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Development of efficient regulatory infrastructure in “newcomer countries”: current situation, challenges, EU assistance

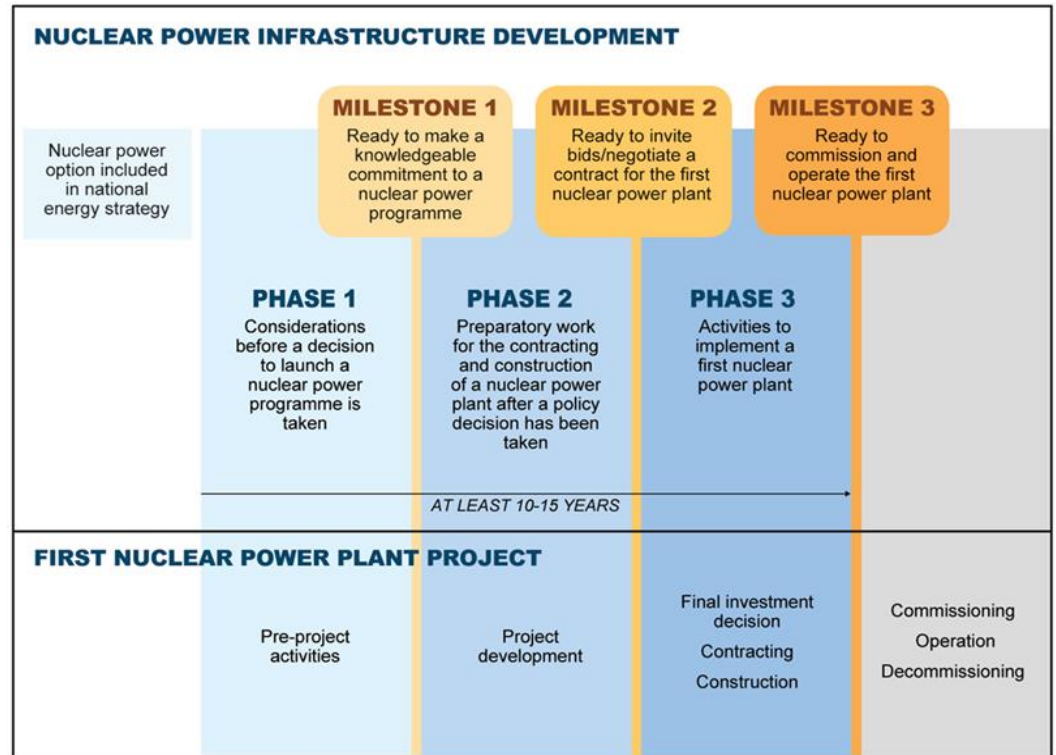
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Introduction

The countries that consider to use nuclear energy for electricity production implement the important efforts on **development of industrial and regulatory infrastructure** in order to meet international obligations and assure the peaceful and safe use of nuclear energy.

All “newcomers” follow the IAEA roadmap for developing of nuclear project infrastructure described in IAEA NG-G-3.1.



Introduction

The **tasks** aimed to the development **of regulatory infrastructure** mainly associated with Phase 2 and 3 of the project.

- On Phase 2, an effectively independent regulatory body should be developed to a level at which it can fulfill all of its authorization and inspection duties. The country should enact **comprehensive national legislation** covering all aspects of nuclear safety, nuclear security, safeguards and civil liability for nuclear damage. The regulatory body will need to **define siting requirements**. It should **determine criteria for** approving NPP **design** and **establish a licensing process**.
- At Phase 3, the regulatory body should be fully operational to **develop safety regulations**, review **contract specifications**, perform the **safety review** for construction license of the plant and carried out **inspections** during construction.

IRSN together with other EU partners provides a valuable assistance to the newcomer countries in development their regulatory infrastructures via EC INSC projects led by RISKAUDIT, or under contractual basis.

Main challenges and proposed solutions

The *main challenges* that embarking countries are faced to during development of regulatory infrastructure could be identified as follows:

- Development of appropriate *competences and expertise*,
- Establishing an efficient *regulatory and licensing framework* and detailed regulatory requirements,
- Assuring the *transparency, independence and sustainability* of the regulatory body and its technical support.

Main challenges: Phase 2

- Challenge 1: Main **functions, structure, requirements to staff and budget** for the Regulatory Authority (RA) should be defined for short and mi-terms perspectives.
- Challenge 2: A **strategy and program for progressive development of competences and capabilities** should be established.
- Challenge 3: The **responsibility and functions of regulatory authority** should be clearly defined in high level legal acts.
- Challenge 4: In case when regulatory authority considers to call or to create the TSO, it is wise to **specify in legal acts the objectives and functions of such TSO and the sources and mechanism of funding**.
- Challenge 5: When developing **site requirements** consider very high **sensitivity of trans-bordering issues**.

Main challenges: Phase 2

- Challenge 6: When establishing the **licensing requirements and procedure**, sufficient time should be allocated for completeness check and safety review itself.
- Challenge 7: To establish regulatory **requirements** and acceptance **criteria for the design of the NPP**, the latest international and national standards/practices that specify the regulatory requirements to Generation III reactors should be analysed and considered.
- Challenge 8: If a country chooses to **adopt the regulations of vendor country**, it is essential that the country fully understand them and be competent to implement them. The adaptation process needs a thorough consideration of country specific issues.
- Challenge 9: When reviewing the contract specifications it is important to introduce the requirements regarding the **scope and delays of license applications**.

Main challenges: Phase 3

- Challenge 10: The development of TSO or regulatory authority **competences to perform the safety review** should be started at least several years before CL application. It is strongly recommended to use foreign/experienced TSO to work together with internal TSO/regulatory team in order to assure the transfer of methodology and quality of the review.
- Challenge 11: Regulatory authority should **recognize the scope of documentation** to be reviewed and **huge amount of work** including management efforts needed **to organize the review** and issuing the licenses.
- Challenge 12: RA and TSO should **progressively develop and reinforce** their **capability** to perform the safety review, understand/recognize the **responsibility of regulator** and **sensitivity of license issuing**.
- Challenge 13: RA should perform **inspections and surveillance** during construction and commissioning process. This requires as regulatory and procedural framework development, as well as competences for surveillance and inspections.

Proposed solutions: Phases 1 and 2

- Support the management of RA in ***defining main functions, structure and staff requirements, developing strategy and action plan***, provide examples from EU practices and assist in developing the Integrated Management System.
- Assist RA to ***establish the courses*** on reactor technology, design and operation in national universities and engineering schools; ***provide the trainings*** on nuclear safety fundamentals for the RA and university's staff involved in educational process. Create tailored training courses for RA staff considering reactor types to be built in the country.
- Assist RA in ***reviewing the nuclear energy law and regulations***, and in particular, on site requirements and to the design safety.
- Start the development of national requirements from those applied in ***country of origin*** (if defined), adopting and modifying them considering the best practices, latest GEN III requirements and country specific issues.

Proposed solutions: Phase 3

- Presenting and explaining EU practice, assist in ***establishing regulatory review process and procedures***.
- The review of licensing procedures and regulations and help to ***establish the licensing plan*** (could be too late, if contract is already signed).
- Providing assistance on ***development of national TSO***. Methodology and code trainings, definition of role, functions, structure, staff requirements and R&D programs.
- ***Transfer of methodology of deterministic and probabilistic safety assessment***, assisting in its application to practice with country-specific examples, assist to draft and implement the license conditions.
- Presenting the best practice and methodologies of ***surveillance and inspection processes*** in EU countries.

Proposed solutions

- The support and assistance are provided via topical **workshops** and seminars, organization of **training courses** and **on-the-job trainings**, including code trainings and case studies on specific safety issues, **review of regulatory documents** by EU experts, **technical visits** of RA staff to the EU countries, **joint inspections** on NPPs under construction in EU (FL3 and OL2), participation in **Factory Acceptance Tests** in EU, joint inspections on NPP under construction in beneficiary country and participation in international conferences on Nuclear Safety.
- The EU experts **on-site mission** could be also given as a positive example of permanent support to the RA.
- The following projects could be underlined as examples: Philippine PH/RA/01, Indonesia ID/RA/01, Vietnam VN/RA/01, Egypt EG/RA/02, Jordan JO/RA/01, Belarus BE/RA/06, BE/RA/07, BE/RA/08.

Proposed solutions

Country	INSC project	Period of implementation	Main tasks						
			Strategy and action plan	Regulatory framework	Site selection and characterization	Licensing framework	Safety review methodology. DSA & PSA	Inspections and surveillance	TSO development
Philippine	PH/RA/01	2013-2016	X		X	X			
Indonesia	ID/RA/01		X		X	X			
Egypt	EG/RA/02	2013-2017	X		X	X	X	X	
Jordan		2012-2016			X	X			
Vietnam	VN/RA/01				X	X	X	X	
Belarus	BE/RA/06	2011-2013	X	X	X	X	X	X	
	BE/RA/07	2013-2016	X	X		X	X	X	
	BE/RA/08	2015-2019		X		X	X	X	X

Practical example: On-Site Mission assistance

Component A of the BE/RA/08 project is focused on assistance to Belarus regulator via transferring of EU approach and expertise in the following areas:

- Development of management and QA systems;
- Improvement of the regulatory framework;
- Establishment of a TSO;
- Inspecting, assessing and reviewing licensing documentation;
- Supervision of safety relevant SSCs;
- Enhancing GAN knowledge of international activities in the nuclear regulatory field.

In order to manage and reinforce these activities, the ***On-Site Mission (OSM) with one permanent and 2 semi-permanent experts*** was established and operated from April 2015 till June 2017.

Practical example: on-site mission assistance

Since beginning of mission, the OSM organized and supported in total 313 events within BE/RA/08 project, including 200 consultancy meetings, 38 monthly seminars on PSA and 42 coordination meetings with GAN management.

Activities	2015										2016												2017						Total
	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6		
Consultancy meetings with GAN staff (CM)	16	6	8	3	8	5	8	0	5	12	15	5	8	8	10	6	7	8	8	9	8	12	2	9	7	4	3	200	
Monthly seminars on PSA (PSA-MS) (Task A4.3)						2	2	2	1	1	2	2	2	2	1	2	1	3	1	1	2	1	2	2	3	2	1	38	
WG on Deterministic Safety Analysis																			2	1							3		
Coordination meetings with GAN Management (CMM)	2	1	3	2	2	2	2	0	1	1	2	1	1	1	1	1	1	3	1	1	2	2	2	2	2	2	1	42	
Preparation/Organization of TMs, WSs and SCs		2		3		1	1	2			1	2	2	2	1			1	0	0	4			3	2	2	1	30	
Total number of events with OSM support	18	9	11	8	10	10	13	4	7	14	20	10	13	13	13	9	9	15	12	12	16	15	6	16	14	10	6	313	

Practical example: On-Site Mission assistance

Considering very positive feedback on OSM activities expressed both by GAN and by EC project management, during the project Steering Committee meeting in May 2017, it was decided to continue OSM activities up to the beginning of the BE/RA/09 project.

The goal is to avoid gaps in the OSM activities in order to maintain the presence of EU experts (even if it is more limited), the completion to the extent possible of the remaining tasks and to bridge the work between the two projects BE/RA/08 and BE/RA/09.

Practical example: Review of national regulatory framework

The review of national regulatory framework was performed by OSM within the Task 2 of the BERA08 project “Assistance in the development of regulatory framework (legislation and regulations)”.

The objective of the assessment was to perform the analysis of Belarusian regulatory corps in order to:

- **Identify the gaps** in existing regulatory framework through a comparative analysis of national regulatory corps with RF and IAEA safety regulations,
- **Define the priority areas** where national safety regulations should be revised or developed to assure NPP licensing and inspection processes,
- **Suggest applicable methods to compensate** and fill in the identified deficiencies,
- **Provide recommendations on adaptation** of Russian and IAEA nuclear safety regulations identifying the limits of their applicability.

Practical example: Review of national regulatory framework

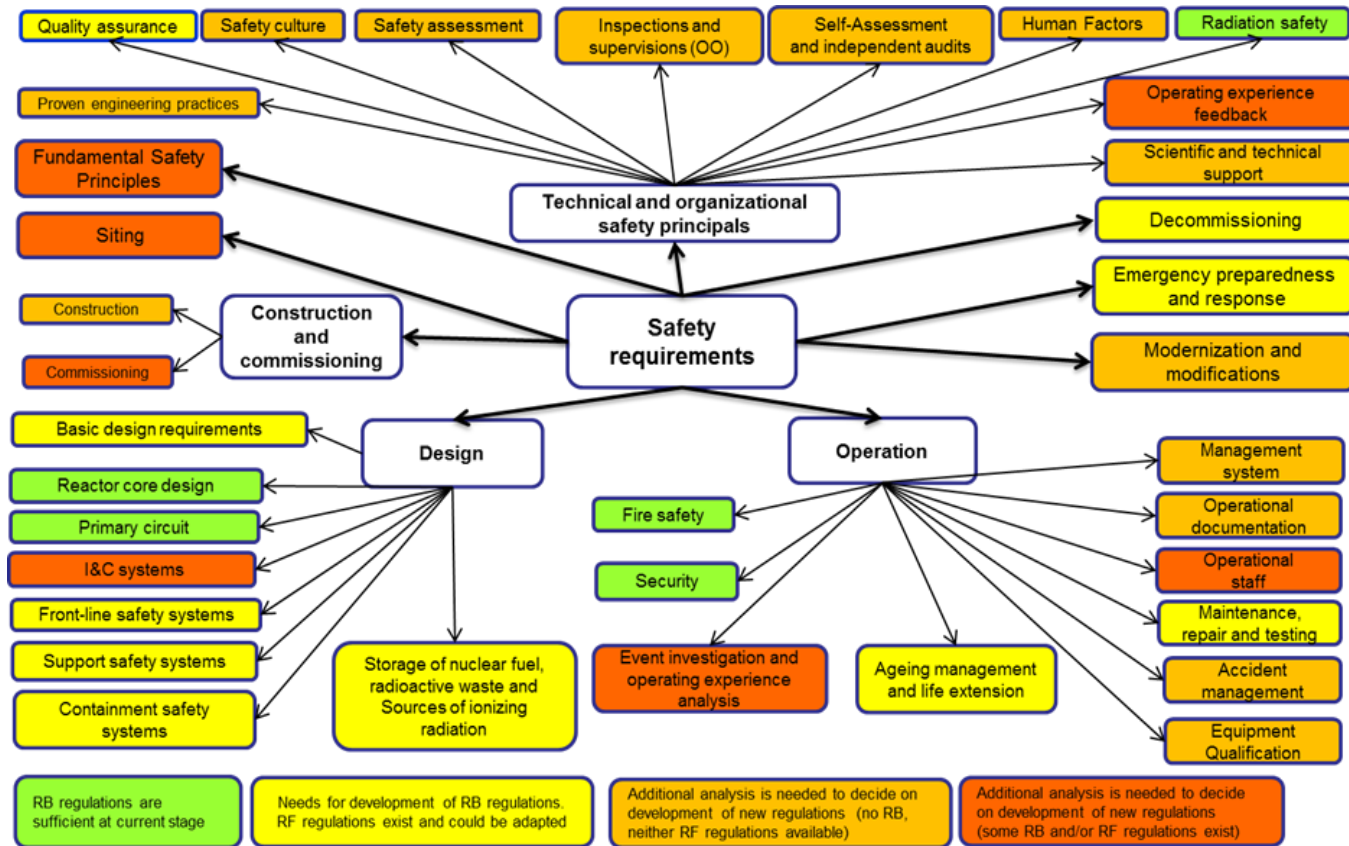
Assessment was performed in three steps:

- Step 1. Identification of existing gaps in TNPA of RF, IAEA regulatory guides and RB
- Step 2. Analysis of TNPA RF and IAEA regulatory guides with regards to possible adaptation to the national context
- Step 3. Comparison of Basic safety principals (Russian standards (OPB88/97 and NP-001-15) vs WENRA requirements to the new PWR reactors)

The assessment was focused on regulations in the fields of nuclear and radiation safety, as well as of safety assessment and review. The results of analysis show the important efforts from GAN side on development of national regulatory framework.

In 2015, 43 national TNPA on NPP safety were in force in Belarus. The comparative analysis was considered 99 regulatory documents (NP, PNAE, RB) of Russian Federation.

Practical example: Review of national regulatory framework



Results of mapping Belarusian and Russian regulations by safety areas/topics as it's defined in Basic Safety Principles.

Practical example: Review of national regulatory framework

- Comparative analysis of national regulatory corps with RF and IAEA safety regulations permitted to identify the gaps and to provide the *recommendations on the areas/topics, adaptation mechanisms and priorities for the further development* of Belorussian regulatory framework.
- On the basis of performed assessment **15 recommendations** on development of the integrated and consistent approach, as well as the *roadmap* for the regulatory requirements development process were provided by OSM.

Practical example: Development of National TSO system.

The OSM had performed an evaluation of GAN's needs in development of Technical Support to effectively perform their regulatory functions.

- The first part of the assessment consisted of
 - Review of **current situation**, including assessment of GAN needs in technical support considering its functions and staffing,
 - **Evaluation of required competences and resources** for short- and mi-terms regulatory tasks (considering NPP licensing/construction schedule);
 - Preliminary **assessment of existing capabilities** in the country.
- The second part was dedicated to
 - Definition of Technical Support **development strategy**,
 - Identification of the **main tasks and stages of development** and
 - Definition of the important **characteristics of TSO system** to be developed.

Practical example: Development of National TSO system.

As a result of the assessment the comprehensive *roadmap on development of national TSO system* was developed and currently is under implementation.

The roadmap includes:

- Development strategy,
- Main tasks and stages of development,
- Types/classification and main characteristics of TSO,
- Areas of work that can be assigned to TSO,
- Technical competences, which are necessary inside or outside Regulatory Authority during construction and commissioning of a new NPP,
- List of critical competencies during NPP operation,
- Requirements to staff/experts qualifications.

Practical example: Development of National TSO system.

It was proposed to apply the *gradual development of Technical Support* strategy, starting from a distributed network, followed by consolidation of TSO functions in the MES subordinated structure.

This development strategy allows GAN to quickly organize technical support in the form of a network of several organizations and individual experts coordinated by GAN (or by one of the organizations included in the network).

Beginning of October 2017, a high level decision had been made on creating the *Republican Centre on Nuclear and Radiation Safety* within the Ministry of Emergency Situations of Belarus. OSM consulted GAN in reviewing the statute, structure, functions and staff requirements of the Centre.

Conclusions

IRSN together with other EU partners provides a valuable assistance to the newcomer countries in development their regulatory infrastructures via EC INSC projects led by RISKAUDIT, or under bilateral/contractual basis.

The intensive support activities for different countries allow to identify the challenges and main issues related to development of regulatory infrastructure that the regulators of embarking countries have to consider during the different phases of their development.

These challenges are addressed within the INSC projects and practical and pragmatic solutions are suggested by EU partners, among them IRSN.

One positive example of such a solution is the On-Site-Mission organization in Minsk, Belarus, within the BE/RA/08 project completion.