PERSPECTIVE FOR YOUR DECISIONS

A NEW PARADIGM FOR INTERNATIONAL STANDARDISATION

HARMONISATION FOR THE DESIGN AND THE ASSESSMENT OF FUTURE NUCLEAR INSTALLATIONS

March 2021

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PERSPECTIVE FOR YOUR DECISIONS

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INTERNATIONAL HARMONISATION OF REGULATION CAN BE A GAME-CHANGER FOR NUCLEAR ENERGY

The interest in harmonizing approaches to the design, the evaluation and the certification of nuclear installations is universally recognised.

Recently, the need for a “paradigm shift” regarding such regulation harmonisation has been recognised: *“ …I think the time is now to think boldly and look critically at regulatory frameworks and be open to the need to re-engineer them. It may be time for a paradigm shift in the regulatory space.”* (ref. CNSC’s President Ms. Rumina Velshi)

Interest in harmonising approaches to the design, evaluation and certification of nuclear installations is universally recognized since longtime. About 30 % cost savings for new nuclear power plants might even be conditioned by such regulation harmonisation.

Significant progress has been made but the process has not yet been completed and the situation now appears to be stagnating.

To make further progress in this difficult area, radical actions should be engaged as suggested during the International Framework for Nuclear Energy Cooperation’s (IFNEC) Global Ministerial Conference.

Practical proposals are necessary to characterise this “Paradigm shift” and to identify how this can be translated into an innovative harmonised approach.

This Perspective by Nuclear-21 aims at proposing the basis for such a paradigm shift in innovative regulation harmonisation which could be a real game-changer for nuclear energy and especially advanced nuclear energy deployment.

Perspectives by Nuclear-21

Our Perspectives aim to bring our views on important developments in nuclear science & technology with potential impact on the development, deployment and overall performance of nuclear science & technology applications worldwide.

Perspectives are the outcome of our think-tank “Let’s Energise Sustainability” contributing to the international thought-processes towards a more sustainable future to us all and the role and options for sustainable energy solutions.

ABSTRACT

The interest in harmonizing approaches to the design, the evaluation and the certification of nuclear installations is universally recognized. Efforts for this harmonization have been underway for several tens of years and significant progress has been made (e.g. with the IAEA safety standards) but the process has not yet been completed.

In parallel with work carried out on a permanent basis, for example by the Reactor Harmonization Working Group (RHWG) of WENRA, recently the need for a "paradigm shift" has been recognized, cfr. CNSC President Ms. Rumina Velshi " *…I think the time is now to think boldly and look critically at regulatory frameworks and be open to the need to re-engineer them. It may be time for a paradigm shift in the regulatory space."*

Looking for this new paradigm, number of questions should be addressed:

- What are the actions already in progress toward the harmonization?
- What are the sticking points that need to be overcome?
- What are the key conditions to achieve the searched New Paradigm?
- What can be the Roadmap for the short and/to medium term?

Without claiming to indicate miracle solutions to achieve the desired harmonization, this Perspectives provides concrete responses to each of these questions and innovative proposals which can help paving the way for the definition of programs whose realization could contribute to the advancement of the reflection.

THE PROGRESS TOWARDS HARMONISATION

The interest in harmonising approaches to the design, evaluation and certification of nuclear installations is universally recognised since longtime (Ref. 1). Already ten years ago it was recognised that the harmonisation represented *"… half a century of efforts"* (Ref. 2). Significant progress has been made (e.g. at the IAEA level with, in particular, the collection of Safety Standards) but the process has not yet been completed. The questions that should be addressed and for which answers should be provided being:

- *What are the actions already in progress towards harmonisation?*
- *What are the sticking points that need to be overcome?*
- *What are the key conditions to achieve the searched New Paradigm?*
- *What can be the Roadmap for the short and medium term?*

Despite the significant progress made, the situation now appears to be stagnating.

More radical actions should be engaged to make further progress in this difficult area.

Such actions should correspond to a "paradigm shift" as suggested at the International Framework for Nuclear Energy Cooperation's (IFNEC) Global Ministerial Conference in November 2019: " *…I think the time is now to think boldly and look critically at regulatory frameworks and be open to the need to re-engineer them. It may be time for a paradigm shift in the regulatory space*" as quoted by Canadian Nuclear Safety Commision's President Ms. Rumina Velshi[i].

The answers to the above questions can help defining the general framework but practical proposals are necessary to materialise what this "Paradigm shift" can be, and that generates complementary questions :

- **What are the conditions for harmonisation to be finalized? e.g.: a new paradigm**
- **What are the conditions that the new paradigm must meet?**
- **What are the essential elements of such a paradigm?**
- **How can these elements generate an innovative approach?**

After a very brief reminder of the actions taken as part of the search for harmonization, in what follows, we put forward proposals to answer the questions raised above.

PRACTICALLY ALL THE BODIES INVOLVED IN NUCLEAR TECHNOLOGIES ARE ENGAGED IN AN EFFORT TO IMPROVE THE CONDITIONS FOR HARMONISATION ON A GLOBAL SCALE

Regulators undertake actions that continue at regional (e.g. Europe with WENRA) or international scales (e.g. IAEA; OECD/NEA/MDEP). Specific activities tackle the problem by focusing on specific sectors probably considered as priority and/or most promising to benefit from such harmonisation (e.g. SMR Regulator's Forum, Ref. (3)). The efforts of regulators are materialised both by in-depth analyses of the differences in certification approaches (e.g. OECD/NEA/MDEP positions papers) and, in parallel, by the definition of requirements applicable to new nuclear installations (e.g. IAEA Safety Standards).

On the their side, designers, operators and, generally speaking, involved stakeholders (IAEA; WNA; WANO; INPO; EUR; EPRI; ENISS/FORATOM, etc.) are also active and various actions have been finalised (e.g. European Utility Requirements – EUR ; Utility Requirements Document – URD , etc.) or are still in progress (e.g. WNA Harmony) with three clearly displayed and shared objectives (cf. the WNA Harmony), i.e.: Create a level playing field in energy markets, Create harmonised regulatory processes, and, Create an effective safety paradigm.

[i] At the International Framework for Nuclear Energy Cooperation's (IFNEC) Global Ministerial Conference - Washington DC, United States - November 13, 2019

WHAT ARE THE CONDITIONS FOR HARMONISATION TO BE FINALIZED?

Before listing what the sticking points can be, it is important to point out that a good level of consensus already exists on the applicable generic terminology (e.g. Risk; Risk Informed; Defense in Depth, Gradual approach, SSCs classification, etc.), on the Safety Objectives in terms of protection of the public and the environment and on the Principles, also generic, on which must lie the definition of requirements applicable to the design and evaluation of nuclear installations (e.g. IAEA Safety Fundamentals, Ref. 5[ii]) .

Nevertheless, despite this consensus applicable to the items used for the certification of nuclear installations, it is clear that differences still exist as regards to the interpretation of their content and the ways for their implementation. **Below are three examples (Risk, Safety Requirements, Safety Objectives) which deserve discussions in order to identify the actions needed to achieve a full consensus about their content. The achievement of such consensus is the first essential step toward the harmonisation** (N.B. the list is not necessarily exhaustive and a specific task should be engaged to comprehensively identify the items on which consensus shall be attained).

The notion of Risk

The concept of Risk is mentioned, for example, by INSAG which, while recognising the role of pivot around which the decision-making process can be built in order to improve the safety of nuclear installations, stresses that a *"common understanding"* should be promoted, implicitly recognising the fact that the consensus is not yet achieved (Ref. 6): *"…This report is intended to promote a common understanding among the international nuclear community (designers, suppliers, constructors, licensees, support organizations and regulators) of how the concept of risk can be used in making safety decisions relating to nuclear installations. The integration of operating experience, deterministic considerations, probabilistic considerations, consideration of uncertainties and other factors serves to help ensure coherent and balanced decisions."*

The concept itself is not unanimously shared. There is a "real risk" (scientifically proven) and a risk perceived by the public which is not a bad thing in itself but which generates an objective difficulty in management (e.g. 100 accidents which cause one death each have not the same "societal" impact as an accident which causes 100 deaths). One can integrate this reality which remains a part of subjectivity in the decision-making by a responsible stakeholder. In any case, the risk domain represented by the "Farmer curve" (possibly corrected to integrate the different perceptions of risk mentioned above) can represent a starting point for arriving at a shared vision of the approach (cfr. Fig. 1).

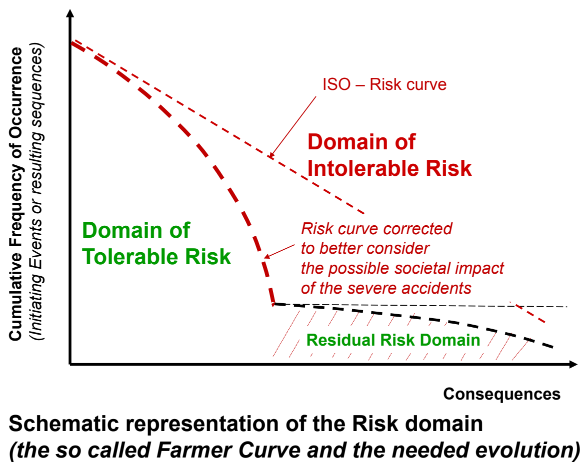


Figure 1 – The principles of the Farmer curve

[ii] In this regard, it is important to underline that, following the Fukushima Dai-Ichi accident and the revision of a certain number of IAEA standards, it was recommended that the IAEA SF1 (Ref. 5) be revised but voices commented this revision as being not essential. (Ref. 30): ***"New insights have been gained over the last ten years and were further developed and incorporated into IAEA or other international organisation documents since the publication of SF-1 in 2006. Although some of them may improve the information about the safety protection concepts currently described in SF-1, these concepts are not called into question and are still valid".***

Safety Related Requirements

In a logic of harmonisation, downstream the Safety Fundamentals (SF), there must be a "top tier level" of Requirements still applicable to any kind of nuclear installation and which, therefore, remains perfectly technology neutral as well as completely independent of the size of the installation.

The IAEA approach, with its logic of Safety Standards Series, partially meets this objective; their content is shared at the level of the principles they convey, but their redaction is not necessarily and systematically "technology neutral". As a matter of example the IAEA NSSR 2.1- Safety of Nuclear Power Plants: Design (Rev.1) (Ref. 7) is structured as follow:

- Management of Safety Design: Requirement 1 to Requirement 3
- Principal Technical Requirements: Requirement 4 to Requirement 12
- General Plant Design: Requirement 13 to Requirement 42
- Design of Specific Plant System: Requirement 43 to Requirement 82

and only the first 42 requirements can really be considered as "technology neutral". The other are developed, in particular, for the LWR and they require adaptation work for other technologies (SFR, MSR, etc.) or specific NPP sizes (e.g. the SMR) or specific uses (e.g. Research Reactors). Other examples, already mentioned above, can be recalled, such as the EUR, URD, WENRA Reference Levels, etc. all fully applicable essentially for LWR.

Moreover, once the redaction is accepted, it is the interpretation which sometimes diverges on essential notions such as (cf. the SMR Regulators 'Forum (Ref. 3))

- Defense in depth and its fundamental principles (e.g. independence between levels),
- Graduated approach and classification of systems / components
- The role of the Human Factor
- ……

The achievement of a set of really technology neutral "top tier level" requirements and a corresponding shared understanding should be considered a priority objective, essential but, still, not necessarily sufficient.

In the quest for harmonization, an important and now shared specification deserves to be recalled insofar it raises specific challenges; this is safety / security harmonization (e.g. (Ref. 7)) : *"Safety measures and security measures have in common the aim of protecting human life and health and the environment.* ***Safety measures and security measures must be designed and implemented in an integrated manner*** *so that security measures do not compromise safety and safety measures do not compromise security".*

Safety Objectives

Several formulations defining the safety objectives are available; they complement the general objective defined by SF1 (*"The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation"*) by detailing some of the most important specifications.

As a matter of example, at the European level, the WENRA/Reactor Harmonization Working Group (RHWG) defined seven Safety Objectives (Ref. 8)[iii], formulated in a qualitative manner, to drive design enhancements for new plants with the aim of obtaining a higher safety level compared to existing plants. As a complement to this publication, the RHWG published in 2013 a set of Positions on "Selected key safety issues"[iv] and a shared interpretation of feedback experience on some Lessons Learnt from the Fukushima Dai-ichi accident[v], providing details for the implementation/ achievement of these objectives (Ref. 9).

As indicated above, the quest for harmonization requires setting ambitious targets which can guarantee such performance even in the event of a severe accident. One can consider that the objectives, as they are defined today, make it possible to satisfy this goal. Without entering into the details, it is commonly agreed that all the safety objectives and positions translate the need for an extension of the safety demonstration (and strengthening its robustness) for new plants, in consistency with the reinforcement of the defence in depth (DiD). To ease the harmonisation, and so to help the demonstration of the DiD reinforcement, the safety objectives should be complemented with criteria and metrics (i.e. quantitative) which will allow and ease the assessment of their achievement.

[iii] O1. Normal operation, abnormal events and prevention of accidents; O2. Accidents without core melt; O3. Accidents with core melt; O4. Independence between all levels of Defence-in-Depth; O5. Safety and security interfaces; O6. Radiation protection and waste management; O7. Leadership and management for safety
[iv] Selected key safety issues -Position 1: Defence-in-depth approach for new nuclear power plants; Position 2: Independence of the levels of Defence-in-depth; Position 3: Multiple failure events; Position 4: Provisions to mitigate core melt and radio-logical consequences; Position 5: Practical elimination ; Position 6: External hazards ; Position 7: Intentional crash of a commercial airplane
[v] Fukushima Dai-Ichi learnings - External hazards; Reliability of safety functions; Accidents with core melt; Spent Fuel Pools; Safety assessment; Emergency preparedness in design

WHAT ARE THE KEY CONDITIONS TO ACHIEVE THE SEARCHED NEW PARADIGM?

In the current situation each regulator has its own rules. As indicated above, officials recommend a “Paradigm shift” which is essential to achieve the requested harmonisation among the national regulators. The objective – extremely ambitious - is to build a universally accepted paradigm[vi] for the safety/security of nuclear installations, that is to say a “model of thought” which organises and directs the analysis, the research and the reflection in the field of knowledge which relate to safety/security.

The previous sections highlight the existence of some convergences and possible differences of interpretation between the different regulators. The development of a new paradigm necessarily involves both compromises on current positions and, where appropriate, the introduction of new tools to facilitate this development.

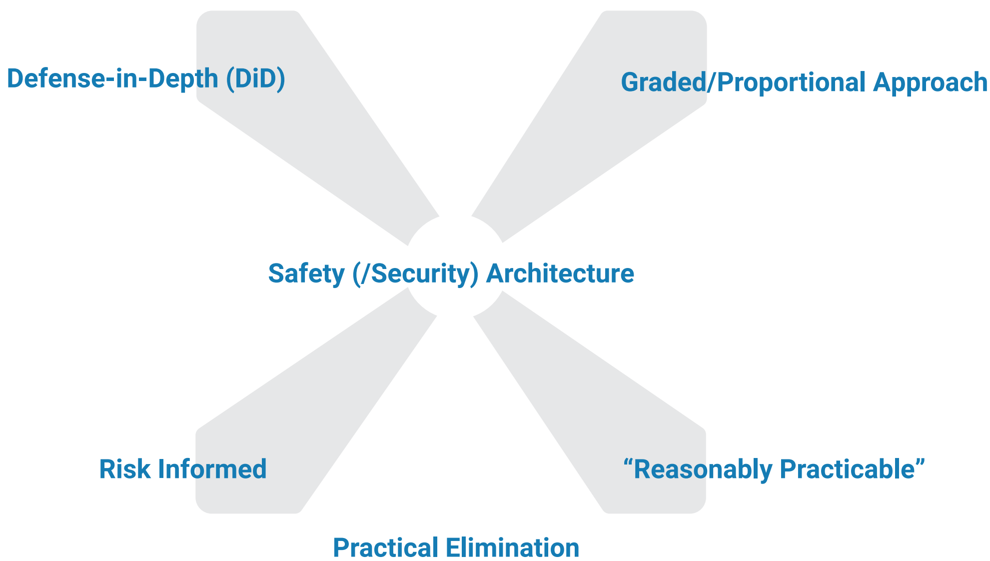
This new paradigm must be:

- **Compliant with fundamental safety principles (Ref. 5)[vii];**
- **Be simple, pragmatic and understandable by all;**
- **Applicable to all the nuclear installations and organised following a Top - Down approach (i.e. in order to be technology and size neutral for their application to nuclear installations and flexible enough to be able to apply to different realities: e.g. NPP, SMR, research reactors, nuclear installations other than reactors, etc.).**

The certification approach which materialise the paradigm implementation shall be based on criteria and metrics which allow assessing the conformity of the design with the fundamental principles (Ref. 5) and the compliance with the available requirements and the safety objectives (Ref. 10).

What are the essential elements of such a paradigm?

The work of reflection is in progress and it is not reasonable to believe that all the solutions are already identified. Below some key subjects of reflection are suggested; they should be explored to identify both the potential and possible limits in terms of regulation harmonization.



[vi] The following definition can be used for the term “paradigm”: the set of beliefs, values and techniques that are shared by the members of a scientific community, during a period of theoretical consensus.
[vii] Principle 1: Responsibility for safety; Principle 2: Role of government; Principle 3: Leadership and management for safety; Principle 4: Justification of facilities and activities; Principle 5: Optimization of protection; Principle 6: Limitation of risks to individuals; Principle 7: Protection of present and future generations; Principle 8: Prevention of accidents; Principle 9: Emergency preparedness and response; Principle 10: Protective actions to reduce existing or unregulated radiation risks

BUILDING BLOCKS TOWARDS AN NEW PARADIGM ON REGULATION HARMONISATION

Safety/Security Architecture

The fact that regulators in nuclear countries have different approaches should not mean that the levels of safety are not equivalent. Tens of years of experience and constant exchanges between regulators, guarantee a high level for the safety of operating plants.

However, it is clear that differences in approaches remain; in these conditions, the objective is to develop tools that can allow better sharing of the unique and invaluable experiences of each designer/regulator[viii] while not jeopardising the continuous improvement in safety levels.

A first element of reflection could be based on a better definition of what can be described as the **safety(/security) architecture** which is expressed by the capability to answer the question when the plant is facing a specific situation: **"who/what does what, when, how ?"**[ix]. It is worth noting that such a term or concept, or nothing similar, is not yet considered, for example, by the IAEA safety glossary (Ref. 11).

The basic idea is that, through the safety architecture, all the elements (provisions) that participate to achieve the operational and or the safety missions are identified and placed on an equality plan as regards their characteristics (active and passive systems, inherent features, procedures, etc.). For a given plant condition (event + status of the installation), it then remains to grant them unequivocally (i.e. without ambiguity) their mission(s) which, in turn, will generate the technical specification (i.e. requested physical performances and reliability) as well as the corresponding safety classification.

The principle being relatively simple, it is essential to find an easy and understandable way to represent this architecture unequivocally.

Defence-in-Depth

As a corollary to this notion of Safety Architecture comes first the concept of defense in depth (DiD) which must be fully implemented with the related associated principles such as the requested reliability for each of the DiD levels and the independence between the levels.

However, as already mentioned, if the concept of DiD is universally accepted, the interpretation of the principles that govern it and their implementation are still subject to different interpretations. Efforts in terms of convergence should nevertheless be highlighted. As a matter of example the reference (Ref. 12), while recognising that the application of DiD principles may result in different national regulatory requirements and based on observations and key elements drawn from experience in European countries, presents the ENISS members' position which endorses the "*following principles for a successful DiD implementation:*

- *Principle 1: DiD concept is, in practice, adequately implemented via a comprehensive set of safety-related considerations, requirements and rules (e.g. deterministic analysis)*
- *Principle 2: A holistic approach should be adopted to ensure DiD robustness, while addressing prevention and mitigation*
- *Principle 3: Independence requirements should be applied in a broad perspective*
- *Principle 4: In order to confirm that the DiD concept and the associated requirements are appropriately implemented, importance should be duly given to probabilistic safety analyses as a complementary approach"*

The objective here is not to comment the details of this reference, but rather highlight certain difficulties that should be overcome.

[viii] Obviously the constant search for improvement of the level of safety must remain an imperative of the approach
[ix] The principle is analogous to that used to present the meaning of risk assessment with the PSA, the so called "Risk triplet" (31), formulated through three important questions relating to the risk and safety of a complex system. These are: 1) What can go wrong? 2) How likely is that to happen? 3) What are the consequences if it does happen?

As an example, discussing and justifying the term "broad perspective", the document (Ref. 12) emphasises that total independence between levels *"could be unachievable and not desirable for the sake of nuclear safety. It should be possible to keep some SSCs shared between more than one DiD level, even for new designs (e.g. control rooms, essential power supply or support systems, possible advantages of cross-connections)"*.

If a principle as important as "the independence between the levels of DiD" leaves the door open to interpretation because it is considered that it is not possible to characterise it by precise criteria and a corresponding metric, the chances of reaching a consensus are obviously reduced.

This is an objective difficulty that can be overcome by generalising the notion of required independence as being, in fact, the need for an "effective functional redundancy" between the different levels i.e., consistent with (Ref. 5), the capacity of a given level, to carry out the requested mission in the event of failure of the previous level[x].

This requires an adequate representation of the whole safety architecture, representation which allows to identify, for all the considered initiating events, the detailed content of each corresponding DiD level, i.e. all the provisions which, for a specific event, achieve together the requested mission. Such a knowledge allows identifying the provisions which, despite the event, having kept their integrity and the capacity to carry out their specific task, can/could be allocated to the successive levels.

By making the notion of "independence between the levels" evolving towards that of "functional redundancy between the levels", the problem could find its solution while complying with the key principle of the DiD.

In this regard, innovative concepts should be proposed to support on one side the establishment of defense in depth and, on the other side, to facilitate the evaluation of the relevance of the options implemented.

Within (Ref. 13), the notion of "Line of protection", developed within the context of the IAEA activities (Ref. 14) (Ref. 15) (Ref. 16) and endorsed, among others, by the Generation IV International Forum / Risk & Safety Working Group (GIF/RSWG), replaces the current notion of "Line of defence". Cf. GIF/RSWG : *"The Line of Protection (LOP) integrates all sort of provisions[xi] and characterizes them, in a homogeneous way, through their performances, their reliability and the conditions of their mutual independence. ...."*

For a given level of the defence in depth, the Line of Protection is an "effective defence" (cf. Ref.5) against a given mechanism or initiating event that has the potential to impair a fundamental safety function. The notion of LOP is perfectly consistent with that of "Layers of provisions" used within the Ref. 17 or Ref. 7 and should be considered interchangeable (LOP in what follow).

For each initiating event, the DiD levels which are implemented to guarantee the prevention, the control, the management and eventually the mitigation of possible consequences, are materialised by LOP which allow meeting the safety objectives. The DiD and the LOP are intimately associated with another concept whose objective is the systematic representation of the safety architecture, the Objective Provision Tree schematised by the figure 2.

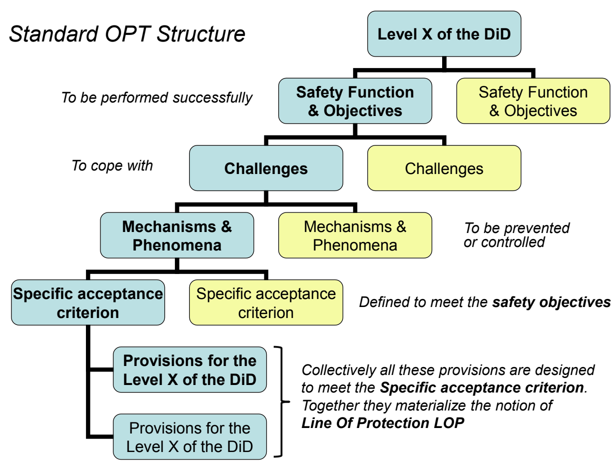


Figure 2 – The standard Objective Provision Tree for the representation of the Safety Architecture

[x] It can be noted that by going from one level to the next, and in accordance with the principles conveyed by the Farmer's curve (i.e. frequency of occurrence inversely proportional to the allowable consequences, cf. Fig. 1), the performances required at level N+1 may be lower than those required at level N because the allowable consequences can be larger.

[xi] This term is used for any set of inherent characteristics, equipment, system (active or passive), etc., and any procedure, all being part of the plant safety architecture, the objective of which is to accomplish jointly the mission needed to achieve a given safety function.

In order to determine the deterministic and the probabilistic success criteria, in terms of required performances and reliability for the lines of protection, the concept of risk space can be used. The overall intent is illustrated schematically in Figure 3; it shows that, for a given initiating event whose consequences are potentially unacceptable, design provisions are implemented[xii]:

- to keep or make the consequences acceptable with regard to the frequency of occurrence of the initiating event (PIE) they are requested to control; this allows defining the success criteria in terms of requested physical performances that allow maintaining or bringing back the installation into the acceptable area (Control – Mitigation: deterministic success criteria) and /or
- to decrease the likelihood of the accidental sequence; this allows defining the success criteria in term of reliability of the layer of provisions required to ensure that, in case of failure, the sequence "PIE + LOP' failure", is within the acceptable area (Prevention: probabilistic success criteria).

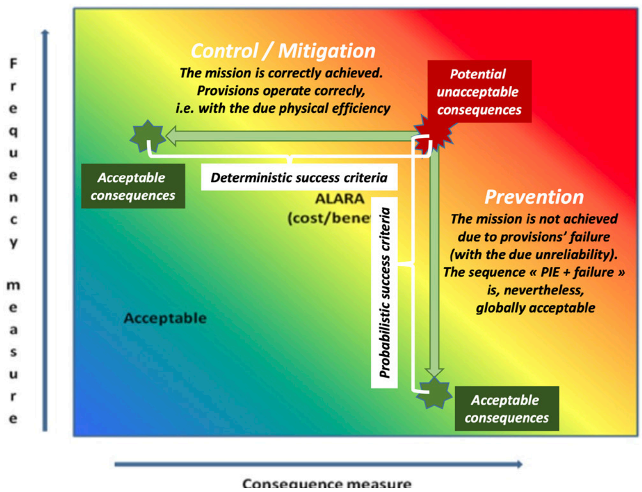


Figure 3 – Risk space and deterministic / probabilistic success criteria[xiii]

The graded/proportional approach

An important objective is that of a graded/proportional approach in the architecture's response to any event which must be reflected in the safety assessment: i.e.: the effort engaged must be proportional to the potential risk.

As a matter of example, reference Ref. 18 indicates that a graded approach is established as a framework of decision-making tools and rules, and is supported by an organization's management system; it points out that the use of the graded approach is consistent with IAEA principles (IAEA Fundamental Safety Principles SF-1 and IAEA GSR Part 1).

The graded approach is defined, e.g. in Ref. 18, as being a method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with:

- *"the relative risks to health, safety, security, the environment and the implementation of international obligations (to which Canada has agreed);*
- *the characteristics of a facility or activity."*

The concept is therefore applicable to what should be the response of the installation to any type of event / solicitation, i.e. proportionate to the risk incurred. Such an interpretation also conforms to what, for example, is requested by the French Regulator and applicable to all the nuclear installations (Ref. 19) *"Article 1.1 - This order sets the general rules applicable to the design, construction, operation, ….Their application is based on an approach that is* ***proportional to the extent of the risks or drawbacks*** *inherent to the installation…".*

Once the notion of "Risk" shared (cf. the notion of risk discussed above), the notion of graded approach helps guiding the optimization efforts and it is essential, in particular with regard to the economy of the system.
In the context of harmonization, it is essential to have suitable and shared tools to assess the effective adoption of this concept. In practice, it is a question of being able to follow, step by step, the installation's response, response for which the availability of a detailed and unambiguous description of the safety architecture, as described above, seems essential.

[xii] For initiating events whose consequences are very low there is no need for mitigation measures; the implementation of provisions to limit the consequences is not necessary.
[xiii] The figure presents only two extreme configurations: layer of provisions' success / failure. Obviously intermediate cases – partial success / failure – have to be considered in an analogous manner.

Reasonably Practicable

WENRA (Ref. 20) indicates that the concept of reasonable practicability is directly analogous to the ALARA principle applied in radiological protection, but it is broader in that it applies to all aspects of nuclear safety. The term “reasonably practicable” is also used in the IAEA’s Vienna declaration (Ref. 21) and the context in which it is used implies the same understanding as in the WENRA text.

The reference Ref. 22 presents a synthesis addressing the notion of “reasonably practicable” as it is understood and shared by different instances in Europe; it points out that “*while in some countries “reasonably practicable” is a regulatory term which serves a special purpose in the licensing process, in other countries regulators currently do not use, promote or transfer this term in their regulatory processes or documents*”. Nevertheless it is judicious to consider that, discussing the harmonisation, the content of this concept will be among the items for which it is important to find common and shared understanding.

The objective here is not to formulate additional proposals with regard to the definition but rather to emphasise **the importance of correlating the role of each provision implemented in the safety architecture to the risk associated with its failure in order to have indicators to judge its relevance versus this notion of reasonably practicable**. The correlation sought can result in a close correspondence with, for example, the results of a PSA type analysis.

Practical Elimination

The amended EU Nuclear Safety Directive (Ref. 23) in its article 8a, and the Principle 1 in the Vienna Declaration for Nuclear Safety (Ref. 21) introduces an objective implying the need to demonstrate the avoidance of early and / or large radioactive releases.

In order to fit with this objective, the principle of "Practical Elimination" complements the domain of the "design basis". The "practically eliminated" situations correspond to accidental situations that could lead to significant early and/or large radiological releases (that is to say with kinetics that do not allow the necessary measures to protect populations to be implemented in time) and for which no specific provisions are implemented within the design to manage their consequences[xiv]. They can also correspond, in very specific cases, to accidental situations leading to significant and late radiological releases (e.g. fuel melt in the NPP fuel building).

The reference (Ref. 24) provides the ENISS views on the demonstration expected to meet the objective and on how it can be supported by the application of the concept of Practical Elimination of scenarios. After the definition of the key terms related to the concept of Practical Elimination (PE) and, in particular that of “Large and Early radioactive Releases” (LER) and “Large and Late radioactive Releases” (LLR), the reference lists three types of scenarios with severe fuel degradation and loss of the confinement function which potential consequences are LER or LLR :

- *“Type 1: Scenarios of severe fuel degradation with, or quickly followed by, a failure of the confinement function leading to LER*
- *Type 2: Scenarios of severe accident (e.g. core melt) resulting in an early failure of the confinement function leading to LER*
- *Type 3: Scenarios of severe accident resulting in a late failure of the confinement function leading to LLR”*

Among the key elements drawn from observations and experiences of application the concept of Practical Elimination, the correlation to the latter with the Defence in Depth seems essential. Different positions are discussed by (Ref. 24) (IAEA, INSAG, OECD, FANC) but what seems important, among the conclusions, is the indication that : “*The evaluation of the Practical Elimination of scenarios is a verification of the capability of the 1st to 4th DiD levels to sufficiently reduce the likelihood of LER or LLR with a high degree of confidence*.”

[xiv] Following Ref. 7: The possibility of certain conditions arising may be considered to have been ‘practically eliminated’ if it would be physically impossible for the conditions to arise or if these conditions could be considered with a high level of confidence to be extremely unlikely to arise

Discussing the approach to identify the scenario to be practically eliminated, the Ref. 24 points out that the ENISS licensees share the view that the approach should be part of the design process and be completed as early as possible and that, among the steps which need to be implemented, it is necessary to *"Identify the existing lines of defence and discuss the likelihood of their failure modes"*.

The conclusions applicable to the new plants are consistent with the notion of Risk Informed:

- The methodology which supports the demonstration of avoidance of LER and LLR should be based on both deterministic and probabilistic analyses.
- Each methodology is defined on a case-by-case basis as a function of the scenario to be practically eliminated.

Among the suggested seven general principles which conclude the Position paper it is interesting to point out that the "*Demonstration of avoidance of LER and LLR (should) credits all the relevant lines of defence as well as the analyses of the Design Basis and Design Extension Conditions, and the Probabilistic Safety Analysis*" (Principle N° 4) which can lay on the availability of an univocal representation of the safety architecture or "*The demonstration of avoidance of LER and LLR should be based on a balanced use of deterministic and/or probabilistic studies, including sensitivity analyses – associated methodologies are developed on a case-by-case basis.*" (Principle N° 6) which stress the need for **an approach consistent with the notion of Risk Informed which should correlate the DiD and the PSA**.

Risk Informed

The reference Ref. 22 address the concern related to the understanding of this notion stressing that *"Application of risk informed approaches does not mean that deterministic safety principles would be abandoned, but rather that* ***deterministic, probabilistic and other reasoning are combined in a complementary way*** *recognizing the strength and limitations of each approach"*.

The retained approach should "*combine risk analysis results or insights from probabilistic results together with inputs from deterministic analysis and other contributions like operational experience feedback and results (OPEX), good practices and standards, economic analysis*". The Figure 4 below shows the basic structure suggested by ENISS[xv].

The document Ref. 22 mentions that *"... ENISS licensees endorse a European approach that would integrate well proven and accepted risk informed methodologies"* without indicating precisely what these methods should be.

In order to contribute filling this gap, the peculiar role of the Defence in Depth concept and the Probabilistic Safety Assessment approach for the optimisation of the safety performances of the nuclear installation have been preliminarily investigated (Ref. 25); in this reference, general indications are provided about a global process for the assessment of the DiD using the PSA, i.e. for the verification that the implemented safety architecture complies with the principles of the DiD while meeting the probabilistic objectives.

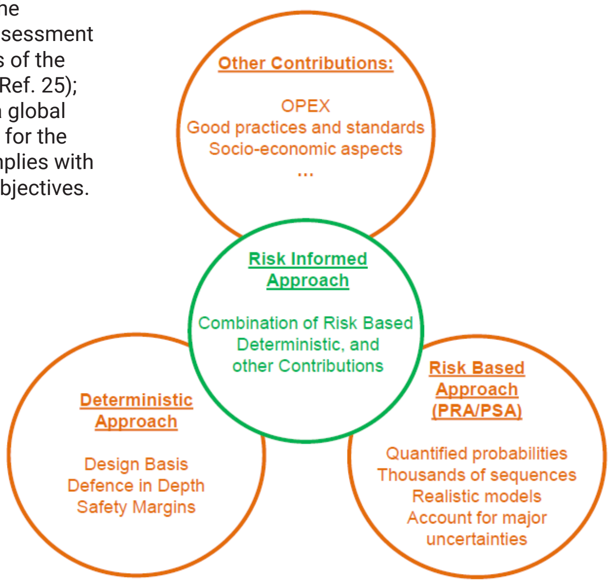


Figure 4 – The Components of the Risk Informed approach as suggested by Ref. 22

[xv] Following the author, the "Other contributions" bubble should not be placed on the same level as the other two but rather as a subset of the "Deterministic Approach" component

THE POSSIBLE RELATIONSHIP BETWEEN DEFENSE-IN-DEPTH (DID) AND PROBABILISTIC SAFETY ANALYSIS (PSA)

To support the effort for the harmonisation, and in compliance with all the indications provided by the previous sections, the objective is to go further making explicit the possible relationship between DiD and PSA.

The process proposed by the reference Ref. 26 is fully consistent with the indications provided by the IAEA GSR Part 4 (Rev 1) (Ref. 10) and is based on concepts introduced by the Generation-IV Risk and Safety Working Group (Ref. 27 and Ref. 13). It is articulated in four main steps devoted to 1) the formulation of the safety objectives; 2) the identification of loads and environmental conditions; 3) the representation of the safety architecture and 4) the evaluation of the physical performance and reliability of the levels of DiD. A final step achieves the practical assessment of the safety architecture and the corresponding DiD with the support of the PSA.

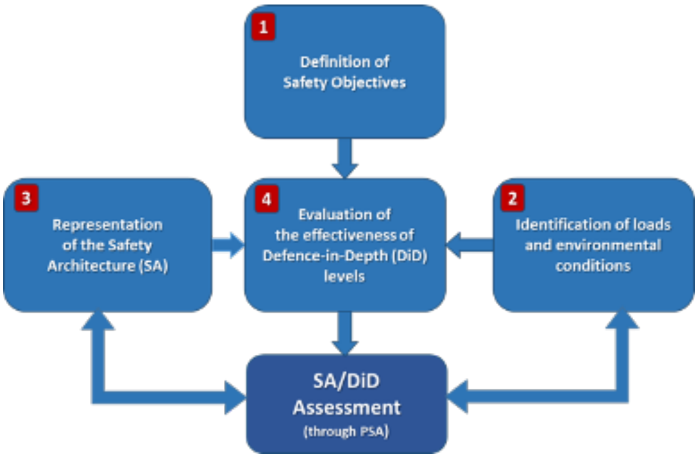


Figure 5 – Process for the PSA assessment of Defense in Depth

Concerning the safety objectives, the reference to the risk space (i.e. the Farmer curve) is considered essential to assess the whole safety architecture with respect to the achievement of deterministic and probabilistic targets, i.e. the performance required for the safety functions to reduce the consequences of plausible events as well as the reliability which has to be allocated to the provisions which achieve these functions (cf. Figure 3).

Additional qualitative key-notions shall be introduced, providing general indications about the criteria and metrics which should have to be defined in details and adopted. They refer to basic design goals (e.g. need for protective measures limited in times and areas in case of severe accidents) and to DiD principles (e.g. independence of DiD levels, practical elimination of events and sequences leading to early or large releases, demonstration of the availability of "adequate margins" against possible cliff edge effects, etc.).

Furthermore, the development of some Safety Fundamentals and Requirements leads to the definition of additional qualitative objectives; they address the search for **exhaustiveness** for the design basis events and the design extension conditions considered for the safety design and assessment[xvi], the need for **progressiveness** in the system's response to abnormal events[xvii], the need for a **forgiving**[xviii] and **tolerant**[xix] character of system safety response, and the suitable **balanced**[xx] contributions of the different events / sequences to the whole risk.

The identification and recognition of all plausible normal and off-normal loads and environmental conditions, that can affect the behavior of the installation, is the result of a detailed analysis of the system complemented, as needed, by the consideration of the experience feedback. Since the years 2000 the basis for the design evolved and, today, all the plausible plants conditions generated by internal and external hazards (Anticipated Operational Occurrences, Design Basis Events and Design Extension Conditions), have to be considered within the Design Basis and, more generically, for the definition of the Safety Case.

Moreover, an explicit one-at-one correspondence is suggested, for example, by WENRA (Ref. 8) and NUREG 2150 (Ref. 28) between, on one side, these plant conditions, the levels of DiD and, on the other side, their positioning within the risk space (cf. Fig. 6). This correspondence is essential for the designer who can so superpose the levels of DiD within the area of allowable risk and, simultaneously, gives explicit targets (success criteria, both in terms of performances and reliability) for these levels (cf. Figure 3). It is worth nothing that these targets are essential to classify the System, Structures and Components, complementing the process defined by the SSG-30 Safety Guide (Ref. 29), and to size the provisions associated with each level of the DiD.

[xvi] An exhaustive defence, i.e.: the identification of the risks, which leans on the fundamental safety functions, should look for exhaustiveness; the identification of the corresponding scenarios to be retained to design and size the safety architecture provisions must be as exhaustive as possible. It has to be noted that, coherently with the defence-in-depth principle possible lacks of exhaustiveness are compensated by consideration of enveloping situations which are taken into account independently of their expected occurrence frequency (single failure criterion; margins; postulated combinations; etc.)
[xvii] A progressive defence; without that, "short" sequences can happen for which, downstream from the initiator, the failure of a particular provision entails a major increase, in terms of consequences, without any possibility of restoring safe conditions at an intermediate stage
[xviii] A forgiving defence, which guarantee the availability of a sufficient grace period and the possibility of repair during accidental situations
[xix] A tolerant defence: no small deviation of the physical parameters outside, the expected ranges, can lead to severe consequences (i.e. rejection of "cliff edge effects")
[xx] A balanced or homogeneous defence, i.e.: no sequence participates in an excessive and unbalanced manner to the global frequency of the damaged plant states.

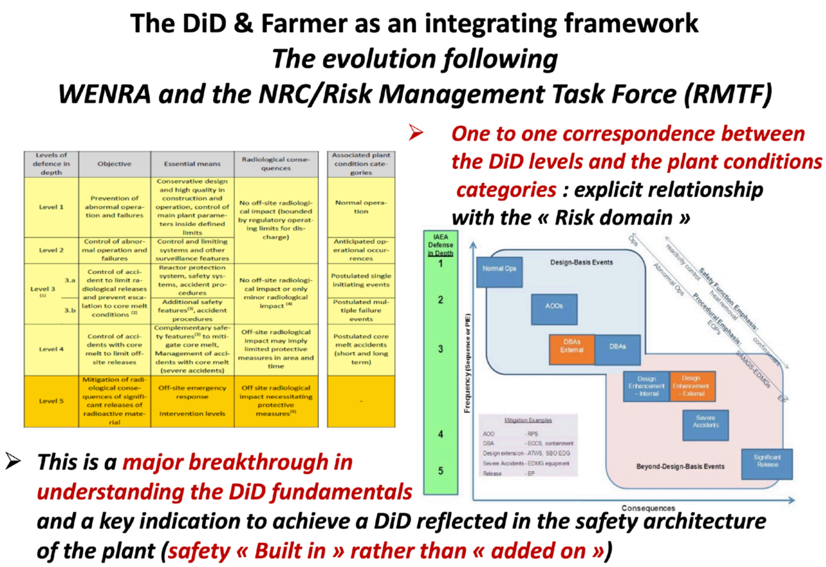


Figure 6 – The defence in Depth and the Risk Domain (the Farmer curve)

As indicated above, the Objective Provision Tree (OPT) methodology and the complementary notion of Line of Protection/ Layers of Provisions (LOP), are proposed for the representation of the safety architecture implemented by the nuclear installation. If correctly implemented, these tools can support the identification of possible lacks or the weaknesses of DiD level(s), e.g. lack of independence between the DiD levels, inadequacy of the layers of provisions allocated to a given DiD level, etc. The OPT and LOP also provide the essential information for the subsequent development of probabilistic studies, by representing the whole safety architecture that should be successively analytically described by the PSA, with all its internal interactions.

THE PROBABILISTIC ASSESSMENT OF THE SAFETY ARCHITECTURE AND DEFENSE-IN-DEPTH (DID)

The Level 1 PSA relies on event trees drawn to determine how, following a given initiating event, the accident sequences progress until the severe accident condition (i.e. a fuel damage state). In order to enable a comprehensive evaluation of the safety architecture, the PSA has to consider all the initiating events, all the safety functions, and all the levels of the DiD.

The current structure of the PSA does not necessarily rely on the DiD representation of the plant's architecture. The availability of an exhaustive - as practicable – representation of the safety architecture allows the development of a PSA model with a structure that better complies with the DiD principles and that, in turn, could allow to evaluate the physical performance and reliability of each DiD levels. This structure is based on Event Trees (ET) built to reflect the crossing of different levels of DiD and on Fault Trees (FT) which, at each crossing, allow assessing the reliability of the implemented layers of provisions[xxi].

The PSA's event trees can be built/re-structured directly starting from a representation of the safety architecture through the Objective Provision Trees. Each OPT is specific of a given level of the DiD, of a given safety function and of a given initiating event. For a given PIE, the PSA's event tree allows modelling the failure of LOPs addressing their concatenation, interactions (e.g. the amplitude and the kinetics of the reactivity control will affect the amount of heat to be removed) and plausible dependent failures (including common cause failures and propagating failures[xxii]). Figure 7 provides the standard structure of the Event Tree for a given PIE which demands for (all) DiD levels intervention. The sequence "hazard + failure of the DiD level 1" materializes the initiating event.

Figure 8 integrates, into the standard Event Tree structure, the indications about the practical elimination of ("short") sequences which by-pass the intermediate levels (2nd and/or 3rd) and which, in case of failure of the 4th level of DiD, lead to unacceptable consequences. It also shows the possible by-pass of the 3a level of DiD (following the WENRA definition) in case of multiple failures events.

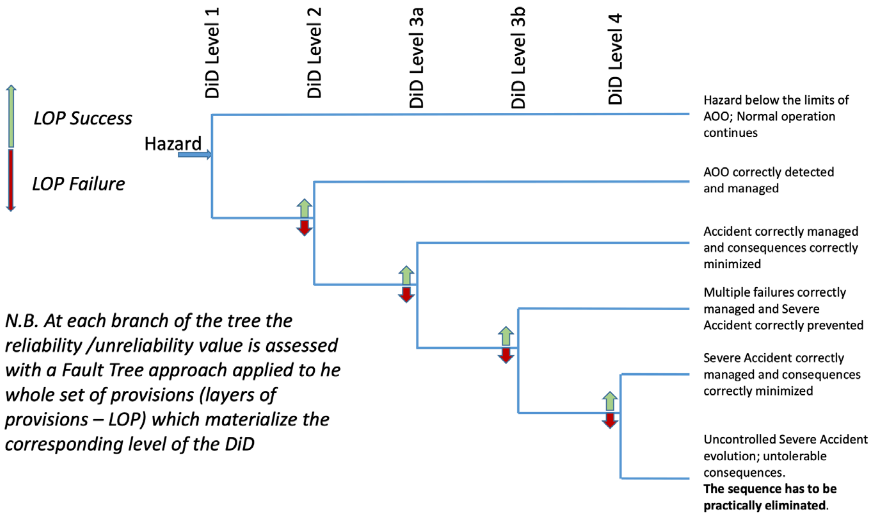


Figure 7 - Example of Event Tree organized following the structure of the DiD

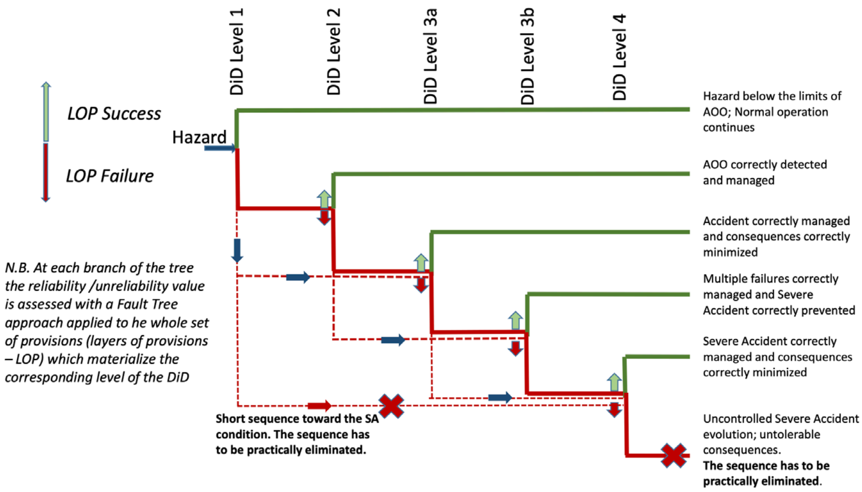


Figure 8 - Updated example of Event Tree organized following the structure of the DiD

With such an approach, in accordance with the requirement to strengthen defense in depth and its evaluation, the proposal is so made for an oriented implementation of probabilistic studies, implementation which would lead to satisfying another important objective, namely that of the harmonization of deterministic and probabilistic approaches.

[xxi] Each node of the ET represents the failure/success of the whole set of provisions (i.e. the layers of provisions / Lines of protection) which materialize the corresponding DiD level, with the respective conditional failure probability. The latter is assessed by a FT which includes all the provisions required to be operational in order to achieve successfully the requested mission: engineered safety systems and all support system components, passive systems and components (e.g. undetected filter blockages, pipe leaks, etc.) as well as procedures and operator interventions.

[xxii] On its side, the specificity of the OPT approach is to identify, for a given initiating event and a given safety function, and for each level of DiD, the corresponding LOP with all its provisions. Obviously for different initiating events, but for the same safety function and / or the same DiD level, LOPs are built specifically and not necessarily with exactly the same provisions. Moreover, the provisions which appear at a given level of DiD for an initiating event and a safety function may intervene at another DiD level for another initiating event or in another level if their performances are not affected by the event under consideration. Under these conditions, concerning the degree of detail for the PSA input data, it is not interesting to introduce directly the failure of single provisions within the ET (this would certainly be very tedious due to the enormous quantity of possible combinations) but to model the failure of the whole LOP within the ET and the failures of its provisions through a dedicated FT.

WHAT LESSONS CAN BE LEARNED FROM PREVIOUS SUCCESSFUL EXPERIENCES? E.G.: THE REGULATION OF THE TRANSPORT OF NUCLEAR MATERIALS

The regulation of the transport of nuclear materials is undoubtedly the best example for the harmonisation between the regulators worldwide.

The transport of nuclear material shall comply with the IAEA Safety Fundamentals and IAEA Requirements. In particular the document IAEA - Regulations for the Safe Transport of Radioactive Material 2018 Edition; Specific Safety Requirements No. SSR-6 (Rev. 1) (Ref. 30) *"establish standards of safety which provide an acceptable level of control of the radiation, criticality and thermal hazards to people, property and the environment that are associated with the transport of radioactive material"*.

Within the document the three safety functions are implicitly identified:

- *"Containment of radioactive material;*
- *The evacuation - if any - of the heat produced;*
- *The control of reactivity"*

The safety objectives and the required performances are clearly and quantitatively defined and easily accessible and measurable (e.g. doses to people and the environment, maximum temperatures and pressures, permissible contamination rates, etc.). Additional parameters allow unambiguous categorization of packages (e.g. the Transport Index, the Criticality Safety Index, etc.), parameters to which specific and quantified requirements can easily be associated. Concerning the testing activity associated to the certification, the recommended tests are implemented to cover any plausible situation, be it normal, incidental or accidental. Moreover, what can be emphasised is the totally passive nature in the realisation of safety functions. Controls (active) are an integral part of safety and complement the "passive" safety architecture.

In these circumstances, it can be considered that the harmonisation effort was "relatively" easy since the design/certification of such an activity is governed by a set of perfectly identified and accessible criteria and metrics upon which, once the figures defined and agreed (which certainly required considerable work with a consistent R & D in different areas), the work that remains to be done is that of control.

Under these conditions, an essential lesson that can be drawn from this experience is the availability of criteria and metrics - measurable and controllable - characterising the level of safety which is unanimously considered acceptable. It is this availability of easily quantifiable and measurable criteria and metrics for relatively simple architectures that nevertheless seems difficult to extrapolate to the otherwise more complex architecture of a nuclear installation.

INTERNATIONAL, REGIONAL NATIONAL IMPLEMENTATION

The discussion about the need for and the way to the harmonisation of the design and the assessment of future nuclear installation may/should obviously include a discussion on the integration of the different levels of legislation/regulation.

A key issue is represented by the need to guarantee the independence of the national safety regulatory authorities that shall remain a national prerogative worldwide. To reconcile this requirement and the objective of harmonisation, the example of the regulation of the transport of nuclear materials is significant: the directives from international organisations such as the International Maritime Organization (IMO) shall be endorsed and systematically transposed within the national regulations and therefore become mandatory to all member states of the said Organization. The responsibility of national regulators is focused on the administrative stage of validating a certificate (e.g. of packaging conformity) issued by a member state in any other state; in parallel – and more generically - they remain strongly involved with their Technical Safety Organisations (TSOs) to define the IAEA safety standards, which could eventually become directives of international organisations and, if this is the case, enter into force as laws for the member states.

As discussed within the section above addressing the lessons learned from previous eperiences, the example is not fully transposable to the certification of a whole nuclear installation because the regulation for the transport can lie on a set of perfectly identified and quantified criteria and metrics and this is likely not fully possible for the certification of an installation but the path should be explored trying to go as far as possible in defining harmonised objectives and shared tools as well as technical and quantified criteria and metrics.

Furthermore, the current authorisation process may differ from country to country; analytical work must be carried out in parallel to fully understand the differences that remain between the approaches of the different member states and the reasons for these differences. As indicated above, the IAEA Standards constitute a solid technical foundation on which national authorities should organise their authorisation process but, as already discussed, an essential prerequisite is that of harmonising both the objectives and the means to demonstrate that the latter are achieved, which implies additional work compared to the current state of these standards, a work that should materialise the “new paradigm”.

Several steps can structure this analysis:

1. Steps and timing from certification to authorization; what is the situation, how could it be improved?
2. Need and possibility to improve the authorization process at the national level?
3. International treaties (Conventions, bilateral agreements) are relatively qualitative. By drawing on the experience of regulating the transport of nuclear materials, with the support of the IAEA Standards, one can imagine rendering them more technical and quantitative (cf. for example the technical evolutions introduced within the Council Directive 2014/87/EURATOM of 8 July 2014 (23) which amend the Directive 2009/71/Euratom and establishes an improved Community framework for the nuclear safety of nuclear installations)
4. Should the Multinational Design Evaluation Programme (MDEP) approach be the rule and how could this process be improved to involve different national authorities?

In such a context, harmonisation work must be organised step-by-step with the primary objective of finding compromises that can facilitate dialogue and understanding between the various safety authorities; this is the raison d’être of the new paradigm that the nuclear safety/security international community must try to define and share as widely as possible.

[xxiii] Of course, and in accordance with the fifth IAEA fundamental principle - Principle 5: Optimization of protection (5)- the ALARA concept (As low as reasonably achievable) complements these objectives.

[xxiv] Within the EU, once a Directive is published, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive (e.g. August 2017 was the deadline for the Council Directive 2014/87/EURATOM of 8 July 2014 (23))

WHAT CAN BE THE ROADMAP?

This Perspective provides Nuclear-21's starting basis contribution to the important topic of furthering the overall competitivness of nuclear energy in sustainable futures and where regulation harmonisation is seen as an important driver facilitating or even enabling such improved competitiveness.

We offer this document for a critical review by various stakeholders in order to help reaching a consensus based on the analysis, positions and proposals that are put forward.

Nuclear-21 will be actively contributing to the various initiatives towards that common goal and will further the analyis of the different topics highlighted and proposed within this Perspective.

Upon agreement achieved with various and among stakeholders, the activity may proceed with the preparation of "position papers" on items such as:

- **Review of the various efforts related to harmonisation (IAEA, ENSREG, WENRA, EUR,...)**
- **Lessons learned from the harmonisation of the nuclear Transport and others such the harmonisation on safety/security rules for the aircraft industry**
- **Identification of the scope of regulations that could benefit from harmonisation**
- **Challenges to harmonisation to date**
- **Critical analysis of the available general and specific Safety Standards**
- **Critical analysis of the available general and specific Safety Guides**
- **....**

Each of these positions papers could be structured in the same way with:

- a first part developing and detailing the subject matter by incorporating comments, remarks and suggestions in order to establish a state of the art and by identifying the sticking points vis-à-vis the harmonisation;
- a second part of the document would define the technical tasks necessary, in particular, to overcome the identified bottlenecks.

Nuclear-21 invites all stakeholders to comment this Perspective and seek common ground to further the proposed activities

CONCLUSIONS

The interest in harmonising approaches to the design, the evaluation and the certification of nuclear installations is universally recognised. Efforts for this harmonisation have been underway for several tens of years with significant progress have been made but the process has not yet been completed.

In parallel with work carried out on a permanent basis, for example by the Reactor Harmonization Working Group (RHWG) of WENRA, **recently the need for a "paradigm shift" has been recognised.** Looking for this new paradigm, number of questions should be addressed:

- What are the actions already in progress toward the harmonisation?
- What are the sticking points that need to be overcome?
- What are the key conditions to achieve the searched New Paradigm?
- What can be the Roadmap for the short and/to medium term?

One can recall that a good level of consensus already exists on the applicable generic terminologies for a number of subjects/themes (e.g. Risk, Safety Requirements, Safety Objectives) but **differences remain and further actions are needed to achieve a full consensus about both their technical content and the ways for their practical implementation. The achievement of such consensus is the first essential step toward the harmonisation.**

The discussion on the practical content of the new paradigm prompts us to propose innovative tools for the representation of the safety/security characteristics of the installation, representation which is essential to assess its conformity with the objectives that should have been also defined and harmonised.

Among these instruments one in particular seems important and potentially very useful; it is **the concept of safety/security architecture and its essential corollary to represent the implementation of defense in depth, namely the concept of Line of Protection which embodies an update of the former concept of "Line of Defense".**

Finally, with regard to evaluation approaches, and in accordance with the requirement to strengthen defense in depth and its evaluation, a **proposal is made for an oriented implementation of probabilistic studies, implementation which would lead to satisfying another important objective, namely that of the harmonisation of deterministic and probabilistic approaches.**

A practical roadmap for this activity is suggested which would start with the critical discussion of the proposals made by the paper followed by the preparation of a set of "position papers" in order to establish the state of the art, by identifying the sticking points which shall be overcome to achieve the searched harmonisation and the corresponding technical tasks.

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As employee of the French Alternative Energies and Atomic Energy Commission (CEA) (1976 – 2010), GLF (nuclear engineer since 1975) gathered more than thirty five years of experience in the formulation, implementation and coordination of theoretical and experimental activities for the design, the operation and safety assessment of nuclear plants, both fission and fusion. Several of these activities have been directly related to support nuclear licensing concerns.

Since 2001, he has been strongly involved in the development of Gen IV collaboration (member of the Generation IV International Forum (GIF) - Roadmap Integration Team for the preparation of the Gen IV Technology Roadmap and as member of the GIF Expert Group; he has been until its retirement co-chairman of the GIF Risk and Safety Working Group.

Significant international experience has been accumulated as correspondent and/or program coordinator of CEA bilateral and multilateral agreements. Gian-Luigi was consultant for the IAEA and for the EU/JRC as specialist for the safety approaches for the design and the assessment of innovative nuclear systems.

Retired from CEA in 2011, Gian-Luigi has been consultant for the Belgian Federal Agency for Nuclear Control until 2014 and Chargé de Mission within the Cabinet of the French High Commissioner for Atomic Energy (Mr. Yves Bréchet) in charge of "Nuclear Safety" until 2018 with specific missions to monitor the licensing procedures for ASTRID (Gen IV Sodium Fast Reactor) and CIGEO (deep geological disposal of high-level long-lived radioactive waste) to check the compliance with the indications of the regulators applicable for future nuclear installation. Currently involved in consultancy activities for the European Commission - JRC as well as for a Governmental Agency in Singapore.

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