Report of CEN-CENELEC Focus Group on nuclear energy

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Executive Summary

Following the Euratom Treaty signed in 1957, nuclear safety of Nuclear Power Plants (NPPs) was situated outside the European competences. Till the end of the 90s, the European Standardization System was de facto aligned on that legal situation and no European standards (ENs) were published.

From 2000 onwards, the situation started changing. WENRA (Western European Nuclear Regulator Association) started its activities and published in 2007 its Safety Reference Levels (SRLs) for operating plants. Following the debate triggered by the publication of the SRLs for operating plants, the CENELEC Technical Board decided in 2007 to activate two CENELEC Technical Committees to produce ENs in the domains of Instrumentation and control of nuclear facilities and of Radiation protection instrumentation. The EU adopted in Council Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations and the Council Directive 2011/70/ EURATOM establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste which complemented the existing legal body on radiation protection.

The above mentioned CEN-CENELEC arrangements only cover the activity areas of sub-committees IEC/SC45A and IEC/SC45B of IEC Technical Committee 45 (IEC/TC45; Nuclear instrumentation) and do not cover the activities in ISO Technical Committee 85 (ISO/TC85; Nuclear energy, nuclear technologies, and radiological protection). This is why the CEN and CENELEC Technical Boards commissioned a report to look into standardization needs for Europe covering the entire nuclear energy production chain and the entire lifecycle of the Nuclear Power Plant.

The report starts by presenting a comprehensive view of the context faced. Information is given concerning the position of nuclear energy in Europe, in a wider international context. The framework of standardization in the nuclear energy sector is described going back in time in order to better understand the current situation. The difference in standardization needs among the stakeholders is touched upon and the support to the efforts currently made at international level towards the harmonisation of standards and associated documents is highlighted.

The information gathered through a questionnaire process during the 1st quarter of 2012 regarding the utilization of nuclear standards in the field of Nuclear energy as well as regarding the utilization of general standards in a nuclear energy context is presented in a summarised form.

Following the analysis of the nuclear energy standardization framework, the report expresses a clear preference for technical standardization activities to take place at the international level, but also recommends that a justified selection of those international standards should become European standards in order to contribute to the harmonisation of nuclear safety and radiological protection in Europe.

This is expressed in a more explicit and formalised wording in the report's recommendations 1 to 4 that are made to the standardization community.

Recommendation 1 recognizes that CENELEC already has a suitable process through its Technical Committees CLC/TC45AX and CLC/TC45B since 2007.

Recommendation 2 confirms the primacy of international standardization in the nuclear energy field and stresses the need for a sufficient European experts participation in the relevant TCs in ISO and IEC to pursue the development of the required standards, both international and European Standards.

Recommendation 3 recommends that for the adoption of selected international standards in the nuclear energy field to become European standards, a process is followed in CEN that is functionally similar to the one in CLC/TC45AX.

Recommendation 4 recognizes the use of standards coming from outside the nuclear energy field in nuclear energy applications and recommends existing and future nuclear TCs to produce at the international level nuclear standards providing guidance on the application of relevant standards from outside the nuclear energy field in the nuclear energy domain.

Recommendation 5 encourages the input from research and development projects in Europe into international standardization.

Recommendation 6 expresses support for initiatives such as the continuation of the "Europeanization" process started in the CEN Workshop 64 “Design and Construction code for mechanical equipment of innovative nuclear installations".

A rationale in support of the above recommendations is presented in the final sections of the report. References are made to the information collected through the questionnaire process, which data are given in more detail in the report's annexes.

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1 - Introduction

Till the end of the 90s, the European Standardization System took into account that there was no explicit European legal framework for nuclear safety and no European standards (ENs) were published in this field. During the 90s, the only major technical harmonisation activity in Europe was the development by the European electricity generation companies of a common specification for generation III plants, the EUR.

From 2000 onwards, the situation started changing. WENRA (Western European Nuclear Regulator Association) started its activities publishing in 2007 its Safety Reference Levels (SRLs). This effort did continue with the publication of SRLs for decommissioning and waste management. Publication of SRLs for geological disposal is underway.

Following the debate triggered by the publication of SRLs for operating plants, CENELEC BT decided in 2007 to activate CLC/TC45AX (CENELEC Technical Committee 45AX (Instrumentation and control of nuclear facilities)) and CLC/TC45B (CENELEC Technical Committee 45B (Radiation protection instrumentation)) to produce EN standards on their respective domains. At the same time, other European initiatives took place like the European Technical Safety Organization Network (ETSON), SNETP – ESNII and Nugenia.

Noting that the above arrangements only cover the activity areas of IEC/SC45A and B, but do not cover the activities in ISO/TC 85 (Nuclear energy, nuclear technologies, and radiological protection), European stakeholders came together on 13 September 2010 to discuss European needs in the area of nuclear energy standardization and to reflect on possible actions through CEN and CENELEC.

The results of this meeting led to the proposal to create a short term group (the CEN-CENELEC Focus Group on nuclear energy) tasked to prepare an overview on suitable standards already publicly available (from ISO, IEC, CEN and CENELEC or other sources) or in preparation, to meet specific needs for products and services in the nuclear sector, and to propose to both the CEN and CENELEC Technical Board (BT) a set of recommendations for standardization work where no suitable standards exist.

The Focus Group collected its information using a questionnaire issued on 7 February and requesting responses by 16 April 2012. The recommendations in this report follow from a discussion in the Focus Group of the information collected.

Focus Group plenary meetings took place on:

- 16 November 2011
- 30 May 2012
- 14 November 2012

In this document the definitions used for the terms “standard” and “European standard” are those of CEN/CENELEC Internal Regulations part 3. These definitions originating from ISO/IEC were used to prepare definitions in official European texts (e.g. 93/38/EEC, 83/189/EEC or 2004/17/EC) but other documents often associated or assimilated to standards exist, e.g. “Codes”, “Rules”.

Nuclear standards are those produced by IEC (IEC/TC45, IEC/SC 45A, IEC/SC45B) and ISO (ISO/TC 85, SC2, SC5, SC6 and ISO/TC 147 SC3).

2 - Nuclear Energy field seen from a standardization perspective

2.1 Nuclear energy in Europe and the need for Standardization

Nuclear has a key role to play in solving European energy problems. Today 138 nuclear power reactors are operated in Europe producing one third of the European electricity.

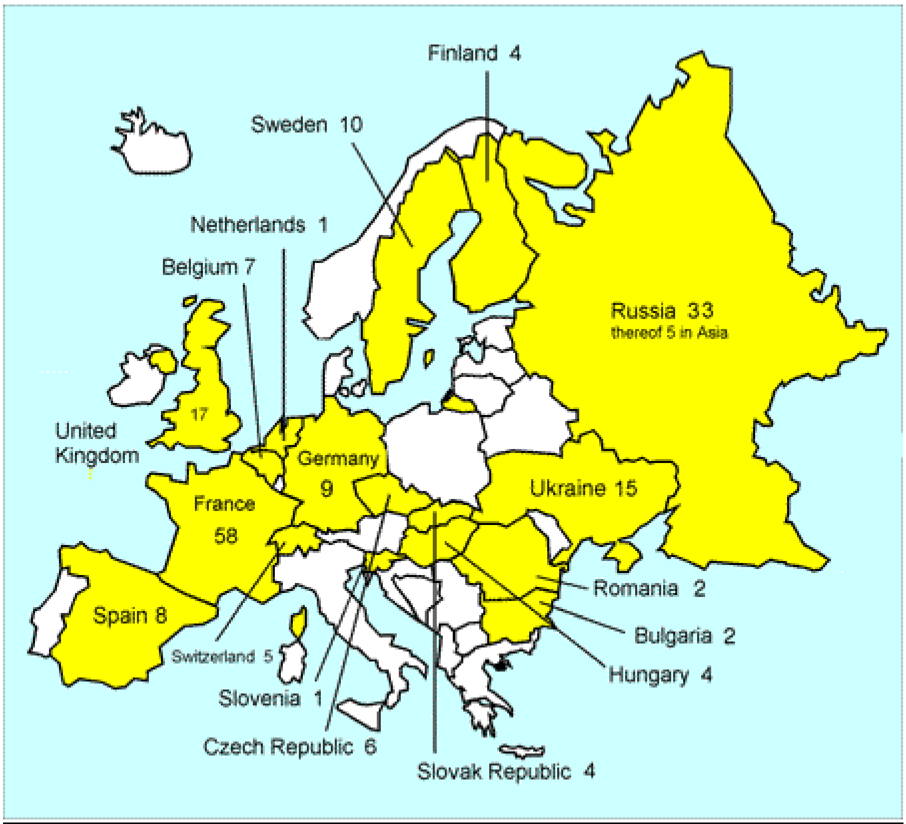

Figure 1 - operating nuclear power reactors in Europe

In Figure 1 there is shown the number of operating nuclear power reactors in Europe. The construction of 2 new EPR-type reactors in Finland and in France and one VVER type reactor in Russia are underway and preparations for building new nuclear power reactors are also taking place in Finland, United Kingdom, Czech Republic, Sweden and Turkey. In addition to operating plants standards are also needed for the 77 reactors in decommissioning and for waste management. Characterization and waste conditioning have an international market.

After the March 2011 Fukushima events, national regulators and the EU initiated a process of safety and risk assessments of NPPs (the so-called stress tests). At the same time some European countries decided to shutdown their old nuclear power reactors or took the path of disengagement from nuclear energy. This means that the number of nuclear installations in decommissioning will increase in the near future as well as the waste management needs.

In this situation, with a large number of reactors in operation, many of which can be expected to move gradually into "Long Term Operation[1]" and the licensing and construction of new reactors, questions about increased standardization are also raised within the European nuclear sector.

The need for standardization, and preferably international, has increased over the years. The infrastructure of the current nuclear power plants is different today compared to the situation when they were designed, constructed and began to operate. There are significantly fewer manufacturers and suppliers, both nationally, regionally and internationally, which are specifically focusing on components and equipment for nuclear activities. It is often difficult and costly for manufacturers and suppliers to enter into the nuclear market since the global scene is relatively small, safety requirements may vary from country to country and quality requirements are usually stricter than in many other industry sectors in the society. This means that manufacturers and suppliers have a strong interest in standardized designs, products and solutions. The same applies to nuclear power licensees who try to buy products and services.

In Europe and other countries different regulatory approaches are applied. Even if various activities to harmonise safety requirements have been initiated over the recent year’s different regulatory regimes exist, both for historical and cultural reasons. In several countries, there is a tradition to apply approaches which focus on the prescriptive element while regulators in other countries use combinations which focus on goal-setting, outcome-based or other approaches.

In a prescriptive approach, the regulator establishes relatively detailed requirements for functions and properties of systems, components and structures in a plant. A prescriptive approach can also include relatively detailed requirements for conducting specific activities. In this type of regulatory regime, the regulatory body may refer in their guides to the standards as a way to meet safety requirements.

[1] With Long Term Operation, LTO, is meant that operation continues beyond the period initially in the design of the plant.

In a goal-setting non-prescriptive approach, the regulator establishes specific goals or outcomes for licensees to attain but does not specify how licensees attain these goals. In this type of regulatory regime, well-developed standards can be even more important elements because the licensee may chose to use them in support of its safety case.

2.2 European directives and the standardization in the nuclear energy sector

The Euratom Treaty signed in 1957 made no reference to safety of NPPs but covered workers and all general public radiation protection. There have indeed been directives on radiation protection since 1959. The current 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 ionizing radiation, was issued in 1996. At the time of writing this report [November 2012], the Directive is under revision due to the publication of the IAEA (International Atomic Energy Agency) GSR (General Safety Requirements) Part 3 (Basic Safety Standard (BSS)) in 2011.

In this context, from the early 60's to the late 90's, the European standardization system was de facto in line with this interpretation of the Treaty and no European standards on nuclear safety were published.

WENRA (Western European Nuclear Regulator Association) started its activities in 1999. This association is a network of chief nuclear safety regulators of the countries with nuclear installations within the EU and Switzerland and observers of other interested countries. The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to review nuclear safety in applicant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues.

After establishing WENRA, two working groups were launched to harmonise safety approaches between countries in Europe - Reactor Harmonisation Working Group (RHWG) and Working Group on Waste and Decommissioning (WGWD). The aim was to continuously improve safety and to reduce unnecessary differences between the countries.

In 2000, as the situation changed, a debate was launched between the representatives of the European National Committees of IEC/SC45A (International Electrotechnical Commission, Sub-Committee 45A (Instrumentation and control of nuclear facilities)) to envisage the possibility to produce European standards related to safety of NPPs. The debate concluded that the development of European standards related to safety of NPPs was premature, but it triggered the development of standards related to radiation protection for workers using published IEC/SC45B (International Electrotechnical Commission, Sub-Committee 45B (Radiation protection instrumentation)) standards.

In 2002, the European Court of Justice (ECJ) clarified in Case 29/99 that the Community shares competences with Member States in respect of nuclear safety as well as radiation protection.

From 2003 till 2007, a task force of CENELEC prepared the endorsement of IEC/SC45B standards on a case by case basis and developed in some cases CMs (Common Modifications) for the standard to be endorsed. 13 European Standards (ENs) based on IEC/SC45B standards were published.

In 2007, WENRA published its Safety Reference Levels for plants in operation. These WENRA reference levels for existing power plants do not have any legal status but the Regulators agreed to use them for their national activities. This process is currently in progress. However, WENRA reference levels represent common understanding shared by nuclear safety regulators in Europe and can serve as a reference to develop nuclear safety standards.

The publication of these WENRA Safety Reference Levels launched again the debate between the representatives of the European National Committees of IEC/SC45A on the possibility of the development of European standards related to the safety of NPPs. A survey was ordered by CENELEC on the use and penetration of IEC/SC45A standards in Europe. On the basis of that report, CENELEC BT decided end 2007 to activate CLC/TC45AX (CENELEC Technical Committee 45AX (Instrumentation and control of nuclear facilities)) and CLC/TC45B (CENELEC Technical Committee 45B (Radiation protection instrumentation)) to produce European Standards (ENs) in their respective areas.

In 2009, the Council Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations was issued. The Directive refers in the preface and justification to relevant fundamental safety principles set by the IAEA as well as to the Safety Reference Levels defined by WENRA. In 2011, the Council Directive 2011/70/ EURATOM establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste was issued.

In 2010, WENRA started working on safety objectives for new power plants. In 2011, the waste and spent fuel storage Safety Reference Levels were published. In 2012, the goal is to publish the report on safety of new NPP designs including position papers on essential topics and the Safety Reference Levels for waste final disposal.

From 2007 to 2012, CLC/TC45AX published 10 ENs which correspond to non-modified IEC/SC45A standards, which are consistent with the IAEA safety principles and terminology. Up to 2012, CLC/TC45B published 17 ENs based on IEC/TC45 and IEC/SC45B standards integrating Common Modifications; this last figure includes the 13 ENs published prior to the CLC/TC45B activation.

2.3 Current context of standardization in the sector of nuclear energy in Europe

2.3.1 Existing organisations producing European or International nuclear standards and use of those standards in Europe

2.3.1.1 International organisations and documents

The international organisations considered here are:

- IAEA (International Atomic Energy Agency) which is part of the United Nations Organization,
- the international counterparts of the European Standards Organizations (ESOs), namely ISO (for CEN), IEC (for CENELEC) and ITU-T (for ETSI). For the nuclear sector, only ISO and IEC are relevant.

a) IAEA (International Atomic Energy Agency)

IAEA covers globally nuclear energy for peaceful purposes. In particular, IAEA develops nuclear safety standards to promote the achievement and maintenance of high levels of safety in applications of nuclear energy, as well as the protection of human health and the environment against ionising radiation. The IAEA safety standards are non-binding.

In1981 a cooperation agreement was signed between IAEA and IEC/TC45. In the same year a memorandum of understanding was signed between IAEA and ISO.

More information on the IAEA document series is available on the IAEA web site: http://www.iaea.org/.

b) IEC (International Electrotechnical Commission)

In IEC, the technical committee related to the nuclear sector is TC45 (Nuclear Instrumentation) with its two subcommittees SC45A (Instrumentation and control of nuclear facilities) and SC45B (Radiation protection instrumentation).

IEC/TC45 prepares international standards relating to electrical and electronic equipment and systems for instrumentation specific to nuclear applications.

IEC/SC45A prepares standards applicable to the electronic and electrical functions and associated systems and equipment used in the instrumentation and control systems (I&C) of nuclear energy generation facilities (Nuclear Power Plants, fuel handling and processing plants, interim and final repositories for spent fuel and nuclear waste) to improve the efficiency and safety of nuclear energy generation. Those standards cover the entire lifecycle of these I&C systems, from conception, through design, manufacture, test, installation, commissioning, operation, maintenance, aging management and modernization to decommissioning. In this context, one of the IEC/SC45A strategic tasks is to review and comment on drafts of IAEA safety requirements in order to maintain consistency between IAEA and IEC documents and identify detailed technical aspects for which IEC standard developments are appropriate and responsive to the market needs.

IEC/SC45B prepares standards covering all fields of radiation protection instrumentation: That is instrumentation used for the measurement of ionising radiation in the workplace, to the public and in the environment for radiation protection purposes. IEC/SC45B addresses also instrumentation used for the illicit trafficking detection and identification of radionuclides and for radiation-based security screening.

The IEC/TC45, IEC/SC45A and IEC/SC45B portfolios comprise respectively 37, 68 and 51 published standards. More information on this committee, these sub committees and the documents they published can be found on the IEC website:
http://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID,FSP_LANG_ID:1244,25

c) ISO (International Standard Organization)

In ISO, the technical committees related to the nuclear sector are ISO/TC85 (nuclear energy, nuclear technologies, and radiological protection) and ISO/TC147/SC3 (water quality, radiological methods).

ISO/TC85 prepares standards in the field of peaceful applications of nuclear energy, nuclear technologies and in the field of the protection of individuals and the environment against all sources of ionising radiations. ISO/TC85 comprises 3 sub committees: SC2 (radiological protection), SC5 (nuclear fuel cycle) and SC6 (reactor technology) and 3 working groups: WG1 (Terminology, definitions, units and symbols), WG3 (Dosimetry for radiation processing) and an Ad-hoc group addressing conformity assessment and management systems standards.

ISO/TC85/SC2 (radiological protection) prepares standards in the field of the protection of individuals (workers, patients, members of the public) and the environment against all sources of ionising radiations in planned, existing or emergency exposure situations linked to nuclear activities, medical activities, industrial activities, research activities and natural radiation sources.

ISO/TC85/SC5 (nuclear fuel cycle) prepares standards in the field of waste management and decommissioning activities (e.g. characterisation (waste, fuel, MOX pellets…), standardization related to criticality safety, transport).

ISO/TC85/SC6 (reactor technology) prepares standards about analysis and measurements dedicated to the safe and efficient operation of nuclear power reactors, standards concerning the safe and efficient operation of research reactors) and the irradiation services from research reactors, standards including reliability data for nuclear power reactors and research reactors, and data related to nuclear power reactor lifetime extension.

The ISO/TC85, ISO/TC85/SC2, ISO/TC85/SC5 and ISO/TC85/SC6 portfolios comprise respectively 27, 66, 65 and 6 published standards. More information on this committee, its sub committees and the documents they published can be found on the ISO website: http://www.iso.org/iso/iso_technical_committee?commid=50266

ISO/TC147 prepares standards in the field of water quality, including the definition of terms, sampling of waters, measurement and reporting of water characteristics; the topic of limits of acceptability of water quality is out of scope. ISO/TC147/SC3 covers radiological methods. In the past, SC3 had been closed due to a lack of interest of the participating members, but in 2011 SC3 was reactivated to deal with the formerly standardised methods on radiological investigation and their updating to the state of the art. The necessity for new standards in this field is acknowledged and 9 projects of standard development are currently ongoing.

The ISO/TC147/SC3 portfolio comprises 8 published standards; more information on this subcommittee and the documents it published can be found on the ISO website: http://www.iso.org/iso/iso_technical_committee?commid=52932

d) Other "standard" organisations publishing documents for the nuclear energy sector

Some national standard organisations are acting at the international level; this is in particular the case for US organisations like ASME, IEEE or ISA. These organisations which are very powerful and are acting worldwide are listed among the 280 Accredited Standard Developers of the American National Standards Institute (ANSI). Indeed, ANSI does not itself develop standards but accredits standards developing organisations to create and maintain American National Standards (ANS). The most important point to be taken into account concerning the nuclear sector is that their basic framework reference is the US regulatory framework which for some aspects is different from the reference in Europe. The US regulator makes for instance a reference to ASME documents, published as ANSI standards.

The nuclear industry makes frequent use of IEEE and ASME documents. More information concerning the issue of penetration of the US standards can be found in the EXPRESS report[2].

In Europe, some organisations are publishing nuclear documents which are used for some NPPs and which have relationships with International or European standards (i.e. referencing ISO and EN standards), but can also potentially conflict with these standards on some particular issues: AFCEN in France and KTA (Kerntechnischer Ausschuss) in Germany.

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[2] The report by The Expert Panel for the Review of the European Standardisation System (EXPRESS) is available at http://ec.europa.eu/enterprise/express

In addition, European and international committees also produce generic standards used in nuclear energy applications in particular in the fields of management systems, mechanical components and equipments, civil structures, electrotechnologies, information technologies and security.

Finally, we can also mention other organisations (e.g. OECD/NEA - CNRA and CSNI, EPRI in the US, JRC in Europe) preparing technical reports which can reflect different levels of consensus and could be used as a basis for developing pre-normative documents or even standards in some particular cases.

2.3.1.2 Nuclear energy sector coverage by ESOs and nuclear European standards

For the time being, the only European standards for nuclear energy are the 10 ENs published by CLC/TC45AX and the 17 ENs published by CLC/TC45B.

Concerning water quality, CEN/TC 230 "Water analysis" is operational at European level and endorses some of the standards published by ISO/TC147. Historically, emphasis has been in ISO/TC 147 on the environmental aspect, that is water quality control in respect to surface water (rivers, streams, lakes, reservoirs, seas), ground water, and precipitation. But quality control of water intended for human consumption or for other purposes such as suitability for industrial processing or for recreation also plays a great role.

Whenever methods are needed in CEN/TC230, it is decided whether the methods should be elaborated under ISO or CEN lead. Special attention is given to all work related to the European Water Framework Directive (Directive's aim is to get polluted waters clean again and to ensure clean waters are kept clean). It is important to note here that no request for endorsement as EN of the standards published by ISO/TC147/SC3 was ever made.

Concerning the utilization of existing nuclear standards in the field of Nuclear energy - standards coming from IEC (IEC/TC45, IEC/SC 45A, IEC/SC45B) and ISO (ISO/TC 85, SC2, SC5, SC6 and ISO/TC 147 SC3) - a series of questions were included in the questionnaire circulated by the CEN/CENELEC focus group (2012/Q1) to evaluate their use and penetration in the European nuclear industry sector. For this particular series of questions answers were sent back from12 European countries on which national territories 112 nuclear power reactors are operated. So 138 nuclear power reactors being operated in Europe, the results of the analysis of those answers are representative of 81% of nuclear power reactors operated in Europe. The questionnaire was not returned by Spain and Czech Republic which both have operating nuclear power plants.

The first set of questions also reviewed the other nuclear standards and information on the conflicting requirements between the different families of standards. The summary of the answers is given in the Table below.

Country	Q 1A Reference to nuclear standards in your Nuclear Energy legal texts (binding regulations)?	Question 1-B References to nuclear standards in your Nuclear Energy regulatory guides (= non binding regulations)?	Question 1C References to nuclear standards in your regulatory activities not specified by regulation	Question 1D References to nuclear standards in your commercial or industrial activities?	Question 1E References to foreign national nuclear standards in your country?	Question 1F Conflicts between national nuclear standards in Europe?
Belgium	No	No	Yes	Yes	Yes	No
Finland	No	Yes	Yes	Yes	Yes	Yes
France	Yes	Yes	Yes	Yes	Yes	Yes
Germany	No	Yes	Yes	Yes	No	No
Italy	No	No	Yes	Yes	Yes	Yes
Lithuania	Yes	Not relevant	Yes	No	No	No
Poland	No	Not relevant	No	No	No	No
Romania	No	Yes	Yes	No	No	No information available
Slovakia	No	Yes	Yes	Yes	Yes	No
Sweden	No	Yes	Yes	Yes	Yes	No
The Netherlands	No	No	Yes	Yes	No information available	No
Turkey		Not relevant	No	No	No	No
UK	No	No	Yes	Yes from the French answer to 45A questionnaire	No	Yes

The details of the analysis of those answers are as follows:

- The number of nuclear standards referenced in national binding regulations is very limited and restricted to some ISO/TC147 standards or ISO/TC85 standards to support national regulations in particular to those related to ADR European regulation.
- 6 countries (Finland, France, Germany, Romania, Slovakia, Sweden)) on which territories 87 nuclear power reactors are operated are indicating they are making references to nuclear standards in their non binding regulations. Concerning the nuclear ISO standards published by TCs not currently activated at European level, 3 countries (Finland, Germany, Romania) operating 15 nuclear power reactors are indicating they are referencing some of them in their non binding regulation.
- 11 countries (Belgium, Finland, France, Germany, Italy, Lithuania, Romania, Slovakia, Sweden, the Netherlands and the UK) on which national territories 112

nuclear power reactors are operated are stating that they are using nuclear standards which are not referenced in their non binding regulation in the frame of regulatory activities. Concerning the nuclear ISO standards published by TCs not currently activated at European level, 6 countries (Finland, France, Italy, Lithuania, Romania, Sweden) operating 74 nuclear power reactors are indicating they are using some of these standards which are not referenced in their non binding regulation in the frame of regulatory activities.

- 9 countries (Belgium, Finland, France, Germany, Italy, Slovakia, Sweden, the Netherlands and the UK) on which territories 110 nuclear power reactors are operated are indicating that nuclear standards are used in the frame of nuclear industrial activities. Concerning the nuclear ISO standards published by TCs not currently activated at European level, 3 countries (France, Germany, Italy) operating 67 nuclear power reactors are using some of them in the frame of nuclear industrial activities.
- 6 countries (Belgium, Finland, France, Italy, Slovakia, Sweden) on which territories 83 nuclear power reactors are operated are indicating they are using foreign nuclear national "standards", mainly US (ASME, ASTM, IEEE, ANSI), German (KTA) and French (RCC-M).
- 4 countries (Finland, France, Italy and the UK) on which territories 79 nuclear power reactors are operated are aware of conflicts between nuclear national "standards" used in Europe. It is important to note that IAEA documents are also cited for this question and that one of the root causes of these conflicts cited by 3 countries (Finland, France, Italy) is the issue of classification of functions and components.

2.3.2 Existing organisations producing European or International generic standards and use of those generic standards in the nuclear energy sector in Europe

The second set of questions reviewed the utilisation of industrial standards in the field of nuclear energy (e.g. IEC/TC65 “Industrial-process measurement, control and automation” standards or ISO/TC 184 “Automation systems and integration” standards, ISO/IEC 27000 series on information security, IEC 61000 series on electromagnetic compatibility, Eurocode ENs, etc.). The questions were answered by the national committees, some licensees and vendors. The scope of the questions is broad and within this report only some examples of the use of standards can be given. For further analysis of the issue a more comprehensive review would be needed. Nevertheless some general conclusions could be drawn from the answers:

- The overall scope of the responding organisations and national committees varies and is reflected in the answers. A first set of answers is from those active in the design and operation of nuclear power plants and related facilities. A second set of answers addresses the radiation protection specific to the use of nuclear energy or the radiological methods in laboratories.

- The macro environment of the use of nuclear energy and radiation protection is reflected in the answers. The national legislation and regulation as well as the national infrastructure varies and is reflected in the answers. However there are several similar industrial standards and standard series which are used in practice and are referenced in nuclear guides or rules (Eurocodes, welding, mechanical harmonised standards…), with complementing provisions (management, …) or where the verification and validation methods presented in the standard at chosen integrity level are applied. The risk assessment in the nuclear field is related to radiation and nuclear safety whereas in the industrial safety the risk assessment is made from the point of view of the work safety (IEC 61508).

The summary of the questions is presented in the Table below.

Country	2-A … preventing for certain domains of engineering (please specify) the use of industrial codes and standards coming from outside the nuclear energy field?	2-B. Do you use reference to standards applied over various sectors or coming from outside the nuclear energy field in your legal texts (binding regulation)?	2-C. Do you use reference to standards applied over various sectors or coming from outside the nuclear energy field in your regulatory guides?	2-D. Do you make use of standards applied over various sectors or coming from outside the nuclear energy field in regulatory activities not specified by regulation…	2-E. For engineering domains where both existing standards in the field of nuclear energy and standards coming from outside the field of nuclear energy are available
Belgium	Not relevant	No	No	Yes	Left to industry
Finland	Yes	No	Yes	Yes	Yes
France	No	No/Yes	No?/Yes	Yes	Yes
Germany	Not relevant	No	No	No	No reply
Italy	No	No	No	Yes	Left to industry
Lithuania	Not relevant	Yes	No	Yes	No reply
Poland	No	Not relevant	Not relevant	No/Not relevant	Not relevant
Romania	No	No	No	Yes	No reply
Slovakia	Yes	Yes	Yes	Yes	No reply
Sweden	No	No	Yes	Yes	Yes
The Netherlands	Not relevant	No reply	Not relevant	Not relevant	No reply
Turkey	No	No	No	Yes	?
UK	Do not know	No	Yes	Yes	Yes

For the question 2A there were two types of interpretations of the question. A first interpretation is that the question covers all similar types of systems, structures and components in general. A second interpretation is that the question asks whether nuclear specific requirements are set for the domain. In general the use of industrial codes and standards is not prevented in any domain of engineering. The nuclear guides and codes present thus the nuclear specific requirements but at the same time a reference is made as appropriate to industrial standards such as EN – standards in the field of mechanical components and Eurocodes in the field of construction.

However there are nuclear requirements that shall be fulfilled inside each domain. For design, construction and operation of a NPP the justification of the choice of standards applied is generally required. Appropriate national and international nuclear standards are used in demanding safety classes for systems, structures and components. Non-nuclear standards may be used in lower classes. But for operation of a nuclear facility, supply of the plant and main systems, structures and components , an ISO 9001 certified management system is for example not sufficient.

The answers to the question 2B show that most of the countries do not include standards in legally binding regulations. The French answer is No or Yes depending on the technical field. The legally binding regulations in Lithuania make reference to industrial standards in the field of respiratory protective devices and management systems and in the Slovak Republic they make reference to standards in the field of management systems and its certification.

The answers to the question 2C show that five countries utilising nuclear energy indicate that industrial standards are referenced in the regulatory guides. The scope of the standards varies widely. The examples given in the answers cover the following technical fields: pressure equipment, the Pressure Equipment Directive (97/23/EC) in lower safety classes, mechanical engineering, civil engineering, conformity assessment bodies and certification of personnel, management systems, environmental qualification of equipment and EMC qualification. The question 2C is related to the question 2B and further studies are needed to build a more complete and consistent picture. In general the nuclear safety guides are above the standards and give guidance and additional requirements for the application of industrial codes and standards to nuclear facilities.

The answers to question 2D show that there are two countries stating only nuclear standards are used in the licensing or other activities. These are Germany and Poland. Nine countries (Finland, France, Italy, Lithuania, UK, Romania, Slovak Republic, Sweden, Turkey) indicate that other than nuclear standards are also used in the licensing process. The list of standards includes those in questions 2A, 2B, 2C and some devoted to a specific issue such as environmental management systems (ISO 14000), traceability of the food chain and FMEA analysis (EN 60812). The national approach is reflected in the answers to the question 2D: the licensee ends up with the same standards but the way of selecting the standards is reflected by the legal framework and the regulatory approach.

The answers to the question 2E show that the general approach is to use nuclear standards if they exist especially for the highest quality group of systems, structures and components. However, for NPP projects in “new comer” countries where the use of nuclear standards is not developed and where localization and use of indigenous industrial capacities are requested (although not only in such case), the use of harmonised non-nuclear specific standards with appropriate complementary provisions to warrant safety may reveal as an appropriate industrial strategy. For some areas there are no nuclear standards and for those purposes the industrial standards are used from the methodological point of view. The risk assessment and the definition of the testing margins are made in nuclear regulation/regulatory guides/ or nuclear standards or codes. The way how the standards are selected depends on the national regulatory framework and regulatory approach (as already addressed in the analysis of question 2D).

2.4 Other international or European harmonisation efforts on standards and associated documents

2.4.1 Definition of standards and some associated documents

As explained in the Introduction section of this report, the definitions used for the terms "standard" and "European standard" are those of CEN/CENELEC Internal Regulations part 3. These definitions originating from ISO/IEC were used to prepare definitions in official European texts (e.g. 93/38/EEC, 83/189/EEC or 2004/17/EC) but other documents often associated or assimilated to standards exist, e.g. "Codes", "Rules".

Concerning the term "Codes" it generally comes with the term "Rules". Obligations linked to administrative or political decisions to be fulfilled are generally associated to the "Rules". Usually the "Rules" do not indicate how the obligations can be fulfilled. The role of the "Codes", produced generally by the industry sector, is to define how to develop a technical solution that, abiding by these "Codes", is fulfilling the "Rules". The term "Codes" has no formal definition and for the time being there are no formal "European Nuclear Rules", the only ones formalised to be found in European countries are "National Rules". Those "National Rules" often differ from country to country. As a consequence we are focussing in this document mainly on "Standards" and "European standards", even if "Codes" can be considered sometimes as pre-normative entry data for the development of a standard or another pre normative document produced by standard organisations (Technical Report, Publically Available Specification, Workshop Agreement …).

2.4.2 European activities on design codes for nuclear systems

Concerning generation IV and fusion, AFCEN and ESNII took the initiative to create CEN WS 64 "Design and Construction code for mechanical equipment of innovative nuclear installations" in 2011. In this CEN Workshop, AFCEN made available the RCC-MRx code to be shared by European R&D projects on generation IV reactors, new research reactors and other nuclear fission or fusion facilities. RCC-MRx references 229 standards of which 197 are EN or ISO standards.

The purpose of this CEN Workshop was to have the feedback of the code users through modification requests to improve and update the code according to the European R&D

projects' needs and feedback. It allows also the identification of pre-normative research needed for medium and long term modifications.

2.4.3 International organisations taking part to those harmonisation activities

Today some international organisations are promoting the harmonisation of standards and associated documents; this is the case of OECD/MDEP and WNA/CORDEL.

The Multinational Design Evaluation Programme (MDEP) is a multinational initiative under NEA/OECD (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development) to develop innovative approaches to leverage the resources and knowledge of mature, experienced national regulatory authorities who are, or will shortly be, undertaking the review of new reactor power plant designs. The MDEP programme incorporates a broad range of activities including the increase of multinational convergence of safety goals, codes and standards.

The MDEP Programme structure includes two groups working in particular towards harmonisation of standards and associated documents:

- The issue specific Mechanical Codes and Standards Working Group (CSWG) pursues the goals of searching for ways to harmonise and converge national Codes, Standards, and Regulatory requirements and practices in this area while recognizing the sovereign rights and responsibilities of national regulators in carrying out their safety reviews of new reactor designs. Key stakeholders with whom this group interacts routinely include organisations such as the American Society of Mechanical Engineers (ASME), AFCEN, the Canadian Standards Association (CSA), the Japan Society of Mechanical Engineers (JSME), Korea Electric Association (KEA), and NIKIET (Russia). The representatives of the participating organisations have already produced a comprehensive report on the Code comparison for Class 1 Nuclear Power Plant Components.
- The issue specific Digital Instrumentation and Control Working Group (DICWG), to which IAEA participates and to which meetings IEEE and IEC are invited, prepared recommendations letters to those two standard organisations indicating its support to the already engaged collaboration to develop common dual logo standards both for new topics to be covered and for the revision of existing standards.

For more information see the OECD website (http://www.oecd-nea.org/mdep/).

The World Nuclear Association's (WNA) CORDEL Working Group was established with the aim of promoting the achievement of a worldwide regulatory environment where internationally accepted standardized reactor designs can be widely deployed without major design changes. Its membership consists of industry specialists in reactor licensing, nuclear law and reactor safety engineering, representing reactor vendor companies, utilities, technical support and consulting services and international organisations involved or directly interested in reactor licensing for new nuclear build.

WNA's CORDEL Working Group recognised the efforts already done to identify differences and develop aligned international codes and standards in various domains such as mechanical codes and instrumentation and control (I&C) through such organisations as ASME and AFCEN, and IEEE and IEC. Representing the coordinated views of the global nuclear industry, the CORDEL Working Group strongly recommended a determined joint effort of industry, governments and regulators to attain the acceptance and application of common safety standards. For more information see the WNA website (http://www.world-nuclear.org).

3 - Recommendations

Recommendation 1: CENELEC standardization in nuclear energy

CEN-CENELEC Focus Group on nuclear energy,

considering CLC/TC 45AX “Instrumentation and control of nuclear facilities” and CLC/TC 45B “Radiation protection instrumentation”,

supports their work process and activities as they are carried out now for the implementation of IEC/TC 45 “Nuclear instrumentation”, IEC/SC45A "Instrumentation and control of nuclear facilities " and IEC/SC45B "Radiation protection instrumentation" standards in Europe.

Recommendation 2: European standardization in nuclear energy

CEN-CENELEC Focus Group on nuclear energy,

considering CLC/TC 45AX “Instrumentation and control of nuclear facilities” and CLC/TC 45B “Radiation protection instrumentation” process for the implementation of IEC/TC 45 “Nuclear instrumentation”, IEC/SC45A " Instrumentation and control of nuclear facilities " and IEC/SC45B " Radiation protection instrumentation" standards in Europe,

considering ISO/TC 85 & SCs “Nuclear energy, nuclear technologies, and radiological protection” scope, standards and work programme,

considering ISO/TC 147 SC3 “Water quality - Radiological methods” standards and work programme,

considering the answers to the CEN-CENELEC Focus Group questionnaire on nuclear energy standardization,

concludes that at the moment no needs for “home grown” European standards have been identified in the field of nuclear energy in Europe and

advises against the development of home grown European standards for the nuclear energy sector at the moment and

recommends the development of international standards in nuclear energy (IEC/TC 45, ISO/TC 85 & SCs or ISO/TC 147 SC3) and the identification of European needs for standards in relevant areas not already covered by the plans of international organisations (IEC/TC 45, ISO/TC 85 and ISO /TC 147 SC3) to add them to the plans of those international organisations and

requests European stakeholders to ensure the adequate resourcing of IEC/TC 45, ISO/ TC 85 and ISO / TC 147 SC3 as to enable the development of the standards that are needed, in order to fulfil European needs.

Recommendation 3: Endorsement process of ISO/TC 85 & SCs and ISO/TC 147 SC3 standards at the European level

CEN-CENELEC Focus Group on nuclear energy,

considering the practice of CLC/TC 45AX “Instrumentation and control of nuclear facilities” of implementing without modification IEC/SC45A standards on a case by case basis,

considering ISO/TC 85 “Nuclear energy, nuclear technologies, and radiological protection” standards harmonization initiatives,

considering the use of ISO/TC 147 SC3 standards in nuclear energy in Europe,

considering the modes of co-operation of the Vienna agreement[3] between CEN and ISO,

recommends the establishment of a process and structure functionally similar to the CLC/TC 45AX one to endorse ISO/TC 85 & SCs existing and forthcoming standards at the CEN level; the CLC/TC45AX transposition methodology is as follows:
CLC/TC45AX transposes IEC/SC45A standards as EN standards without modifications. This transposition proceeds after having confirmation that the IEC candidate standards have been approved at the IEC final stage of development by the majority of the European National Committees entitled to vote and that no European National Committee has raised significant concerns for the application of these standards in the European countries. CLC/TC45AX verifies that these conditions are fulfilled before the CENELEC voting process is started,

recommends that this process includes the endorsement of the ISO/TC 147 SC3 standards needed at the European level in CEN/TC 230 "Water analysis",

recommends therefore that for standards within the scope of the ISO/TC 85 & SCs and ISO/TC 147 SC3 the process as described in section 11.2.1.2 of the CEN-CENELEC Internal Regulations 2012 Part2 (July 2012) is established[4].

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[3] information on the Vienna Agreement is available at http://www.cen.eu/go/va/

[4] As the basis for the European Standard, it shall first be established whether

a) there is published international work in the field and that international work would be acceptable as a European Standard;

b) the work can be developed within the framework of the international agreements that CEN and CENELEC have with ISO and IEC respectively.

Recommendation 4: Harmonisation in Europe

CEN-CENELEC Focus Group on nuclear energy,

considering that standards coming from outside the nuclear energy field are used in nuclear energy applications,

considering the need of harmonisation identified in the CEN-CENELEC Focus Group on nuclear energy through the questionnaire,

recommends existing and future nuclear TCs to produce at the international level nuclear standards providing guidance on the application of relevant standards from outside the nuclear energy field in the nuclear energy domain.

Recommendation 5: Pre-normative research in nuclear energy

CEN-CENELEC Focus Group on nuclear energy,

considering research and development activities at European level supported by DG Research and Innovation, in JRC, in NUGENIA (generation II and III), in SNETP-ESNII (generation IV) as well as in other industrial initiatives,

considering national research and development programmes,

considering that research is essential in ensuring and continuously improving nuclear safety,

confirms that technology development and safety needs should be the main drivers for these research and development activities,

encourages the inputs from these research and development activities into international standardization, and

supports initiatives such as CEN WS64 for innovative nuclear installations.

Recommendation 6: Follow up of CEN WS 64 initiative

CEN-CENELEC Focus Group on nuclear energy,

considering CEN WS 64 initiative and results on "Design and construction code for mechanical equipments of innovative nuclear installations",

considering nuclear new power plants or research facilities projects in Europe,

considering AFCEN's role as international industrial platform on which a European approach of codification can be built,

supports the follow up of the example of the "Europeanization" initiative of AFCEN code RCC MRx for Generation IV reactors done in CEN WS 64 via a new CEN Workshop,

supports in particular the initiative to enlarge this "Europeanization" process to other AFCEN codes using CEN workshops with the aim to answer the needs of the nuclear industry for Generation III reactors.

4 - Identified standardization needs (as emergent from the questionnaire results)

4.1 Standardization needs identified in the field of nuclear energy in Europe

As described in Chapter 2, standardization technical committees in nuclear energy already exist at the international level both in ISO and IEC. They are supported by the European countries involved in nuclear energy standardization.

For the electrotechnical standardization, the relevant IEC/SC45A and IEC/SC45B standards that are acceptable for Europe can be endorsed by CLC/TC45AX and CLC/TC45B. The European endorsement of the ISO standards in nuclear energy and radiation protection (ISO/TC 85 and SCs and ISO/TC 147 SC3) relevant in and acceptable for Europe is proposed. The promotion of the participation of European experts in the international committees and subcommittees is encouraged accordingly.

The review of the proposals for new work made during the enquiry which is available in annex 1 (nuclear energy standards) shows that most of these needs are in the scope of the international structure with sometimes standards development going on or under preparation. Civil and mechanical standards for nuclear energy are not addressed in ISO/TC 85 but, as described before, are addressed by CEN initiatives.

This led to the conclusion that at the moment there is no need for “home grown” European standard in the field of nuclear energy in Europe. The establishment of a light European structure working as CLC/TC 45AX and the use of the Vienna agreement for the endorsement of ISO standards at the European level on a case by case basis without modification is preferred.

From the questionnaire, specific national documents appropriate to offer to the EU-level or international level were proposed by DIN, UNI, NEN and SFS. These are in annex 2. Many of them are within the scope of existing international technical committees. In some cases standards have already been proposed but planning of development is very uncertain, due the non-availability of resources.

French national documents have already been proposed as inputs during the drafting of international standards.

Besides standardization, the topic of codes for NPP Design and their harmonisation in Europe was raised. The feasibility to have an harmonisation process in Europe is still to be determined.

The dynamics of the European projects (EPR, ITER, generation IV, ESS ...) in Europe is an opportunity to elaborate an European common approach regarding nuclear codification.

AFCEN constitutes an international industrial platform on which this European approach to codification can be built.

The CEN WS64 work in 2011 and 2012 is a positive concrete exercise of sharing and consideration of the needs of the nuclear European stakeholders in the AFCEN codification RCC-MRx for the innovative installations (generation IV).

The continuation of this initiative of "Europeanization" of the AFCEN code for generation IV (RCC MRx) must be considered within the framework of a long-lasting collaboration to be defined between AFCEN and the CEN Workshop

Such an initiative could be extended to the other AFCEN codes to meet the needs of the European nuclear industry for generation III.

4.2 Standardization needs from the nuclear energy stakeholders identified outside the field of nuclear energy

The answers to the questions related to the need for a better consistency among existing standards as well as the need for applying "generic" standards to the nuclear sector showed that adaptation of existing standards for use in nuclear energy applications is often made through the codes, regulation, regulatory guides or complementary specifications. Thus, most of the time, no further standardization work is asked for by the stakeholders. When the “nuclear” adaptation of standards is needed, giving priority to the international level, with ISO and IEC standards development to be endorsed at European level, is most of the time proposed.

Several needs for adaptation, for the application in nuclear energy, were identified and could be progressed in accordance with recommendation 4:

- Management systems, certification and accreditation,
- Mechanical components and equipments,
- Electrotechnologies,
- Information technologies and security,
- Eurocodes from the nuclear energy perspective.

Some details are given in annex 3.

Inconsistencies have been reported between for instance non-nuclear specific codes and standards, nuclear ones and other standards (including national standards) .Some of these cases are listed in annex 4.

4.3 harmonisation: a key element for the nuclear sector

A need of harmonisation was also clearly identified from the questionnaire results.

On the one hand, several restraints to harmonisation in the field of standardization were identified like (below are quotes from responses to the Questionnaire):

- The specificity and the lack of harmonisation of regulatory national requirements is the main restraint identified. Long national history of NPP safety regulations and differences in regulatory frameworks and approaches have led to several groups of standards e.g. design codes…. The actual reinforcement of IAEA rules and standards, the works on harmonisation between regulators (CNRA/WGRNR, MDEP, WENRA, HERCA) and also among industries and utilities (WNA/CORDEL, EUR, ENISS) worldwide or through European initiatives will permit a better standardisation of industrial practices in the future.
- Trade requirements: frequently, some national standards are imposed by national laws in some Countries (especially in Eastern Europe and Russia). Furthermore, when working for a foreign country, the issue at stake is working with the licensee or purchaser to sort out the standards that can be used. As far as possible, the use of harmonised standards (ISO or IEC) which are equivalent to or more stringent than their national standards in proposed. But in some countries the translation of the harmonised standard has to be provided to work with local suppliers. Aspects of protection of national industry have also to be considered.
- Where a set of standards is coherent as a whole, adapting or modifying one standard or even one aspect of one standard may have a consequence on the whole set and therefore constitutes a major restraint to harmonisation.
- The experience of IEC/SC 45A shows that individuals' interpretations of certain texts which are not very explicit can lead to difficulties. The implementation at European level between nuclear regulators of a voluntary mutual acceptance mechanism such as that proposed by the ENEF (European Nuclear Energy Forum) core group ERDA (European Reactor Design Approval) could help overcome such specific issues.

- Significant differences exist between US construction and design codes and European ones (civil work, pressure equipment): safety criteria are not on the same parameters between US and Europe. So only principles can be harmonised (requirements...) but not the operational design codes.

The introduction of national specificities in the adoption of International or European standards is a limitation to harmonisation.

On the other hand, for engineering domains, the reasons for promoting convergence between existing standards in the field of nuclear energy and standards coming from outside the nuclear energy field were analysed. Two aspects are to be considered: new equipment to be used for nuclear and non-nuclear applications and existing equipment widely used.

A Swot analysis of the reasons for promoting convergence between standards in the field of nuclear energy and standards coming from outside the field of nuclear energy is in Figure 2.

Strengths	***Weaknesses***
Mutual progress Lower cost for Components Off-The-Shelf Higher standardization: reduced set of spare parts	the nuclear sector is very small compared to other industrial sectors When different standards have been created, it requires much time and effort (it may even be impossible) to come back and converge Radiation protection requirements are specific for this industry and lead to specific constraints
Opportunities	***Threats***
Broader range of qualified material, components and systems, suppliers Better practices and sharing the innovative trends are the most important reasons Benefit for nuclear in terms of technology innovation, continuously performed in the broader industrial market (e.g. "functional safety"). Build European industrial markets	Specific constraints that must be taken into account and it is often not possible to promote our point in generic meetings. Divergence between nuclear and non-nuclear standards

Figure 2: Swot analysis of the reasons for promoting convergence between standards in the field of nuclear energy and standards coming from outside the field of nuclear energy

Two strategies can be considered:

- Either broaden the scope of non-nuclear specific standards, e.g. by including a "nuclear application appendix" or,
- Generalise the principle of accepting either nuclear-specific standards or as an alternative non-nuclear-specific standards supplemented by specific provisions (e.g. regarding quality assurance). In many cases, the experience shows that what is at stake are not purely technical criteria but often quality assurance and administrative provisions.

As a conclusion, harmonisation needs identified for standardization in Europe in nuclear energy are consistent with the current initiatives in Europe and at the international level.

The participation of European stakeholders in the existing structures is encouraged.

The development of international technical standards would be facilitated by a more harmonised regulatory framework.

4.4 Identification of the European standardization needs

The value of pre-normative research (PNR) is recognised.

Through SNETP, frameworks exist now in Europe to identify and develop pre-normative research: NUGENIA for generation II and III reactors has a research area on harmonisation; ESNII for generation IV reactors has proposed the CEN WS 64 initiative. The development of this PNR should lead to inputs in standardization in a near future.

Annex 1 Standardization needs identified

Standardization needs proposed	**Comments and existing structures**
A new national standardization need is identified on the qualification of instrumentation used in severe accidents. For some equipment standards are needed for their use and exposure for long periods of time.	These new standards will be proposed to be developed at the international level and could be endorsed at the European level The survival of equipment in a high radiation/temperature environment can be addressed within the existing structures. Guidance was forthcoming in IEC/TC 45 on requirements for accident systems I&C after the Fukushima incident. Pre-normative research is needed here.
Design and manufacturing of nuclear electrical components such as cables, cabinets, etc.	Need as regards the design and manufacturing of nuclear components; today traditional standards are used with some additional requirements
IEC standard that corresponds to IEEE 308 (requirements on class 1E equipment). That shall point to other standards that cover all voltage classes and different electrical transients' types	IEC/SC 45A
IEC 61226 covers only categorisation of functions in instrumentation and control. There is a need for a standard for categorisation/classification of all types of electrical and I&C systems.	IEC/SC 45A This standard will be reviewed after Fukushima incident, this review is part of the normal work stream
It should be analysed if there is a need for a standard for safety classes for electrical and I&C systems (supplementing ANS 51.1 and 52.1)	IEC/SC 45A
Standards for robustness and transparency of built-in functions for equipment protection in modern electrical power equipment.	IEC/SC 45A

Standardization needs proposed	**Comments and existing structures**
Other fields proposed: Qualification of NDE systems- ISI, Standard for inspection bodies in the nuclear area, Standards for inspection of Containment structures Quality and safety adjusted for European system as for example PED, Standard for clearance measurements, Standard for risk analysis in decommissioning classes for nuclear	ISO/TC 85 For Non-destructive testing in cooperation with CEN/TC 138 and ISO/TC 135 " Non-destructive testing" For accreditation and conformity assessment bodies, discussion in ISO/TC 85 for nuclear energy requirement need for expertise and liaison with IAEA.
Water quality. Rn -222 activity determination by LSC; Determination of Sr-90 activity concentration by Cerenkov counting	ISO/TC 147 SC3 and ISO/TC 85 SC2 depending on the support (water or other)
Activity measurement by whole body counter	ISO/TC 85 SC2 and IEC/SC 45B Standards already exist
Reference (standard) phantoms used for calibration of whole body and organ counters (in vivo systems) - specifications requirement: European transposition and development of ANSI/HPS N13.35- 1999) Reasons: - experimental calibration methods harmonisation - necessary for laboratory licensing Experimental calibration of whole body and organ counters (in vivo systems) using reference (standard) phantoms requirements Reasons: - experimental calibration methods harmonisation - necessary for laboratory licensing Theoretical (virtual) calibration of whole body and organ counters (in vivo systems) by Monte Carlo simulation method requirements : European standard Reasons: - Virtual calibration methods harmonisation - necessary for laboratory licensing	Out of the scope of CEN CENELEC FG Nuclear energy report but relevant to ISO/TC 85 SC2 and/or IEC/SC 45B
Standardization related to radiological passport	FG Nuclear Energy

Standardization needs proposed	**Comments and existing structures**
Evaluation and routine testing in medical imaging departments. Acceptance tests - Imaging performance of X-ray equipment for radiographic and radioscopic systems (Withdrawn IEC 61223-3-1).	Out of the scope of CEN CENELEC FG Nuclear energy report but relevant to IEC/TC 62
NPP DESIGN PHASE Methodology for Qualification of Non-Destructive Testing (more information from European Methodology for Qualification of Non-Destructive Testing - Third Issue - August 2007 ENIQ Report nr. 31 EUR 22906 EN	ISO/TC 85 in cooperation with CEN/TC 138 and ISO/TC 135 " Non-destructive testing"
NPP OPERATIONS, NPP PERIODIC SAFETY REVIEW, COMPONENT OPERATION, MATERIALS AND SAFETY MANAGEMENT Application of probabilistic fracture mechanics and structural reliability methods in assessing the failure probabilities and remaining lifetime of passive NPP components This standard would be needed for more realistic and comprehensive assessment of ageing of passive NPP components, and the need for such standard is increasing as most of the existing NPPs have been in operation for more than three decades.	IAEA and OECD/NEA existing work Confirmation of standardization need to support the implementation of the IAEA guidance on periodic safety review (PSR) – ISO/TC 85
Standard for decommissioning (SFS)	ISO/TC 85 SC5 has started planning
Adaptation of ISO 9001 versus NSQ 100 (Nuclear management system) taking into account IAEA requirement of GS-R-3 is confirmed.	Currently in ISO/TC 85 a WG group has been established and European experts are invited to work in the WG.

Annex 2 National documents appropriate to offer to the EU-level or international level

National document	Existing structures
OPERATIONAL AND DECOMMISSIONING WASTE MANAGEMENT UNI 10621 - Radioactive waste packages. Characterization UNI 10704 - Radioactive waste packages. Classification UNI 11193 - Radioactive waste packages - Qualification of conditioning processes for Category 2 packages UNI 11194 - Radioactive waste packages. Radiological characterization of Category 2 packages for the purpose of disposal in the final repository UNI 11195 - Radioactive waste packages. Information system for the management of a surface repository Category 2 packages UNI 11196 - Radioactive waste packages. Containers for the final repository of Category 2 packages UNI 11197 - Radioactive waste packages. Identification procedure and traceability of information for Category 2 packages UNI 11279-1 - Engineered repository for Category 2 radioactive waste packages. Part 1: Basic design criteria UNI 11279-2 - Engineered repository for Category 2 radioactive waste packages. Part 2: Basic qualification criteria for engineered barriers UNI 11279-3 - Engineered repository for Category 2 radioactive waste packages. Part 3: Surveillance and monitoring basic criteria	ISO/TC 85 SC5
NEN 5699 and NEN 5697 on radon measurements	translated and are part of the European standards development within CEN/TC 351/WG 3"Radiation from construction products", ISO/TC 85 SC2 WG 17 and standards ISO 11665-1 to 11 “Measurement of radioactivity in the environment -- Air: radon-222
DIN 25475-3 Nuclear facilities - Operational monitoring - Part 3: Determination of thermal loadings	
Guidelines of the common German/Swiss “Fachverband für Strahlenschutz”, section Environmental monitoring (AKU) on specific items of environmental monitoring	still to be selected and presented to ISO/TC85/SC 2
At the European level, there is also the experiment on RCCMRx code proposed by AFCEN and ESNII via CEN/WS64	

Annex 3 Need for adaptation for use in nuclear energy applications of standards not dedicated to nuclear energy applications

Some needs of adaptation for the application in the Nuclear energy applications have been proposed in the fields of nuclear management systems, mechanical components and equipments, civil structures, electrotechnologies, information technologies and security.

Nuclear management systems **Certification & accreditation**	Adaptation of ISO 9001 in ISO/TC 85 vs NSQ 100 (Nuclear management System) taking into account the IAEA requirement of GS-R-3 Standards related to "Accreditation requirements" Application guide on generic standards used as accreditation requirements for use in nuclear energy applications might increase harmonisation and mutual acceptance in the nuclear energy field. Generic standards used in accreditation of laboratories, inspection bodies and certification bodies are: - EN ISO/IEC 17025:2005: General requirements for the competence of testing and calibration laboratories In France, the adaptation of ISO 17025 and the complementary requirements are in the regulation - EN ISO/IEC 17020:2012: General criteria for the operation of various types of bodies performing inspection - EN ISO/IEC 17021:2011: Conformity assessment - Requirements for bodies providing audit and certification of management systems - EN ISO/IEC 17024:2003: Conformity assessment. General requirements for bodies operating certification of persons - EN 45011:1998: General requirements for bodies operating product certification systems (will be replaced by EN 17065 in 2012)
Mechanical components and equipments (including materials)	EN 13445 Creep amendment, at least as European Standard; this part of the standard is the state of the art for the manufacturing of high temperature component. Modern design tools and models are provided. Design by Analysis is introduced with two methods: Direct Route and method based on stress categories. Creep amendments are continuously updated with the contribution of the European Creep Collaborative Committee. EN 10028 about steels and steel properties. EN 10028 has been introduced in place of national codes and standards and it is well accepted everywhere in Europe. Part 2 and Part 7 are for high temperature alloy steel and for stainless steels. The materials of this standard can be compared with ASME Sect. II materials. EN 61439 on electrical cabinets, EN 60947 on breakers, etc

	Standards related to "Cranes" The crane standards which need to be adopted in the nuclear sector are EN 13001-series of design calculation standards and product standards e.g. EN 60204-32, EN 13135, EN 14492-2, EN 15011, EN 12077-2.
Civil Engineering	The European code for civil structure design and seismic justification of building (EN 1998) is quite different from EDF rules written on RCC-C and then on ETC-C (edited by AFCEN). These standards have to be improved to cover the needs of the nuclear sector.
Electro technologies	Some examples in the electro technical standardization are given IEC 61503 series on functional safety and IEC 61000 series on EMC are used e.g. for category C and non-classified NPP I&C systems. They are adopted European Standards EN by CENELEC on the basis of the Dresden Agreement The following were raised by SFS and will have to be discussed Standards related to "Control room design and human-machine-interface design" In IEC standards dealing with control room design and human-machine-interface design (such as IEC 60964, 61227, 61771, 61772, 61839, 62241, 60965), design of ergonomics is not managed well enough. In this sense, ISO 11064 is better and it supports the practical design process better.
Information technologies and security	The following were raised by SFS and will have to be discussed Standards related to "System and software engineering" - ISO/IEC 12207:2008 Systems and software engineering -- Software life cycle processes - ISO/IEC/IEEE 42010:2011 Systems and software engineering -- Architecture IEC 61508 gives more practical advice on verification and validation of software based systems in different safety applications. Standards IEC 61513 and IEC 60880 could be enhanced by including similar type of approach. The following international standards should be adopted as European standards (from comment SFS on question3A): -- INSTRUMENTATION AND CONTROL ISO JTC 1/SC 7 Software and systems engineering ISO/IEC 12207 Systems and software engineering -- Software life cycle processes ISO/IEC 15288 Systems and software engineering -- System life cycle processes ISO/IEC CD 330xx Software and Systems Engineering - series for SW Process assessment (15504 series) ISO/IEC 250xx Software Engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Guide to SQuaRE (series) ISO/IEC/IEEE 42010 Systems and software engineering -- Architecture

	-- SAFETY MANAGEMENT ISO JTC 1/SC 27 IT Security techniques ISO/IEC 27005:2011 Information technology -- Security techniques -- Information security risk management >> The safety systems will be more and more based on software based systems and components

Annex 4 Inconsistencies identified

Inconsistencies have been reported between for instance non-nuclear specific codes and standards, nuclear ones and other standards (including national standards).

Codes AFCEN RCCE code and IEEE/NPEC standards. AFCEN works for harmonisation, but the major problems are classification and safety terminology, This is why the safety terminology of IAEA was adopted via IEC/SC45A. Note : Mechanical AFCEN codes and ASME code (ASME III and ASME XI) are on the same technical field. Other international codes are also on the same technical fields (JSME (Japan), KEPIC (Korea), NIKIET (Russia)). A general code comparison has been performed (initiated by MDEP (multinational design evaluation program)) and harmonisation actions are defined. In KTA Code the pressure test requirements are different from ASME and RCC-M codes. Quality Assurance and Control procedures should be harmonised considering the use of Authorised Inspectors and the Third Party.
The KTA 3053 includes only environmental policy qualification for hardware, thus software policy qualification is not included in KTA.
The German regulation KTA3902 is in conflict with European crane standards (see 4-A) when referring to DIN 15018. The present information is however that this DIN standard on cranes will be withdrawn in 2012.
The following publications/requirements/standards are in conflict in a number of details concerning requirements for inspections, pressure tests and acceptance of flaws: - ASME Boiler and Pressure Vessel Code, Section XI, Rules for Inservice Inspection of Nuclear Power Plant Components, the American Society of Mechanical Engineers, New York, 2010. - RSE-M, In Service Inspection Rules for the Mechanical Components of PWR Nuclear Power Islands. AFCEN, France, 1997 Edition. - Safety Standards of the Nuclear Safety Standards Commission (KTA), Parts 3201.1, 3201.2, 3201.3, 3201.4 and 3211.4. Germany. - British Standard BS 7910: 2005, Guide on methods for assessing the acceptability of flaws in fusion welded structures, 4th draft after public comment. England, 28 September 2007.
Use of standards for nuclear applications CIVIL WORK: the European code for seismic justification of building (EN 1998) is quite different from EDF rules written on RCC-C and then on ETC-C (edited by AFCEN). So government regulator may consider EN1998 as minimum rules, but actually, the concept of NPP civil work design is not compatible with this common standard.

RADIATION MEASUREMENT ISO/TC85 SC2 and IEC/SC 45B on radiation measurements and illicit trafficking of radioactive Materials
MECHANICAL EQUIPMENT DESIGN AND INSPECTION PRACTICES RCC-M and RCC-MR can be conflicting standards with EN10028, as there are some differences for material properties. The method to calculate negligible creep can be conflicting with EN13445
FIRE PROTECTION National standards may cause important changes in standardized NPPs design
STANDARDS FOR LIFTING AND HANDLING EQUIPMENT

Annex 5 Participants in the meetings of the Focus Group

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Annex 6 Abbreviations frequently used in the report

ADR	From "Accord européen relatif au transport international des marchandises Dangereuses par Route" European Agreement concerning the International Carriage of Dangerous Goods by Road
AFCEN	From "Association Française pour les règles de Conception, de construction et de surveillance en exploitation des matériels des Chaudières Electro Nucléaires" French Association for the rules governing the Design, Construction and Operating Supervision of the Equipment Items for Electro Nuclear Boilers.
ASME	American Society of Mechanical Engineers
ASTM	(formerly) American Society for Testing and Materials
BT	Technical Board (of CEN or CENELEC)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CORDEL	Co-operation in Reactor Design Evaluation and Licensing (working group under WNA)
CRNA	Committee on Nuclear Regulatory Activities (under NEA)
CSNI	Committee on the Safety of Nuclear Installations (under NEA)
EN	EN European Standard
EPRI	Electric Power Research Institute
ESNII	European Sustainable Nuclear Industrial Initiative
ESO	European Standardization Organization (CEN, CENELEC and ETSI)
ETSI	European Telecommunications Standards Institute
ETSON	European Technical Safety Organization Network
EU	European Union
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ISA	International Society of Automation
ISO	International Organization for Standardization

ITU	International Telecommunication Union
ITU-T	ITU’s Telecommunication standardization sector
I&C	instrumentation and control
JRC	Joint Research Centre (of the European Commission)
KTA	KTA Kerntechnischer Ausschuss
MDEP	Multinational Design Evaluation Programme (under NEA)
NEA	Nuclear Energy Agency (of the OECD)
NPP	nuclear power plant
Nugenia	Nugenia Nuclear GEneration II & III Association
OECD	Organisation for Economic Co-operation and Development
SC	sub-committee (in ISO, IEC or CENELEC)
SNETP	Sustainable Nuclear Energy Technology Platform
SRL	Safety Reference Level
TC	Technical Committee (in CEN, CENELEC, ETSI, ISO or IEC)
WENRA	Western European Nuclear Regulator Association
WNA	World Nuclear Association

Annex 7 Bibliography and web-sites

CLC/TC45AX and CLC/TC45B Business Plans, providing the scope of CLC/TC45AX and CLC/TC45B

IEC TC 45/SC 45A/SC 45B STRATEGIC BUSINESS PLAN in SMB/4828/R (2012-06), providing the scope of IEC/TC45, IEC/SC45A and IEC/SC45B

ISO/TC 85 Business Plan, ISO/TC 85 N1223, providing the scope of ISO/TC85, ISO/TC85/SC2, ISO/TC85/SC5 and ISO/TC85/SC6

Multinational Design Evaluation Programme (MDEP) web-site (at http://www.oecd-nea.org/mdep/), providing the scopes of the issue working groups on Mechanical Codes and Standards and Digital Instrumentation and Control

WNA Report: Annual Report (2011-2012) of the Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group

http://afcen.com/

http://ec.europa.eu/dgs/jrc/index.cfm

http://ec.europa.eu/enterprise/express

http://www.iaea.org/

http://www.iec.ch/

http://www.iso.org/

http://www.nugenia.org/

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http://www.oecd-nea.org/mdep/

http://www.snetp.eu/

http://www.wenra.org/

http://www.world-nuclear.org