European Nuclear Energy Forum
Bratislava - Prague

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WG RISKS / WG OPPORTUNITIES

"EUROPEAN REACTOR DESIGN ACCEPTANCE (ERDA)" CORE GROUP

Roadmap Towards European Reactor Design Acceptance

31 July 2012

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Executive Summary

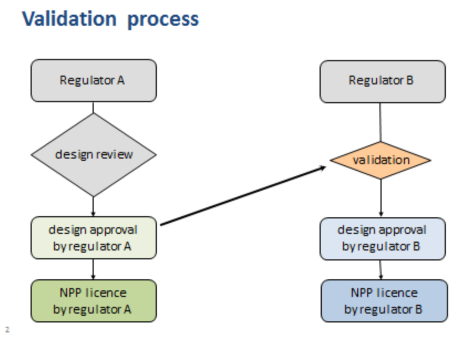
In this paper, the concept of a **European Reactor Design Acceptance (ERDA)**, developed by a dedicated group within the European Nuclear Energy Forum (ENEF), is presented to the stakeholders of nuclear energy in the EU and to the public.

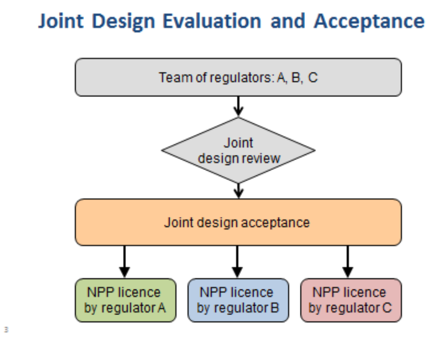
The ERDA concept is based on the idea that a nuclear reactor design should be reviewed and approved in a more harmonized, efficient and consistent way rather than being separately reviewed by each national regulator in each EU Member State where a nuclear power plant of that design is to be built, as is the case now. Instead of "re-inventing the wheel" every time, ERDA looks at ways to achieve a **common design review and acceptance, the results of which are shared among several EU Member States**. Such a reactor design acceptance would be issued or mutually shared by a voluntary group of national regulators. As a result, a given reactor design can be built in the same way in all participating countries, except for necessary adaptation to specific local conditions.

ERDA is **not suggesting reactor licensing by a new dedicated EU authority**. Instead, it builds on new coordination of the structures and the players of national licensing procedures and reactor safety standard setting, mainly the national regulators, but also technical support organisations (TSOs) and industry standardization organisations. The following elements of an **overarching ERDA concept** are proposed:

- All interested Member States should introduce a **"stand-alone design acceptance"** process as a first step in their licensing regime, as it already exists in some Member States. Such a process allows for assessment of a design independently of a specific project for construction. It results in a "design acceptance certificate" which is both useful for subsequent domestic licensing processes as well as for the work of other regulators.
- Progress in **harmonization of safety requirements** is an obvious prerequisite for common reactor design acceptance. Harmonization in the EU is already well underway through IAEA standards and the work of WENRA; this needs to be continued. Additionally, further work could be done to promote the recognition and adoption of nuclear industry common standards.
- Based on these steps, a **"validation" process** (*see schedule on next page*) could be envisaged in a situation where an operator applies for a nuclear power plant licence based on a reactor design previously assessed in another Member State. The national regulatory body receiving this application should maximize the benefit of the technical work already done rather than repeating it. In close cooperation with the first regulator and after its own review, the regulator could "validate" the design acceptance of its fellow regulator, if necessary with some changes or caveats.

- When a reactor design is submitted to a licence process in several countries at roughly the same time, the national regulators should create a joint team of experts from their own staff with the adequate competencies and perform a **joint design evaluation and acceptance** (*see schedule below*). In a first, more informal phase, the common result would be voluntarily transferred into a more streamlined national licensing process by each participating regulator. In a more advanced phase, there could be a multinational agreement between the Member States concerned, installing a system of joint acceptance of new designs proposed for implementation in several of them. Such a multilateral agreement could work similarly to the well-known “Schengen Agreement” about abolition of frontier checks and a common external frontier which was concluded between a subset of EU countries willing to take this issue forward. Formal delivery of a license by the national regulator would still be necessary for any nuclear power plant project to proceed in a particular country
- Finally, substantial support could come from the **collaboration of European TSOs** who could perform joint design reviews under the auspices of a regulator or a group of regulators in the context of the cooperation models presented above.





The solutions described above are essential to reach the aim of **standardization of reactor designs in the EU**. Standardization means there would be several fleets, each consisting of nearly identical reactors of the same design, across Europe. Standardization would have two main substantial benefits for industry and society. It would contribute to the EU goal of **constantly improving nuclear safety** by establishing a broader basis for sharing experience feedback and for jointly implementing design improvements. Construction of a series of nearly identical units of any design will bring significant economic benefit and will reduce the complexity and uncertainty of licensing, thus **helping to make investment in new nuclear projects**. Both benefits, and potential disadvantages, are explored in detail in the report.

It should be emphasised that this concept is not revolutionary. There are **models in other industries** for achieving standardization through a system of international cooperation of regulators and cross-acceptance of licences. The report looks at the solutions found in the civil aviation industry and in the

European rail network and discusses the elements to be taken as a model for nuclear. Besides, there have been promising examples even in the nuclear field. Some of them are described in some detail in the **Annexes**.

The report is addressed to all actors in evaluation and licensing of nuclear reactor designs in the EU. It puts a special emphasis on **exploring possible facilitative actions of the EU**. While, as already stated, ERDA does not involve a centralised EU acceptance process and is not based on the creation of an EU authority, the EU could facilitate the cooperation of regulators, TSOs and industry with legislative and non-legislative action within the scope of its competences.

ERDA is an essential step to achieve the deployment of standardized reactor designs in Europe contributing to the potential role of nuclear energy in the long-term low carbon energy mix in the EU[1]. Given the current situation where a number of EU Member States is willing to pursue new build programmes, but where economic and regulatory uncertainties and challenges seem to be major hurdles for investment decisions in nuclear power plant projects, in the long-term there is **no alternative to such a standardization approach** for reducing the investment risks and at the same time for reaching an even higher and harmonized level of safety.

[1] EU Energy Roadmap 2050, EC 2011

1. Introduction

1.1 Background

The Commission has already expressed in several policy papers its intention to promote and develop a harmonized licensing process for nuclear facilities at the EU level. In its 2008 Nuclear Illustrative Programme[2], the Commission addressed under the chapter of "Licensing issue" the need for planning stability and for a reduction of investment risks due to regulatory uncertainty for investors and other stakeholders. In the Commission Communication[3] "Energy 2020 – A strategy for competitive, sustainable and secure energy", under the item "Continuous improvement in safety and security", the Commission underlines again the high importance of actively pursuing the harmonization of plant design and certification at the international level.

The nuclear industry commenced initiatives to achieve standardization of reactor design at the European level in the nineties with the European Utilities Requirements (EUR) program. In recent years, the World Nuclear Association (WNA) pledged for a cooperative effort between the industry and regulatory authorities to achieve greater standardization of reactor design and harmonization of design requirements across the world. The WNA expert working group on Cooperation in Reactor Design Evaluation and Licensing (CORDEL) published in 2008 a first report about the "Benefits Gained through International Harmonization of Nuclear Safety Standards for Reactor Designs"[4] and in January 2010 a more detailed proposal about the "International Standardization of Nuclear Reactor Designs"[5].

At the international regulators' level, MDEP (Multinational Design Evaluation Program) was launched in 2006 between 10 regulators of countries interested in building new NPPs, among them the regulators of three Member States: France, the UK and Finland. The purpose was to foster cooperation and exchange of information between regulators tasked to review new reactor designs. Up to now MDEP has been working on AP1000 and EPR as well as on some generic subjects. MDEP published some common positions, but it has to be noted that MDEP is not expressly aiming at safety requirements harmonization and that national regulators retain sovereign authority for all licensing decisions.

On a practical level, the need for more standardization and more cooperation in reactor design acceptance has become apparent through the fact that Areva's EPR design has been licensed in Finland (Olkiluoto 3) and in France (Flamanville 3) with substantial differences in certain areas. Some of them were due to customer's request, but others resulted from diverging regulatory

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[2] Communication from the Commission to the European Parliament, the Council and the Economic and Social Committee, Update to the European Commission's 2007 Nuclear Illustrative Programme in the context of the second strategic energy review, COM(2008) 776 final, 13.11.2008 .

[3] Commission Communication "Energy 2020: A strategy for competitive, sustainable and secure energy" (16096/10) published on November 10, 2010

[4] www.world-nuclear.org/uploadedFiles/org/reference/pdf/ps-cordel.pdf

[5] www.world-nuclear.org/uploadedFiles/org/reference/pdf/CORDELreport2010.pdf

approaches and licensing/oversight processes. In the UK the GDA process regarding the EPR has already included modifications in the design resulting from specific UK Safety Assessment Principles and practices.

The current status of new reactor projects (excluding those which are already under construction) in the EU appears to be:

- Countries where the regulatory process is already activated: UK, Finland, France, Bulgaria
- Countries where utilities/future operators have issued bid invitation: Czech Republic, Lithuania, Romania
- Countries, where utilities have made request for vendor information: Poland, Sweden, Slovakia, Hungary.

1.2 ENEF Mandate

The ENEF SWG "Nuclear Legal Roadmap (NLR)" produced in October 2008 a paper "The Importance of New Approaches in Licensing"[6], stressing the need for more efficient, more predictable and more harmonized licensing processes in the EU. In cooperation with the Commission, in 2010 the SWG launched a Survey of licensing procedures for new nuclear installations in EU countries with the aim of making a comparative analysis and, if possible, of recommending best practice models.

The ENEF WG Risks recommended at its meeting in January 2011 in order to use the ENEF resources most efficiently and to proceed at the European level that a core group of interested members of ENEF SWGs "Nuclear Installation Safety (NIS)" and NLR as well as experts nominated by WGs Risks and Opportunities be set up. The ERDA (European Reactor Design Acceptance) Core Group was created on this basis with Terms of Reference[7] endorsed by the WG Risks.

The objective of the ERDA Core Group is to find, and propose via ENEF to the Commission, ways of achieving a "European Reactor Design Acceptance", issued by a national or a group of national authorities adhering to a common initiative and accepted in several or all EU member states where new nuclear power plants are or will be built. The Core Group will analyse, besides related activities in the nuclear regimes, existing European models for enhanced cooperation of regulators and mutual acceptance of approvals implemented in other industries, for instance in the aviation industry or in the cross-border accreditation of European high speed trains.

On the ENEF Plenary May 2011 the contribution of nuclear to low carbon electricity mix, pointing out the opportunities and threats in a long-term perspective, was addressed. In order to achieve a low carbon future with nuclear energy, it was underlined that certainty is the key requirement at all levels of the investment chain; cost effectiveness concurrent with a high level of safety will play an important role in EU new built projects. It was recommended that the

[6] ec.europa.eu/energy/nuclear/forum/opportunities/doc/legal roadmap/the_importance_of_new_approaches_in_licensing.pdf

[7] WG Risks/WG Opportunity, CORE GROUP "EUROPEAN REACTOR DESIGN ACCEPTANCE (ERDA)", Terms of Reference, 23 May 2011

Opportunities and Risks Working Groups should progress towards the harmonization of licensing and reactor design acceptance at European level. The ENEF Plenary May 2012 has confirmed this approach.

1.3 The concept of European Reactor Design Acceptance

This paper proposes elements and a way forward towards a European Reactor Design Acceptance (ERDA). Generally, this concept is based on the idea that a nuclear reactor design should not be reviewed and approved independently by each national regulator in each EU Member State where a nuclear power plant of that design is to be built, as is the case now. Instead of "re-inventing the wheel" every time, ERDA looks at ways to achieve a common design review and acceptance, the results of which are shared among several EU Member States. This would mean that the reactor design can be more or less built in the same way in all participating countries, except for necessary adaptation to specific local conditions, leading to effective international standardization of reactor designs. This would also allow a broader basis for sharing experience feedback with the corresponding safety benefit. Furthermore construction of a series of nearly identical units will bring significant economic benefit.

It must be pointed out from the start that this does not mean establishing a European supranational authority issuing reactor licenses that would apply all over Europe. It does not mean either taking the licensing procedure of nuclear power plants away from Member States. Design review and acceptance is just one part of the licensing process for a nuclear power plant, but a very important one for the deployment of standardized designs. National regulators will still have to formally accept the standardized designs and make a full assessment of the suitability of the site and of the operators' capabilities. Therefore a European Reactor Design Acceptance would leave enough room for site-specific adaptations, which will be under full control of the national regulator. Finally, every national regulator concerned should be fully involved in any element of ERDA. The aim is not to erode national sovereignty but to reap benefits from stronger and more efficient cooperation.

1.4 EU competence and the principle of subsidiarity

Any action to be taken by the EU proposed by the ERDA Core Group will have to be justified as being within the EU's competence. This applies particularly to legislative acts. While it is now accepted that the EU has certain competences in the field of nuclear safety, these do not encompass all issues of safety in a general way – EU competence has to be asserted for each topic and each kind of legislation separately. This will be addressed in chapter 2.

Even when an EU competence is established, the principle of subsidiarity has to be taken into account. Under this principle, the EU shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, but can better be achieved on EU level (Art. 5 para. 3 TEU). "The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators" (Protocol No. 2 to the TEU, Art. 5). Therefore, in chapter 4 the strengths and weaknesses of introducing a multinational approach to reactor design acceptance will be outlined.

2. Legal Basis for actions of the European Commission

The EU Commission has many instruments at its disposal to encourage and facilitate the actions proposed in this paper. The ability, however, to enact legislation (especially a directive) is dependent on two factors:

- first, whether there is a competence assigned to the EU by the EURATOM Treaty
- second, whether the Council (i.e. the member states) adopts the act with a qualified majority.[8]

The assessment and the approval or licensing of nuclear reactors is part of the overall issue of nuclear safety. Today, it is generally accepted that the EURATOM Treaty (the Treaty) confers some competences in the field of nuclear safety to the EU; however, this is not a global full-scope authorisation and EU competence needs to be asserted for each topic separately.

According to Art. 30 of the Treaty, the EU can establish "basic standards ... for the protection of the health of workers and the general public against the dangers arising from ionizing radiation". Since the further wording of Art. 30 and the following articles only mention matters of radiation safety and since the safety of nuclear facilities is nowhere expressly mentioned, EU competence for nuclear safety as such (in contrast to radiation protection) was under discussion for a long time. A landmark in this issue was the judgment of the Court of Justice of the EU in case C-29/99, 10.12.2002[9], dealing with the accession of the EU to the Convention on Nuclear Safety. The Court states:

> (para. 82)*... it is* ***not appropriate****, in order to define the community's competence, to* ***draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation****.*

The Court then proceeds to an analysis of different subject matters of nuclear safety (following the different articles of the Convention on Nuclear Safety) and states which competence the EU has for each of these subject matters. Concerning licensing (Art. 7 of the CNS), the Court states:

> (para. 89) *Even though the Euratom Treaty does not grant the Community competence to authorise the construction or operation of nuclear installations, under Articles 30 to 32 of the Euratom Treaty the Community possesses* ***legislative competence to establish****, for the purpose of health protection,* ***an authorisation system which must be applied by the Member States****. (...)*

Concerning safety requirements for design, construction and operation, the Court states:

[8] According to Art. 203 of the Treaty, the Council can adopt legislation even if there is no competence of the EU, provided it decides in unanimity. This option is disregarded here because it seems highly unrealistic.

[9] Commission of the European Communities vs. Council of the European Union, C29/99, Judgment of 10.12.2002, European Court reports 2002, p. I-11221 (available at EURLEX [eur-lex.europa.eu])

(para. 105) *The measures ... concerning the **design, construction and operation of nuclear installations** can be the subject of the provisions which the **member states** lay down to ensure ... compliance with the basic standards. However, the **commission has competence to make recommendations** for harmonizing those provisions...“*

All this was recently reiterated and confirmed by the Court in its judgement C 115/08, delivered on 27 October 2009, on the Temelín NPP (para. 102 and 103)[10].

On these bases, the EU adopted the Nuclear Safety Directive 2009/71, which is now to be revised.

From the two judgements, it seems to follow

- that the EU cannot adopt its own safety standards by way of a regulation or a directive (para. 105 of C29/99),
- but that, in contrast, there seems to be some leeway for legally binding provisions on licensing procedures, especially by virtue of para. 89 of the judgement C-29/99. However, this is subject to interpretation and politically dependent on the qualified majority in the Council.

On a more organisational level, the Commission can take a Decision establishing organisations or structures in the field of nuclear safety. An example for this is the Commission Decision 2007/530 establishing ENSREG.

The implications of this legal basis will be discussed more in detail below together with the different implementation options.

[10] Land Oberösterreich vs. CEZ as, C115/08, Judgment of 27.10.2009, O:J. C312/5 of 19.12.2009

3. Towards ERDA: Initiatives for shared design acceptance processes

3.1 Introduction

As set out in the introduction, the goal of ERDA is to achieve progress towards a multinational approach within the EU to assess nuclear reactor designs in order to allow for standardization of these designs. As has been done in some other industries, full-scope standardization of reactors would be reached in Member States if a complete harmonization of safety requirements and national licensing practices were achieved. For nuclear reactors, however, this seems to be far away, given the present situation where:

- nuclear safety is a national responsibility and the European Union has only limited competency in this area,
- licensing processes are different and independent of each other and embedded in national laws or high level regulations,
- safety requirements are somewhat different, at least in the way they are implemented in different countries,
- on safety related technical decisions, the national executive branches of the governments cannot interfere with their regulators (as independence is required by the EU Safety Directive), therefore the European Commission has little influence on regulators on this field.

Nevertheless some progress could be made in the short- and mid-term towards the goal of having standardized designs of the nuclear island of a nuclear power plant deployed in Europe and the European Commission could play a facilitating role in that respect. Acting pragmatically depending upon the circumstances, the Commission can propose incentives, take some initiatives, propose recommendations and may, under certain circumstances, even ask the Council to enact legislation (directive). Some of these are explained below.

3.2 Nuclear licensing: A stand-alone design acceptance process

Typically, a nuclear licensing process for a nuclear installation would begin after a political decision on the deployment of new nuclear power plants is taken by the country executive branch and/or its legislative one. This might be preceded by a public debate. In many Member States the next important step is the application by a licensee to install a nuclear reactor followed by the granting of the nuclear construction license. For a specific project, the nuclear construction license will result from a detail assessment by the regulatory body of the plant design and its adaptation to the site. But it becomes more frequent that generic assessments of different reactor designs (nuclear island as discussed below) take place independently of any specific site or project. It could be a high level assessment of the basic design characteristics such as the “safety options” process in France or the “Generic Design Assessment” process in UK somewhat similar to the “Design Certification process” in the US which gives rise to more in-depth review. Before and/or during the construction phase, the assessment of the detailed design might continue and in any case, the regulator follows the quality of construction and checks the compliance of the construction with the construction license through a control and oversight process including inter alia inspections and hold points. Usually specific regulatory authorizations are needed to begin with the installation of safety related structures, systems and components, commissioning tests and fuel loading. The last step is the granting of the operation license once every design and construction issues have been cleared and the operator has demonstrated his capacity to safely run the plant.

As the recently published survey financed by the Commission on nuclear licensing processes shows very well, all national nuclear licensing processes in Europe encompass most of these components, with somewhat different scopes and arrangements. The authorizations corresponding to the different steps are sometimes given by the government or by the regulator. But every licensing process includes safety assessment of the design of the **nuclear island** which is the most important part for the sake of reactor standardization. For the standardization purpose, harmonization of this generic design assessment is the priority since it is the lengthiest part of licensing process (up to 5 years for country acceptance of a new design) and at the same time the one with a significant economic impact. Avoiding undue repetition of this design assessment in different countries simultaneously or sequentially should be a first objective. To facilitate this it is important that the initial design assessment process is robust (and recognized as such) to ensure the delivery of a safe and economic design.

In this context a useful initiative that the Commission could take is to promote in Member States, through EU legislative framework, a “stand-alone design acceptance” process. Member States should be encouraged and could be required to introduce in their national legislation such “stand-alone design acceptance process” as a first step in their licensing regime. It could be either a specific process as it is the case in the USA with the Design Certification process and in the UK with the GDA (**details see Annex A: The UK process of a Generic Design Assessment**) or part of a specific project assessment process; in the latter case, it should however contain a clear distinction between the generic part that could be reused elsewhere and the project specific part related to site, operator or country license conditions. This kind of stand-alone process already exists in France at a conceptual design stage with the “option de sûreté” (safety options) process that has been used in the past for various designs of the French fleet and more recently and formally on the ATMEA1 design (**details see Annex B: The Safety Options review for the ATMEA1 reactor**). Pre-licensing assessment has been used in the UK in the past and is now applied to a more detailed definition of designs with the “Generic Design Assessment” process for AP1000 and EPR. In this process an applicant (usually a vendor and a utility or at least a vendor with the support of one or several utilities) requests a regulator to make an assessment of a proposed design and to give its views on the safety level of this design and whether it seems to be acceptable for a license. These processes allow for a well-structured assessment of a design independently of a specific project of construction, therefore independently of a specific site and even of a specific future licensee. Description of the design and its safety demonstration is included in a set of well-defined documentation and the regulator is able to state precisely how the design complies with its own regulation, what is accepted and will not be reopened for future challenges and which questions remain open. At the end of the assessment the regulator will issue a “stand-alone design acceptance certificate” that could be used by other regulators. This certificate will be valid for some years (typically 10 to 20 years). This process would be very helpful first for the applicant (vendors and/or vendors in conjunction with potential interested operators) in reducing the technical and financial risk of an eventual project. It would also be very helpful for the other regulators where the accepted design is considered to be built. The more detailed the definition of the design is available the more in depth the assessment could be made and the more useful for the sake of standardization it will be. Ideally the level of description of the design and its assessment should be sufficient to enter into the detailed design development phase and to prepare specifications for equipment procurement. It would be a prerequisite for the validation process mentioned further down in this report.

The scope of this stand-alone design acceptance should encompass the part of the plant that is not site dependent: the Nuclear Island (NI) housing the Nuclear Steam Supply System (NSSS) with the main primary and secondary circuits and their direct supporting systems. Experience shows that the design and layout of these systems, structures and components (mechanical systems, electrical systems, control and instrumentation) within the NI should not be significantly or even at all affected by specific site conditions. In limited and very specific cases, interface with civil works (anchoring) might have to be adapted in some cases and if necessary, the robustness of the civil work could be adapted to take into account specific site characteristics (e.g. more stringent seismic conditions or man-made hazards). However the conditions considered by vendors to establish their generic design are usually based on common site characteristics representative of a large number of existing or potential NPP sites in Europe. Therefore in many cases, it is recognized that adaptation to local site conditions that could affect the design of the nuclear island, should not invalidate the “stand-alone design acceptance certificate” delivered on a safety assessment.

Beyond this design assessment, essential elements of any particular NPP licensing process would remain to be performed by national regulators strictly on their own responsibility. They would review the detailed design and decide about all aspects which are not generic safety aspects of the design, for example the suitability of the site, the adaptation of the design to specific country conditions and, for the specific site, grid and operating conditions and the capability of the applicant to safely construct and operate the nuclear power plant.

3.3 Harmonization of safety requirements: How to make progress?

Some experts think that it is not possible to harmonize licensing processes without first harmonizing safety requirements. However, when talking about technical nuclear safety requirements, we should make a clear distinction between **legally binding requirements** that are included in laws, ordinances or decrees, and **requirements coming from historical methods and practices** of performing safety assessments, often set out in guidance or “informal” documents. The technical safety requirements at the national level are generally based on IAEA safety standards and therefore have much in common across the Member States. They have been aligned on the basis of the WENRA Reactor

Safety Reference Levels[11] and will in the near future also meet the WENRA Safety Objectives for New Nuclear Power Plants[12]. As technical safety activities have always been a national responsibility, national regulators have over time developed different practices and different tools with Technical Support Organisations (traditional TSOs or technical review institutions like TUV or contractors) in each country that are responsible for the detail technical assessment of nuclear projects. This has resulted in the situation where different countries used somewhat different "informal requirements" although meeting similar legally binding requirements. These "informal requirements" are significant obstacles for design standardization. However when TSOs are working together to assess a reactor design they can develop common approaches and understanding that could lead to a convergence in these "informal requirements". A good example of this in practice can be found in the Franco-German review of the EPR (**details see Annex C: Franco-German cooperation in the EPR development**) in the nineties when the TSOs of both countries (IRSN and GRS) worked together to develop common detailed technical guidelines[13] for this design under the auspices of the French and German regulators. If Germany had not reversed its nuclear policy at the end of the nineties it is very likely that EPRs built in France and Germany would have had a very similar design basis of the nuclear island.

This means that some progress can be achieved by pragmatic collaboration even without having to change formal, legally binding requirements. For full harmonization, however, such changes would be necessary.

The last layer of "requirements" used in design and construction of NPPs are the industry technical codes and standards such as those developed by KTA in Germany, AFCEN in France, BSI in the UK or ASME in the US. These codes and standards define how practically to comply with safety requirements of higher level. Although they are developed mainly by industry, the regulators rightfully want to approve them as they are the basis of the detailed design and construction activities or at least to assess their compliance with national regulations. Through the years regulators have influenced significantly the content of these design codes and standards. The end result is that today there are some significant differences in these codes and standards which are an obstacle to reactor standardization. At least it complicates the licensing processes when the regulator or the utility does not know the code used by the designer. An example of this difficulty was faced by the Bulgarian regulator in the licensing process of the Belene nuclear project (**details see Annex D: Design assessment in the Belene project**) proposed by the Russian vendor, because the experts in charge of assessing the design were not sufficiently familiar with the Russian codes and standards.

For now several decades, harmonization of technical standards in Europe has been a powerful tool in the hand of the Commission through Directives and

[11]WENRA Reactor Safety Reference Levels, January 2008; available at http://www.wenra.org/dynamaster/file_archive/080121/1c826cfa42946d3a01f5ee027825eed6/List_of_reference_levels_January_2008.pdf

[12]WENRA Statement On Safety Objectives For New Nuclear Power Plants, November 2010

[13] Technical guidelines for the design and construction of the next generation of nuclear power plants with pressurized water reactors; adopted during the GPR/German experts plenary meetings held on October 19th and 26th, 2000

recommendations to promote the European Common Market and to remove barriers to free trade of goods and services in Europe. A typical example is the Pressure Vessel Directive issued by the Commission in the early 2000, but not applicable for safety related nuclear equipment. This policy of European technical standards development has been recently reinforced by the expert panel for the review of the European Standardization System published in February 2010.[14]

Up to now this policy of standardization has not encompassed nuclear equipment. An exception is the recent initiative of the CEN/CENELEC (one organisation of the European Standard System in the area of electrotechnical activities) that some few years ago began to review IEC (International Electrotechnical Commission) standards on instrumentation and control equipment of nuclear facilities to endorse them with few, if any, modifications, making them *de facto* European Standards. Up to now about 30 standards (including some covering safety related equipment) have been published. This effort should be fully supported. CEN/CENELEC could also be encouraged in endorsing at the European level existing national or international industry standards without developing new ones from scratch.

In expanding the scope of existing standards to the nuclear domain, the European Commission could take benefit of past or current initiatives by the industry.

In parallel of the development of the EPR design, German and French industries worked together to establish common codes based on German KTA standards and French RCC (Règles de Conception et de Construction) to come up with the ETC (European Technical Codes) series covering the main technical areas of an NPP. Once the EPR will receive its license in France, Finland and UK, these ETC would have been de facto recognized by the corresponding regulators (with potentially some caveats) and could serve as a good basis for a technology neutral European nuclear code.

On the request of MDEP, several National Standards Organizations undertook a very comprehensive comparison of various mechanical codes. It covers US (ASME), Japanese (JSME), Korean (KEA), Canadian (CSA), Russian (PNAEG) and French (RCCM) mechanical codes with the aim of identifying the differences, those due to industrial practices or to regulatory influences[15]. In collaboration with the WNA CORDEL working group on codes and standards, work is in progress to as far as possible overcome these differences either by demonstrating that the results in safety level are equivalent or by entering into a revision of codes in order to close the gap.

One can mention also the civil engineering industry that produced during the last decade the EUROCODE. Although it is not formally applicable to safety related building of NPPs[16] it could be a basis for a European nuclear civil engineering code.

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[14] Standardization for a competitive and innovative Europe: A vision for 2020 (EXP 384)
[15] ASME – Code Comparison Report for Class-1 Nuclear Power Plant Components (STP-NU-051-2012)
[16] Example EUROCODE 8

In conclusion, harmonization of safety requirements is already well underway at an upper level through the IAEA fundamental principles and design requirements (SSR-2.1 issued March 2012) and the WENRA work. The Commission may wish to more formally recognise these requirements. But the most useful action the Commission should take is to promote the recognition and adoption of nuclear industry standards, both international existing ones and those that could result from various recent initiatives mentioned above, and to endorse them at the EU level.

3.4. Validation process

A “validation” process would be very efficient in a situation where an applicant in a Member State decides to apply for a NPP project based on a reactor design (nuclear island) previously assessed in another Member State. Today this could be typically the case for an application to build for instance an EPR, AP1000, ABWR or AES92. The national regulatory body receiving this application should make arrangements to benefit from the assessment previously performed in order to avoid repeating the technical work already done. Of course, it would have to be convinced that the scope covered by the design already reviewed would not be adversely affected by specific site conditions and it should develop cooperation with the first regulator in order to understand the safety case produced and to identify any potential adaptation of the design to comply with its own binding safety regulation. The regulator could then “**validate**” the design of the nuclear island approved by its fellow regulator with some potential caveat.

This type of validation could be easier if the first approval of the design was based on a reference design independent of a specific project. A “stand-alone design acceptance certificate” (cf § 3.2 above) could be issued with a clear basis of documentation including the safety demonstration provided by the vendors or the applicant, and the assessment undertaken by the first regulator, thus making it feasible for another regulator to validate and adopt the results. The validation process of other regulators would reference this certificate. The regulators using this certificate should agree not to amend it and not to require its applicant to change the design already certified because of potential different assessment practices. Amendments to the certificate could be considered only to comply with national binding national regulations or site specific aspects.

This type of validation might first result from voluntary arrangements between regulators, but the Commission could encourage them. As mentioned, the two main elements of such an approach would be

- to include in each national licensing process a standalone design evaluation process of the nuclear island leading to a design acceptance independent of a construction license, thus facilitating transfer to other countries,

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Eurocode 8, denoted in general by EN 1998: “Design of structures for earthquake resistance”, applies to the design and construction of buildings and civil engineering works in seismic regions. It covers common structures and, although its provisions are of general validity, special structures, such as nuclear power plants, large dams or offshore structures are beyond its scope. Its seismic design should satisfy additional requirements and be subject to complementary verifications.

- and to enable the “validation” by a regulator of the design acceptance previously given by one of its peers.

These two elements could be considered as good practices in an EC recommendation. Under the caveats given above in the chapter on legal bases, it might even be an option to include them in a revision of the Nuclear Safety Directive 2009/71. This could require Member States to include a design acceptance and a “validation” mechanism in their national regulatory framework.

It is however necessary that the recipient regulatory body acquires sufficient knowledge and understanding of the reactor design in order to be able to exercise meaningful and effective oversight during the NPP construction and the commissioning process and even more important, during the NPP operation. The recipient regulator should become an “intelligent regulator”: Acquisition of design knowledge and understanding might be particularly a challenge for regulatory bodies from countries with little experience of nuclear power or with little experience of a particular reactor technology.

Past experience shows that a regulatory body needs several years to develop the specialized competencies and capabilities needed to effectively perform its functions. In case of the first NPP project in a new entrant country or in case of a new technology NPP project, it is very likely that a certain support would be necessary from a mature approving regulatory body, preferably from a country having already licensed the reactor design and/or from the country of origin (of the vendor company).

Historically, for export projects in the past, such assistance and accompanying partnerships were implemented on a bi-lateral basis. More recently, the Multinational Design Evaluation Program was launched when regulatory bodies from several countries decided to join and share reflection on licensing issues of specific reactor designs.

To be effective, the ERDA validation model would have to facilitate cooperation between the recipient regulatory body and the regulatory body having already evaluated or licensed (if applicable, along with a technical support organization) the particular reactor design, or even impose that the recipient regulatory body officially seeks support from either or both a regulatory body and its technical support organization(s) that already evaluated the reactor design. It should however be recognized that although the issue of a nuclear construction license is a very important step in the licensing process, the recipient regulatory body does not need at this stage to have completed the detailed knowledge acquisition process. Such technical knowledge can be further developed as needed through the oversight process taking place during the construction and commissioning stage and prior to the granting of the operating license which can be considered as the ultimate and most crucial step of the licensing process.

It is also necessary to ensure that the future licensee has sufficient knowledge of the design it intends to build and operate. First it is very likely that this licensee would have participated in the EUR assessment of the design it has selected, getting through this utility assessment a first knowledge of the design. Then it will have to provide evidence and convince its national regulator that it put in place specific arrangements to ensure it is an “intelligent customer”, and that it has not merely appended its stamp on the safety analysis report drafted by the vendor. This assessment of the capability of the license to be an “intelligent customer” will be an important part of the national licensing process by the regulatory body.

3.5 Joint design acceptance by several regulators

Different implementation models could be envisaged for the idea of a joint design acceptance.

a) A first pragmatic approach could be used if there is a request to assess one design in two or several European countries at about the same time. This request could come either from a utility applying for a construction license to build the same design in more than one country, or from a vendor to ensure that its design of the nuclear island could be licensed identically in several countries, or from utilities in different countries wishing to get a green light from their national regulators on the licensability of a design before formally applying for a construction license. In this situation the different regulators who have to assess the same design should not do this independently of each other. Instead, they should work together and conduct a joint assessment through a formal agreement. They should develop arrangements to put in place a joint team of experts from their own staff with the adequate competencies. They might decide that some part of the team will look more specifically to such or such a part of the safety justification of the design but every representative of the participant regulators should have access to the same information and share the results of the assessment of the entire design. The team of experts will conduct an assessment of all generic aspects of the proposed design that will *de facto* result in a “stand-alone design assessment”. The scope and level of detail of this assessment would be agreed in common by the participant regulators and preferably as described above in § 3.2. For the implementation of the outcome, there are two key elements. The design assessment will have no legal form as such, it has to be transferred by each participating regulator into the licence he has to issue according to his national legislation. At the same time, it is crucial that the results of the joint assessment between regulators are transposed in their national licensing process (and preferably into their national stand-alone design acceptance) without substantial modifications (“copy and paste”). This should be ensured by the regulators’ previous voluntary agreement.

b) A more developed and formal version of this model would imply a multilateral agreement enacted between several Member States where the regulators of the participating countries will commit to join their resources to systematically jointly assess the new designs that could be submitted to any of them. Quite naturally, such an agreement would be of interest only to a limited number of Member States interested in new design construction. Legally speaking, this is not a problem. This multilateral agreement could work similarly to the well-known “Schengen Agreement” about abolition of frontier checks and a common external frontier which was concluded between a subset of EU countries willing to take this issue forward. The joint design review would result in a formal document which could be called a “European Reactor Design Acceptance” (ERDA), with at its core a statement by the “Nuclear Schengen Group” that the reactor design can be deployed in the participating countries.

Not all participating regulators will be interested in reviewing all relevant designs. For example, a country may have the policy of pursuing only PWR options and would not be interested in BWR designs. However, within the “Nuclear Schengen” system there should be no “sub-Schengens”. The idea is to have a strong and coherent system in which all regulators participate in all design reviews. The Terms of Reference of the “Nuclear Schengen Group” would have to include a commitment of every participating regulator to contribute a minimum of resources in staff and money to each design review. Of course, regulators interested in a particular design would be free to invest more than this mandatory scope of contribution. Likewise, the particular strengths of individual regulators (e.g. engineering, I&C...) should be taken into account when distributing the work.

In return for the regulators’ obligation to share the assessment burden, there must be some criteria for a design to be eligible for such a review – the requesting party must take some “hurdles”:

- First, only designs should be reviewed which have a credible chance of being chosen for an NPP in one of the member states. In the UK Generic Design Assessment (GDA), vendors had to find a “sponsor” from utilities planning to construct and operate new power stations in the UK. In the EUR, a vendor needs two sponsors to trigger a review. A similar prerequisite could be adopted for the “Nuclear Schengen” system.
- Second, there might be a first check whether the design seems to be basically able to comply with the criteria applied by the “Nuclear Schengen Group” (see below). Only if this is demonstrated in a first assessment step, the application would be “docketed” (a term taken from the licensing procedure of the US-NRC). This would eliminate, for example, Generation II designs.

Besides, the requesting party would have to pay a fee covering all the expenses of the “Nuclear Schengen Group” incurred when reviewing the design.

A joint assessment by several regulators would imply a common set of requirements. As mentioned above in §3.3, European nuclear safety requirements can be shortly considered as *de facto* harmonized with the ongoing work of IAEA and WENRA. Some few differences in national legally binding regulations might remain. More likely, differences in safety assessment practices will surface. The regulators will be constrained to discuss and justify these differences and their positions between peers, making a distinction between those that have a direct impact on the design and those that are just differences in the safety demonstration methodology without consequences on the design itself. Putting a spot light on these national deviations would be a very beneficial effect of the process. It is likely that through these interactions regulators will come up with a common agreement. Should there remain any deviation in legally binding documents, this could be treated by exceptions or preferably by evolution of national regulation. In any case, deploying a standard design throughout several countries has safety benefits which may justify a deviation from single national requirements.

Scope of the design review and the final ERDA should be the nuclear island in its entirety. As to the level of depth and of detail, the review should cover the basic design as described in standard reports comparable to step 4 of the UK GDA. Basis for the ERDA (“licensing basis”) should be a consolidated set of documents. Any changes occurring before the reactor design is referenced in an NPP licensing procedure must be clearly indicated and justified. Should the assessment be deeper, there would be a need to build common set of codes and standards (such as the ETCs for the EPR).

The ERDA may also indicate topics in which a satisfactory result has not yet been achieved, but where it seems feasible to do this in an ensuing NPP licensing procedure (“ERDA issues”, modelled on the UK’s “GDA issues”). These could also be called “exclusions” or “conditions”. They do not hinder the grant of an ERDA but must be taken into account in the subsequent national licensing procedures.

If the design has to be modified after having obtained an ERDA, the question is whether the applicant should apply for a modified/revised ERDA or whether the modification should be addressed only in the national NPP licensing procedure. This is a difficult issue (see the experiences with the US design certification) which would need to be addressed by the Nuclear Schengen Group in its Terms of Reference and/or in guidance to the applicants. Generally, it seems preferable to change the ERDA as this would make sure that the design keeps its standard format and is not fragmented in the different national projects. But in any case all parties should be encouraged to refrain from frequent changes and justification should be required for any change, since the basic idea is to deploy a design in the same shape in different countries over a certain period of time.

The general effect of an ERDA would be that in a national NPP licensing procedure, the basic design of the reactor as such would not be re-assessed. The applicant could refer to the ERDA. The national regulator would concentrate his assessment on site-specific and applicant-specific aspects.

Concerning the reactor design, the national regulator would (only) have to check whether the design submitted to him is identical with the design for which an ERDA has been issued. Concerning site-specific issues, the ERDA could be modelled on an envelope of criteria. In an NPP licensing procedure, the applicant would either demonstrate that the site is within the envelope or, if this is not the case, he would have to demonstrate compatibility of the design (with or without changes) with the site.

If the “Nuclear Schengen Group” is an informal association of regulators with its own Terms of Reference, there is no need for an EU legal instrument to implement this option; multinational agreements between the participating Member States would be sufficient. If the “Nuclear Schengen Group” is based on a multinational agreement between some Member States, it could be installed on a “sub-Union” level.[17] In any case, it should be investigated whether the agreement could be constituted under the “Enhanced Cooperation” scheme of Art. 20 TEU in order to achieve a stronger link to EU legislation. Finally, it is not excluded that in the long run such an agreement would be transferred into EU law – as has been done with the Schengen agreement.[18] The EU would be expected to support and to facilitate the installation of the “Nuclear Schengen Group”, for example by providing a secretariat.

[17] On the legal feasibility of such an agreement, see Nicole Ahner/Jean-Michel Glachant/Adrien de Hauteclocque, Legal Feasibility of Schengen-like Agreements in European Energy Policy: The Cases of Nuclear Cooperation and Gas Security of Supply, European University Institute, Robert Schuman Centre, 2010, p. 17-18. The text is available at http://cadmus.eui.eu/bitstream/handle/1814/13976/RSCAS_2010_43.pdf?sequence=1

[18] The Schengen Agreements of 1985 (Schengen I) and 1990 (Schengen II) were integrated into the framework of the European Union by the Treaty of Amsterdam of 2 October 1997 and since constitute the *Schengen acquis* (see Protocol no. 19 to the Treaty of Lisbon on the *Schengen acquis*).

Under Article 41 EURATOM, the EU receives an investment notification for each large nuclear project in the EU and the Commission issues a statement. In the past years, this statement has been constantly enlarged in scope and now normally also encompasses a statement on the safety of the reactor design. In order to establish a link with ERDA, the Commission could agree to issue a positive statement for the design of any NPP of a design which has received the ERDA. In return, the Commission could be involved (by receiving regular information) in the work and the output of the "Nuclear Schengen Group". This would seem to be similar to the work of WENRA in assessing the safety of reactor designs of EU candidate countries in Central and Eastern Europe in the early 2000s, when the Commission endorsed the expertises given by WENRA.

3.6 Joint design assessment by TSOs

Irrespective of the approval process used for the next nuclear project to be launched in Europe, a very helpful initiative to progress towards standardization will be for the Technical Support Organizations (TSOs) to work together. Today in Europe the majority of regulators rely on national TSOs or technical review institutions for technical safety assessment. European TSOs have established ETSON (European Technical Safety Organisation Network) as a non-profit organisation at the European level with the aim of exchanging analysis and R&D in the field of nuclear safety by sharing experiences, to contribute to fostering the convergence of technical nuclear safety practices within the European Union and beyond and to work together in safety assessment and research projects. They have already launched working groups on various safety issues with the aim to develop common safety assessment guidance. As different assessment practices are a substantial obstacle to standardization, joint assessment work by TSOs for several regulators on specific projects will encourage them to find consensus and *de facto* progressively to harmonize their practices.

There is already an example of such a joint assessment by a group of TSOs: In 2008, the Bulgarian regulator (BNRA) requested a joint team of GRS and IRSN (both member of ETSON) to assist in reviewing the Belene project. The conclusion of this review was that:

> ”*On the basis of the material presented in the ISAR (Interim Safety Analysis Report), the Technical Design documents provided, the PSA and the outcome of the discussions with Russian experts during specialists' meeting in Moscow and Sofia and all new information obtained in the present review, the Reviewer concludes that the proposed Technical Design of Belene NPP is in general in conformity with IAEA Design Safety Requirements, Bulgarian legislation and best international practice.”*

The European Commission could take the initiative of recognizing and supporting ETSON. But the Commission could also establish a European Nuclear Safety Assessment Team (ENSAT) based on technical resources of ETSON and other technical review institutions. ENSAT would be manned by a permanent small team of project managers and experts could be drawn from the human resources of ETSON members to be temporarily assigned to each specific project.

ENSAT and/or ETSON could be used in combination with the other two instruments explained above (Validation and Joint design acceptance). It could be solicited and work only under the auspices of

- a regulator of a European country facing an application for a construction permit of a new design, but with insufficient national human resources to conduct a detail safety assessment on its own,
- a regulator involved in a “validation” process (cf. § 3.4 above), where support by an international team of TSO staff – with substantial involvement of the TSO of the country where the design was first licensed – would make great sense,
- or a group of European regulators that would decide to conduct jointly (cf. § 3.5 above) an assessment of a specific design proposed simultaneously in their countries by one or several utilities (joint design approval) – here too, support by an international team of TSO staff would fit perfectly.

In every case the cost will be supported by the requesting regulators, who may seek reimbursement by the applicant(s) through their national financial arrangements.
ENSAT assessment could be done on a basic design description of the project, corresponding roughly to the level called “safety options” in France. This would be very similar to the assessment level made by the EUR (European Utility Requirement) organization that has a good experience of such international review where experts from various utilities get together to assess a design submitted by a vendor and to reach a consensual opinion. The two reviews, by ENSAT and by EUR, could be run in parallel. That would provide to a vendor and consequently to interested customer utilities a very good view of the chance of the design to be built in European countries without too many national modifications.

ENSAT assessment at a more detailed level corresponding to the Generic Design Assessment (GDA) in UK or the Design Certification process in US would imply a common reference safety framework and an involvement of the regulator(s) having solicited ENSAT. At the end of the process the requesting regulator(s) would issue an Acceptance Certificate (with potential caveats) based on ENSAT assessment with a European Stamp that could be used by other national regulators in their national construction permit processes. The national specific aspects of the project and the capacity of the operator to safely run the plant would then need to be analysed at the national level.

ENSAT could be established and run by a voluntary decision of ETSON members only. However it seems likely that involvement of the European Commission would provide it with more credibility in the eyes of some national regulators and public opinion. A potential role for the Commission could be to promote ENSAT and to incentive regulators to use its services. Its involvement could take also the form of funding the ENSAT permanent staff and approving its quality management system.

For its assessment, ENSAT would have to use as reference at least the relevant WENRA documents, IAEA Safety Requirements and any finalised common safety assessment guidance mentioned above.

Establishment of ENSAT will not prevent regulators from acquiring sufficient knowledge to discharge their regulatory duties. Today in Europe the majority of regulators rely on national TSOs and have arrangements to acquire and maintain this knowledge. The same arrangements would have to be defined between regulators and ENSAT. In addition it is worth noting that a very important part of the necessary knowledge could be acquired by the regulator during inspections at factories and construction sites that would remain national responsibilities.

4. Strengths and weaknesses of the ERDA process

The implementation of the European Reactor Design Acceptance (ERDA) process in the European Union is expected to facilitate the deployment of a number of standardized nuclear power reactor designs in Europe, thus bringing significant benefits to most stakeholders.

Some of the initiatives on reactor design standardization mentioned in the introduction have made reference to the associated benefits, mainly the two WNA Reports mentioned above[19] and the EUR document[20]. These reports discuss safety and licensing benefits as well as the economic aspects and stakeholders' acceptance. This chapter tries to depict more in detail the benefits and potential drawbacks associated with the development of ERDA and the deployment of standardized reactors in the EU.

The chapter will concentrate on the inherent strengths and weaknesses of the ERDA concept. Opportunities and threats are more difficult to analyse in the scope of this report. They will be shortly summarized in the synthesis at the end of this chapter.

4.1 Strengths

In the following paragraphs the strengths of the ERDA concept relating to safety benefits and to economic and licensing benefits are addressed.

4.1.1 Safety benefits in general

The existing nuclear power plants in the EU belong to many different designs. They are different from country to country and even within most countries the reactors were not constructed to standardized designs (France being a notable exception).

One of the most important factors in further improving the safety of nuclear power plants is the exchange of lessons learned and of experience. There are several mechanisms in place to ensure this information exchange, both on national level and on EU (Clearinghouse in Petten) and international level (NEA and IAEA systems and WANO). However, this information is not always applicable to every design. It is difficult to draw valid conclusions from a finding in another nuclear power plant if this is of a totally different design. The same goes for a possible improvement of a design – any backfitting and improvement measures would have to be adapted to the specific design, if they fit at all.

This is where ERDA would ensure a much better basis for improving safety. The safety benefits of the concept of common reactor acceptance are based on the fact that future nuclear power plants in the EU, contrary to the existing ones, will be part of fleets consisting of a number of power plants of the same design. The

[19] See footnotes 4 and 5.
[20] European Utilities Requirements for LWR Nuclear Power Plants, Revision C-05, April 2001, Volume 1 Chapter1, Introduction and Road Map.

deployment of standardized reactors will offer a much broader basis of experience feedback in design, construction and operation compared to the existing system with its many different designs. In this context, lessons learned – like the ones from the Fukushima accident – will be much easier to share. It will be easier to identify areas for design improvements. These design improvements could be planned and implemented consistently within each fleet.

This approach would help to keep the standardized plant at the most advanced level of safety, in accordance with newly gained experience or progress in technology, and would thus enhance the concept of "*continuous improvement of nuclear safety*" (cf. article 1 para. (a) and article 6 para. 2 of the Nuclear Safety Directive 2009/71[21]). This concept is more effective when applied to a fleet of standardized reactors considering the larger base for experience feedback and analysis and the fact that the related efforts for continuous improvement could be supported and shared by multiple operators. The main opportunity to do this is during the Periodic Safety Reviews (PSR) which are carried out in all EU nuclear countries. While today the PSR results are only applicable to the NPP concerned, in future one might imagine implementation of identical improvements in the entire fleet of each design through initiatives of strengthened "Owner's Groups" or "families" of operators of a same design (see the CORDEL report referenced in footnote 5).

4.1.1.1 Safety benefits from the future operators' viewpoint

It is undeniable that standardization of nuclear power reactor designs would bring significant safety benefits to the future operator of these reactors.

During the licensing stage, the existence of a common safety case for a standardized reactor design would be a sound basis for a new operator to develop and demonstrate technical capability for safety and take ownership of the safety demonstration of the selected standardized reactor design. Having a standardized approved design safety case at the beginning of the project would facilitate early understanding of, and focus on, significant safety issues by the future operator. This would also facilitate an appropriate allocation of efforts and resources for dealing with adaptation to local conditions as necessary. Verification and validation of the safety case could also be diversified and made more robust as different operators will be involved.

During the construction (including component manufacturing) and commissioning phases, the future operator would be able to benefit from the experience feedback of previous construction projects of the standardized reactor design, thus contributing to and facilitating the achievement of the required quality of the end product.

Regarding operation and maintenance, the deployment of standardized reactor designs would also facilitate training, management and turnover of personnel, with good opportunities for sharing, preserving and extending knowledge, know-how, as well as operational experience feedback within the same company as

[21] Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, O.J. L 172/18, 2. 7. 2009

well as between a group of utilities operating the same standardized reactor design (concept of Owners' Group).

Standardization could also allow overcoming obsolescence of some spare parts: Suppliers would be keener to continue production of specifically qualified spare parts as they will be serving a fleet instead of a limited number of plants. Alternatively, utilities operating the same design may decide to share some stock of spare parts.

4.1.1.2 Benefits for the nuclear regulatory bodies

In a similar manner as for the operators, nuclear regulatory bodies would also benefit from the standardization of nuclear power reactor designs sustained by the ERDA process

- to share resources in performing the safety assessment supporting the authorization process;
- to take common and consistent positions on generic safety issues
- and to exercise oversight during the construction process as well as during subsequent commissioning, operation and maintenance.

They would have the opportunity to share experience and possibly resources, with nuclear regulators from countries where the other standardized reactor designs are deployed. This may be a decisive issue for regulatory bodies with limited resources who might have difficulties in performing a full-scope design review in a time compatible with energy and industrial needs.

The effectiveness and efficiency of regulatory design reviews, which are central to the national licensing processes, would be improved by **sharing methods and data arising from safety evaluations**. The process of identifying and resolving safety issues is clearly more effective if it is handled internationally. Moreover, knowledge transfer on all regulatory issues, including regulatory practice, could greatly facilitate the development of civil nuclear energy in emerging nuclear countries, which have yet to develop or to reinstate well-established and independent regulatory regimes.

Another issue where closer collaboration based on harmonized requirements is urgently needed is in **quality inspections in construction and component manufacturing**. Given the large number of contractors and sub-contractors from all parts of the world that are involved in a new build project, collaboration among regulators is essential in order to provide for an efficient handling of manufacturing oversight issues. Sharing inspection practices between regulators is already successfully tested in the framework of an MDEP working group.

The process of harmonization in itself can lead to better national regulations because the regulators can obtain insights into why different solutions have been chosen in the past. This cooperation may lead to a **common choice of the most reasonable and convincing solution**. Cooperation also allows a country with little or no prior nuclear experience to establish a regulatory framework through international cooperation in a more efficient and timely manner, thereby opening up opportunities for nuclear power where it has not previously been a viable option.

4.1.1.3 Safety benefits from the public's perspective

Finally the deployment of standardized nuclear power reactors based on the ERDA process would ensure that the public in the countries where the reactor design is being considered or constructed, all over Europe, gets access to identical information on the safety of an approved reactor design. The implementation of the ERDA process would mean that several Member States in the European Union agree upon the fact that a certain reactor design meets common European design safety goals. The public would be assured that a homogeneous level of safety by design would be guaranteed in case of deployment of such standardized reactor design to be built in their country has been peer reviewed by other countries, thus guaranteeing a homogeneous level of safety.

The ERDA process could facilitate public participation in the safety and information process and would reinforce the notion of priority to, and responsibility for, safety all over the European Union as well as openness and transparency. Already now, cross border hearings and public inquiries are elements of many licensing processes for nuclear power plants by virtue of the EU legislation on Environmental Impact Assessment (EIA) and the Espoo Convention[22]. This development could be consolidated by an ERDA process with public participation. By extension, it can be anticipated that having built a broad public opinion at European level with a homogeneous level of information and expectation might facilitate the expansion of such practice worldwide.

4.1.2 Economic and licensing benefits

The approach of standardization and common licensing embodied in ERDA has been chosen with the aim, besides improving safety, to facilitate licensing and to improve the economics of new nuclear build. Three different kinds of economic and licensing benefits can be envisaged.

First, a European design acceptance process introduces much more certainty and could, under appropriate circumstances, be the decisive factor to induce utilities and investors to implement a nuclear power plant project (in those countries which have decided to allow nuclear new build).

Second, once a design has been taken through a European design acceptance process, the licensing procedure of nuclear power plants in the different Member States would be shorter and less complicated and less vulnerable to delays and re-design work. This leads to savings in costs of licensing and in overall project costs.

Third, on the level of actually implementing an nuclear power plant project, a European design acceptance process could lead to a "series effect" with a number of reactors being built to the same design in different European countries. It is quite obvious that a series effect reduces the cost of each single

[22] Convention on Environmental Impact Assessment in a Transboundary Context (Espoo, 1991)

unit of the series and enhances the competitiveness of the European nuclear supply chain.

These effects will be further explained in the following subchapters.

4.1.2.1 Reducing uncertainty for nuclear new build

Experience has shown that nuclear new build in the EU has not been progressing to the extent which had been projected in optimistic terms. Even in countries which generally favor the establishment of a nuclear new build programme and which have decided to introduce or to maintain nuclear as a substantive part of their overall energy mix, some projects have not been forthcoming due to hesitation on the part of investors. One of the main reasons is that the overall project risk is deemed to be too high. There have been examples of projects not running smoothly, of delays and the necessity of re-design which have led to dramatic cost increases. In a certain sense, every time a design is deployed for the first time in a European country it is a first-of-a-kind, even if it has already been licensed or built in another country.

A European reactor design acceptance process would introduce more certainty to the licensing of nuclear power plants. If an investor is confident that the reactor design as such will be accepted by the regulator, a major obstacle is removed and all parties involved can concentrate on site-specific and project-specific issues. This is the main reason why the US and the UK have introduced a generic reactor design evaluation and approval process (the Design Certification in the US and the Generic Design Assessment in the UK) – it was perceived in both countries that otherwise nuclear new build would be more difficult in a competitive, deregulated market. A European reactor design approval process would take up this idea and spread it over a group of EU member states.

Such a process would also strengthen the industrial basis in the EU and make best use of the remaining nuclear expertise. Therefore, the supply chain risk is reduced in the same way as the licensing risk.

All these factors contribute to decisively reducing the perceived overall project risk. This may induce investors, especially in countries with smaller nuclear programmes, to move forward with nuclear power plant projects which otherwise they might not pursue. The benefits of this are difficult to quantify for any single project, but they are obviously very substantial.

For new and advanced designs the uncertainties of the first of a kind will be particularly large. A joint design acceptance as proposed by ERDA would be very beneficial for the introduction of new technology.

4.1.2.2 Reducing the cost of licensing

If, by way of a European reactor design acceptance process, the design is already approved, it was estimated that the cost of obtaining a construction license for a specific reactor of that design could be reduced by around 50 million Euros[23] for the first project in a recipient country.

Beyond this immediate effect on the pure cost of licensing, a previous European approval would greatly reduce the need to re-do assessment and engineering work every time, which is the case now. The savings related to re-engineering studies for the implementation of different national safety requirements might amount up to several million man-hours for the first project in a recipient country – this means an amount of hundreds of millions of Euros. The regulatory authority would benefit in the same way, reducing the strain on its staff and financial resources. Nevertheless it must be stressed at this point that even when making use of the work of other regulators, the recipient national regulatory authority will still need to develop and maintain the required technical competences to be able to exercise control and oversight of design site adaptations, construction, commissioning and operation.

4.1.2.3. Economies of scale

The series effect

Over the world, little quantitative feedback is publicly available regarding the economic benefits derived from the deployment of a fleet of standardized nuclear power reactor designs ("series effect") compared to a series of individual non standardized projects.

Existing experience

The most significant feedback available comes from the national French NPP programme. From that experience, EDF, the single nuclear operator in France, was able to derive a tentative model regarding the impact of the "**series effect"**[24] on the investment cost and on the construction cost of NPP units, based on the successive PWR series in France.

The following table is based on this EDF past experience. It presents the specific investment cost ratio for a series of N units in relation to the specific investment cost for a series of 10 units. The units are assumed to be identical (same detailed design and suppliers) and undertaken at a regular rate over a decade (i.e. a rate of 1 unit per year for 10 units).

Number of units: N	1	3	5	10	20
Investment cost per unit Ratio series of N units/series of 10 units	1,6 to 2,2	1,15 to 1,30	1,05 to 1,15	1	0,95 to 0,98

[23] Based on UK GDA process and several US Design Certification processes in the nineties
[24] B. Roche, EDF, "Lessons Learned from Standardized Plant Design and Construction", IAEA Symposium on Evolutionary Reactors, Seoul, 30 Nov. – 4 Dec. 1998

Another example in Europe is the installation of the three Konvoi plants in Germany[25] using the same design, the same licensing process and the same suppliers. The main driver of this concept was to reduce the uncertainties in the licensing and oversight process.

Similar savings associated with series production to those observed by EDF have been observed by KEPCO[26].

European deployment of standardized reactor designs

The French data only apply to the EDF nuclear power plant programme and therefore to a programme implemented in one country by the same main actors. The boundary conditions for implementation over a range of different countries would be different.

Assuming that a specific reactor design could be implemented in more than one member state, the standardization and series effect demonstrated above on a national basis (France) could potentially be observed in the same way. Trying to establish an estimate of the potential economic benefits resulting from such a European deployment of standardized reactor designs, the series model mentioned above could be used under the following assumptions:

- all the standardized projects performed under the same contract model,
- the same supply chain is used for all the standardized projects,
- sites could receive multiple units.

Should the ERDA process be implemented in several countries for the same reactor design and assuming the cost of the first of the kind being around 4 billion Euros, the table above shows that cost of the 5th unit would be reduced approximately by 1.5 billion Euros.

Economies in procurement

ERDA could have a positive impact on the procurement activities and more specifically on the European nuclear equipment manufacturing industry, allowing the production of much longer series of identical components. This would permit lower costs and better quality of equipment. ERDA would also facilitate the implementation of an “off-the-shelf standardized equipment” policy with cost savings as a direct consequence. This would be particularly valid for nuclear pressure retaining equipment whose manufacturing process can spread over several years (up to 5-6 years for a large capacity PWR reactor pressure vessel). This would allow long-term planning and smoothing of the manufacturing factories’ activities, avoiding risk of “bottleneck” effect, especially regarding forging of very heavy ingots for which the number of qualified and competent forge masters worldwide is limited.

This would have positive impact on employment for the whole supply chain and, as important, for the inspection sector where bottleneck effects can also be observed among approved inspection bodies. In addition, this would facilitate

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[25] Isar 2, Emsland, Neckarwestheim 2

[26] *The economics of advanced forms of nuclear energy,* by Paul Howarth and Darren Potter, to be published in Vol. 8 Issue 4 (July 2012) of *Nuclear Future*

knowledge management, education and training, maintenance and transfer of know-how between generations.

Global economic benefits

Given the economic benefits mentioned above, nuclear power competitiveness will be improved. This would provide a low carbon source of power while reducing or at least stabilizing the cost of electricity in Europe with corresponding benefit for European citizens and industry.

4.2 Weaknesses

In the following some real or perceived weaknesses and threats regarding the ERDA process and reactor standardization are analysed.

4.2.1 Can standardization lead to detrimental effects on safety?

In a scenario of European deployment of a limited number of standardized designs, if a design shortcoming were to be revealed at one plant, then the whole fleet of standard plants could potentially be affected at one time. A design fault could theoretically be spread over a number of plants. However, the probability of such an error being detected at the initial stages is much higher if a greater number of reactors of one design is deployed, due to the accumulation of experience and knowledge exchange during evaluations (*e.g.* in the framework of a Probabilistic Safety Assessment), testing and operation.

Further, in the unlikely event of a significant generic shortcoming, remedying and back fitting measures could be organised and implemented in a more efficient manner across all plants, as the operators, vendors and regulators involved could easily cooperate on the basis of international agreements, voluntary initiatives, and reporting requirements. In such a case, the civil aviation industry might serve as a model: if a shortcoming is detected, the designer's competent authority (for example, the US Federal Aviation Administration, FAA) will, after a consultation with the affected vendor, issue an "airworthiness directive" which will be taken on by the authorities in all countries concerned. In this model, back fitting measures are taken quickly and uniformly, offering a maximum benefit for safety internationally. We believe that there is scope for moving some way towards this approach in the nuclear industry, but not, of course, in a way that would compromise the full independence of national nuclear regulatory bodies.

It is also possible that a significant generic shortcoming could have economic downsides for operators. For example, it can be argued that a need for back fitting a greater number of reactors might occur simultaneously, which could involve shut-downs and underproduction of electricity and cause a bottleneck in industrial capacity for the procurement of necessary replacement components. However, this would not be a safety-related issue and the small likelihood of it occurring would have to be weighed against the other much greater economic benefits of standardization.

Therefore, we believe the aspect of a possible "common cause" design fault is not a decisive weakness of the standardization approach.

4.2.2 Level of confidence between regulators

National regulators in Europe have a different history, different organisations and different structures. Some have important in-house staff while others rely more on TSOs or external technical expertise. Their human resources are quite different, depending on the size of the country's nuclear programme. They are not involved at the same level in safety research activities. Their scope of detailed technical expertise may also vary.

Most of the initiatives this report suggested above (cf. §2) imply regulators working together. This means not just exchanging information, as it is widely the case today, but sharing the assessment of a design and relying at least partly on the work made by other to take a position. This assumes a high degree of confidence on the level of competence between counterparts and such confidence may take some time to build up. In the aviation industry this high level of confidence is achieved between Europe, the USA and some few countries, allowing for a quasi-automatic recognition of certificates issued by one of these country by the others. But it will take some time for instance for Europe to recognize a flight certificate issued by a third country aircraft regulator with little recognition in the international aeronautics landscape.

Fortunately, through bilateral contacts and mostly through the WENRA initiative during the last ten years, European regulators have begun to develop a good knowledge of each other. They have learned to work together and the stress test defined commonly after the Fukushima accident was a further step forward. In addition, inside the MDEP framework, UK, Finland and France are sharing their respective assessments of the same design; they even take common positions on specific issues about this design. Therefore whereas it is too early to consider a common multilateral assessment of reactor designs involving all regulators at the European level, there is already a small number of countries that could join their efforts for a common work in that direction. In addition it is realistic to think that regulators with less experience will be more prone to rely on, and have confidence in, more experienced regulators. Thus, they could join the club of their peers.

4.2.3 Complexity of collaboration

Getting a collaboration agreement between different organizations, such as regulators, takes time: Discussions about the exact level of cooperation, the roles and responsibilities of the various partners, the legal aspects, might likely be cumbersome and, even with good will, consensus would be slow to build. In addition political interferences could occur and slow down the process.

This could delay the deployment of a specific project or group of projects, if the discussions did not begin in advance. In order to avoid this, a general framework between countries potentially interested by the kind of collaboration described in this document could be very useful. The Commission could play a role in preparing such a general framework.

4.2.4 Piling up different requirements

Regulators or their supporting TSOs working on a joint assessment of a design may wish to use the complete set of their own regulation and assessment practices. If they cannot agree on a unique set of harmonized assessment criteria, there is a risk that they request the implementation of the envelope of the different requirements. That would certainly introduce complexity in the design and increase the cost of the plant. It may also have some safety drawbacks. Each national set of safety requirements and assessment practices results from a safety approach that has its own logic and consistency. They might differ between countries: some requirement apparently less stringent on one point is compensated by a more stringent requirement elsewhere. Mixing various sets of requirements coming from different approaches would bring inconsistencies. An example is the use of mechanical component codes. They usually have different parts covering design, construction and in-service inspection. These parts are consistent and especially the inspection requirements are in line with the design aspects (i.e the minimum sensibility of the inspection technique to detect potential defects should be coherent with the maximum defect size considered in the design calculation). Taking the design requirements of one code with the inspection requirements of another one might result in an unsafe product.

As a positive prospect, the elaboration by WENRA of their safety objectives for new nuclear power reactors in 2010 and more recently, the preparation of position papers which elaborate some of these objectives, tend to show that such collaborative activities between regulators, including constructive exchanges with the industry, can be transparent, effective and efficient and result in balanced and consensual common positions.

4.2.5 Access of new vendors to the market

A possible weakness may be seen in the observation that vendors having obtained an ERDA might have a competitive advantage to the detriment of others who might face a serious obstacle for entering the market.

Quite naturally, having participated in an ERDA step makes a design commercially more attractive. This is demonstrated by the GDA process in the UK. The GDA is not legally a prerequisite to apply for a nuclear site licence with a certain design. In practice, however, no applicant would take a design which has not received, or is about to receive, the Design Acceptance Confirmation which is the outcome of the GDA. Otherwise the outcome of the Nuclear Site Licence process would be too uncertain.

This underlines the requirement that there should be no discrimination in access to ERDA mechanisms. Clear and objective access criteria need to be established. At the same time, it has to be underlined that ERDA only makes sense for designs which have a realistic option of being chosen for a new NPP. The resources of all parties involved in ERDA initiatives, especially the regulators, should not be wasted. Therefore, a selection criterion that a design has to be “sponsored” by a utility – this was the choice taken by the UK for the GDA process – should be acceptable. If a vendor does not succeed in winning the interest of any utility in his design, then he has no real prospect of access to the EU market at this point in time anyway. Should this change later, the vendor can always apply for participation in one of the ERDA instruments – there is no inherent time limit.

Some ERDA instruments need no specific access at all and benefit all designs. For example, the idea to introduce, in each participating Member State, an independent design acceptance, would immediately be valid for all designs for which a licence application is submitted in one of the countries.

All in all, ERDA does not establish a "club" of privileged vendors and does not introduce new barriers to the EU market. It is open to all reactor designs which have a certain prospect of being chosen by utilities for investment in the EU.

4.3 Synthesis of strengths and weaknesses, opportunities and threats

The analysis has shown that the ERDA approach with its set of complementing ideas and instruments presented in this report has great inherent strengths. ERDA leads to greater standardization of reactor designs and enables regulators of EU Member States to license nuclear power plants without introducing substantial design changes due to national regulations and safety assessment practices. This standardized and cooperative approach has a beneficial effect on safety as well as on the effectiveness of licensing and the economics of new nuclear build.

Some weaknesses have been analysed and shown to be negligible or to be far outweighed by the benefits. In terms of safety, the overall balance is far positive. In terms of opening of markets, competitivity of European nuclear industry would be much strengthened and there are no effects of market foreclosure by a "club" of vendors with an ERDA certificate.

The benefits of ERDA would be shared by all parties: by regulators who profit from closer cooperation without giving up their national sovereignty, by industry which benefits from the reduced licensing risk and cost and by the EU public which is involved in a more consistent manner than today.

As to threats and opportunities for the ERDA approach, these are much more difficult to define. One potential threat has been outlined: ERDA can only work if the regulators of participating EU Member States build confidence in each other. If this process is based on robust peer reviews and on the experience of past successful cooperation, it should be possible to overcome this obstacle.

It is difficult to make a statement whether the current general situation in the nuclear field in the EU constitutes more of a threat or more of an opportunity for ERDA. ERDA is about facilitating the licensing of new nuclear power plants. Currently, there is only a limited number of EU Member States actively pursuing a programme of new nuclear build; the Fukushima accident as well as the difficult economic situation and market conditions unfavourable to long-term investment have led to a possible stagnation of nuclear projects in some countries. The impact on ERDA could be seen in two opposing ways. It could be argued that the current situation with less than vigorous development in new build and with a small number of projects does not lend itself easily to an application of ERDA ideas. The other way round, it can be said that implementation of the ERDA approach might contribute substantially to giving a new impetus to new nuclear build in the EU. Therefore, ERDA could constitute an important element in the EU's nuclear policy.

In chapter 6, some possible examples for an application of ERDA instruments in the EU will be given.

5. Models from other industry sectors

In this chapter, two models for mutual acceptance of licensing results will be shortly presented: civil aviation and the European rail system. It is to be acknowledged that both cases focus on transportation objects moving around and crossing borders (which is of course not the case for NPPs, although radiation released in an accident does have the potential to cause cross border impact), necessitating quite naturally a multinational approach. On the other hand, in both sectors licensing harmonization is mainly done for safety reasons and here there is a clear parallel to the nuclear field. While not all aspects of multinational aviation and railway safety regulation may be eligible for transfer to nuclear, some of them certainly are.

5.1 Aviation

5.1.1 International Framework

In civil aviation, there is an international framework for licensing based on the Chicago Convention on International Civil Aviation linked to a specialized UN agency, the International Civil Aviation Organization (ICAO).

In each country where an aircraft of a certain type is to be registered, a Type Certificate is awarded to the designer/manufacturer of the design by the competent national or regional aviation authority. Type Certificates are issued first by the regulator of the country of origin of the design (State of design) and then by the regulators of all countries where an aircraft of this design is to be registered (State of registry). The Type Certificate, which attests compliance of an aircraft type (design) with applicable safety standards, can be roughly compared to the reactor design certification, conceptualized in this paper. In addition, each individual aircraft needs an Airworthiness Certificate granted by the State of registry; this could be somewhat compared to the licence of a specific NPP. For ERDA purposes, however, the Type Certificate is more relevant.

A carefully balanced international system exists to facilitate and streamline the certification processes:

- The Chicago Convention on International Civil Aviation provides a general international framework for regulatory cooperation and an envelope of minimum safety standards which are complemented by more detailed national codes.
- There is no automatic international validity of a Type Certificate issued by the regulator of the State of design or by any other regulator. However, authorities collaborate in type certification on the basis of bilateral agreements. Through conducting an evaluation of each other, participating authorities conclude that the other party is a trustworthy and experienced regulator with well-established procedures. This is the basis for concluding the bilateral agreement which leads to mutual acceptance of Type Certificates under certain conditions.

- When performing its design reviews, the aviation authority of the State of design involves experts from the aviation authorities of the major other countries in the review team. This results in literally simultaneous production of Type Certificates in all countries involved. Authorities which do their review later will also closely cooperate with the authority of the State of design.
- When performing their own design reviews, the authorities of the other countries will not re-do the assessment done by the authority of the State of design. Instead, they will concentrate on validating the Certificate against those requirements which are specific to their own regulations (the “national delta”). In practice this may have the additional effect of leading to a re-evaluation of those deviating requirements whether they are really justified.

Once the Type Certificate is issued, the authorities will work together closely both among themselves and with the designer and the operators to exchange findings and to find common agreed solutions for design improvements (Airworthiness Directives).

5.1.2 Development in the EU

In the EU, this international system has been taken to a new level by the creation of the European Aviation Safety Agency (EASA) in 2002. The EASA is competent in the EU to issue Type Certificates which are valid in all EU Member States. ERDA does not propose, at least not in the short- and mid-term, to achieve anything comparable for nuclear by founding a European Nuclear Agency. Instead, it would already be a major step forward if the existing international (non-EU) system of regulatory cooperation and harmonization of standards, as explained above, could be taken as a model.

However, it is of high interest to analyse the development leading to the creation of EASA. The process started with a voluntary cooperation of the national aviation authorities. In 1970, they founded the Joint Aviation Authorities (JAA). The main objectives of this association were to facilitate certification of aircraft designed jointly in Europe (like the Concorde) and to achieve a greater alignment of European national standards with each other and with the US standards. Quite obviously, both aims were driven by the European aircraft industry and they were strongly supported by politics. Nevertheless, the JAA was a voluntary association of national regulators. From 1970 onwards, considerable alignment of national standards along “Joint Aviation Requirements” (JARs) was reached.

In the course of time, an additional objective came into focus: to achieve a more integrated structure with stronger collaboration of regulators and a common approach on certification. This stage was concluded with the signing, by the national regulatory authorities, of the “JAA arrangements” in Cyprus in 1990

(**Cyprus** Arrangements).[27] They are founded on “the benefits of a European approach to obtain a high consistent level of safety”.[28]

The parties agreed to

- Develop common rules and certification procedures and to transpose them in their legal order
- Certify collectively the products designed in their countries or imported from a third country
- Conduct regular peer inspections to verify that the common rules and procedures are effectively and uniformly implemented by all parties.

Like in ERDA, the first two points – application of common standards and shared certification – were closely connected. It has to be pointed out, however, that the alignment of national requirement was done on a voluntary basis. There was a commitment by the participating authorities to gradually phase out national deviations, and there certainly was a strong peer pressure to do so. However, in the Cyprus Agreements there was a clause safeguarding that any authority would only take over the common standards and procedures as long as “they allow fulfilment of its national obligations as civil aviation Authority”.

The implementation of regular peer inspections among regulators was seen to be of vital importance, as strong collaboration could not simply be imposed by political decision, but could only evolve in a framework of growing mutual trust. The aim of the peer inspections was to foster this trust.

JAA eventually became history when Europe went even further and EASA took over its functions. Given the current status in the nuclear field, the 1990 Cyprus Arrangements could be used as a blueprint for a voluntary association of regulators under common Terms of Reference with the aim of sharing design reviews, without in any way compromising the national sovereignty and full-scope competence of all authorities involved. **The most interesting provisions of the Cyprus Arrangements have been compiled in Annex E**.

5.2 European rail system

The situation in the transboundary European railway system is somewhat more complicated than in aviation. Legislation is based on two EU directives, the Interoperability Directive 2008/57/EC and the Safety Directive 2004/49/EC.

Backbones of harmonization are Technical Specifications for Interoperability (TSIs). They are decided by a Committee of Member States and the Commission and implemented by national safety authorities and notified bodies. TSIs normally only apply to new vehicles and therefore currently have a still limited scope. There is an important effect on licensing: If a vehicle has been approved in one Member State according to TSIs, another Member State is not allowed to re-do the assessment. Exceptions are special national requirements which may

[27] Arrangements Concerning the Development, the Acceptance and the Implementation of Joint Aviation Requirements, Cyprus, 11 September 1990, available at https://easa.europa.eu/rulemaking/docs/international/archive/cyprus.pdf

[28] Cyprus Arrangements, page 1, Considerations, first bullet point

require additional assessment (example: requirements for resistance against extreme cold in Finland).

Concerning the existing rolling stock which is not affected by the TSIs, a Reference Document has been established listing all national rules and parameters for authorisation of vehicles. The rules are classified in three groups: those which are equivalent, those which are necessarily different ("legacy", for example deviating tunnel gauges) and the rest which should be progressively reduced. The standards in the "equivalent" group need not be checked by every authority separately. This categorisation and the so-called "Cross Acceptance" for equivalent standards is a pragmatic, non-legalistic solution for the time the TSIs have not yet deployed their full scope. They may be a model for ERDA.

6. Examples of potential application of ERDA initiatives to incoming nuclear projects in the EU

The implementation of the full ERDA process will take time. However if Europe had already established such procedures the upcoming New Build Projects (as of 2012) would have immediately benefited from this.

Stand-alone design acceptance process

In most European countries the design review is part of the project specific (site) license. A formal Stand Alone Design Acceptance exists only in few countries.

As described before, the UK has introduced the GDA process which is independent of a specific project. This generic process already incorporates many features of a stand-alone Design Acceptance as proposed in this document (cf. §3.2 above). As the result, the GDA made the safety evaluation of the different designs very transparent across Europe. Although the national regulator stayed completely independent this stand-alone process facilitated international collaboration between the regulators and it is seen as a very effective tool to introduce a new design to UK.

For any future project in different countries in Europe it would not be a significant additional effort to issue a stand-alone design acceptance report which then would be referenced in the project specific license. If this could be done for example in Romania for the CANDU design the safety evaluation would be more transparent across Europe. Even a participation of other European regulators is feasible if this is done on a generic basis. The same is true if the ABWR would be subject to a licensing process in Finland. A stand-alone design acceptance is also feasible as part of the licensing process of the VVER 1000 in Bulgaria.

Validation

If Europe had already introduced rules and regulation for such a stand-alone design acceptance and a mechanism for validation of such an acceptance by other countries, this would help building new reactors. For instant the envisaged projects in Central and Eastern Europe could have benefited much from such a process. In case Poland or other EU Member States plan to build an EPR or AP1000 their regulators could base their work on the GDA in UK. This would be facilitated if a prescribed process for this was defined. In such a case the respective regulator would fully benefit from the advantages outlined above.

A stand-alone design acceptance for the ABWR in Finland could be validated in Sweden if needed. Similarly a stand-alone design acceptance for the VVER 1000 in Bulgaria could be validated in Czech Republic if needed.

Joint Review

For projects in the more distant future it is self-evident that a joint review is most efficient. Much as interested utilities join their effort in the EUR process to assess potential new designs submitted by vendors, regulators should combine their efforts to perform a joint design review. This could be applied for instance to new designs like Kerena and ATMEA1. Also the introduction of a European version of the ABWR would be facilitated by such a process. Even for the VVER such a process is feasible. Applicant should be the designer/vendor together with a group of interested operators. The group of customers can be small or larger. Such a process would reduce the uncertainties connected with a First of a Kind project.

Even if there is no commercial project on the horizon, a joint review would appear to be most valuable for next generation designs like GenIV or others. It would make no sense if such a reactor design would be reviewed separately in different countries with potential different outcome. For example, foreign regulators could benefit from the first evaluation of ASTRID prototype performed by the French regulator and its TSO through the validation process or as an input for a joint design review.

Finally it should be mentioned that all described processes can exist in parallel. However an established stand-alone design acceptance process in the countries concerned is mandatory.

7. Conclusion

To progress towards harmonizing licensing processes in Europe and ultimately allowing deployment of standardized reactor designs, the European Commission could take several initiatives that have been described in this paper.

The Commission should encourage Member States to introduce in their national regulation a stand-alone design assessment process independent of a specific NPP project, covering the Nuclear Island. It will allow other regulators to benefit later efficiently of the job already done by their peers.

The Commission might reference formally at the European level the already issued WENRA Safety Objectives and IAEA design safety requirements (SSR-2/1). It should also promote the development of industrial standards applicable to nuclear installations and endorsed as European Industrial codes.

The Commission should promote mutual recognition mechanisms for Member States to allow their regulators to benefit from the generic design assessments already done in another Member State through a validation process. That would avoid redoing entirely the design assessment while letting national regulators assess the detailed design and its conformity with their national legally binding requirements and the site and licensee aspects as well.

The Commission should facilitate through an adapted framework the task of regulators to conduct joint assessment of reactor designs either under informal arrangements or under a more formal multilateral agreement at the Member States level similar to the “Schengen” agreement. That would eventually allow for the issuance of a “European Reactor Design Acceptance” certificate that could be referenced in national licensing processes.

The Commission should support initiatives of European TSOs working together to develop common assessment guidelines and performing, under the auspices of regulators, joint technical assessment of proposed reactor designs to be built in European countries.

Achieving greater design standardization and a close cooperation of EU Member States’ nuclear regulators in licensing of new nuclear power plants would bring substantial benefits both to safety and to the further development of the EU nuclear industry. The possible actions and initiatives listed above are not without precedent. They can build up on existing examples and they can be modelled on developments in other industries which have successfully taken the step to mutual acceptance and trans-boundary validity of certifications.

Annex A: The UK process of a Generic Design Assessment

Introduction

The Generic Design Assessment process has been introduced to facilitate the licensing of new reactor designs in the UK. In 2006 the Government carried out an Energy Review and as part of this asked the Health and Safety Executive (HSE) to produce an expert report (Ref A) addressing various issues associated with a wide range of electricity production and distribution technologies, including nuclear. The Energy Minister particularly asked HSE to report on the potential role of pre-licensing assessments of candidate designs.

Pre-licensing is nothing new to the UK. At the request of the Government, the Office for Nuclear Regulation (ONR) (previously the Nuclear Installations Inspectorate - NII) undertook a pre-licensing assessment of the generic safety aspects of pressurised water reactors in the 1970s – well in advance of the subsequent application for the construction of Sizewell B in 1981. Likewise, in advising the Government on its *Nuclear Review* in 1994, NII undertook some preliminary pre-licensing assessments of a variety of then current reactor designs.

In the Expert Report HSE noted that, "in response to the Minister's request, HSE has undertaken a review of its possible approach to any new requests that it may receive to undertake prelicensing assessments. These could be from private sector organisations with an interest in building and operating Generation III (or III+) designs in the UK. In undertaking this review, HSE has engaged in an open and transparent way with a range of stakeholders. As a result of that interaction, combined with our own further analysis and the expert advice from the IAEA regulatory review team, we have concluded that in future, new nuclear power plants could be subject to a more methodical, better defined, multi-stage assessment and licensing process. This would have two phases, Design Acceptance and Site Licensing. These proposals are described in more detail in Annex 2" (of reference A).

The changes proposed did not fundamentally change the UK licensing process and so required no new legislation. The only change necessary was a change to the funding regulations to allow NII to reclaim costs. Normally NII can reclaim their costs from licensees, but for the process envisaged the request for an assessment would come from a vendor rather a licensee, or licence applicant.

This annex summarises the UK licensing process and the anticipated changes that led to the introduction of the Generic Design Assessment (GDA) process as well as outlining the process and the progress which has been made. In conjunction with this a parallel assessment process is run by the Environment Agency addressing the issues associated with environmental authorisations. The two regulators work together on this via a joint programme office.

UK licensing

The independent licensing of nuclear power stations was introduced when the first commercial plants were introduced in the late 1950s and the Nuclear Installations Inspectorate was established by the 1959 Nuclear Installations Act. The current licensing regime is based on the Nuclear Installations Act 1965 (as amended). The safety of nuclear installations in the UK is secured primarily through the nuclear site licence. Nuclear site licences are granted for an indefinite term and one licence may cover the lifetime of an installation from design, siting, construction, commissioning, operation, and modification through to eventual completion of decommissioning.

Originally all the commercial nuclear power stations in the UK were owned and operated by two state owned corporations: CEGB covering England and Wales and SSEB covering Scotland. In practice for new plants CEGB was the lead licensee. Prelicensing discussions took place prior to a formal application but the results of these were not formalised. The CEGB's investment decision would be in line with Government policy and its obligations to ensure security of supply and would be informed by its understanding of the work necessary to satisfy the regulator.

Following the privatisation of the electricity industry the situation changed. The Government sought to increase competition in the Generation sector and so it could be anticipated that if new nuclear plants were built this would involve a range of designs and a number of new licensees. Hence the proposal for the adoption of a two phase process: Design Acceptance + Site Licensing.

Although this does not change the basic process it does introduce the need to formalise the results of the design acceptance. (Note that in the UK the regulator has never formally "approved" a design.) Potential licensees want to see an element of competition between the designs on offer but would want reassurance that they provided a sound basis for the granting of a site licence. GDA provides a way to do this.

The process previously in place involved the applicant maintaining dialogue with HSE/ONR throughout the development of the safety case and as aspects of the design reach the point where their safety can be assessed, submissions are made to ONR. These submissions may be discussed and further analysis or design modifications may be necessary before HSE permissions the relevant activity. To help assess the applicant's submissions HSE may seek independent data and advice from external sources. Major submissions may include:

- a reference design (an initial statement of design and the safety criteria to be applied);
- a preliminary safety report (intended to show, in principle, the means by which the reference design can meet the applicant's safety criteria);
- a pre-construction safety report (a more comprehensive statement on safety analysis);
- proposed research and development work in support of the safety case;
- proposals for quality assurance (the means for ensuring that design, manufacture, inspection and construction are carried out reliably to the required standard); and
- a contract design (the design intended for construction).

As will be seen the GDA process preserves the essential elements but it is driven by a "requesting party" (vendor/designer) rather than the licence applicant. The process is outlined below.

The GDA process

The GDA is divided into 4 steps as set below and guidance on the process is provided in reference B.

Step 1: Design and safety case preparation

This is the preparatory part of the design assessment process. The bulk of the work will be undertaken by the Requesting Party (generally vendors) in writing and preparing the safety submissions for Step 2. It also involves discussions between the Requesting Party and ONR to ensure a full understanding of the requirements and processes that will be applied and to arrive at formal agreements for cost recovery. The initial submission corresponds to a Preliminary Safety Report. To justify the expenditure of regulatory time and resources the Department of Energy and Climate Change (DECC) specified that in order to be considered for GDA the request must also be supported by at least one credible operator i.e. an existing or potential UK licensee with experience in the operation of nuclear power stations.

Step 2: Fundamental safety overview

This is an overview of the fundamental acceptability of the proposed reactor design concept within the UK regulatory regime, including review of key safety claims. The aim of this step is to identify any fundamental design aspects or safety shortfalls that could prevent the proposed design from being licensed in the UK. It also introduces HSE inspectors to the fundamentals of the design and provides a basis for planning subsequent assessment.

Step 3: Overall Design Safety Review

This is an ONR review of the safety case arguments of the proposed reactor design. The general intention will be to move from the fundamentals of the previous step to an analysis of the design, primarily by examination at the system level and by analysis of the Requesting Party's supporting arguments which will be presented in the form of a draft Pre-Construction Safety Report. The specific aims of this step are to:

- improve HSE knowledge of the design;
- identify significant issues;
- identify whether any significant design or safety case changes may be needed;
- identify major issues that may affect design acceptance and attempt to resolve them;
- achieve a significant reduction in regulatory uncertainty.

The exact scope and focus will depend on the design and on the outcome of Step 2.

Step 4: Detailed design assessment

Step 4 is an in-depth NII assessment of the safety case evidence and generic site envelope submitted. This step may take about two years, based on the assumption of assessing one design. The general intention of this step is to move from the safety arguments and system level assessment of Step 3 to a fully detailed examination of the evidence, on a sampling basis, given by the safety analyses. The aim of this step is:

- to confirm that the higher level claims such as system functionality are properly justified;
- to complete sufficient detailed assessment to allow NII to come to a judgment whether a Design Acceptance Confirmation (DAC) can be issued.

The exact scope and focus will depend on the design and on the outcome of Step 3.

There could be three potential outcomes at the end of Step 4:

1) If ONR are fully content with the generic safety and security aspects then it would provide the Requesting Party with a DAC which would mark the end of GDA for that generic design.
2) If ONR were largely content with the generic safety and security aspects then it would provide the Requesting Party with an interim DAC (iDAC) and identify the unresolved GDA Issues. These issues would need to be cleared before a final DAC could be provided or before ONR would consider granting permission for the start of nuclear island safety - related construction for a power station based on that design.
3) If ONR were not content with the generic safety and security aspects then no DAC would be issued.

GDA Issues are defined as: "*Unresolved issues considered by regulators to be significant, but resolvable, and which require resolution before nuclear island safety - related construction of such a reactor could be considered.*"

1. In addition the detailed assessments result in findings which will be addressed through the site licensing, construction and commissioning stages. GDA Assessment Findings are defined as: "*Findings identified during the regulators' GDA assessment that are important to safety, but not considered critical to the decision to start nuclear island safety - related construction of such a reactor.*"

Any Design Acceptance Confirmation issued would apply for that generic design for a period of ten years. This would be subject to no significant new information arising during that period which might call into question the basis of HSE's original assessment of the design. This period of validity is based upon the existing HSE requirement for licensees to undertake periodic safety reviews of their existing nuclear facilities every ten years.

Experience with the process

In 2007, 4 designs came forward for assessment and successfully went through the first two steps. No fundamental barriers to licensing were identified. The process involved assessment by ONR staff as well as discussions with other regulators; primarily those of the country of origin, but also other regulators who were in the process of licensing the designs. Although in some cases construction licences had been issued these were all for multistep licensing processes so had not yet covered all the issues required to be addressed for the UK single licence.

The resources required by both requesting parties and the regulators were significant and in 2008 two of the designs withdrew/suspended their involvement in the process at different stages to focus on addressing issues for other markets.

In 2011, two designs "completed" the four steps and ONR were largely satisfied but in both cases there were unresolved issues so interim DACs were issued and resolution plans were agreed for remaining issues. These will need to be addressed before ONR will provide a final DAC or agree to nuclear island safety related construction.

References

A HSE, 2006, "The Health and Safety Risks and Regulatory Strategy Related to Energy Developments: An expert report by the Health and Safety Executive contributing to the Government's Energy Review, 2006, 28 June 2006 http://www.hse.gov.uk/consult/condocs/energyreview/energyreport.pdf

B ONR, "Guidance - assessment of new nuclear power stations", http://www.hse.gov.uk/newreactors/guidance.htm

Annex B: The Safety Options review for the ATMEA1 reactor

The ATMEA company, a joint venture of AREVA and Mitsubishi Heavy Industries, has requested the French safety authority, ASN, and its technical support IRSN to review the safety options of the ATMEA1 reactor, the Generation III+ 1100MWe PWR that it is currently ready for bidding.

This reactor is designed for a 60-year lifetime, according to US standards (10CFR50 - 52, GDC, TG; NUREG, SRP, ASME). In order to assess its possible licensing in another nuclearized country, the French safety authority agreed to carry out a review of ATMEA1 Safety Options, as if they were submitted according to the French Safety Approach. ATMEA provided on June 2010 the corresponding file. On this basis, a contract between ATMEA and a consortium ASN/IRSN was signed in July 2010, and an appendix related to the study of aircraft crash in May 2011. The objective was to obtain the position of ASN on the Safety Options for the end of 2011, including the first lessons from the Fukushima-Daiichi accident.

Prior to the signature of the contract, the parties addressed a number of issues related to the objective of the contract, the technical topics to be addressed, the assessment process, the planning for its completion, the means needed by ASN and IRSN, the financial conditions, the corresponding deliverables and other associated conditions including intellectual property.

Pursuant to the provisions of the contract, IRSN carried out the technical review, analysed all significant safety issues and produced its technical conclusions on the safety options. On this basis, ASN gave a positive evaluation of these options and concluded that they globally satisfy French regulatory requirements.

Although there are currently no application or plans for the licensing of an ATMEA1 reactor in France[29], the review was thus performed under the conditions that apply to the licensing of nuclear facilities in France. The process applied involved the technical review of IRSN and the advice of the Reactor Safety Advisory Committee, in the same manner as in a standard licensing process. In such a process, the evaluation and conclusions by ASN would be a preliminary step to a possible construction license application. It should be noted that, in its review, IRSN has suggested conclusions on ATMEA1 reactor design bases that might serve, as needed, in the frame of any subsequent assessments.

The reference documents used by IRSN for the review consisted of the following:

- Current French regulation;
- Technical Guidelines for the design and construction of the next generation of nuclear power plants with pressurized water reactors;
- Para-regulatory texts still applicable to the design of the next generation reactors.

[29] It should also be noted that, under French regulations, such an application would be submitted by the operator and not by the vendor of the reactor.

The Safety Options file submitted by the ATMEA company consisted of the safety options issues proposed by the ATMEA1 project and the detailed design bases necessary for their review. In cases where the proposed reference documents could not cover certain safety options areas, IRSN's review was based on the codes and standards proposed by the ATMEA1 project, without assessing those proposed standards.

ASN and IRSN have conducted this review over a period of 18 months and have published their conclusions in January 2012. The evaluation was conducted in two phases:

- Phase 1 consisted in a first review of the safety options. At the end of this phase, IRSN concluded that the safety options report provided a satisfactory level of completeness; it identified the issues that seemed to be addressed satisfactorily and those that were to be addressed in detail during phase 2, as well as the necessary supporting documents to be provided by the ATMEA company;
- Phase 2 included the comprehensive review of the Safety Options Report and of complementary reports on issues identified during the Phase 1. The review during Phase 2 also included a preliminary Probabilistic Safety Analysis (PSA) of level 1 performed by the ATMEA1 project at the end of the basic design phase. During Phase 2, the Reactor Safety Advisory Committee held five meetings.

Safety options were found to be globally satisfactory and in compliance with requirements. It should be noted that, in subsequent steps of a licensing process, the applicant should demonstrate that the detailed design complies with design and safety options. In this regard, the conclusions of the review identified certain points on which detailed specifications and requirements should be defined, and analyses and demonstrations would be required.

In particular, important conclusions for any next steps were drawn on the following points, which exemplify the level of the analysis performed during the review:

- Safety objectives, which were found to be in compliance with the Technical Guidelines;
- Situations to be practically eliminated : although compliant with the Technical Guidelines, the Standing Committee strengthened its previous position and asked for a minimum common ground for requirements to be defined;
- Situations leading to boiling of water in the spent fuel pool are taken into account and demonstration should be provided when a construction permit is filed;
- Break preclusion: Technical Guidelines requirements are considered and demonstration should be provided when a construction permit is filed;
- Leaks and rupture of high energy pipes: the ATMEA1 project decided to implement the American approach, which differs from the French approach. For an ATMEA1 reactor to be licensed in France, the specific French regulations in force complemented with the requirements of the Technical Guidelines would have to be effectively taken into account;

- Options for the Safety Injection System, the Containment Spray System and Residual Heat Removal system (RHRS) provide adequate assurance at this stage and demonstration should be provided when a construction permit is filed;
- Sump plugging options provide adequate assurance at this stage and demonstration should be provided when a construction permit is filed;
- I &C design was found to be satisfactory;
- Containment design was found to be satisfactory;
- Annulus seal: additional reviews should be performed on technical requirements and follow-up during operation;
- Mechanical behaviour of the containment under aircraft impact was found to be consistent with maintaining its integrity;
- Control of the pressure in the building containing RHRS in case of break and design of building structures: an appropriate method should be used to design structures;
- Diversification of the Ultimate Heat Sinks was found to be satisfactory;
- Functional diversification: automation should be studied;
- Accumulation of situations and hazards was found to be satisfactory;
- Lessons from the Fukushima-Daiichi accident: it was found that an appropriate approach was used by ATMEA with adequate safety criteria.

For further information, the summary of the review performed by IRSN is available online[30]. ASN has published its conclusions on its web site[31].

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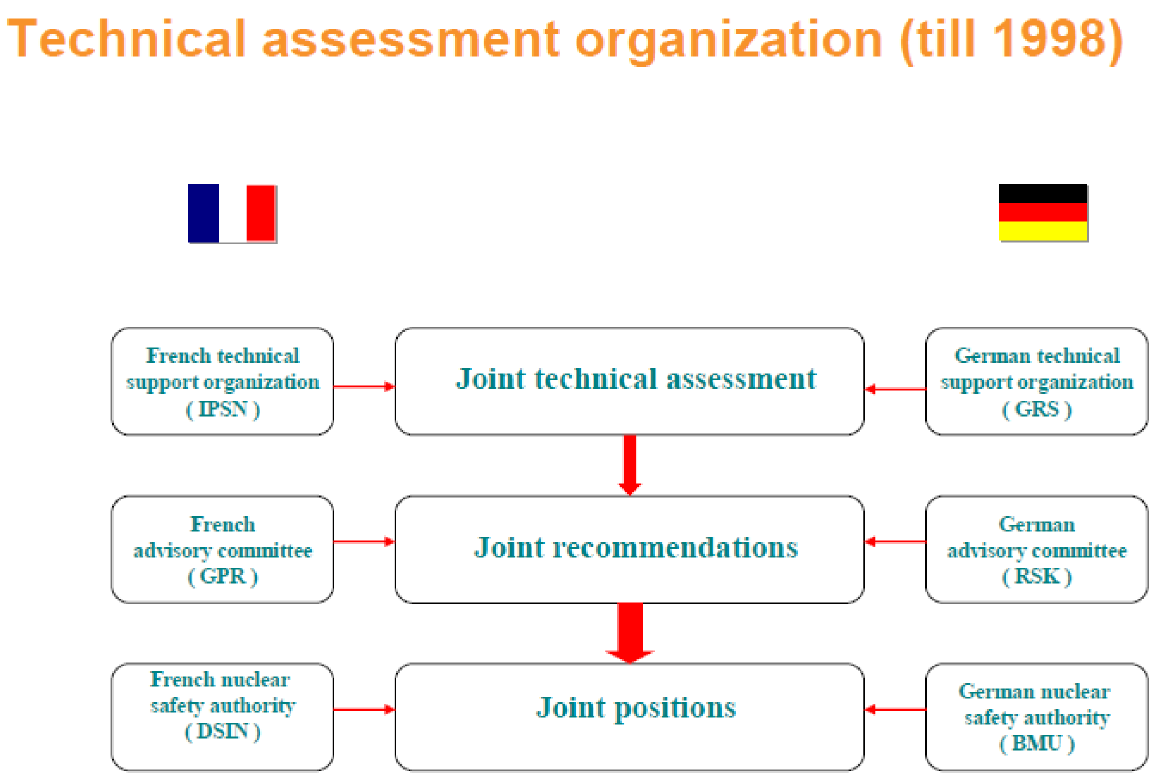
[30]http://www.irsn.fr/EN/newsroom/News/Pages/20120319_ATMEA1-safety-options-review.aspx

[31] http://www.asn.fr/index.php/Les-actions-de-l-ASN/La-reglementation/Bulletin-Officiel-de-l-ASN/Avis-de-l-ASN/Avis-n-2012-AV-0143-de-l-ASN-du-31-janvier-2012

Annex C: Franco-German cooperation in the EPR development – A good example for joint design acceptance

In 1989, Framatome and Siemens founded a joint venture called Nuclear Power International (NPI), whose primary aim was to develop a standard PWR design. France and Germany both backed NPI with financial and human resources. In 1995, EDF and German nuclear utilities supported further development of NPI under a basic design contract. This basic design phase was completed in 1996 and then additional studies followed to fine-tune the design. This 'basic design optimization phase' was completed in 1998. In the early 2000s, NPI's work was delayed due to the German utilities withdrawing their support following the German nuclear power phase-out agreement. Siemens carved out its nuclear activities from its main business and, in 2001, merged its nuclear activities with Framatome SA to become Framatome ANP. The German utilities' participation in the EPR project was finally terminated at the beginning of 2002.

A key goal of the EPR development was to ensure licensability of the design in France and Germany. The French and German Safety Authorities (then the DSIN and BMU) had long cooperated in relation to the safety of existing NPPs, but in the context of EPR development, they extended this co-operation to developing a common safety approach for future NPPs. At ministry level, a German-French Directorate (DFD) was founded to harmonize the general safety requirements. There was also cooperation between the advisory groups of both countries – GPR (Groupe Permanent Réacteur, in France) and RSK (Reaktor-Sicherheits-Kommission, in Germany) – to harmonize the French and German licensing requirements (see figure below).



The technical support organisations (TSOs) of the two countries – IRSN (Institut de Radioprotection et de Sûreté Nucléaire) from France and GRS (Gesellschaft für Anlagen- und Reaktorsicherheit) from Germany – also cooperated to establish joint working groups which provided coordinated technical support to their respective regulatory authorities.

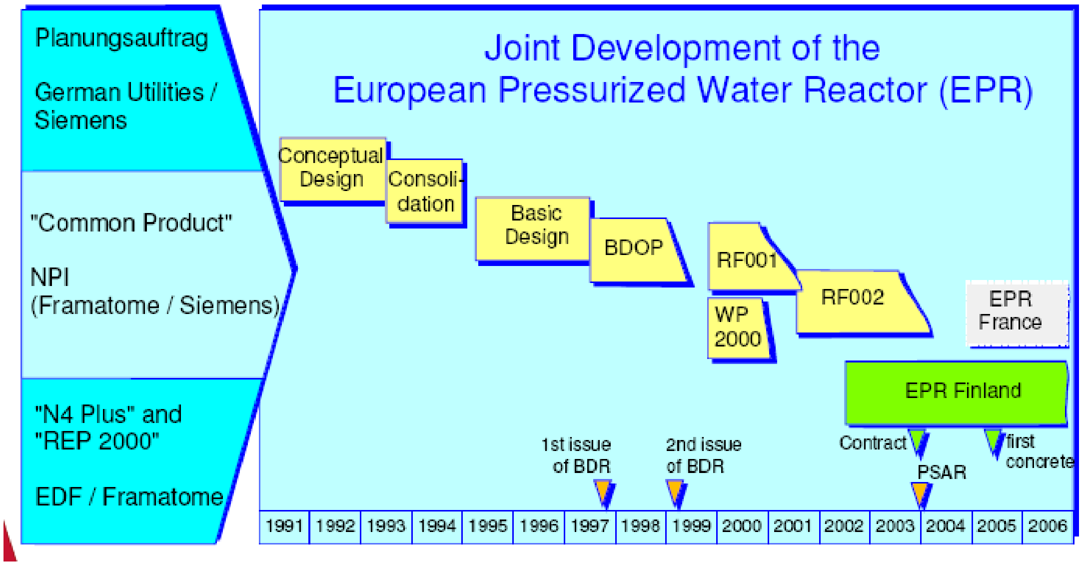
In order to facilitate the acceptance of the EPR project by the French and German Safety Authorities and to take full benefit of both countries' experience, it was clear that a unified design should be developed. Furthermore, it was decided that the EPR approach should be based on both French and German rules and regulations to the fullest extent possible. Where unavoidable conflicts existed in the two countries' rules, harmonized compromise positions were formed on important basic issues such as the rules governing the organisation of the safety systems, the overall design of the main structures and the general arrangement and internal layout of the buildings.

In July 1993 the GPR and RSK issued their joint proposal (GPR/RSK Proposal for a Common Safety Approach for Future Pressurized Water Reactors), which essentially adopted an evolutionary approach to nuclear safety:

> Faced with the current situation of nuclear energy in the world, the various nuclear steam supply system constructors are developing new products, all of them claiming their intention of obtaining a higher safety level, but through various ways. It is believed that, for the operation of a new series of NPPs at the beginning of the next decade, the adequate way is to derive the design of these plants in an "evolutionary" way from the design of existing plants, taking into account the operating experience and the in-depth studies conducted for such plants. Nevertheless, introduction of innovative features must also be considered in the frame of the design of the new series of plants, especially in preventing and mitigating severe accidents. A significant improvement at the design stage of the safety of the next generation of NPPs appears necessary, compared to existing plants. If the search for improvement is a permanent concern in the field of safety, the necessity of a significant step at the design stage clearly derives from better consideration of the problems related to severe accidents, not only in the short term but also in the long term…[32]

These recommendations were taken into account both in the formulation of EPR design targets and in the EPR's conceptual design. The following sets out the design phases and development of the EPR.

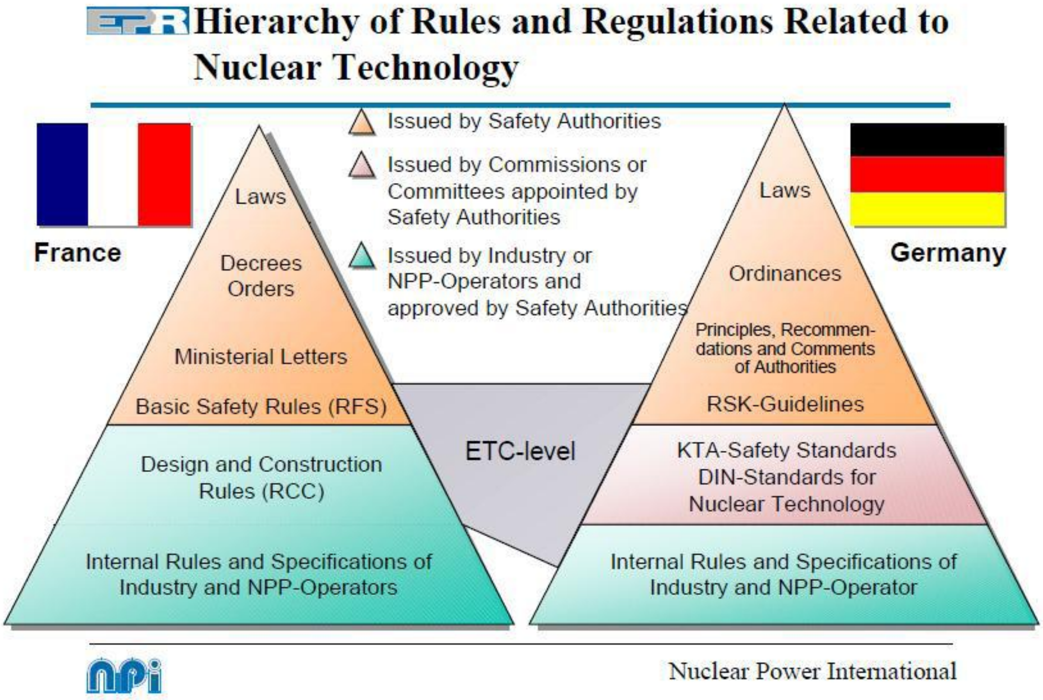
[32] GPR/RSK Proposal for a Common Safety Approach for Future Pressurized Water Reactors, 25 May 1993

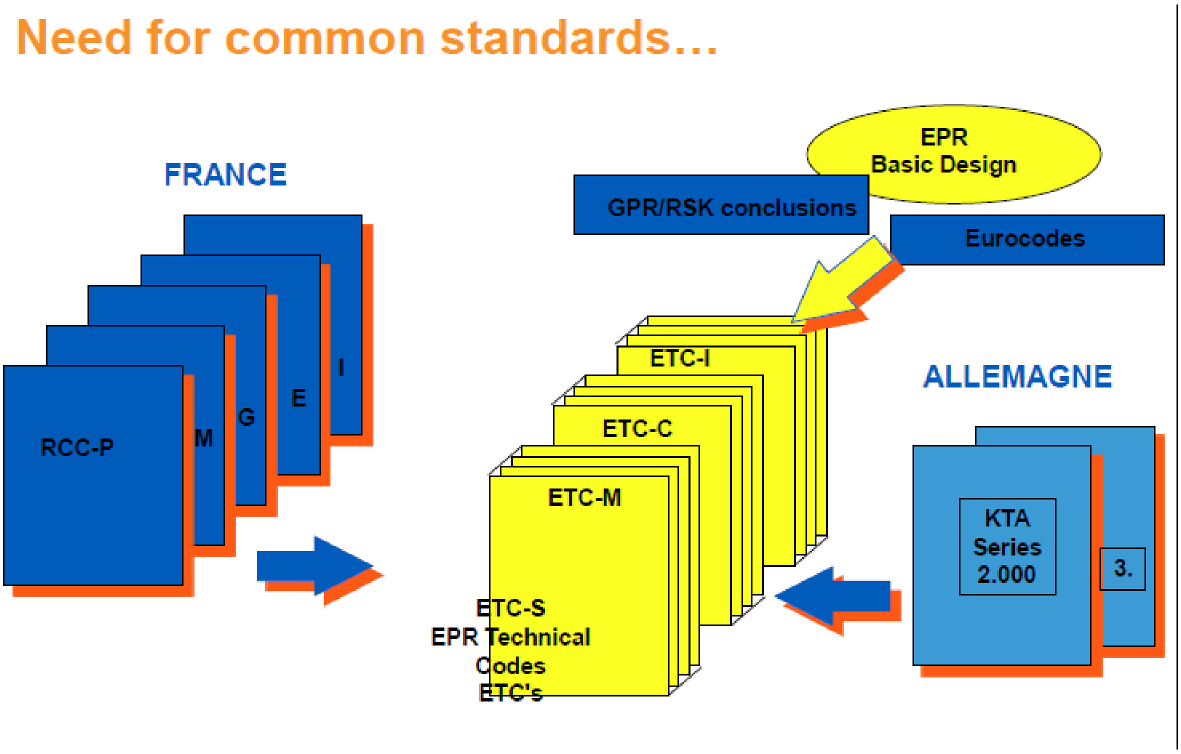


During the conceptual design phase (1991 to 1993) the German utilities, EDF and NPI harmonized the technical requirements for the EPR, which were documented in the Conceptual Safety Features Review File (CSFRF, issued in mid-1993). During the consolidation phase which followed, a detailed review was conducted by the French and German TSOs and GPR/RSK. The EPR design addressed these issues, which included: (i) radiological consequences of severe accidents; (ii) external hazards including airplane crash; (iii) safety system design improvements; and (iv) the use of probabilistic safety analysis (PSA). To be in compliance with the DSIN/BMU recommendations, the EPR design was modified accordingly.

The first part of the basic design phase, between 1995 and 1997, culminated in the 1997 EPR Basic Design Report (1997 BDR). The 1997 BDR proposed a site-independent, standardized Nuclear Island (NI), and it contained sufficient information to enable the French and German Safety Authorities to perform the safety assessment of the EPR, including: (i) a description of the design bases; (ii) the acceptance criteria used for design and assessment; (iii) the results of the assessments and verifications; and (iv) a comprehensive and complete plant description of the reactor building, steam and feed water valve station housing, fuel building, safeguard buildings, nuclear auxiliary building and diesel buildings. The BDR also specified, for buildings outside of the NI, the requirements for layout, function, safety and interface with the NI buildings.

The systems within the scope of the NI were also identified and described in the BDR. A safety analysis of the response of systems or parts of systems outside the scope of the NI was conducted. It was determined that the scope and content of the BDR should have such a level of detail that it could be used as an applicant document to set up a licensing procedure for the construction of an EPR in France or in Germany. It was also determined that the BDR should enable the French and German Safety Authorities to perform the safety assessment of the EPR. Therefore the EPR project decided that the BDR level of detail should be in compliance with Franco-German regulations. This meant that together with the EPR Technical Codes the nuclear island design (see figures below) should be equivalent to what was specified in the German BMU guideline “Compilation of Information Required for Review Purposes under





Licensing and Supervisory Procedures for NPPs (ZPI)”.[33] The BDR also contained a level of detail equivalent to the standard part of the Preliminary

33 Compilation of Information Required for Review Purposes under Licensing and Supervisory Procedures for NPPs (ZPI), issued September 1982 by BMU.

Safety Analysis Report (PSAR) required in France.[34] In addition, the table of contents of the BDR also follows the U.S. NRC Regulatory Guide 1.70 Rev. 3.

Between 1995 and 1997, the power generation cost of conventional power plants decreased drastically, mainly due to increased international competition for investment in non-nuclear plants and reduced fossil fuel prices. This negatively affected the economic competitiveness of nuclear power generation, including the EPR. In order to ensure the continued competiveness of the EPR, the EPR design went through a process of optimisation (the “basic design optimisation phase”). This resulted in the second issue of the EPR Basic Design Report in 1999 (1999 BDR).

In October 2000, the results of EPR safety assessment – performed by GPR/IRSN together with GRS experts under the auspices of DSIN – were issued in the document “Technical Guidelines for the Design and Construction of the Next Generation of NPPs with Pressurized Water Reactors”.[35] These technical guidelines present the opinion of the GPR concerning the safety philosophy and approach as well as the general safety of the requirements to be applied for the design and construction of the next generation of nuclear power plants of PWR type assuming the construction of the first units of this generation would start at the beginning of the 21st century. The assessment of the optimised EPR design against these guidelines confirmed the efficacy of the chosen design of the EPR Nuclear Island. The EPR reflected a robust, sophisticated evolutionary NPP design ready to meet the challenges of the nuclear renaissance.

[34] Instruction du 27 Mars 1973 relative à l’application du décret n° 73-278 du 13 Mars 1973 portant création d’un Conseil supérieur de la sûreté nucléaire et d’un Service central de sûreté des installations nucléaires au ministère du développement industriel et scientifique

[35] Technical Guidelines for the Design and Construction of the Next Generation of NPPs with Pressurized Water Reactors adopted during the GPR/German experts plenary meetings held on October 19th and 26th , 2000

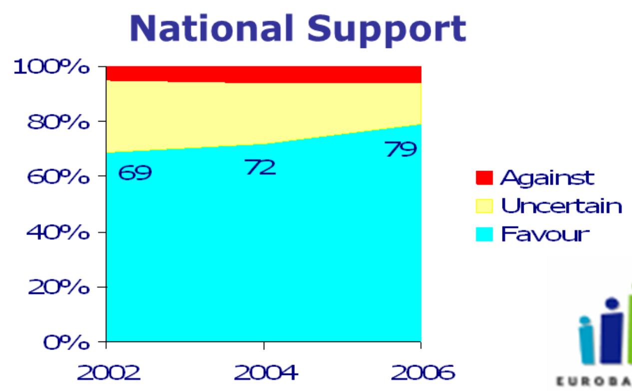
Annex D: Design Assessment of AES 92 in Bulgaria, Belene NPP Project, 2005-2012

I. Background Information on Belene NPP Project

1. Applicant

The Applicant for implementation of Belene NPP project is Natsionalna Elektricheska Kompania (NEK), a 100% state single-owner joint-stock company. Bulgarian Energy Holding (BEH) is the holder of the capital of NEK. In execution of NEK Technical Council decision of 26.01.2000, and with the assistance of IAEA, the Ministry of Energy and Energy Resources[36] researched the possible new-generation reactor units constructed and offered in the world market.

2. Public Acceptance



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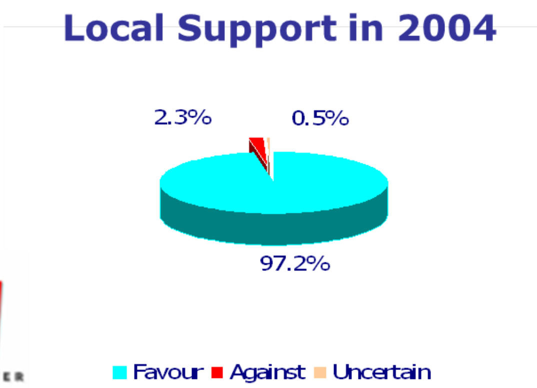

3. Technical Requirements of the Applicant

In 2005 the document “European Utility Requirements for LWR Nuclear Power Plants” (EUR) has been accepted by NEK as a suitable basis for development of Bid Invitation Specification (BIS) for Belene NPP project.

II. Licensing of Belene NPP Project

1. Licensing of a NPP in Bulgaria

The Act for Safe Use of Nuclear Energy (ASUNE) and respective ordinances thereto defines responsibilities related to government regulated safe use of nuclear energy. The process of licensing a nuclear power plant is covered by the ASUNE and consists of the following phases:

– Application for site selection permit[37];
– Application for design permit[38];

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[36] At present Ministry of Economy, Energy and Tourism (MEET)

[37] The deadline for issuing an order of approval of site selected is nine (9) months after the date of application; the application is to contain all documents according to Article 37 of the Ordinance for the Procedure for Issuing Permits and Licenses for Safe Use of Nuclear Energy (OPIPLSUNE)

– Application for construction permit[39];
– Application for commissioning permit[40].

2. Design Approval by BNRA

1. Site selection phase:
   – Site selection application (June 2004);
   – Site selection permit (December 2004);
   – Site approval order (December 2006).
2. Design phase:
   – Design permit application (October 2005);
   – Design permit (May 2007);
   – Design approval application (April 2008).

3. Investment Design Approval by EC

1. Article 105 by EURATOM Treaty:
   – Notification of EC (January 2007);
   – EC positive statement (October 2007).
2. Article 41-44 by EURATOM Treaty:
   – Notification of EC (December 2006);
   – Design presentation to EC (July 2007);
   – EC positive statement (December 2007).
3. Article 79 by EURATOM Treaty and Rules of Procedure No 302/2005**:**
   – Notification of EC (June 2009).

4. European Certification

AES 92 design certification as 3rd generation by the twelve leading European Utilities (EUR, Requirements to LWR of European Utility Companies):

– Certificate of Compliance with EUR (April 2007).

The design is designated by the EC as a model of a 3rd generation reactor in the updated Exemplary Nuclear Program in the context of the Second Strategic Energy Review, with the recommendation that all future reactors in the EU shall meet the same safety requirements:

– Communication of EC, COM/2008/776 (13 November 2008).

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[38] The deadline for issuing an order of approval of technical design is nine (9) months after the date of application; the application is to contain all documents according to Article 40 of the OPIPLSUNE

[39] The deadline for issuing construction permit is nine (9) months after the date of application; the application is to contain all documents according to Article 41 of the OPIPLSUNE

[40] The deadline for issuing commissioning permit is nine (9) months after the date of application, the application is to contain all documents according to Article 43 of the Ordinance for the OPIPLSUNE

III. AES 92 DESIGN ASSESSMENT

1. Terms of References

The Terms of References (ToR) present the Applicant's requirements for design, erection and commissioning of Belene NPP. They are elaborated based on BIS Part 2 and address the AES 92 option with reactor plant type B-466 selected by the Applicant.

2. Codes and Standards

ToR defines five levels (hierarchical structure) of the used codes and standards:

- Level I: Bulgarian legislation (top level);
- Level II: Basic regulations;
- Level III: Process oriented nuclear documents;
- Level IV: Component oriented nuclear documents;
- Level V: Conventional codes and standards (low level).

3. Preparation of the Technical Design

AES 92 Technical Design (TD) is developed based on the ToR, approved by BNRA.
TD contains 14 chapters and 4 Attachments, including:

- Attachment 1: Interim Safety Analysis Report (ISAR);
- Attachment 2: Probabilistic Safety Analyses (PSA).

4. Review of the Technical Design

AES 92 Technical Design was reviewed by:

1. NEK experts;
2. Review team of the Architect Engineer (Worley Parsons & Risk Engineering);
3. IAEA International Probabilistic Safety Assessment Review Team (IPSART);
4. External experts, assisting BNRA:
   - RISKAUDIT IRSN/GRS International (GEIE);
   - Enpro Consult Ltd. (Bulgarian engineering company).

5. Conclusion of RISKAUDIT

The conclusion of RISKAUDIT concerning TD Revision 2 is: *"On the basis of the material presented in the ISAR, the Technical Design documents provided, the PSA and the outcome of the discussions with Russian experts during specialists' meeting in Moscow and Sofia and all new information obtained in the present review, the Reviewer concludes that the proposed Technical Design of Belene NPP is in general in conformity with IAEA Design Safety Requirements, Bulgarian legislation and best international practice."*

IV. Main Difficulties during AES 92 Design Assessment

1. Issue 1: List of Codes and Standards

ToR Chapter 2.5 “Codes and Standards” lays down the framework to determine which codes and standards shall be used for the design of the Belene NPP. It classifies them in five levels and indicates the criteria on their applicability to the different safety categories and classes of SSCs. The chapter also indicates how to resolve discrepancies between alternative codes and standards. The chapter does not include a list of codes and standards to be applied.

The ToR require that the Designer shall establish precise correlations between the categories and classes of all structures, systems and components, and the various requirements in the codes and standards applicable thereto, taking into account the requirements on reliability of the equipment. In the beginning, the Designer shall define and submit to the Applicant for approval the list of codes and standards applicable for each part and stage of the design.

CONCERNING ISSUE 1: It is extremely difficult for the Applicant to approve a list of applicable codes and standards since there is no suitable comprehensive Bulgarian nuclear legislation (from level I to level IV). This issue is relevant for the European countries where nuclear codes and standards of level III and level IV do not exist.

POSSIBLE WAY OF RESOLVING ISSUE 1: Elaboration of recommendable lists of codes and standards applicable in EU for different nuclear reactors of 3rd generation. Such approach could be very useful for member-states without comprehensive national nuclear legislation.

2. Issue 2: Safety Classification

The Russian safety classification described in PNAE-G-1-011-97 (Level III in the hierarchy of codes and standards) is applicable for Belene NPP.
Suitable Bulgarian legislation base for safety classification of Belene NPP SSCs is missing, namely:

1. There is no applicable Bulgarian safety classification of SSCs (only generic requirements are available);
2. There is no applicable IAEA safety classification of SSCs (generic recommendations only);
3. There is no common European safety classification of SSCs (specific levels of safety functions and safety categories are established in EUR[41])

CONCERNING ISSUE 2: The comments related to AES 92 safety classification sometimes are made by experts who are not familiar with the respective mandatory Russian nuclear codes and standards, and are therefore not quite relevant. Such kind of comments and recommendations resulted in licensing

[41] The levels of safety functions in EUR are defined as F1 and F2. The level F1 is subdivided into sublevels F1A and F1B. The other functions are defined as Non-Safety. Equipment and structures are assigned to the following categories: 1) Safety category I (safety functions F1A, F1B), sometimes referred to as "safety classified"; 2) Safety category II (safety functions F2), sometimes referred to as "important to safety"; and 3) Non-Safety.

delays and respectively additional engineering work leading to unnecessary costs for the Applicant.

POSSIBLE WAY OF RESOLVING ISSUE 2: Elaboration of recommendable safety classification applicable in EU for different nuclear reactors of 3rd generation (for instance on the basis of the EUR classification). The correlations between the national safety classifications and the recommendable European safety classification could be presented in the form of specific correlation tables (as it has been done for the AES 92 design, i.e. the Russian safety classification in comparison with the EUR safety classification).

3. Issue 3: Format and Content of Safety Analysis Report

The ISAR for Belene NPP has been developed on the base on the ToR safety requirements.

The format and content of the Belene NPP ISAR were established on the base of US NRC Regulatory Guide 1.70 “Standard format and content of safety analysis reports for nuclear power plants (LWR edition)”, November 1978. The Russian PNAE G-01-036-95 "Requirements for contents of report on WWER plant safety assessment” has not been used for Belene NPP (Level III in the hierarchy of codes and standards).

Suitable Bulgarian legislation base for format and content of SAR of Belene NPP is missing, namely:

1. There is no applicable Bulgarian guide concerning preparation of SAR (only generic requirements are available);
2. There is no applicable IAEA guide concerning preparation of SAR (generic recommendations only);
3. There is no common European guide concerning preparation of SAR;

CONCERNING ISSUE 3: It is extremely difficult for the Applicant to approve the SAR format and content since there is no suitable Bulgarian comprehensive nuclear legislation (from level I to level IV). This issue is relevant for the European countries where nuclear codes and standards of level III and level IV do not exist.

POSSIBLE WAY OF RESOLVING ISSUE 3: Elaboration of recommendable format and content of safety analysis report applicable in EU for all nuclear reactors of 3rd generation. As suitable reference, US NRC Regulatory Guide 1.206 “Combined license applications for nuclear power plants (LWR edition)”, June 2007, could be used.

Annex E: The Cyprus Arrangements of the Joint Aviation Authorities – A model for ERDA

In chapter 5.1, the role of JAA and the 1990 "Arrangements Concerning the Development, the Acceptance and the Implementation of Joint Aviation Requirements" (Cyprus Arrangements)[42] in cooperation of aviation authorities of EU member states has been outlined. Some of the basic provisions of the Cyprus Arrangements will be quoted in this Annex since they may serve as "blueprint" for an agreement between nuclear regulators on a joint design review in the framework of the ERDA concept.

One set of provisions concerns the completion of the system of common design standards (called JARs, Joint Aviation Requirements). The Authorities agreed

> *To define as soon as possible the general structure of the whole set of JARs and the scope of each JAR so that each Authority can adopt this structure and to work to remove as rapidly as possible any National Variants or national regulatory differences with the aim that each individual existing JAR becomes a uniform code for all JAA countries and no further national regulatory differences are applied.*[43]

There was a practical mechanism for reaching this aim without jeopardising the Authorities' obligations and duties founded on their national legislation:

> *Each Authority intends to withdraw the provision for codes other than JAR where the procedures established to check compliance of products, services, persons or organizations with JAR are deemed to be satisfactory by the Authority concerned both technically and timewise, i.e.: when that Authority estimates that the procedures are such that they allow fulfilment of its national obligations as civil aviation Authority and achievement of the associated deadlines using only JARs.*[44]

Concerning joint assessment and approval of aircraft designs, the Authorities agreed on the principle

> *... to make only once all the technical findings in those fields while each national Authority would still make the legal findings*[45]*.* [Note: "technical findings" is defined as *the* assessment of compliance of a design with applicable requirements, while "legal findings" is defined as the act of granting a certificate as required by national laws and procedures[46]. So, shortly speaking, the aim was to make design evaluation only once while each national Authority would still issue its own licence.]

Founded on this principle, the Authorities agreed

> *To establish procedures based on the use of the Authorities' resources, that:*

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[42] Arrangements Concerning the Development, the Acceptance and the Implementation of Joint Aviation Requirements, Cyprus, 11 September 1990, available at https://easa.europa.eu/rulemaking/docs/international/archive/cyprus.pdf
[43] Cyprus Arrangements, part 2 (Functions of JAA), (b).
[44] Cyprus Arrangements, part 3 (Commitments of Authorities), (b), note.
[45] Cyprus Arrangements, part 1 (General), second paragraph.
[46] Cyprus Arrangements, part 0 (Definitions), under (d) „Certification".

(i) allow the use of only one set of technical findings in the field of design, manufacture, maintenance and operations for the benefit of and in a manner acceptable to all Authorities;

(ii) include practical measures for making the technical findings only once to the benefit of all Authorities...[47]

To establish administrative and technical procedures which would require a single administrative action from the applicant for each application and which would replace the currently existing national administrative documents by a single one valid under the national laws and procedures of each Authority.[48]

Again, there were practical steps to assure compliance of each Authority with its national legislation:

In doing so, the JAA will take into consideration the needs of all Authorities and agree priority criteria and working methods which allow the performance of the work in an acceptable timescale.

The JAA may consider such methods as:

- the creation of agreed teams to perform a task,
- the standardization reviews by teams agreed,
- the direct acceptance of work performed by one Authority,
- the delegation to industry on the basis of agreed approval standards.[49]

Finally, this system was based on mutual knowledge and trust that each JAA member had adequate practices. Accession of new members to JAA was possible provided

- That authority explains to the JAA its system, methods and practices in the field of design, manufacture, maintenance and operations; and

- that Authority commits itself to the terms and duties as set out in these Arrangements including the procedures agreed by the JAA.[50]

The new Party was allowed to accede when

- an adequate knowledge of the Applicant's practices has been acquired,

- the changes necessary for the use of the JAR's within this State are made that would permit fairness to and consistency with other Parties allowing therefore the exchange of products, services or persons or reliance on organizations.[51]

As a result, certificates issued collectively by the parties, in accordance with common rules and procedures, were accepted automatically without additional conditions for the issuing of any party's national certificate. Certificates for smaller products, for organisations and for personnel were issued by national regulators individually but the same acceptance mechanism applied.

[47] Cyprus Arrangements, chapter 2 (Functions of JAA), (c).
[48] Cyprus Arrangements, chapter 2 (Functions of JAA), (d).
[49] Cyprus Arrangements, Appendix 2 (Joint implementation of JAR and joint performance of certification), (e), second paragraph.
[50] Cyprus Arrangements, chapter 6 (Membership), (a).
[51] Cyprus Arrangements, chapter 6 (Membership), (b).