing full implementation of the European nuclear safety legal framework in all Member States.

3.8.2. Article 31 Group of Experts

It is laid down in Article 31 of the Treaty establishing the European Atomic Energy Community (the "Euratom Treaty") that a Group of scientific experts shall be attached to the Commission and shall have advisory status.

By virtue of the very high standing of its members, and their qualification in the fields of radiation protection and public health, the Group of scientific experts referred to in Article 31 of the Euratom Treaty (the "Group") is called upon to assume the all-important function of adviser to the Commission on preparing the basic standards to be established by the latter. Moreover, the Treaty itself requires the Commission to consult the Group when revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Articles 31 and 32 of the Euratom Treaty). Thus, when putting forward proposals concerning the basic standards, the Commission convenes the Group so that it may formally obtain an expert opinion to enable it to guide its decisions and make the requisite choices. Such decisions are collectively given by the Group whose members, each being appointed on a personal basis, speak on their own behalf and act independently of all external influence.

The Commission may convene the Group not only on the occasions specifically laid down in the Treaty, but also whenever it considers such action to be necessary. A schedule of at least two meetings a year should permit the Commission to keep up a fruitful dialogue with the Group, whilst periodically requesting exchanges of view and guidance on any major problem affecting radiation protection. If necessary, additional meetings can be held or matters can be dealt in written procedure.

⁴² http://www.ensreg.eu/sites/default/files/attachments/ensreg_report_november_2015.pdf

⁴³ <http://www.ensreg.eu/document/third-report-european-nuclear-safety-regulators-group-july-2013>.

The members of the Group are appointed for a term of five years, renewable, by the Scientific and Technical Committee set up in compliance with Article 134 of the Treaty. In its present composition the Group's expertise is primarily in the field of radiation protection as specified in Articles 30 to 32 of the Euratom Treaty. For this reason it focuses its opinions on those aspects of draft legislative measures which would enhance the overall objectives of radiation protection.

The Group has adopted their own Rules of Procedure⁴⁴.

Every year, the Commission organises, in cooperation with the Group of Experts referred to in Article 31 of the Euratom Treaty, a Scientific Seminar on emerging issues in Radiation Protection – generally addressing new research findings with potential policy and/or regulatory implications⁴⁵. Leading scientists are invited to present the status of scientific knowledge in the selected topic. Based on the outcome of the Scientific Seminar, the Group of Experts referred to in Article 31 of the Euratom Treaty may recommend research, regulatory or legislative initiatives. The Commission takes into account the conclusions of the Experts when setting up its radiation protection program. The Experts' conclusions are valuable input to the process of reviewing and potentially revising European radiation protection legislation.

During the discussions on the revision of Community legal acts in the area of radiation protection, the expert group established on the basis of Article 31 Euratom Treaty adopted their Opinion on the Revised Basic Safety Standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation on 24 February 2010⁴⁶.

In November 2012, the Group of experts adopted an opinion on the proposal for a Council Regulation laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency⁴⁷.

The expert group established on the basis of Article 31 Euratom Treaty was also consulted on the Proposal for Council Directive amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations and on 26 March 2013 the group adopted their opinion⁴⁸.

3.8.3. Article 37 Group of Experts

Under Article 37 of the Treaty Euratom Treaty, each Member State shall provide the Commission with general data relating to any plan for the disposal of radioactive waste in

⁴⁴ https://ec.europa.eu/energy/sites/ener/files/documents/2007_11_procedure_rules.pdf. The opinions on legislative proposals of the Commission are published at: <https://ec.europa.eu/energy/node/1183>.

⁴⁵ <https://ec.europa.eu/energy/en/radioactivity-seminars>.

⁴⁶ Available at:

https://ec.europa.eu/energy/sites/ener/files/documents/2010_02_24_opinion_on_bss.pdf.

⁴⁷ Available at:

https://ec.europa.eu/energy/sites/ener/files/documents/2012_11_opinion_foodstuff_regulation.pdf.

⁴⁸ Available at:

https://ec.europa.eu/energy/sites/ener/files/documents/2013_04_opinion_nuclear_safety.pdf.

whatever form. On the basis of these data and following consultation of the Group of Experts referred to in Article 31, the Commission shall determine whether the implementation of such a plan is liable to result in the radioactive contamination of the water, soil or airspace of another Member State and deliver its opinion within six months.

The Group of Experts referred to in Article 37 and created pursuant to Article 31 was, originally, the same as the group participating in the development of the basic safety standards and therefore comprised mainly public health experts. However, given the technical problems inherent in examining general data relating to the disposal of radioactive waste from fuel cycle facilities, the Commission decided, very early on, to ask the Scientific and Technical Committee (the STC created pursuant to Article 134 of the Euratom Treaty, and, pursuant to Article 31, responsible for the appointment of experts to the group mentioned in Article 31), to appoint another group of scientific experts for the activities coming under Article 37. Members are appointed to the group every five years. The chairmanship of the group follows that of the Council of the EU.

Nevertheless, for a project presented by the Member State holding the Presidency, the chairmanship is assured by an expert from the Member State which held the previous Presidency or is due to hold the following one. The Secretariat of the Article 37 Group of Experts is provided by the Commission.

In the years 2010-2015, the Commission delivered sixty-four opinions. It is noteworthy that the opinions delivered are increasingly concerned with decommissioning and dismantling plans as well as radioactive waste management plans.

3.9. Nuclear safety research supported by Euratom

Euratom supports nuclear safety-related research through the Euratom Research and Training Programmes (hereinafter the "Euratom Research Programme"). Article 7 of the Euratom Treaty foresees the establishing of multi-annual Community research and training programmes in the fields of nuclear energy and uses of radiation. A significant part of this research falls within the scope the Convention. ***Euratom activities in the area of nuclear fission and radiation protection have been thoroughly reviewed, in the context of the post-Fukushima era.***

The current Euratom Research Programme was established by the Council Regulation (Euratom) N°1314/2013 of 16 December 2013 for five years: 2014-2018. The Euratom Research Programme follows a general objective to pursue nuclear research and training activities with an emphasis on a continuous improvement of nuclear safety, security and radiation protection, and to contribute to the long-term decarbonisation of the energy system in a safe, efficient and secure way by supporting research in nuclear fission and fusion. The Euratom Research Programme is implemented through direct actions – research performed by the Joint Research Centre, one of the Services of the Commission, and through indirect actions – via competitive calls for proposals managed by the Commission's Directorate-General for Research and Innovation. Euratom fission research and training falling under both direct and indirect actions and respectively managed by the Joint Research Centre and the Commission's Directorate General for Research and

Innovation is contributing to the development of safer technologies and publicly acceptable solutions for the management of radioactive waste and furthering the understanding of the effects of low doses of ionising radiation on humans and the environment. Euratom fusion research falling under indirect actions and managed by the Commission's Directorate General for Research & Innovation is aimed at developing magnetic confinement fusion as a new energy source.

3.9.1. Specific Programme for nuclear research and training activities implemented through indirect actions

Activities to implement the safety-related objectives of the Euratom Research Programme indirect actions in nuclear fission are specified in Annex I of the Council Regulation (Euratom) N°1314/2013 and include several specific objectives such as:

(a) Supporting safety of nuclear systems through joint research activities regarding the safe operation and decommissioning of reactor systems in use in the Union or, to the extent necessary in order to maintain broad nuclear safety expertise in the Union, those reactor types which may be used in the future, focusing exclusively on safety aspects, including all aspects of the fuel cycle such as partitioning and transmutation.

(b) Contributing to the development of safe, longer term solutions for the management of ultimate nuclear waste, including final geological disposal as well as partitioning and transmutation through joint and/or coordinated research activities on remaining key aspects of geological disposal of spent fuel and long-lived radioactive waste with, as appropriate, demonstration of technologies and safety. Support is to be provided also to research activities related to the management of other radioactive waste streams for which industrially mature processes currently do not exist.

(c) Supporting the development and sustainability of nuclear expertise and excellence in the Union, through the promotion of joint training and mobility activities.

(d) Supporting radiation protection and development of medical applications of radiation.

(f) Ensuring availability and use of research infrastructures of pan-European relevance.

For the implementation of the Euratom research programme, the European Commission adopted two bi-annual work programmes for 2014-15 and for 2016-17.

With regard to safe operation of nuclear systems, the 2014-15 Work Programme supported three call topics (approximately EUR 28 million available for research grants) focused on supporting the continuous improvement of nuclear safety of the existing reactor fleet and to optimising the safety characteristics in the design of future reactors, e.g. by an

implementation of passive safety features and by increasing the redundancy and diversity or by performing experimental tests and developing advanced simulation tools.

Regarding solutions for the management of radioactive waste (approximately EU 16.5 million available), the call topics addressed different issues such as supporting the implementation of the first-of-the-kind geological repositories and their licencing.

In the field of radiation protection (EUR 19 million available), the 2014-15 Work Programme supported the setting up of the European Joint Programme in low dose research.

The 2016-2017 Work Programme provides support up to a total amount of more than EUR 100 million, in 14 different call topics grouped under six themes that address important challenges in nuclear research.

Regarding the safe operation of nuclear systems (approximately EUR 52 million available for research grants), three call topics focus on safety of existing (Generation II and III) and future (Generation IV and smaller modular reactor designs) nuclear power plants. This research is to be complemented by two further topics investigating safety of closed nuclear fuel cycles and pursuing materials research for Generation IV designs. Regarding solutions for the management of radioactive waste (approximately EUR 19 million available), the call topics address three different issues. The first concerns deep geological disposal of radioactive waste and in particular validation of the properties of engineered barrier materials and the confirmation of performance of engineered barrier systems. The second supports research for the overall management of radioactive waste other than geological disposal and encompasses the characterisation and treatment of different sorts of radioactive waste such as legacy waste, and waste arising from refurbishment or decommissioning. Particular attention is paid to the long-term safety of waste storage, the minimisation of the volume and of the toxicity of waste, as well as to the facilitation of waste handling and management. The third topic supports knowledge sharing and development of skills on radioactive waste management.

In the field of radiation protection (EUR 9 million available), the 2016-2017 Work Programme supports research on impacts of low-dose exposure by funding epidemiology studies of people undergoing radiology procedures. This should allow the formulation of practical recommendations and improving protection of patients and staff in everyday medical practice.

Two further topics of the 2016-17 Work Programme (approximately EUR 7.7 million available) address important strategic priorities for Europe, namely security of supply for nuclear fuel for research reactors and coordination of their exploitation. The development of adequate nuclear fuel, particularly important in view of the conversion from HEU to LEU, is also expected to contribute to the sustainable supply of medical radioisotopes. The coordination of the exploitation of research reactors aims at optimising the use of irradiation time in research reactors in order to avoid disruptions and delays in experiments and technical applications.

The fifth thematic area addressed in the 2016-17 Work Programme (approximately EUR 6 million available) focuses on human resources and potential through inviting proposals for training schemes and grant programmes in order to maintain an adequate number of educated and trained nuclear researchers and professionals. The sixth theme concerns cross-cutting research of importance both in nuclear fission and fusion, and addresses the areas of multi-scale modelling of materials and tritium management (approximately EUR 8 million available).

Indirect actions supported by the Euratom Research Programme are implemented by different research stakeholders (universities, industry, national laboratories) grouped in the technology platforms and independent expert bodies.

The Sustainable Nuclear Energy Technology Platform (SNETP), launched in September 2007, brings together all the key nuclear industrial and research organisations in Europe (over 100 organisations from 21 countries (20 EU Members States and Switzerland)) around a common vision for nuclear systems and safety-related research and development. The platform's Strategic Research and Innovation Agenda (SRIA), *providing technology roadmaps and deployment strategies supporting the identification of opportunities for international cooperation, has been updated and is available online*⁴⁹.

Particularly for Generation II & III nuclear systems, members of SNETP have created, in November 2011, an international non-profit making organisation: the NUClear GENeration II & III Association (NUGENIA)⁵⁰, with utilities and vendors financial participation. The SARNET (“Severe Accident Research network of excellence”), coordinated by IRSN, France, in FP6 and FP7) which is drawing the lessons from Fukushima, has been integrated in NUGENIA under Technical Area 2.

The Implementing Geological Disposal Technology Platform (IGD-TP) was launched in November 2009. It provides the necessary focus in the lead up to the operation of geological repositories for high-level nuclear waste in Europe. *It is overseeing the Coordination and Support Action “Towards a Joint Programming on Radioactive Waste Disposal” (the JOPRAD project), supported by the current Euratom Research Programme to assess the feasibility and, if appropriate, to prepare a proposal for a Joint Programme in the field of Radioactive Waste Management, including geological disposal.*

*Preparations of the Euratom research strategy for radiation protection is in the hands of the Multidisciplinary European Low Dose Initiative. MELODI is a non-profit making association focussing on research related to the impact of low dose radiation. MELODI cooperates with partner associations in radio-ecology, dosimetry, emergency management*⁵¹, *as well as with five medical associations*⁵². *Effective cooperation between these various scientific*

⁴⁹ <http://www.snetp.eu>.

⁵⁰ NUClear GENeration II & III Association (NUGENIA) under 1921 Belgian law - <http://www.nugenia.org/>

⁵¹ ALLIANCE – European Radioecology Alliance, EURADOS – European Radiation Dosimetry Group, NERIS – European Platform on preparedness for nuclear and radiological emergency response and recovery.

⁵² EANM – European Associations of Nuclear Medicine, EFOMP – European Federation of Organisations in Medical Physics, EFRS – European Federation of Radiographer Societies.

communities and the coherent integration of their activities are a key objective of the recently established European Joint Programme (EJP)⁵³ in this field.

The above stakeholders groups are also instrumental in the design and implementation of nuclear education and training actions.

Euratom provides its contribution to the international cooperation on nuclear safety also under the legal framework of different bilateral cooperation agreements as follows: the Research & Development-PUNE Cooperation Agreement with China, the Technical Arrangement on nuclear safety research with the USA, and the Cooperation Agreements on nuclear safety with Russia, Ukraine, and Kazakhstan. Furthermore, several third countries (Canada, Japan, Mexico, Norway, Russia, Ukraine and the USA) are participating in Euratom nuclear safety projects launched following the Euratom 2014-2015 call for proposals: CEBAMA, CONCERT, ESSANUF, FASTNET, SAMOFAR and SESAME. Moreover, the Euratom-China parallel project ALISA, allowing access to large infrastructures for severe accidents of both parties, is successfully on-going.

Details of all projects are available at: <http://cordis.europa.eu>.

3.9.2. Specific Programme for research and training activities implemented by direct actions and carried out by the Commission's Joint Research Centre (JRC)

The main activities of the JRC under *the Euratom Research and Training Programme* is to support both the Commission and Member States in fulfilling their Euratom Treaty's obligations, *as well as contribute to the nuclear safety research needed for safe, secure and peaceful use of nuclear energy and other non-fission applications, and provide a scientific basis for the relevant Union policies.*

The main objectives of the Programme include improving nuclear reactor and fuel safety, radioactive waste management, including final geological disposal, partitioning and transmutation; development and assessment of innovative technologies and techniques applied to nuclear decommissioning; emergency preparedness; improving nuclear security, nuclear safeguards, non-proliferation, combating illicit trafficking, and nuclear forensics; increasing excellence in the nuclear science base for standardisation; fostering knowledge management, education and training; and supporting the policy of the Union.

The main JRC activities related to nuclear reactor and fuel safety are addressed below:

- Further developing the “EU Nuclear Safety Clearinghouse for Operational Experience Feedback”, (organised via a network of EU regulators and Technical Support Organisations (TSOs), and operated by a centralised office located at the JRC). In this frame, the JRC regularly delivers topical reports on subjects important to the safe operation of European NPPs, and publishes quarterly reports on worldwide NPP operational events⁵⁴.

⁵³ CONCERT: <http://www.concert-h2020.eu>

⁵⁴ <https://clearinghouse-oef.jrc.ec.europa.eu/>.

- Providing regular technical support for the implementation of EU instruments promoting the improvement of nuclear safety outside the EU. This includes technical input for the development and implementation of projects of the Instrument for Nuclear Safety Cooperation (INSC) and Instrument for Pre-Accession Assistance (IPA).
- *Providing technical support for the implementation of EU policy in the area of nuclear safety in particular the implementation of Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations and of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.*
- In the framework of the lessons-learned from Fukushima, specific efforts have been dedicated, since 2011, to better assess plant behaviour beyond the design base accidental conditions. It has been developing research in nuclear severe accident *management and prevention modelling (including the source term) and participating in related OECD/NEA and IAEA Task Groups. Activities include modelling as well as dedicated experiments to characterise degraded/molten fuel in view of developing accident mitigation strategies and techniques for the remediation of a severe accident site. In this context, JRC's experts contributed to the IAEA's DG Report on the Fukushima accident, released in the summer of 2015.*
- *Production and qualification of reference samples and scientific data for safety assessment of both conventional and innovative nuclear fuels under operational, transient and accident conditions. These data provide input to the continuous upgrades of computer codes such as the TRANSURANUS code developed by the JRC.*
- *Contributing to international databases of high accuracy nuclear reference data for nuclear energy and non-fission applications, in cooperation with IAEA and OECD-NEA.*
- Reducing uncertainties associated with geologic repository of nuclear waste, and at implementing safe decommissioning, this taking into account that long-term storage (up to a few hundred years) of spent fuel as well as retrievability and recoverability requirements are becoming an option considered in several EU Member States.
- Pre-normative R&D and the participation in Materials Codes and Standards. *The JRC carries out studies on structural materials performance and component integrity of nuclear materials, materials qualification, inspection and design in view of the safe long term operation of nuclear power plants.*
- The JRC is the Euratom implementing agent for the Generation IV International Forum (GIF) research and contributes to the development of evaluation methods to assess and compare safety and performance of next generation reactors, fuels, and fuel cycles concepts.
- Maintaining and further improving the operability of the Commission's tools for exchange of information in case of nuclear emergency (ECURIE), and routine environmental monitoring and exchange of data (EURDEP). Improvements include the development of

the new WebECURIE software (with full compatibility with IAEA systems) as well as the preparation of the EURDEP technology to be used on a global level by the IAEA.

- Regarding the routine environmental monitoring, the JRC maintained and upgraded the EURDEP databases and provided regular training courses to Member States. Annual inter-comparison harmonisation exercises with the national EU laboratories were also undertaken.
- *Support to the implementation of the Basic Safety Standards Directive (Council Directive 2013/59/Euratom of 5 December 2013), and, in particular to the preparation of the European Atlas of Natural Radiation, the collection and harmonisation of indoor radon data to extend and update the European Indoor Radon Map. The aim is to facilitate harmonisation of the various techniques for monitoring indoor radon, agreeing on common procedures to estimate radon prone areas, as well as to inform the general public of the risks related to radon and natural radiation in general.*
- EU-wide monitoring on training and education needs on human resources in the nuclear sector through the European Human Resource Observatory - Nuclear (EHRO-N).,EHRO-N analyses the supply and demand for nuclear experts in the EU, identifies gaps and deficiencies in the European nuclear education and training infrastructure and elaborates recommendations for remedial actions and optimisation for a more efficient management of the existing resources.
- *Strengthening nuclear knowledge management and dissemination, through a broader, open access programme to the JRC research infrastructures, education and training courses for students and professionals, and the organisation and coordination of competence building and related activities.*

3.10. Continuation of existing programmes and initiatives

3.10.1. European Union financial assistance to decommissioning

Upon their accession to the EU, Bulgaria, Lithuania and Slovakia committed to close down eight Soviet-designed nuclear power plants before the end of their scheduled lifetime. In exchange, the EU committed to provide financial assistance to the three Member States for decommissioning the designated power plants, namely:

- *Kozloduy Nuclear Power Plant (NPP) units 1 to 4 in Bulgaria;*
- *Ignalina NPP in Lithuania; and*
- *Bohunice VI NPP in Slovakia.*

Since 2014, the scope of the nuclear decommissioning assistance programmes^{55, 56} is to assist the relevant Member States in implementing the steady process towards the decommissioning end-state whilst ensuring that the highest safety standards are applied.

⁵⁵ Council Regulation (Euratom) No 1368/2013 of 13 December 2013 on Union support for the nuclear decommissioning assistance programmes in Bulgaria and Slovakia, and repealing Regulations (Euratom) No 549/2007 and (Euratom) No 647/2010 (OJ L346, 20.12.2013, p.1) & correction (OJ L8, 11.1.2014, p.31).

In all three cases, the end-state is defined as brownfield: the nuclear reactor buildings will be dismantled as well as those auxiliary buildings that are not intended for re-use; near-surface repositories will be built or upgraded to dispose of low and intermediate level radioactive waste from decommissioning; and interim storage facilities will be commissioned for spent fuel and radioactive waste that cannot be disposed of in near-surface repositories. Beyond decommissioning the disposal of spent fuel and radioactive waste in a deep geological repository is developed by each Member State in its national programme for the management of spent fuel and radioactive waste as required by the relevant directive⁵⁷.

The current assistance programme provides no new financial support for mitigation measures in the energy sector⁵⁸; the implementation of existing projects will, however, continue for several years.

Article 2 of each of the two regulations defines the main specific objectives of the decommissioning programmes for the 2014-2020 funding period. These objectives were further detailed in implementation procedures⁵⁹ adopted by the Commission in August 2014 and new baselines were established for each decommissioning programme up to the respective end-state.

3.10.2. Euratom loans

Euratom gives loans to finance investment in nuclear installations for the industrial production of electricity or the nuclear fuel cycle in Member States. It also gives loans to finance projects for improving nuclear safety in certain non-Member States.

This lending instrument was established by Council Decision 77/270/Euratom of 29 March 1977⁶⁰ empowering the Commission to issue Euratom loans for the purpose of contributing to the financing of nuclear power stations (the "Establishing Decision") in Member States. The ceiling for borrowing to fund Euratom lending was originally fixed by Council Decision 77/271/Euratom of 29 March 1977⁶¹. Subsequently, by various amendments of that Decision, the latest of which⁶² increased it by 1 000 million Euro to 4 000 million Euro, the scope of the Euratom lending instrument was extended.

⁵⁶ Council Regulation (EU) No 1369/2013 of 13 December 2013 on Union support for the nuclear decommissioning assistance programme in Lithuania, and repealing Regulation (EC) No 1990/2006 (OJ L346, 20.12.2013, p.7) & correction (OJ L8, 11.1.2014, p.30 & OJ L121, 24.4.2014, p.59).

⁵⁷ Council Directive 2011/70/Euratom of 19 July 2011 on establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, OJ L199, 2.8.2011, p. 48-56.

⁵⁸ In previous financial frameworks, EU financial assistance was established to support Member States to safely decommission reactors subject to early closure and to implement mitigation measures in the energy sector, such as replacement capacity, environmental upgrading, modernisation and energy efficiency.

⁵⁹ Commission Implementing Decision of 7.8.2014 on the rules of application for the nuclear decommissioning assistance programmes for Bulgaria, Lithuania and Slovakia for the period 2014-2020 — C(2014) 5449 final.

⁶⁰ Council Decision 77/270/Euratom of 29 March 1977 empowering the Commission to issue Euratom loans for the purpose of contributing to the financing of nuclear power stations, OJ L 88, 6.4.1977, p. 9–10.

⁶¹ Council Decision 77/271/Euratom of 29 March 1977 on the implementation of Decision 77/270/Euratom empowering the Commission to issue Euratom loans for the purpose of contributing to the financing of nuclear power stations, OJ L 88, 6.4.1977, p. 11.

⁶² Council Decision 90/212/Euratom of 23 April 1990, OJ No L 112, 03.05.1990, p 26.

In a Decision dated 21 March 1994⁶³ the Council authorised the Commission to contract Euratom borrowings in order to contribute to the financing required for improving the degree of safety and efficiency of nuclear power stations in certain non-Member countries (the "Scope Extension Decision"). The proceeds of these borrowings would be assigned, in the form of loans, to the funding of projects to increase the safety and efficiency of the nuclear facilities in certain CEEC and NIS. In the last years, Euratom loans have been granted to three projects: the safety upgrade of the Kozloduy Power Plant Units 5 and 6 in Bulgaria, the completion of Cernavoda Power Plant Unit 2 in Romania, and the safety upgrade of Khmel'nitsky Power Plant Unit 2 and Rovno Power Plant Unit 4 in Ukraine.⁶⁴ ***In 2013, a Euratom loan has been granted to the project "Complex (Consolidated) Safety Upgrade Program of Nuclear Power Units" in Ukraine.***

3.10.3. European Nuclear Energy Forum - ENEF

In the framework of the European Council Summit of 8 and 9 March 2007, the Heads of State and Government had an exchange of views on the contribution of nuclear energy in meeting the growing concerns about security of energy supply, reduction of CO₂ emissions and competitiveness, while taking fully into account nuclear safety and security aspects. In the Presidency conclusions⁶⁵, they also endorsed the Commission proposal to organise a broad discussion among all relevant stakeholders on the opportunities and risks of nuclear energy.

Since 2007 the European Nuclear Energy Forum (ENEF) has aimed to provide a unique platform for organising a broad discussion on opportunities and risks of nuclear energy, free of any "taboos", among all relevant stakeholders in the nuclear field: governments of the 28 EU Member States, European Institutions including the European Parliament and the European Economic and Social Committee, nuclear industry, electricity consumers and the civil society. ***The next plenary meeting will take place on 3-4 October 2016, in Bratislava, and will cover the topics of investment considerations of nuclear energy, as well as emergency preparedness and response.***

4. OTHER SAFETY RELATED ACTIVITIES

4.1. Radioactive Waste and Spent Fuel Management

On 19 July 2011 the Council adopted the "Radioactive waste and spent fuel management Directive"⁶⁶, proposed by the Commission on 3 November 2010. The Directive, which came into force on 22 August 2011, obliges member states to establish a national legislative, regulatory and organisational framework covering all aspects of the management of spent fuel and radioactive waste from generation to final disposal. Member states were required to

⁶³ Council Decision of 21 March 1994 amending Decision 77/270/Euratom to authorize the Commission to contract Euratom borrowings in order to contribute to the financing required for improving the degree of safety and efficiency of nuclear power stations in certain non-member countries, OJ L-84, 29.03.1994 p 4.

⁶⁴ http://ec.europa.eu/economy_finance/financial_operation_instruments/financing_investment75_en.htm.

⁶⁵ Council of the European Union Document No. 7224/1/07 REV 1 of 2 May 2007 (not published in the Official Journal), http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/ec/93135.pdf

⁶⁶ Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, OJ L199 of 2.8.2011, p. 48-55.

transpose the directive into their national legislation and inform the Commission of the relevant provisions before 23 August 2013. *To date all Member States have notified the Commission of their full transposition of the Directive and the Commission is in dialogue with the Member States to finalize its conformity assessment in 2016.*

Each Member State must prepare a national programme, which states amongst others; their national policy together with their plans and measures for the implementation of the policy to ensure the responsible and safe management of spent fuel and radioactive waste, including plans for disposal of these materials.

National programmes had to be notified to the Commission not later than 23 August 2015. The Commission is currently requesting clarification from the Member States on the final programmes, prior to issuing opinions on whether the content of the national programme is in line with the Directive.

Member States had to report on the implementation of the directive by 23 August 2015 and every three years thereafter. All Member States have submitted their national reports. At the end of 2016 the Commission is planning to submit a report to the Council and the European Parliament on the status of implementation of the Directive in the Member States and on the inventory of spent fuel and radioactive waste on the EU territory, in line with Art 14 of the Directive.

Moreover, as a Contracting Party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Euratom Community will present a report on the implementation of this Convention in view of the next review meeting of 2018.

4.2. Shipments of radioactive waste and spent fuel

A first report on the implementation of the Council Directive 2006/117/Euratom⁶⁷ was adopted by the Commission in April 2013⁶⁸.

The second notification of the shipments carried out by Member States in the period 2012-2014 had to be submitted by 25 December 2014, according to Art 20 of Council Directive 2006/117/Euratom.

To date all Member States have notified their reports to the Commission. The Commission is assessing the reports, and plans, in accordance with Article 21 of this Directive, to present a summary report for the European Parliament, the Council and the European Economic and Social Committee, at the end of 2016.

⁶⁷ Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel between Member States and into and out of the Community; OJ L337 of 5.12.2006 p 21-32.

⁶⁸ Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation by the Member States of Council Directive 2006/117 EURATOM on the supervision and control of shipments of radioactive waste and spent fuels, COM (2013) 240 final, 25.4.2013.

SECTION III

IMPLEMENTATION OF THE CONVENTION

ARTICLE BY ARTICLE REVIEW

1. ARTICLE 6: EXISTING NUCLEAR INSTALLATIONS

Each Contracting Party shall take the appropriate steps to ensure that the safety of nuclear installations existing at the time the Convention enters into force for that Contracting Party is reviewed as soon as possible. When necessary in the context of this Convention, the Contracting Party shall ensure that all reasonably practicable improvements are made as a matter of urgency to upgrade the safety of the nuclear installation. If such upgrading cannot be achieved, plans should be implemented to shut down the nuclear installation as soon as practically possible. The timing of the shut-down may take into account the whole energy context and possible alternatives as well as the social, environmental and economic impact.⁶⁹

Euratom does not possess, nor operate any nuclear installations as defined in Article 2(1) of the Convention. Such nuclear installations exist only in the territories of the Member States of the European Atomic Energy Community, to which the Euratom Treaty applies.

Council Directive 2009/71/Euratom, as amended by Council Directive 2014/87/Euratom, establishing a Community framework for the nuclear safety of nuclear installations (collectively referred to hereinafter as the "amended Nuclear Safety Directive") applies to a wider range of nuclear installations than the Convention. This Directive applies to any civilian nuclear installation subject to a licence as defined in Article 3(4)⁷⁰, and at all stages covered by this licence (including the decommissioning stage). This means that the Nuclear Safety Directive applies to nuclear power plants, enrichment plants, nuclear fuel fabrication plants, reprocessing plants, research reactor facilities, spent fuel storage facilities and also to storage facilities for radioactive waste that are on the same site and are directly related to the abovementioned nuclear installations.

2. ARTICLE 7: LEGISLATIVE AND REGULATORY FRAMEWORK

(1) Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations.

(2) The legislative and regulatory framework shall provide for:

⁶⁹ Not applicable according to the revised Declaration of Competences (Annex 1; see Chapter 4 Statement of the Commitment of the Contracting Party to the Convention, p. 17 and Annex 1), which takes into account the Judgement of the Court of Justice of the European Union in case 29/99.

⁷⁰ All references here to articles under Council Directive 2009/71/Euratom as amended by Council Directive 2014/87/Euratom refer to the consolidated version of the text available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1408542850618&uri=CELEX%3A02009L0071-20140814>.

- i. The establishment of applicable national safety requirements and regulations;**
- ii. A system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a licence;**
- iii. A system of regulatory inspection assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licences;**
- iv. The enforcement of applicable regulations and the terms of licences.**

This section summarizes the existing legislative system affecting the safety of nuclear installations in the Member States and includes statements with regard to the adequacy and effectiveness of that system.

2.1. Article 7(1) - The legislative and regulatory framework governing the safety of nuclear installations

This section introduces the legal system of the European Atomic Energy Community (hereinafter referred to as 'Euratom') and its relationship to the national laws of the Member States of the European Union. It gives an overview on the legislative procedure on the basis of the Euratom Treaty.

2.1.1. The Euratom Treaty

The Treaty establishing the European Atomic Energy Community (hereinafter: Euratom Treaty) provides the legal framework for the competences and activities of the European Atomic Energy Community. The signatories of the Euratom Treaty stated in the Preamble to the Treaty that they were in particular:

- Anxious to create the conditions of safety necessary to eliminate hazards to the life and health of the public;
- Desiring to associate other countries with their work and to cooperate with international organisations concerned with the peaceful development of atomic energy.

These statements are in complete accordance with the objectives of the Convention, as set out in Article 1 thereof.

There are three types of Euratom law: The primary law is the Euratom Treaty. The secondary law are regulations, directives, decisions, recommendations and opinions on the basis of the Treaty adopted by the EU Institutions (the Commission or the Council, which are also Euratom Community Institutions). The final source of law is the case law including interpretation of treaties and institutional acts carried out by the Court of Justice of the European Union. The whole body of EU and Euratom law is jointly referred to as the "*acquis*".

Under the institutional provisions of the Euratom Treaty, Euratom possesses its own mechanisms to control the compliance of the national laws of all Member States with the

relevant Community legal acts. This includes the possibility to accordingly obtain a decision by the Court of Justice of the European Union, based in Luxembourg.

The relationship between the legal acts adopted by Euratom and national legislation of the Member States of the European Union (hereinafter referred to as 'Union') is as follows according to Article 288 of the Treaty on the Functioning of the European Union (TFEU):

“To exercise the Unions competences, C the institutions shall adopt regulations, directives, decisions, recommendations or opinions.

A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.

A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only upon them.

Recommendations and opinions shall have no binding force.”

Member States must take all appropriate measures, whether general or particular, to ensure the fulfilment of the obligations arising out of the Euratom Treaty or resulting from action taken by the institutions of the Community. They have to facilitate the achievement of the Community's tasks and abstain from any measure which could jeopardize the attainment of the objectives of the Euratom Treaty (Art. 192 Euratom).

With effect of 1 January 2010, Article 13 of the Treaty on the European Union establishes the common institutional framework for both the European Union and Euratom. In accordance with Article 106a paragraph 1 of the Euratom Treaty, Articles 223 to 287 of the Treaty on the Functioning of the European Union describe the methods, responsibilities and measures of the individual institutions which are available for both Euratom and the European Union with more detail.

With the Lisbon Treaty, the European Council⁷¹ – commonly known as "EU Summit" – officially gains the status of an EU institution, thus being separated from the Council of Ministers or Council of the European Union. The European Council's task is to define the general political direction and priorities of the European Union. It is composed of the heads of state or government of the Union's Member States along with the (nonvoting) President of the Commission. The new position of a long-term (2½ years term) President of the European Council has been introduced with the Lisbon Treaty to represent the European Union to third countries. The High Representative of the Union for Foreign Affairs and Security Policy has been established to a united position on EU policies. The conclusions of the European Council are referred to as "European Council Presidency Conclusions".

⁷¹ Articles 15 and 18 TEU and 235 to 236 TFEU.

The Council⁷² exercises the legislative and - together with the European Parliament - the budgetary functions, as well as policy-making and coordinating functions. It consists of the respective ministers of national governments of each Member State. The Council shares with the European Parliament only the responsibility for passing general EU laws and taking general EU policy decisions. Under the Euratom Treaty the Council only consults the European Parliament and then decides alone on the legislation proposed by the Commission, The Lisbon treaty has established the use of qualified majority voting in the Council as the ordinary voting procedure in almost every policy area⁷³. Such legislative procedural meetings that include debate and voting in the Council of Ministers must now be held in public (televised). The Council meets in different configurations and is assisted by the General Secretariat. Each Member State presides over the Council for a six-month period. In addition a "Triple Presidency" is formed by three consecutive Presidencies in order to provide more continuity to their conduct.

The Members of the European Parliament⁷⁴ represent the citizens of the EU Member States. They are elected by direct universal suffrage for five years. The plenary sessions of the Parliament are held in Strasbourg, others in Brussels. Together with the Council of the European Union it exercises legislative and budgetary functions and functions of political control and consultation. In the framework of the Euratom Treaty, however, the Parliament has only a consultative role, although the Parliament and the Council share responsibility for approving the EU annual budget.

The Commission⁷⁵ is responsible for promoting the general interest of the Union and take appropriate initiatives to this end. It ensures the application of the Treaties and of measures adopted by the institutions. As the "Guardian of the Treaties" it oversees the control of Union and Euratom law under the control of the Court of Justice of the European Union, by initiating proceedings against Member States which did not implement Euratom law. It executes the budget and manages and has coordinating, executive and management functions. In its role as the manager and executor of common policies and of international trade relationships the Commission manages the EU budget, implements the agreed policies and programmes of the Communities, ensures the external representation of the EU and Euratom (with the exception of the common foreign and security policy) and negotiates external agreements with other countries on behalf of the EU. According to the Euratom Treaty, the Commission concludes

⁷² Articles 16 TEU and 237 to 243 TFEU.

⁷³ *Taking effect in 2014, the definition of a qualified majority will change: A qualified majority is reached when at least 55% of all Member States, who comprise at least 65% of EU citizens, vote in favour of a proposal. When the Council of Ministers is acting on a proposal neither of the Commission nor of one of the High Representative QMV requires 72% of the Member States while the population requirement remains the same. To block legislation, at least 4 countries (representing at least 35% of the EU population) have to vote against the proposal. Hence, the voting powers of the Member States are based on their population, and are no more dependent on a negotiable system of voting points. The current rules for QMV, as set in the Treaty of Nice, require a majority of countries (50% / 67%), voting weights (74%), and population (62%). This rule remains in place until 2014. Between 2014 and 2017 a transitional phase will take place where the new QMV rules apply, but where the old Nice treaty voting weights can be applied when a member state wishes so. Moreover, from 2014 a new version of the 1994 "Ioannina Compromise" will take effect, which allows small minorities of EU states to call for re-examination of EU decisions.*

⁷⁴ Articles 14 TEU and 223 to 234 TFEU.

⁷⁵ Articles 17 TEU and 244 to 250 TFEU.

also international agreements (Art. 101 of the Euratom Treaty). The Commission is independent of national governments and represents and upholds the interests of the Communities as a whole. In carrying out its duties the Commission is responsible to the European Parliament. While the Council and the Parliament may request legislation, the Commission is the only body that can formally propose new legislation. Having heard the opinion of consultative bodies provided for by the Euratom Treaty, the Commission presents the new proposals to the Council. The 28 Commissioners together form the Commission, or so called 'College', the Commission decision making body.

The Court of Justice of the European Union⁷⁶, including the Court of Justice *and* the General Court of the EU, ensures that the law is observed in the interpretation and application of the Treaty on the European Union, the Treaty on the Functioning of the European Union, the Euratom Treaty, binding international agreements entered into by the Union and/or Euratom and of the provisions laid down by the competent EU institutions. The Court of Justice has competence, inter alia, as regards actions against Member States for failure to fulfil obligations, references for a preliminary ruling and appeals against decisions of the General Court. It adjudicates most commonly on matters of interpretation of European Union law, raised by:

- Claims by the Commission that a Member State has not implemented a EURATOM Directive or other binding legal requirement, in the framework of an infringement procedure.
- Preliminary references made by national courts in the EU Member States asking the Court of Justice questions about the meaning or validity of a particular piece of EU law. The Court of Justice gives its ruling on the interpretation of the law, which is binding on the national court.

The General Court rules in principle on applications for annulment or actions for failure to act brought by a Member State, an institution or natural or legal persons if the latter are directly and individually concerned. *A natural or legal person may also institute proceedings against a regulatory act which is only of direct concern to them and does not entail implementing measures.*

The legislation procedure for acts of secondary law (regulations, directives, decisions, recommendations and opinions) is laid down in the Euratom Treaty itself. For matters related to radiation protection and safety relevant to this convention, the Commission receives guidance from a group of scientific experts established under Article 31 of the Euratom Treaty⁷⁷, which then gives rise to a Commission proposal for a Council Directive, Regulation, Decision or Recommendation. The proposal is submitted first to the Economic and Social Committee. Upon incorporation of all or a part of the observations of this Committee, the proposal is transmitted to the Council of the European Union, which has to consult the European Parliament before adoption. The European Parliament then may propose amendments to the Commission

⁷⁶ Articles 19 TEU 251 to 281 TFEU.

⁷⁷ Group of Scientific Experts Referred to in Article 31 of the Euratom Treaty, Rules of Procedure, approved by the Group of experts at the meeting on 13-14 November 2007:

https://ec.europa.eu/energy/sites/ener/files/documents/2007_11_procedure_rules.pdf.

proposal, which the Council may examine and take into consideration. In the end, under the terms of the Euratom Treaty, the act is adopted by a qualified majority by the Council.

Member States are obliged to transpose or implement the existing binding Euratom legal acts within a certain period of time, as detailed in the Act itself. A directive needs to be transposed into national legislation; regulations and decisions are directly applicable in the Member States.

The Euratom Treaty provides for a number of mechanisms to ensure that the relevant legislation is complied with by all Member States.

Under Article 33 of the Euratom Treaty, “*each Member State shall lay down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with the basic standards*” (paragraph 1), which cover, according to the case-law, comprehensive and systematic safety assessments in the sense of Article 14(I) of the Convention. To this extent, “*the Commission shall make appropriate recommendations for harmonizing the provisions applicable in this field in the Member States*”. Member States must notify to the Commission all national legislation in the areas covered by the Euratom Treaty, both

- before adoption, so that the Commission can formulate, as the case might be, appropriate recommendations in order to harmonise the implementing national provisions throughout the European Union according to Article 33 of the Euratom Treaty and
- After adoption, so that the conformity of the final measures can be controlled.

Whenever the Commission in its role as "Guardian of the Treaties" considers that a Member State is infringing the Euratom provisions, for example if a Member State did not transpose a directive into national law within the given deadline, the Commission requests information from the authorities of the Member State concerned and, if explanations are not satisfactory, it can initiate proceedings against Member States. A proceeding can imply lodging an application before the Court of Justice of the European Communities. If the Member State does not take the necessary measures to comply with the ruling of the Court of Justice, the Court can decide to impose a lump sum or penalty on the Member State. In case of urgency, the Commission is entitled to directly hold the Court of Justice (Article 38 of the Euratom Treaty)⁷⁸; though this situation has never occurred.

The Commission controls the implementation in practice through verifications of the environmental monitoring facilities on the basis of Article 35 of the Euratom Treaty⁷⁹ and through the examination of plans for the disposal of radioactive waste submitted to the Commission for opinion on the basis of Article 37 of the Euratom Treaty⁸⁰.

In addition, the Commission contributes in achieving a high level of harmonization in Europe by (non-binding) actions including

⁷⁸ See Article 38 of the Euratom Treaty.

⁷⁹ See below chapter 10.2.5, Verification of environmental radiological surveillance facilities, p. 69.

⁸⁰ See chapter 12.1, Description of the licensing process, including summary of laws, regulations and requirements relating to the siting of nuclear installations, p. 82.

- Non-binding Commission Recommendations in the areas of the Euratom Treaty⁸¹.
- Other non-binding guidance documents, such as
 - "Radiation Protection Series" Publications of the Commission;
 - Recommendations of Advisory Groups of the Commission⁸²

2.1.2. *Uniform Safety Standards to protect the health of workers and the general public*

Article 2 of the Euratom Treaty states that in order to perform its task, the Community shall, as provided for in the Treaty, in particular, establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied.

Title Two, Chapter 3, Health and Safety, sets out a number of detailed provisions intended to establish, give effect and apply the basic standards mentioned in Article 2(b) of the Euratom Treaty. A substantial corpus of Euratom legal acts⁸³ has been adopted and updated in the course of the years and is completed by a set of legal instruments of different binding nature, covering a wide range of aspects such as:

- operational protection of workers (including outside workers) and population,
- natural radioactive sources,
- high activity sealed sources and orphan sources,
- emergency preparedness,
- nuclear safety,
- medical applications,
- control and supervision of shipments of spent fuel and radioactive waste,
- as well as a number of regulations establishing provisions on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power plant, aimed at safeguarding the health of consumers of such products.

2.1.3. *EU framework for the nuclear safety of nuclear installations*

Nuclear safety remains an absolute policy priority for the EU.

⁸¹ See Annex 3.

⁸² See chapter 3.8 Experts Groups of the Commission , p. 30

⁸³ See Annex 3.

The Council Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations⁸⁴ (the "Nuclear Safety Directive") was unanimously adopted by the Council on 25 June 2009, subsequent to a very large support expressed by the European Parliament and the European Economic and Social Committee.

The Nuclear Safety Directive created a solid and flexible legal framework that defines basic obligations and principles governing nuclear safety throughout the EU. It is based on Chapter 3 of the Euratom Treaty, (articles 31 and 32) in order to achieve the objective established in Article 2b, which provides for the establishment of uniform safety standards to protect the health of workers and of the general public⁸⁵. ***That Directive has been amended⁸⁶ following a mandate in March 2011 from the European Council "to review the existing legal and regulatory framework for the safety of nuclear installations" and propose any improvements that may be necessary in the spirit of continuously improving standards to enhance nuclear safety in the Union.***

The Nuclear Safety 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 Basic Safety Standards Directive. It does not prevent Member States from taking more stringent safety measures in the subject-matter covered by this Directive, as long as they are compatible with Euratom law. It is built upon the nuclear safety requirements of the Convention on Nuclear Safety and of the Safety Fundamentals established by the IAEA.

The Nuclear Safety Directive recognizes the principle of national responsibility, the principle of continuous improvement of nuclear safety, and the principle of prime responsibility of the licence holder for the nuclear safety of a nuclear installation under the supervision of its national competent regulatory authority. Licence holders are required to undertake systematic and verifiable safety assessments, including the verification of "defence-in-depth" measures. The Directive aims to enhance these principles and to reinforce the role and independence of the competent national regulatory authorities. The goal of the Nuclear Safety Directive is to maintain and promote the continuous improvement of nuclear safety and to ensure that a high level of nuclear safety is provided by EU Member States to protect workers and the general public against dangers arising from ionizing radiations from nuclear installations.

While the Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the Community, the Nuclear Safety Directive requires Member States to establish and maintain a national legislative, regulatory and organisational framework governing the safety of nuclear installations. As stated in the recitals, Member States may decide on their energy mix in accordance with relevant national policies. When developing the appropriate national framework under this Directive, national circumstances will be taken into account.

⁸⁴ Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, OJ L 172, 2.7.2009.

⁸⁵ First Recital of the Nuclear Safety Directive 2009/71/Euratom, OJ L 172, 02/07/2009, p. 18.

⁸⁶ Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations, OJ L 219, 25.7.2014.

The national framework should be 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. In addition, periodic safety assessments of their national framework and competent regulatory authorities shall be organised by the Member States, supplemented with international peer reviews, including the verification of "defence-in-depth" measures. In keeping with the commitment to maintain and improve safety, Member States should take those factors into account when extending their nuclear power programme or deciding to use nuclear power for the first time.

The abovementioned Nuclear Safety Directive was amended in 2014, with modifications to:

- *strengthen the independence of national regulatory authorities;*
- *set up a European system of peer reviews on specific safety issues every six years (the first one to begin in 2017);*
- *increase transparency on nuclear safety matters by informing and involving the public; and*
- *promote an effective nuclear safety culture;*
- *introduce high-level EU-wide safety objectives to prevent accidents and avoid radioactive releases.*

As regards safety objectives for nuclear installations, 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 accidents⁸⁷. It applies to nuclear installations for which a construction licence has been granted for the first time after 14 August 2014. Moreover, the safety objective is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations.

The Directive provides for regular safety reassessments of nuclear installations, to be carried out by the licence holder under the supervision of the competent regulatory authority, to identify further safety improvements, taking into account, inter alia, ageing issues.

⁸⁷ Article 8a (1) of Council Directive 2009/71/Euratom.

The high-level EU-wide safety objectives are in line with the set of principles and implementation mechanisms to improve and enhance the safety of nuclear power plants as enshrined in the Vienna Declaration on Nuclear Safety adopted in 2015.

2.2. Article 7(2) – requirements for the legislative and regulatory framework

2.2.1. Article 7(2) i – establishment of applicable national safety requirements and regulations

Article 4(1) of the amended Nuclear Safety Directive on the legislative, regulatory and organisational framework states that 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) the allocation of responsibilities and coordination between relevant state bodies;

(b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;

(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.

Furthermore, Member States must 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.

2.2.2. Article 7(2) ii - system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a licence

The Member States are responsible for the establishment and maintenance of the national legislative, regulatory and organisational framework, which allocates responsibilities for the provision of a system of licensing and prohibition of operation of nuclear installations without a licence (Article 4(1) c of the amended Nuclear Safety Directive).⁸⁸

Article 4(1) of 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

⁸⁸ See Article 4(1) of the Directive, as cited above under 2.2.1.

ionizing radiation⁸⁹ requires that Member States shall require prior authorisation in particular for the operation and decommissioning of any facility of the nuclear fuel cycle and exploitation and closure of uranium mining. *Article 28(b) of the revised Basic Safety Standards Directive (2013/59/Euratom) provides that: "Member States shall require licensing for.... (b) the operation and decommissioning of any nuclear facility and the exploitation and closure of uranium mines"*.

Article 44 of the Directive 96/29/Euratom

“Operational protection of the population in normal circumstances from practices subject to prior authorisation means all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation involving exposure to ionizing radiation, are liable to create a risk of exposure for the population which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

- (a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;
- (b) acceptance into service of such new installations subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;
- (c) examination and approval of plans for the discharge of radioactive effluents.

These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the extent of the exposure risk involved.”

Respectively, Article 65 of the revised Basic Safety Standards Directive reads as follows:

"Article 65 - Operational protection of members of the public"

1. Member States shall ensure that the operational protection of members of the public in normal circumstances from practices subject to licensing shall include, for relevant facilities, the following:

- (a) examination and approval of the proposed siting of the facility from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions;*
- (b) acceptance into service of the facility subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter of the facility or radioactive contamination liable to extend to the ground beneath the facility;*
- (c) examination and approval of plans for the discharge of radioactive effluents;*

⁸⁹ OJ L 159, 29.6.1996, p. 1.

(d) measures to control the access of members of the public to the facility.

2. The competent authority shall where appropriate establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which shall:

(a) take into account the results of the optimisation of radiation protection;

(b) reflect good practice in the operation of similar facilities.

In addition, these discharge authorisations shall take into account, where appropriate, the results of a generic screening assessment based on internationally recognised scientific guidance, where such an assessment has been required by the Member State, to demonstrate that environmental criteria for long-term human health protection are met.

3. For practices subject to registration, Member States shall ensure the protection of members of the public in normal circumstances through appropriate national regulations and guidance."

2.2.3. *Article 7(2) iii – system of regulatory inspection assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licences*

The Member States are responsible for the establishment of the national framework, which must establish the responsibilities for the adoption of national nuclear safety requirements, the provision of a system of nuclear safety supervision and enforcement actions, including suspension of operation and modification or revocation of a licence (Article 4(1) c and e of the Nuclear Safety Directive).

2.2.4. *Article 7(2) iv - enforcement of applicable regulations and the terms of licences*

In addition to the national responsibility of Member States for the enforcement of national regulations and terms of licences, it is the supranational nature of EU and Euratom law that makes the Nuclear Safety Directive a milestone in international and regional nuclear law. The Directive attributes a number of powers to the Commission, and more importantly, to the Court of Justice of the European Union. The Commission as the Guardian of the Treaty and the measures taken by the institutions ensures that EU legislation is applied correctly by the Member States. It can start infringement procedures if not satisfied with a Member State's implementation of the Directive and refer the matter to the Court of Justice of the European Union. As a last resort the Court may impose a lump sum or penalty payment on the Member State, which fails to fulfil its obligations (Art. 143 Euratom Treaty, repealed by Lisbon Treaty and replaced by Article 260 of the Treaty on the Functioning of the European Union - TFEU).

2.3. Summary of laws, regulations and requirements affecting the safety of nuclear installations, the licensing system and the inspection, assessment and enforcement process

See Annex 3.

3. ARTICLE 8: REGULATORY BODY

(1) Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities.

(2) Each Contracting Party shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organisation concerned with the promotion or utilization of nuclear energy.⁹⁰

National responsibility of Member States for the nuclear safety of nuclear installations is the fundamental principle on which nuclear safety regulation has been developed at the international level, as endorsed by the Convention on Nuclear Safety. The Nuclear Safety Directive aims to reinforce the role and the independence of the competent national regulatory authorities by building on their competences. It recognises the fundamental principle that only independent and strong regulators can guarantee the safe operation of the nuclear installations in the EU.

3.1. Article 8(1) – Establishment of a Regulatory Authority

Article 5 of the amended Nuclear Safety Directive obliges Member States to establish a competent regulatory authority, which is equipped with the required legal power (=authority), human and financial resources.

A ‘competent regulatory authority’ is defined as an "authority or a system of authorities designated in a Member State in the field of regulation of nuclear safety of nuclear installations as referred to in Article 5."⁹¹ Member States must *make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness*⁹². This applies both to operators and to regulators.

3.2. Article 8(2) – "Independence" of the regulatory authority

Article 5(2) of the amended Nuclear Safety Directive requires Member States to ensure that the competent regulatory authority *"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 organisation when carrying out its regulatory tasks"*.

The provisions on independence have been reinforced in the amended Nuclear Safety Directive, notably with a new requirement on the prevention of conflicts of interest. Article 5 of the amended Nuclear Safety Directive contains a series of criteria that define the status of the regulatory authorities (Article 5(2) from (a) to (f) of the amended Nuclear Safety Directive).

⁹⁰ Not applicable (according to the Declaration of Competences, Annex 1).

⁹¹ See Article 3(3) of the amended Safety Directive.

⁹² See Article 7 of the amended Safety Directive.

4. ARTICLE 9: RESPONSIBILITY OF THE LICENCE HOLDER

Each Contracting Party shall ensure that prime responsibility for the safety of a nuclear installation rests with the holder of the relevant licence and shall take the appropriate steps to ensure that each such licence holder meets [his] responsibility⁹³.

The prime responsibility of licence holders for nuclear safety, as endorsed by the Convention, is explicitly recognised by the amended Nuclear Safety Directive in its Article 6(a) that states that "the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That 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."

Art. 3 (5) of the amended Nuclear Safety Directive defines 'licence holder' as a legal or natural person having overall responsibility for a nuclear installation as specified in a licence. A 'licence' is defined by 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 (Article 3(4) of the amended Nuclear Safety Directive).

EU Member States are obliged to ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder.

5. ARTICLE 10: PRIORITY TO SAFETY

Each Contracting Party shall take the appropriate steps to ensure that all organisations engaged in activities directly related to nuclear installations shall establish policies that give due priority to nuclear safety.⁹⁴

Article 6 (b) of the amended Nuclear Safety Directive provides that "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".

Moreover, Article 6 (d) of the Nuclear Safety Directive obliges Member States to 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.

6. ARTICLE 11: FINANCIAL AND HUMAN RESOURCES

(1) Each Contracting Party shall take the appropriate steps to ensure that adequate financial resources are available to support the safety of each nuclear installation throughout its life.

⁹³ Not applicable according to the Declaration of Competences (Annex 1).

⁹⁴ Not applicable according to the Declaration of Competences (Annex 1).

(2) Each Contracting Party shall take the appropriate steps to ensure that sufficient numbers of qualified staff with appropriate education, training and retraining are available for all safety-related activities in or for each nuclear installation, throughout its life.⁹⁵

The amended Nuclear Safety Directive in Article 5(2)(c) and (d) obliges Member States to ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety.

Likewise, Article 6(f) of the amended Nuclear Safety Directive requires Member States to ensure that the national framework in place requires licence holders to *"provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the 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 competences to fulfil their obligations"*.

7. ARTICLE 12: HUMAN FACTORS

Each Contracting Party shall take the appropriate steps to ensure that the capabilities and limitations of human performance are taken into account throughout the life of a nuclear installation.⁹⁶

Article 7 concerning 'Expertise and skills in nuclear safety' holds that Member States *"shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness"*.

8. ARTICLE 13: QUALITY ASSURANCE

Each Contracting Party shall take the appropriate steps to ensure that quality assurance programmes are established and implemented with a view to providing confidence that specified requirements for all activities important to nuclear safety are satisfied throughout the life of a nuclear installation.⁹⁷

Pursuant to the amended Nuclear Safety Directive, 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 (Article 8(b)).

⁹⁵ Not applicable according to the Declaration of Competences (Annex 1).

⁹⁶ Not applicable according to the Declaration of Competences (Annex 1).

⁹⁷ Not applicable according to the Declaration of Competences (Annex 1)

9. ARTICLE 14: ASSESSMENT AND VERIFICATION OF SAFETY

Each Contracting Party shall take the appropriate steps to ensure that:

(1) Comprehensive and systematic safety assessments are carried out before the construction and commissioning of a nuclear installation and throughout its life. Such assessments shall be well documented, subsequently updated in the light of operating experience and significant new safety information, and reviewed under the authority of the regulatory body;

(2) Verification by analysis, surveillance, testing and inspection is carried out to ensure that the physical state and the operation of the nuclear installation continue to be in accordance with its design, applicable national safety requirements, and operational limits and conditions.

9.1. Article 14 (1) - Safety assessments

Nuclear safety assessments carried out in installations based in the EU Member States are a responsibility of the Member State where the installation is based. The amended Nuclear Safety Directive requires regular nuclear safety supervision, carried out by the regulatory authority and the licence holder throughout the whole lifetime of nuclear installations (Article 5(3) a, b, c, d). Member States must 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 (Article 6(c)). *Any grant of a licence to construct or 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 nuclear safety objective of accident prevention and mitigation. The licence holder is also required to re-assess, at least every 10 years, the safety of the nuclear installation (Article 8c).*

In order to strengthen the powers of European regulatory authorities, the Directive provides for extended regulatory powers in the interest of safety, by clearly spelling out their right to suspend the operation of a nuclear installation, if safety cannot be fully guaranteed. These internal verifications should be supplemented with periodic international peer reviews of the relevant segments of the Member States' national nuclear safety frameworks and/or their authorities.

The amended Nuclear Safety Directive requires the licence holder under the regulatory control of the competent regulatory authority, to re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation. That 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. In addition, there are obligations for international peer reviews of the national framework, involving the competent regulatory authority. Member States shall also ensure that arrangements are in place to allow for a first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.

9.2. Article 14(2) - Verification programmes

Licence holders are required to undertake systematic and verifiable safety assessments. Nuclear safety verification programmes carried out in installations based in the EU Member States are a responsibility of the Member State where the installation is based. This principle of national responsibility for nuclear safety assessment is also confirmed in the amended Nuclear Safety Directive.

10. ARTICLE 15 - RADIATION PROTECTION

Each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits.

10.1. Summary of laws, regulations and requirements dealing with radiation protection as applied to nuclear installations⁹⁸

Article 2(b) of the Euratom Treaty requires Euratom to establish uniform safety standards to protect the health of the workers and of the general public and to ensure that they are applied. Article 218 of the Treaty underlines the importance for Euratom of the basic standards as these had to be determined within one year of the entry into force of the Treaty. They were first established in 1959 and have regularly been amended (in the years 1962, 1966, 1976, 1980, 1984, 1996 and 2013), taking account of the latest scientific findings and recommendations. The latest safety standards are set out in Council Directive 2013/59/Euratom of 5 December 2013 (the Basic Safety Standards (BSS) Directive)⁹⁹.

Progress in radiation protection science, technological development, and operational experience with current requirements motivated the European Commission to revise the European radiation protection legislation. One driver¹⁰⁰ for this revision was the publication of the 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103¹⁰¹, in which ICRP modifies the underlying radiation protection philosophy and proposes to categorise exposure situations in planned, existing and emergency, while maintaining the set of principles of radiation protection, justification of exposure, optimisation of protection and dose limitation, emphasizing their importance. In publication 103, ICRP recommends the consistent integration of natural radiation sources into the radiation protection system. The new Basic Safety Standards follow this modified ICRP radiation protection philosophy to the extent possible.

⁹⁸ See Annex 3

⁹⁹ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union (OJ L13, 17.01.2014, p. 1 -73).

¹⁰⁰ *Lessons learned from the Fukushima accident as regards emergency preparedness and response were incorporated into the BSS Directive.*

¹⁰¹ International Commission on Radiological Protection, the 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103, Ann. ICRP 37 (2-4), Elsevier Ltd, 2007.

At the same time the Commission undertook to consolidate the existing set of Euratom radiation protection legislation by merging five Directives – the Basic Safety Standards Directive¹⁰², the Medical Exposure Directive¹⁰³, the Outside Workers Directive¹⁰⁴, the Public Information Directive¹⁰⁵ and the High Activity Sealed Sources Directive¹⁰⁶ – and a recommendation on indoor radon exposure¹⁰⁷ into one single piece of legislation.

The Directive is consistent with the International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources, sponsored and issued by the International Atomic Energy Agency and jointly sponsored by five other international organisations with competence in radiation protection.

10.2. Implementation of applicable laws, regulations and requirements relating to radiation protection

10.2.1. Radiation dose limits

As both the 96/29/Euratom and the 2013/59/Euratom Basic Safety Standards Directives are currently in force until 6 February 2018, when the former will be repealed by the latter, in this Report there will be reference to the provisions contained in both of them not only for the sake of completeness but also as a means of illustrating some of the changes introduced by the latest revision.

More specifically, as regards dose limitation, the 1996 Basic Safety Standards Directive sets out dose limits for exposed workers, for apprentices and students and for members of the public. The relevant Articles of the Directive are as follows:

“Article 9 – Dose limits for exposed workers

- (1) The limit on effective dose for exposed workers shall be 100 millisievert (‘mSv’) in a consecutive five-year period, subject to a maximum effective dose of 50 mSv in any single year. Member States may decide an annual amount.
- (2) Without prejudice to paragraph 1:

¹⁰² 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 radiation, Official Journal of the European Communities, Series L, No. 159, 1996

¹⁰³ Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the danger of ionizing radiation in relation to medical exposure, Official Journal of the European Communities, Series L, No. 180, 1997

¹⁰⁴ Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas, Official Journal of the European Communities, Series L, No. 349, 1990

¹⁰⁵ Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, Official Journal of the European Communities, Series L, No. 357, 1989

¹⁰⁶ Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources, Official Journal of the European Communities, Series L, No. 346, 2003

¹⁰⁷ European Commission, Commission Recommendation 90/143/Euratom of 21 February 1990 on the protection of the public against indoor exposure to radon, Official Journal of the European Communities, Series L, No. 80, 1990

- (a) the limit on equivalent dose for the lens of the eye shall be 150 mSv in a year;
- (b) the limit on equivalent dose for the skin shall be 500 mSv in a year. This limit shall apply to the dose average over any area of 1 cm², regardless of the area exposed;
- (c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a year.”

“Article 11 –Dose limits for apprentices and students

- (1) The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to use sources shall be the same as the dose limits for exposed workers laid down in Article 9.
- (2) The limit for effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to use sources shall be 6 mSv per year.

Without prejudice to this dose limit:

- (a) the limit on equivalent dose for the lens of the eye shall be 50 mSv in a year;
 - (b) the limit on equivalent dose for the skin shall be 150 mSv in a year. This limit shall apply to the dose average over any area of 1 cm², regardless of the area exposed;
 - (c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.
- (3) The dose limits for apprentices and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as the dose limits for members of the public specified in Article 13.”

“Article 13 – Dose limits for members of the public

- (1) Without prejudice to Article 14, the dose limits for members of the public shall be as laid down in paragraphs 2 and 3.
- (2) The limit for effective dose shall be 1 mSv in a year. However, in special circumstances, a higher effective dose may be authorised in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year.
- (3) Without prejudice to paragraph 2:
 - (a) the limit on equivalent dose for the lens of the eye shall be 15 mSv in a year;
 - (b) the limit on equivalent dose for the skin shall be 50 mSv in a year averaged over any 1 cm² area of skin, regardless of the area exposed.”

Respectively, the relevant Articles of the 2013 Directive are as follows:

"Article 9 - Dose limits for occupational exposure"

"1. Member States shall ensure that dose limits for occupational exposure apply to the sum of annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification in accordance with Article 54(3), and other occupational exposure from existing exposure situations in accordance with Article 100(3). For emergency occupational exposure Article 53 shall apply.

2. The limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations specified in national legislation, a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.

3. In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, as specified in national legislation.

(b) the limit on the equivalent dose for the skin shall be 500 mSv in a year, this limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 500 mSv in a year."

"Article 11- Dose limits for apprentices and students"

"1. Member States shall ensure that the dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources, shall be the same as the dose limits for occupational exposure laid down in Article 9.

2. Member States shall ensure that the limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources, shall be 6 mSv in a year.

3. In addition to the limits on effective dose laid down in paragraph 2, the following limits on equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;

(b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 150 mSv in a year.

4. Member States shall ensure that the dose limits for apprentices and students who are not subject to the provisions of paragraphs 1, 2 and 3 shall be the same as the dose limits for members of the public as specified in Article 12."

"Article 12 - Dose limits for public exposure"

"1. Member States shall ensure that the dose limits for public exposure shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices.

2. Member States shall set the limit on the effective dose for public exposure at 1 mSv in a year.

3. In addition to the dose limit referred to in paragraph 2, the following limits on the equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the eye shall be 15 mSv in a year;

(b) the limit on the equivalent dose for the skin shall be 50 mSv in a year, averaged over any 1 cm² area of skin, regardless of the area exposed."

In a nutshell, the 2013 Directive offers some substantial changes with regard to dose limits for occupational exposure. First, Article 9 provides that dose limits for occupational exposure apply to the sum of annual occupational exposures of a worker from all authorised practices, radon at workplaces requiring notification, and occupational exposure from existing exposure situations. This may imply that for a worker who is exposed to several of the mentioned sources, the contribution of each source can only be a fraction of the annual dose limit defined.

Second, the limit on the effective dose for occupational exposure shall now be 20 mSv in any single year. The previous Directive (96/29/Euratom) still allowed for a dose limit of 100 mSv averaged over five years (with a maximum of 50 mSv in any single year). This is now only allowed for specific circumstances which need to be specified in national legislation.

Third, the limit on the equivalent dose for the lens of the eye has been considerably lowered from 150 mSv/year to 20 mSv/year. Although the lowering of the dose limit for the lens of the eye will have essentially no impact on the majority of workplaces, there are specific occupational categories in the medical area, such as interventional radiologists and interventional cardiologists, who receive substantial doses to the lens of the eye and who will merit closer attention.

As regards dose limits for apprentices and students, the requirement is mainly unchanged from Directive 96/29/Euratom, with the exemption of the dose limit for the lens of the eye. The limit on the equivalent dose for the lens of the eye for apprentices and students has also been considerably lowered from previously 50 mSv/year to now 15 mSv/year.

As far as dose limits for public exposure are concerned, while the numerical values of the limits for public exposure remain unchanged from Directive 96/29/Euratom, there is a substantial change in that the dose limits for public exposure shall now "... apply to the sum of annual exposures of a member of the public resulting from all authorised practices". With

this, Member States need to evaluate all authorised practices which may contribute to the exposure of an individual member of the public and ensure that the sum of exposures remain below the dose limit.

10.2.2. Fulfilment of conditions for the release of radioactive materials

As regards practices involving a risk from ionising radiation for the population, Article 43 and Article 44 of the 1996 Basic Safety Standards Directive require Member States to apply the fundamental principles governing operational protection of the population. In particular, Article 44 states:

“Operational protection of the population means all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation involving exposure to ionising radiation, are liable to create a risk of exposure for the population which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

- (a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;
- (b) acceptance into service of such new installations subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;
- (c) examination and approval of plans for the discharge of radioactive effluents.

These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the extent of the exposure risk involved”.

Respectively, the strengthened relevant Article 65 of the revised 2013 Directive reads as follows:

"Article 65 - Operational protection of members of the public

1. Member States shall ensure that the operational protection of members of the public in normal circumstances from practices subject to licensing shall include, for relevant facilities, the following:

- (a) examination and approval of the proposed siting of the facility from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions;***
- (b) acceptance into service of the facility subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter of the facility or radioactive contamination liable to extend to the ground beneath the facility;***

(c) examination and approval of plans for the discharge of radioactive effluents;

(d) measures to control the access of members of the public to the facility.

2. The competent authority shall where appropriate establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which shall:

(a) take into account the results of the optimisation of radiation protection;

(b) reflect good practice in the operation of similar facilities.

In addition, these discharge authorisations shall take into account, where appropriate, the results of a generic screening assessment based on internationally recognised scientific guidance, where such an assessment has been required by the Member State, to demonstrate that environmental criteria for long-term human health protection are met.

3. For practices subject to registration, Member States shall ensure the protection of members of the public in normal circumstances through appropriate national regulations and guidance."

10.2.3. Steps taken to ensure that radiation exposures are kept as low as reasonably achievable

The Optimisation (ALARA) Principle is enshrined in the 1996 Basic Safety Standards Directive: The general principles of radiation protection: justification, optimisation and dose limitation are mandatory under Article 6. In particular, as regards optimisation, Article 6 paragraph 3a reads:

"Each Member State shall ensure that, in the context of optimisation, all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account."

Article 5 of the 2013 revised Directive ("General principles of radiation protection") provides respectively that:

"Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations, reflect a system of radiation protection based on the principles of justification, optimisation and dose limitation:

(a) Justification: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.

(b) Optimisation: Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably

achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in Article 56. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.

(c) Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures."

The optimisation principle thus requires that radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable, economic and societal factors taken into account. To further emphasise the importance of optimisation, the 2013 Basic Safety Standards Directive requires the introduction of the new concepts "dose constraints" and "reference levels" for the purpose of optimisation of protection. The transposition and implementation of these new concepts in the area of protection of workers and protection of the public may be a challenge to Member States, competent authorities and operators.

10.2.4. Estimates and records of population doses

Article 49 of the 1996 Basic Safety Standards Directive requires Member States to consider the possibility of radiological emergencies from practices subject to the Directive, and to assess the distribution of the radioactive substances dispersed and corresponding potential exposures. *The same concern is addressed in an even more detailed way in Article 97 of the 2013 Directive, which reads as follows:*

"Article 97 - Emergency management system

1. Member States shall ensure that account is taken of the fact that emergencies may occur on their territory and that they may be affected by emergencies occurring outside their territory. Member States shall establish an emergency management system and adequate administrative provisions to maintain such a system. The emergency management system shall include the elements listed in Section A of Annex XI.

2. The emergency management system shall be designed to be commensurate with the results of an assessment of potential emergency exposure situations and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events.

3. The emergency management system shall provide for the establishment of emergency response plans with the objective of avoiding tissue reactions leading to severe deterministic effects in any individual from the affected population and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Chapter III."

The new Basic Safety Standards (BSS) Directive and the amended Nuclear Safety Directive both regulate emergency preparedness and response. The amended Nuclear Safety Directive deals with on-site emergency preparedness and response, whereas the new BSS Directive regulates on-site and off-site protective measures.

10.2.5. Verification of environmental radiological surveillance facilities

In line with the implementation of Article 14 (ii) of the Convention, Article 35 of the Euratom Treaty provides:

“Each Member State shall establish the facilities necessary to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards.

The Commission shall have the right of access to such facilities; it may verify their operation and efficiency.”

The result of the checks carried out by the Member States under Article 35 of the Euratom Treaty are periodically communicated to the Commission under Article 36 of the Treaty. Commission Recommendations 2000/473/Euratom¹⁰⁸ and 2004/2/Euratom¹⁰⁹ aim at ensuring uniformity, comparability, transparency and timeliness of the data reported, respectively for levels of radioactivity in the environment and for discharges of radioactive effluent. The Commission regularly publishes summaries of the data reported by Member States¹¹⁰. It also exercises its right of access conferred on it by Article 35 of the Euratom Treaty.

Taking into account previous bilateral protocols, a Commission Communication has been published in the Official Journal on 4 July 2006¹¹¹ with a view to define some practical arrangements for the conduct of "Article 35 verification visits" in Member States. These may be amended as needed.

The primary objective of the "Article 35 verifications" is to establish the efficiency of the facilities installed for the measurement of environmental radioactivity and of radioactive discharges, and to establish the adequacy of the environmental monitoring programme. The efficiency and adequacy are assessed in relation to the overall approach developed at national level to ensure the protection of members of the public in compliance with the Basic Safety Standards.

Verifications are initiated:

- where and when the Commission estimates it to be appropriate
- on request (invitation) of national authorities

¹⁰⁸ OJ L 191 of 17.07.2000 p. 37.

¹⁰⁹ OJ L 2 of 6.1.2004, p. 36.

¹¹⁰ See <http://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/monitoring-radioactivity>.

¹¹¹ Verification of environmental radioactivity monitoring facilities under the terms of Article 35 of the Euratom Treaty - Practical arrangements for the conduct of verification visits in Member States (2006/C 155/02), OJ C-155 of 04.07.2006 p. 2.

- on request of the European Parliament
- on request of a Member State (to verify a neighbouring Member State)

Verifications may extend to all installations discharging radioactive substances into the environment such as:

- nuclear fuel cycle installations (mainly power stations and reprocessing facilities)
- research reactors,
- radioactive isotope production facilities,
- users of radioactive isotopes (i.e. hospitals),
- Naturally Occurring Radioactive Material (henceforth: NORM) industries discharging effluents containing enhanced levels of natural radioactivity.

Verification activities cover all facilities and provisions for monitoring/sampling of:

- discharges of radionuclides into the environment (airborne and liquid effluents)
- environmental radioactivity around installations discharging radionuclides;
- environmental radioactivity as part of a national network (regional, national level).

Environmental monitoring includes:

- routine measurement of radioactivity in air, water, soil and biota;
- provisions in case of radiological emergencies (alarms and data collection, but not emergency response planning)

Verification activities basically cover:

- Monitoring/sampling devices (operation and efficiency)
- Monitoring/sampling procedures (methodologies and representativeness).
- Data handling and management procedures (reporting and archiving).
- Consistency of source data (operational records) with values reported under Articles 36 and 37 of the Euratom Treaty.
- Quality control and assurance programmes applied to the above fields of activity (working instructions, peer review, inter-comparison and accreditation).

Since 1999, about **80** verification reports pursuant to Article 35 of the Euratom Treaty have been made publicly available with consent of the competent authorities of the Member States concerned¹¹². The official results of a verification visit are laid down in a document referred to as the Main Conclusions. A Technical Report is annexed to it. The Main Conclusions are based on the observations and recommendations detailed in the Technical Report, but without the technical elements.

Data reporting under Article 36 also encompasses information on the discharge of radioactive effluents. Nuclear sites, in particular nuclear power stations and reprocessing sites, may discharge airborne and liquid radioactive effluents into the environment on condition that these discharge operations abide by regulatory conditions and restrictions as defined in their respective operating licenses. It is a recognized practice in the framework of Article 35 verifications¹¹³ that the environment starts where radioactive discharges leave operational control i.e. at the last measurement points that quantify these discharges. Consequently these discharge measurement points are deemed to be environmental monitoring devices, the results of which shall be communicated to the Commission. In 2004 the Commission issued Recommendation 2004/2/Euratom providing guidance to Member States as to this type of reporting. The Commission's Radioactive Discharges Database (RADD), publicly accessible on the EUROPA web site (<http://europa.eu/radd/>), presents airborne and liquid radioactive discharge data from nuclear power stations (with a capacity greater than 50 MWe) as well as from nuclear fuel reprocessing sites. In order to provide a useful time span the database contains information from 1995 onwards. For new Member States, information is present starting from the respective accession years: 2004 or 2007.

10.2.6. Regulatory control activities

Not applicable.

11. ARTICLE 16 - EMERGENCY PREPAREDNESS

(1) Each Contracting Party shall take the appropriate steps to ensure that there are on-site and off-site emergency plans that are routinely tested for nuclear installations and cover the activities to be carried out in the event of an emergency.

For any new nuclear installation, such plans shall be prepared and tested before it commences operation above a low power level agreed by the regulatory body.

(2) Each Contracting Party shall take the appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of the nuclear

¹¹² <https://ec.europa.eu/energy/en/verifications-radiation-monitoring-eu-countries>

¹¹³ Commission Communication "Verification of environmental radioactivity monitoring facilities under the terms of Article 35 of the Euratom Treaty — Practical arrangements for the conduct of verification visits in Member States", OJ C55 of 04.07.2006, p. 2–5.

installation are provided with appropriate information for emergency planning and response.

(3) Contracting Parties which do not have a nuclear installation on their territory, insofar as they are likely to be affected in the event of a radiological emergency at a nuclear installation in the vicinity, shall take the appropriate steps for the preparation and testing of emergency plans for their territory that cover the activities to be carried out in the event of such an emergency.

The primary responsibility of protecting the general public in the event of a nuclear or radiological emergency lies with the Member States' authorities; however Euratom has some legislative competences regarding emergency preparedness and emergency response. In addition, the Commission contributes in this work by initiating and participating in international systems for radiological emergency preparedness.¹¹⁴

The Union Civil Protection Mechanism has continued to contribute to reinforcing Europe's preparedness to nuclear incidents. Two key instruments in force today in this area for civil protection at European level are the *Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism* and *Commission Implementing Decision 2014/762/EU of 16 October 2014, laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism and repealing Commission Decisions 2004/277/(EC, Euratom) and 2007/606/(EC, Euratom)*. ***Both decisions aim to improve the effectiveness of response to major emergencies and to enhance preventive and preparedness measures for all kinds of emergencies and providing the framework for financial support available at European level.***

The aim is to support, coordinate and supplement the actions of 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 of all kinds within and outside the Union. Specific objectives include (a) to achieve a high level of protection against disasters by preventing or reducing their effects and by fostering a culture of prevention (b) to enhance the Union's state of preparedness to respond to disasters (c) to facilitate rapid and efficient emergency response interventions in the event of major disasters.

The Commission follows an all-hazard approach, including preparedness and response measures related to nuclear /radiological emergencies.

As regards prevention, the legislation provides for specific obligations for Member States as regards the preparation of national risk assessments and communication of summary thereof to the Commission, as well as regarding the assessment of Member States risk management capability.

As regards preparedness, as part of the EU CBRN Action Plan, the Commission DG ECHO promotes training, workshops, exercises and interoperability between Member States' response

¹¹⁴ See Chapter 11.3 International arrangements, including those with neighbouring countries, p. 79.

capacities. Large scale CBRN European exercises have been regularly organised the European Civil Protection Mechanism and co-financed by the European Civil Protection Mechanism.

The inter-operability of Member States' disaster response capabilities has been greatly improved through the development of pre-defined civil protection "modules" for which the main types of response capacities minimum conditions have been defined and agreed at EU level. In the field of CBRN, the Member States have registered at European level a number of CBRN detection and sampling modules and Urban Search and Rescue modules capable of working in CBRN conditions. Exercises for modules are also conducted and financed under the EU Civil protection Mechanism.

As regards response to emergencies, at any time an affected state can turn to the EU Civil Protection Mechanism for expert support and assistance. The European Civil Protection Mechanism offers a framework for the mobilisation of Participating States' assistance in response to such emergencies that overwhelm the response capacities of individual states. Any Member State or third country affected by natural and man-made disasters, including nuclear or radiological events, can make a request for in-kind assistance (teams and means) to the Commission's Emergency Response Coordination centre (ERCC), which will then facilitate the coordination and deployment of Participating States' offers of assistance.

11.1. General description of laws, regulations and requirements for on-site and off-site emergency preparedness

Under the amended Nuclear Safety Directive, there is a requirement for more specific arrangements for accident management and on-site emergency response addressing the prevention and mitigation of accidents. The licence holder should provide for procedures, guidelines and arrangements that address accidents and severe accidents, that could occur in all operational modes, including full power, shutdown and transitional states, including those simultaneously affecting several units, ensuring consistency and continuity between all such procedures and arrangements, and ensuring that they are exercised, reviewed and updated. The licence holder is required to 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, and the arrangements should be in accordance and without prejudice to the relevant provisions of the Directive 2013/59/Euratom. (Article 8d). This provision is intended to ensure complementarity of the measures taken between the two Directives, as the amended Nuclear Safety Directive contains enhanced measures for emergency preparedness and response which concern on-site aspects, whilst the provisions in the BSS Directive apply to both on-site and off-site aspects.

Council conclusions on Off-site nuclear emergency preparedness and response, adopted on 15 December 2015 invites Member States and the Commission to further strengthening cross border cooperation with the aim of coherent protective measures along adjacent national borders to protect populations against the effects of ionising radiation in case of an emergency.

11.1.1. Council Directive 96/29/Euratom

Article 50 of Council Directive 96/29/Euratom, on "Intervention preparation", provides as follows:

- “1. Each Member State shall ensure that account is taken of the fact that radiological emergencies may occur in connection with practices on or outside its territory and affect it.
2. Each Member State shall ensure that appropriate intervention plans, taking account of the general principles of radiation protection for intervention referred to in Article 48 (2) and of the appropriate intervention levels established by the competent authorities, are drawn up at national or local level, including within installations, in order to deal with various types of radiological emergency and that such plans are tested to an appropriate extent at regular intervals.
3. Each Member State shall ensure, where appropriate, that provision is made for the creation and appropriate training of special teams for technical, medical and health intervention.
4. Each Member State shall seek to cooperate with other Member States or non-Member States in relation to possible radiological emergencies at installations on its own territory which may affect other Member States or non-Member States, in order to facilitate the organisation of radiological protection in these States.”

11.1.2. Council Directive 2013/59/Euratom

The new Basic Safety Standards Directive contains new and strengthened provisions on emergency preparedness and response (EP&R). As the revision of the BSS Directive was underway at the time of the Fukushima accident in Japan in 2011, some of the lessons learnt as a result of the accident were taken into account.

The new BSS Directive follows the situation-based approach to radiation protection recommended by the International Commission on Radiological Protection (ICRP), distinguishing between existing, planned and emergency exposure situations. With regard to the management of emergency exposure situations, the current approach based on intervention levels is replaced by a more comprehensive system comprising an assessment of potential emergency exposure situations, an overall emergency management system, emergency response plans, and pre-planned strategies for the management of each postulated event.

The essential elements to be included in an emergency management system (prior assessment emergency exposure situations, allocation of responsibilities, efficient coordination, cooperation and communication measures etc.) and in an emergency plan (reference levels for exposure, optimised protection strategies, pre-defined generic criteria, default triggers or operational criteria etc.) are specified.

The need for efficient management of an emergency with cross-border consequences is recognised through provisions for enhanced cooperation between Member States in emergency planning and response. The new BSS Directive requires Member States to cooperate with other Member States and with third countries which may be involved or are likely to be affected by an emergency, with a view to sharing the assessment of the exposure situation and coordinating protective measures and public information by using bilateral or international information exchange and coordination systems.

The emphasis on optimisation, using reference level, in emergency and existing exposure situations expands the earlier use of optimisation from planned activities to all exposure situations. To achieve optimised protection strategies, accounting for the effects of ionising radiation as well as other societal criteria, is of particular importance in an accident and a post-accident phase.

It should also be mentioned that the new BSS Directive incorporates provisions of Council Directive 89/618/Euratom on informing the general public about measures to be taken in the event of a radiological emergency.

General description of new and extended provisions in the BSS Directive:

i. Emergency management system

Member States are required to take account of the fact that emergencies may occur on their territory and that they may be affected by emergencies occurring outside their territory. The new BSS Directive requires the establishment of a national emergency management system and adequate administrative provisions to maintain such a system. The management system shall be designed to be commensurate with the results of an assessment of potential emergency exposure situations and be able to respond effectively to these emergency exposure situations. For the various types of emergency identified by the above mentioned assessment, facility-specific or activity-specific emergency response plans need to be established in advance. These plans need to be tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and the results of the participation in emergency drills at national and international level. The emergency response plans shall also include provisions for the transition from an emergency exposure situation to an existing exposure situation. Annex XI of the new BSS Directive provides detailed elements which need to be covered by the national emergency management system and emergency response plan.

Amongst the preparation measures, members of the public likely to be affected by an emergency should be given prior information about health protection measures they should take in the event of an emergency.

ii. International cooperation

The new BSS Directive contains strengthened requirements on international cooperation in case of an emergency (in an EU MS) which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in all countries affected. In case of an emergency, this cooperation shall allow to promptly establish contacts with countries likely to be affected, share the assessment of the exposure situation, coordinate protective measures and inform the public by using bilateral and international information exchange and coordination systems. Member States shall also cooperate in the transition from an emergency exposure situation to an existing exposure situation.

iii. Emergency response

The installation or undertaking concerned is required to notify the competent authority immediately of any emergency in relation to the practice for which it is responsible and to take all appropriate action to mitigate the consequences. The undertaking is also responsible for making an initial provisional assessment of the circumstances of the emergency and to assist with protective measures.

In case of such an event, the authorities in the Member State concerned are responsible for the protective measures to be taken with regard to the radiation source, to reduce or stop the radiation, including the release of radionuclides, with regard to the environment, to reduce the exposure of individuals resulting from radioactive substances through relevant pathways, and with regard to individuals, to reduce their exposure. Further requirements concern the provision of medical treatment of those affected, if the situation requires. In case of a real emergency, the public actually affected must be informed without delay about the facts of the emergency and the protection measures to be taken.

iv. Reference levels for public exposures in an emergency situation

The new BSS has introduced the concept of “reference levels” for emergency and existing exposure situations. It allows for the protection of the individual as well as consideration of other societal criteria in the same way as dose limits and dose constraints for planned exposure situations.

v. Protection of emergency workers

Special emphasis has been put on the protection of emergency workers. The Directive contains specific requirements on the information and training to be provided to emergency workers prior to an accident and in case of a real event. Emergency occupational exposure shall remain, whenever possible, below the dose limits for occupational exposure. For situations where this is not possible, reference levels for emergency exposures of maximum 100 mSv shall be set, however in exceptional circumstances this may be set up to 500 mSv. In these cases, emergency workers shall be subject to appropriate radiological monitoring and special medical surveillance.

The provisions related to emergencies and the recovery from such emergencies, are enunciated in five of the main Chapters of the Directive (Chapters III, IV, VI, VIII, and IX) and related annexes (Annexes I, XI and XII), and split according to the different emergency exposure situations and corresponding existing exposure situations.

11.1.3. Council Directive 89/618/Euratom on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency

Council Directive 89/618/Euratom¹¹⁵ deals with informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency¹¹⁶.

The Directive specifies two types of information that has to be given to the members of the public:

- Prior information to be given to the population groups for which Member States have drawn up intervention plans in the event of a radiological emergency;

¹¹⁵ OJ L 357, 07.12.1989, p 31.

¹¹⁶ This directive has been repealed by Council Directive 2013/59/Euratom as of 6 February 2018.

- Information in the event of a radiological emergency, to be given to the population groups actually affected in the event of a radiological emergency and for which specific protection measures are taken.

The Directive also requires that emergency workers regularly undergo medical surveillance and are informed about their health. In 1991 the Commission adopted a Communication on information for the implementation of Articles 5 and 6 of Council Directive 89/618/Euratom.¹¹⁷

11.1.4. Council Decision 87/600/Euratom on Community arrangements for the early exchange of information in the event of a radiological emergency

Council Decision 87/600/Euratom sets out arrangements for the early exchange of information between competent authorities in the event of a radiological emergency (ECURIE). These arrangements “apply to the notification and provisions of information whenever a Member State decides to take measures of a wide-spread nature in order to protect the general public in case of a radiological emergency” (Article 1 of the Decision). A radiological emergency may be declared either due to an accident at a facility where a significant release of radioactive material occurs or is likely to occur, or due to detection of abnormal levels of radioactivity in the environment.

Article 2(i) of this Decision sets out the actions to be taken by the Member State that initially decides to take measures as referred to in Article 1 of this Decision as follows:

- (a) Forthwith notify the Commission and those Member States which are, or are likely to be, affected of such measures and the reasons for taking them;*
- (b) Promptly provide the Commission and those Member States which are, or are likely to be, affected with available information relevant to minimising the foreseen radiological consequences, if any, in those States.*

Member States notify without delay their “intention to take measures as referred to in Article 1”. The Decision also specifies the nature of the information that shall be provided and requires that the initial information is supplemented at appropriate intervals. The Commission makes available the information it receives from a Member State to all the Member States. The Decision applies to the Member States of Euratom. It also applies to Switzerland, Norway and the Former Yugoslav Republic of Macedonia following an agreement between Euratom and these Countries. The Decision is broadly compatible with the Convention on Early Notification of a Nuclear Accident, as demonstrated by several exercises carried out in co-operation with the IAEA and the States participating in such exercises. ***Work is ongoing in order to adapt both the Web-ECURIE and IAEA USIE (Unified system for Information Exchange in Incidents and Emergencies) systems to make them compatible so that information appearing on one can also appear on the other. In this way Member States with obligations under both arrangements can satisfy both requirements without duplication of effort.***

¹¹⁷ OJ C 103, 19.04.1991, p 12–16.

11.1.5. Regulations laying down maximum permitted levels of contamination of contamination of food- and feeding stuffs for use or sale (for future accidents)

Following the Chernobyl accident a set of Euratom regulations¹¹⁸ laying down maximum permitted levels of radioactive contamination of foodstuffs and feeding stuffs following a nuclear accident or any other case of radiological emergency were put in place. These pre-established maximum permitted levels could be made immediately applicable through the adoption of a regulation by the Commission if the latter receives official information about an accident through the ECURIE system (Council Decision 87/600/Euratom) indicating that these levels are likely to be reached or have been reached.¹¹⁹ ***On the basis of the experience gained the Commission proposed to the Council in 2014 a revision of the existing legislation establishing maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other radiological emergency. In January 2014 the Commission adopted its final proposal for a Council Regulation, after having received the opinion of the Article 31 Group of Experts and of the European Economic and Social Committee. Technical agreement was reached in the Working Party on Atomic Questions (WPAQ) of the Council at the end of 2014. The opinion of the European Parliament was received on 9 July 2015. Council Regulation (Euratom) 2016/52 was then adopted on 15 January 2016¹²⁰.***

The revised Regulation:

i. Consolidates existing Euratom legal acts for future accidents.

ii. Brings the procedure in line with the new Comitology system.

iii. Provides more flexible procedures allowing specific reactions to any nuclear accident or radiological emergency in the EU, in the vicinity of the EU or in a remote country.

11.2. Implementation of emergency preparedness measures, including the role of the regulatory body and other entities

11.2.1. Classification of emergency situations

Not applicable.

11.2.2. Overall emergency preparedness scheme

Not applicable.

¹¹⁸ Council Regulation No 3954/87 of 22 December 1987, OJ L-371 of 30.12.1987 p. 11, as amended by Council Regulation No 2218/89 of 18 July 1989, OJ L-211 of 27.07.1989 p. 1; Commission Regulation No 770/90 of 29 March 1990, OJ L-83 of 29.03.1990 p. 78; Commission Regulation No 944/89 of 12 April 1989, OJ L-101 of 13.04.1989 p. 17; ***These regulations are now repealed.*** Council Regulation No 2219/89 of 18 July 1989, OJ L-211 of 22.07.1989 p.4.

¹¹⁹ See Annex 3

¹²⁰ ***Council Regulation (Euratom) No 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90.***

11.2.3. On-site and off-site emergency plans of research reactors, including supporting agencies and schemes

Not applicable.

11.2.4. Measures for informing the public about emergency preparedness in the vicinity of the nuclear installations

Not applicable.

11.2.5. Conduct of emergency exercises

The Commission organises radiological emergency preparedness exercises within the framework of the ECURIE (European Community Urgent Radiological Information Exchange) arrangements. This is normally done once per year.

The ECURIE system may on request also be used as an information exchange tool for national exercises.

In addition, the Commission participates in selected international exercises organised by the Member States, the IAEA or the OECD-NEA such as the ConvEx or the INEX series using the capabilities of the ECURIE system as well as - if deemed necessary - the activation of the radiation protection unit's emergency team. The ConvEx series ranges from tests of reaching the contact point to full scale exercises with a hypothetical large accident scenario. The INEX series is mainly a tool to help develop/enhance appropriate systems for emergency preparedness on national and international levels and is normally on a table-top basis.

11.3. International arrangements, including those with neighbouring countries

11.3.1. ECURIE (European Community Urgent Radiological Information Exchange)

ECURIE is a 24h rapid alert and information exchange system. The system notifies the competent authorities of the participating States (currently EU Member States, Switzerland, Norway and the former Yugoslav Republic of Macedonia) and the Commission in case of a major nuclear accident or a radiological emergency. During an emergency the system provides an information exchange platform for the participating States in order to inform about the current and foreseeable status of the accident, meteorological conditions, national countermeasures taken, etc.

The legal basis for participation in ECURIE by the EU Member States is the EU Council Decision 87/600/Euratom and the Agreement between Euratom and non-member States of the European Union on the participation of the latter in ECURIE¹²¹. The Commission is responsible for ECURIE management and development and maintains a 24h preparedness service in order to activate the system in the event of a nuclear or radiological emergency¹²². There is an ongoing effort between IAEA and EC services on the issue of having compatible technical systems for the ECURIE MS for notification purposes which would deal with

¹²¹ OJ C 102 of 29.4.2003, p. 2.

¹²² For more information on the ECURIE system see <https://ecurie.jrc.ec.europa.eu>.

ECURIE messages as well as the IAEA's Emercon messages. With the latest generation of the ECURIE notification software it is possible to send a notification to both the Commission and the IAEA simultaneously. It is expected that this functionality will be implemented during 2017 following appropriate testing by the Commission and the IAEA.

11.3.2. EURDEP (EUropean Radiological Data Exchange Platform)

EURDEP is both a standard data format and a network for the exchange of environmental radiation monitoring data between European countries in real-time which is managed by the Commission's Joint Research Centre in cooperation with DG ENER. Participation of the EU Member States is based on the Council Decision 87/600/Euratom. Participation of the various non-EU countries is on a voluntary basis. Currently EURDEP gathers and presents data from 41 networks in 38 European countries, totalling about 5500 automatic monitoring stations. The data servers are currently hosted by the JRC services in Italy, DG ENER services in Luxembourg and the Bundesamt für Strahlenschutz (BfS) in Germany. Countries which make their national radiological monitoring data available to EURDEP have access to the data from all the other participating countries. The system is continuously operating in routine mode (i.e. for gamma dose rate hourly; weekly for air concentration). During an emergency the rate of data exchange in case of air concentration is increased to a daily basis.

¹²³

11.3.3. IACRNE

The Commission participates in the Inter-Agency Committee on Response to Nuclear Emergencies (IACRNE) and *is a co-sponsor of the Joint Radiation Emergency Management Plan of the International Organisations (J-Plan) which seeks to lay out how the associated International Organisations should interact in the event of a major radiological emergency.*

11.3.4. Other activities

Other radiological emergency preparedness activities in the Commission include training of national authorities, assistance to research activity co-ordination, regular preparedness exercises and co-operation with other international organisations and other Commission emergency services. Additionally the Commission provides an INES (the International Nuclear Event Scale) liaison officer and organises regular meetings of Member States radiological emergency preparedness authorities.

In December 2015, the European Council, under the Luxembourg Presidency, adopted a set of "Council Conclusions" concerning off-site emergency preparedness and response¹²⁴. These Council Conclusions, reemphasising the fact that emergency preparedness and response (EP&R) arrangements, established for many years in the EU Member States are tested and organised regularly, highlight some of the opportunities to achieve consistent approaches to protect the population in case of an emergency, reflecting recent developments and activities in the field of response to nuclear emergencies, especially in view of lessons

¹²³ For more information on the EURDEP system see <https://ecurie.jrc.ec.europa.eu>.

¹²⁴ *Outcome of the Council Meeting, 3439th Council meeting, General Affairs, Brussels, 15 December 2015.*

learnt from the Fukushima accident. The Conclusions also stress the benefits of involving civil society in preparedness activities.

12. ARTICLE 17 – SITING

Each Contracting Party shall take the appropriate steps to ensure that appropriate procedures are established and implemented:

- i. For evaluating all relevant site-related factors likely to affect the safety of a nuclear installation for its projected lifetime;**
- ii. For evaluating the likely safety impact of a proposed nuclear installation on individuals, society and the environment;**
- iii. For re-evaluating as necessary all relevant factors referred to in subparagraphs (i) and (ii) so as to ensure the continued safety acceptability of the nuclear installation;**
- iv. For consulting Contracting Parties in the vicinity of a proposed nuclear installation, insofar as they are likely to be affected by that installation and, upon request providing the necessary information to such Contracting Parties, in order to enable them to evaluate and make their own assessment of the like safety impact on their own territory of the nuclear installation.**

This section of the Report describes the relevant Euratom legal acts which affect the siting of a nuclear facility.

12.1. Description of the licensing process, including summary of laws, regulations and requirements relating to the siting of nuclear installations

Under Article 37 of the Euratom Treaty, the Community possesses competence as regards "any plan for the disposal of radioactive waste in whatever form" if the implementation of that plan is liable to result in the radioactive contamination of the water, soil or airspace of another Member State. That fact provides sufficient grounds to conclude that Euratom possesses competence in the field covered by Article 17 of the Convention.¹²⁵

Article 44 of the Council Directive 96/29/Euratom provides that: "Operational protection of the population in normal circumstances from practices subject to prior authorization means all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation involving exposure to ionizing radiation, are liable to create a risk of exposure for the population which cannot be disregarded from the radiation protection point of view. Such protection shall include the following tasks:

¹²⁵ Judgment of the Court of 10 December 2002, *Commission of the European Communities v Council of the European Union*, C-29/99, ECLI:EU:C:2002:734.

(a) examination and approval of plans for installations involving an exposure risk, and of the proposed siting of such installations within the territory concerned, from the point of view of radiation protection;

(b) acceptance into service of such new installations subject to adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter, taking into account, if relevant, demographic, meteorological, geological, hydrological and ecological conditions;

(c) examination and approval of plans for the discharge of radioactive effluents.

These tasks shall be carried out in accordance with rules laid down by the competent authorities on the basis of the extent of the exposure risk involved."

More or less the same requirements are included in article 65 of the revised Basic Safety Standards Directive, as already mentioned.

The amended Nuclear Safety Directive contains only a reference to the licence holder's responsibility for siting, by defining the term "licence" as "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" (Art. 3(4) of Directive 2009/87/Euratom). In addition, Article 6(2) sets up a general obligation for licensees: "Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess, verify and continuously improve, as far as reasonably achievable, the safety of their nuclear installations in a systematic and verifiable manner. ***That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence- in-depth provisions;***"

Furthermore, under the Directive, a high level safety objective has been introduced covering all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning), with the aim of preventing accidents and, should an accident occur, mitigating its consequences and avoiding early and large radioactive releases. 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.

12.1.1. Criteria for evaluating all site-related factors affecting safety

There are no detailed applicable Euratom legal acts currently in force which set out criteria for the siting of nuclear installations. The siting of a nuclear installation necessarily includes taking into account factors relating to radiation protection, such as the demographic characteristics of the site. It is apparent that Article 17(ii) of the Convention relates to those factors.

12.1.2. Criteria for evaluating the nuclear safety impact of the nuclear installations on the surrounding environment and population:

Not applicable

12.2. Implementing provisions for fulfilment of the above mentioned criteria

Not applicable

12.3. Activities relating to maintenance of the continued safety acceptability of the nuclear installation, taking account of site-related factors

Not applicable

12.4. International arrangements, including those with neighbouring countries, as necessary

Not applicable

13. ARTICLE 18 – DESIGN AND CONSTRUCTION

Article 18: Each Contracting Party shall take the appropriate steps to ensure that:

(a) The design and construction of a nuclear installation provides for several reliable levels and methods of protection (defence in depth) against the release of radioactive materials, with a view to preventing the occurrence of accidents and to mitigating their radiological consequences should they occur;

(b) The technologies incorporated in the design and construction of a nuclear installation are proven by experience or qualified by testing or analysis;

(c) The design of a nuclear installation allows for reliable, stable and easily manageable operation, with specific consideration of human factors and the man-machine interface.

This section of the Report describes the relevant Euratom legal acts which affect the design, construction and operation of a nuclear facility.

In this regard there are no detailed Euratom legal acts currently in force. The design, construction and operation of nuclear installations lie within the competence of the national authorities. However, in its Judgement of 10 December 2002 the Court held that "*the measures required by Articles 18 and 19 of the Convention concerning the design, construction and operation of nuclear installations can be the subject of the provisions which the Member States lay down to ensure, in accordance with the first paragraph of Article 33 of the Euratom Treaty, compliance with the basic standards. However, the Commission has competence to make recommendations for harmonising those provisions, as is clear from the second paragraph of Article 33 of the Euratom Treaty, interpreted in the light of the considerations set out in paragraphs 75 to 83 of the present judgment. The Member States are required to assist in drawing up those recommendations through the communications referred to in the third paragraph of Article 33 of the Euratom Treaty*"¹²⁶.

¹²⁶ Judgment of the Court of 10 December 2002, *Commission of the European Communities v Council of the European Union*, C-29/99, ECLI:EU:C:2002:734, para. 105.

Corresponding to Article 18 (1) of the Convention on Nuclear Safety, the amended Nuclear Safety Directive provides in Article 6(c) that *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. This shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions.*

Furthermore, under the Directive, a high level safety objective has been introduced covering all stages of the lifecycle of nuclear installations (including design and construction), with the aim of preventing accidents and, should an accident occur, mitigating its consequences and avoiding early and large radioactive releases. 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. This objective shall also be used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the scope of periodic safety reviews.

Article 37 of the Euratom Treaty and its practical implementation as laid down in Commission Recommendation 2010/635/Euratom does directly affect national nuclear licensing processes.

Article 37 provides that "Each Member State shall provide the Commission with such general data relating to any plan for the disposal of radioactive waste in whatever form as will make it possible to determine whether the implementation of such plan is liable to result in the radioactive contamination of the water, soil or airspace of another Member State." and that "The Commission shall deliver their opinions on planned disposal of radioactive waste within six months, after consulting the group of experts referred to in Article 31."

The "disposal of radioactive waste" within the meaning of Article 37 covers any planned or accidental release into the environment of gaseous, liquid or solid radioactive substances.

The Member State should submit general data to the Commission whenever possible one year but not less than six months before the intended granting of a radioactive waste discharge authorisation or, before the intended start-up of a nuclear operation for which no such authorisation is foreseen. The Member State is not entitled to grant the discharge authorisation (or the start-up of an operation for which no such authorisation is foreseen) without the Commission having delivered its opinion on the submitted general data.

Commission opinions, since Article 37 is part of Chapter III of the Euratom Treaty on "Health and Safety", are in essence statements about the significance from the point of view of health of potential radioactive contaminations of the water, soil or airspace of another Member State (the potential trans-boundary radiological health impact of planned operations).

A non-binding Commission opinion under Article 37 is formally notified to the submitting Member State and is published in the Official Journal of the European Union. *In the years 2010-2015, the Commission delivered sixty-four opinions. It is noteworthy that the opinions delivered are increasingly concerned with decommissioning and dismantling plans as well as radioactive waste management plans.*

The Commission periodically reports to Council and European Parliament on the application of Article 37 of the Euratom Treaty. The latest such document, covering the period from January 2004 to December 2012, was issued on 12 June 2013 (SWD(2013)216 final)¹²⁷.

14. ARTICLE 19 – OPERATION

Article 19: Each Contracting Party shall take the appropriate steps to ensure that:

- a) The initial authorisation to operate a nuclear installation is based upon an appropriate safety analysis and a commissioning programme demonstrating that the installation, as constructed, is consistent with design and safety requirements;**
- b) Operational limits and conditions derived from the safety analysis, tests and 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 accidents;**
- e) Necessary engineering and technical support in all safety related fields is available throughout the lifetime of a nuclear installation;**
- f) Incidents significant to safety are reported in a timely manner by the holder of the relevant licence to the regulatory body**
- g) Programmes to collect and analyse operating experience are established, the results obtained and the conclusions drawn are acted upon and that existing mechanisms are used to share important experience with international bodies and with other operating organisations and regulatory bodies;**
- h) The generation of radioactive waste resulting from the operation of a nuclear installation is kept to the minimum practicable for the process concerned, both in activity and in volume, and any necessary treatment and storage of spent fuel and waste directly related to the operation and on the same site as that of the nuclear installation take into consideration conditioning and disposal.**

The design, construction and operation of nuclear installations lie within the competence of the national authorities. However, in its Judgement of 10 December 2002 the Court ruled that "the measures required by Articles 18 and 19 of the Convention concerning the design, construction and operation of nuclear installations can be the subject of the provisions which the Member States lay down to ensure, in accordance with the first paragraph of Article 33 of the Euratom Treaty, compliance with the basic standards. However, the Commission has competence to

¹²⁷ https://ec.europa.eu/energy/sites/ener/files/documents/2013_cswd.pdf.

make recommendations for harmonising those provisions, as is clear from the second paragraph of Article 33 of the Euratom Treaty, interpreted in the light of the considerations set out in paragraphs 75 to 83 of the present judgment. The Member States are required to assist in drawing up those recommendations through the communications referred to in the third paragraph of Article 33 of the Euratom Treaty"¹²⁸.

Under the amended Nuclear Safety Directive, when applying for a licence, including for operation, the applicant is required to submit a demonstration of nuclear safety, the scope and detail commensurate with the potential magnitude and nature of the hazard (Article 6b). Licence holders are also required to regularly assess, verify, and continuously improve in a systematic and verifiable manner the nuclear safety of their nuclear installations. This shall include verification that defence in depth provisions are applied and that measures are in place for the prevention of accidents and mitigation of the consequences (Article 6c).

Under the amended Nuclear Safety Directive, a high level safety objective has been introduced covering all stages of the lifecycle of nuclear installations (including operation), with the aim of preventing accidents and, should an accident occur, mitigating its consequences and avoiding early and large radioactive releases. 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. This objective shall also be used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the scope of periodic safety reviews.

This provision also corresponds to the Article 4(2) of the amended Nuclear Safety Directive. Results of operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant should be used by Member States for updating and improving their national nuclear safety framework.

¹²⁸ Judgment of the Court of 10 December 2002, *Commission of the European Communities v Council of the European Union*, C-29/99, ECLI:EU:C:2002:734, 102-103.

“Declaration by the European Atomic Energy Community pursuant to Article 30 paragraph 4 (iii) of the Nuclear Safety Convention”

The following States are at present members of the European Atomic Energy Community: the Kingdom of Belgium, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, the Hellenic Republic, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland.

The Community declares that Articles 1 to 5, Article 7 and Articles 14 to 35 of the Convention apply to it.

The Community possesses competences, shared with the abovementioned Member States, in the fields covered by Article 7 and Articles 14 to 19 of the Convention as provided for by the Treaty establishing the European Atomic Energy Community in Article 2(b) and the relevant Articles of Title II, Chapter 3, entitled "Health and Safety".

Rapporteur's' Report for EURATOM of 25 March 2014 in the 6th Review Meeting under the Convention on Nuclear Safety

(1) Challenges

- *Build on the experience of the stress tests to further promote harmonization of safety approaches in Europe through cooperation on specific subjects including peer reviews.*
- *Continue the dialogue with IAEA and WANO to ensure that the addition of new peer review activities does not duplicate peer review activities from the other organisations.*
- *Complete the legislative follow-up activities related to the Fukushima lessons.*

(2) Good Practices

- *No good practices were identified.*
- *A good initiative that Euratom is exploring a recurring peer review process that is based upon the stress tests and includes design issues.*
- *The new nuclear decommissioning assistance programs and the new instrument for international nuclear safety cooperation are good initiatives.*

(3) Suggestions

- *Provide an update on the new, targeted Euratom peer review process during the 7th CNS [Review Meeting] and include a discussion on the resource impact.*
- *Provide an update on legislative activities related to Fukushima lessons.*

List of the *acquis* on the basis of the Euratom Treaty
(new legal instruments in ***bold italics***)

1. Nuclear Safety

Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, Official Journal L 172, 2.7.2009.

As amended by:

Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

2. Radioactive Waste

Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, OJ L 199 of 2.8.2011, p. 48–56.

3. Radiation protection

Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption, Official Journal L 296, 7.11.2013, p. 12–21

Commission Recommendation 2010/635/Euratom of 11 October 2010 on the application of Article 37 of the Euratom Treaty, Official Journal L-279 of 11.10.2010, p. 36.

Communication 2006/C/155/02 from the Commission *on Verification of environmental radioactivity monitoring facilities under the terms of Article 35 of the Euratom Treaty — Practical arrangements for the conduct of verification visits in Member States*, Official Journal C-155 of 4 July 2006, page 2.

Commission Recommendation 2004/2/Euratom of 18 December 2003 *on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation*, Official Journal L-002 of 6.1.2004 page 36.

Commission Recommendation 2000/473/Euratom of 8 June 2000 *on the application of Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole*, Official Journal L-191 of 27.7.2000, page 37.

Commission Recommendation 91/444/Euratom of 26 July 1991 *on the application of the third and fourth paragraphs of Article 33 of the Euratom Treaty*, Official Journal L-238 of 27.8.1991 page 31.

4. Basic Safety Standards

Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal L13, 17.1.2014, pages 1 - 73)

Council Directive 96/29/Euratom of 13 May 1996 *laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation*, Official Journal L-159 of 29 June 1996, page 1, repealing and replacing Council Directive 80/836/Euratom of 15 July 1980, OJ L-246 of 17 September 1980, page 1, and Council Directive 84/467/Euratom of 3 September 1984, OJ L-265 of 5.10.1984 page 4.

Communication 98/C133/03 *from the Commission concerning the implementation of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation*, Official Journal C-133 of 30.4.1998 p. 3.

5. Outside workers

Council Directive 90/641/Euratom of 4 December 1990 *on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas*, Official Journal L-349 of 13.12.1990 page 21.

6. Information

Commission Communication 91/C103/03 *on the implementation of Council Directive 89/618/Euratom*, Official Journal C-103 of 19.4.1991 page 12.

Council Directive 89/618/Euratom of 27 November 1989 *on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency*, Official Journal L-357 of 7.12.1989 page 31.

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*, Official Journal L-371 of 30.12.1987 page 76.

7. Contamination of foodstuffs and feeding stuffs - Post-Chernobyl

Commission Regulation (EC) No 1635/2006 of 6 November 2006 *laying down detailed rules for the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station*, Official Journal L-306 of 7.11.2006 page 3.

Commission Recommendation (EC) No 274/2003 of 14 April 2003 *on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the*

Chernobyl nuclear power station, Official Journal L-99 of 17.4.2003 page 55, amended by corrigendum published in Official Journal L-109 of 1.5.2003 page 27.

Commission Regulation No 1609/2000/EC of 24 July 2000 *establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station*, Official Journal L-185 of 25.7.2000, page 27.

Council Regulation (EC) No 1048/2009 of 23 October 2009 amending Regulation (EC) No 733/2008 *on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station*, Official Journal L-290 of 6.11.2009, page 4.

Council Regulation (EC) No 733/2008 of 15 July 2008 *on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station* (codified version), Official Journal L-201 of 30.07.2008, page 1.

8. Future accidents

Council Regulation (Euratom) 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90, Official Journal L 13, 20.1.2016, pages 2–11).

Council Regulation No 2219/89/EEC of 18 July 1989 *on the special conditions for exporting foodstuffs and feeding stuffs following a nuclear accident or any other case of radiological emergency*, Official Journal L-211 of 22.7.1989 page 4.

9. Shipments of radioactive waste and substances

Council Directive 2006/117/Euratom of 20 November 2006 *on the supervision and control of shipments of radioactive waste and spent fuel between Member States and into and out of the Community*; Official Journal L-337 of 5.12.2006 page 21.

Council Regulation No. 1493/93/Euratom of 8 June 1993 *on shipments of radioactive substances between Member States*, Official Journal L-148 of 19.6.1993 page 1.

Commission Communication 2009/C41/02 concerning Council Regulation (Euratom) No 1493/93 on shipments of radioactive substances between Member States, Official Journal C 41 of 19.2.2009, page 2.

10. Control of radioactive sources

Council Directive 2003/122/Euratom of 22 December 2003 *on the control of high-activity sealed radioactive sources and orphan sources*, Official Journal L 346, 31.12.2003 pages 57–64.

11. Safeguards

Commission Regulation (Euratom) No 302/2005 of 8 February 2005 *on the application of Euratom safeguards*, in: O.J. L 54 of 28 February 2005, page 1 – 70.

Commission Recommendation of 15 December 2005 *on guidelines for the application of Regulation (Euratom) No 302/2005 on the application of Euratom safeguards*, in: O.J. L28 of 1 February 2006, pages 1 – 85.

12. Euratom Supply Agency

Council Decision of 12 February 2008 *establishing Statutes for the Euratom Supply Agency* (2008/114/EC, Euratom), O.J. L 41 of 15 February 2008, pages 15 – 20, as amended by Council Regulation (EU) No 517/2013 of 13 May 2013 (O.J. L 158 of 10 June 2013, pages 1–71), namely the Annex thereof, under "8. Energy", point 2.

Commission Regulation (Euratom) No 66/2006 of 16 January 2006, exempting the transfer of small quantities of ores, source materials and special fissile materials from the rules of the Chapter on supplies (O.J. L 11 of 17 January 2006, pages 6-7).

Rules of the Supply Agency of the European Atomic Energy Community determining the manner in which demand is to be balanced against the supply of ores, source materials and special fissile materials (of 5 May 1960) (O.J. L No 32, 11.5.1960, p. 777 - English special edition Series I Volume 1959-1962, pages 46 - 47), as amended by the Regulation of the Supply Agency of the European Atomic Energy Community of 15 July 1975 (O.J. L 193, 25.7.1975, pages 37–38) [corrected, for the English version, by the Consolidated text of corrigenda to instruments published in Special Editions 1952-72, p. 3 (511/60)].

13. Euratom loans

Council decision 94/179/Euratom of 21 March 1994 amending decision 77/270/Euratom, to authorize the Commission to contract Euratom borrowings in order to contribute to the financing required for improving the degree of safety and efficiency of nuclear power stations in certain non-member countries, O.J. L 112, 3 May 1990, page 26.