ROMANIA

National Commission for Nuclear Activities Control

IMPROVEMENTS OF THE REGULATORY FRAMEWORK FOR NUCLEAR INSTALLATIONS IN THE AREAS OF HUMAN AND ORGANIZATIONAL FACTORS AND SAFETY CULTURE

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Major Nuclear Installations in Romania

Cernavoda NPP

Units 1 & 2 in operation ; Units 3 & 4 are deferred projects waiting for restart of construction

All units are pressurized heavy water reactors (PHWR) of CANDU-6 type.

TRIGA-type Material Testing Reactor (operational)

Other major nuclear facilities in Romania include a nuclear fuel production plant and facilities for uranium ore mining, milling and processing.

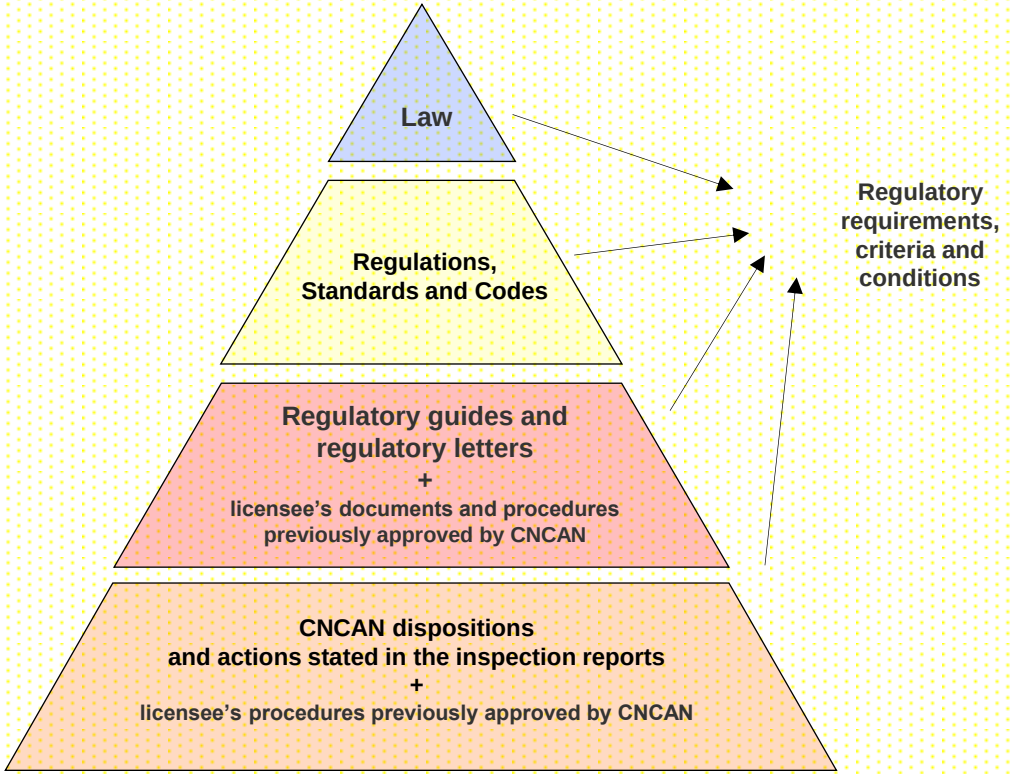
Legal and Regulatory Framework for Nuclear Safety and Security in Romania

- The Nuclear Act of Romania is the Law no. 111/1996 on the Safe Deployment, Regulation, Licensing and Control of Nuclear Activities, republished, with subsequent modifications and amendments
- CNCAN (the National Commission for Nuclear Activities Control) is the national competent authority responsible for the regulation, licensing and control of nuclear and radiological installations, nuclear and other radioactive materials and all associated activities.
- The regulations issued by CNCAN cover the following areas:
  - nuclear safety,
  - radiological protection,
  - management systems for nuclear installations and associated activities;
  - physical protection of nuclear installations and materials,
  - non-proliferation of nuclear weapons,
  - safe management of radioactive waste and spent fuel,
  - transport of nuclear and other radioactive materials,
  - on-site emergency preparedness and response.
  - protection of nuclear installations against cyber threats.
- CNCAN ensures that nuclear safety, security and safeguards are regulated in an integrated manner

The regulatory requirements are based on the Law no. 111/1996 and are specified in regulations and regulatory letters.

The review, assessment and inspection criteria used by CNCAN in the licensing process are derived from a number of sources, such as:

- **Regulations issued by CNCAN ;**
- **Limits and Conditions specified in the licenses;**
- **Applicable Standards and Codes approved or accepted by CNCAN;**
- **Licensing basis documentation produced by the licensees and approved or accepted by CNCAN;**
- **IAEA Safety and Security Publications;**
- **Other international standards, guides and recommendations, including regulatory documents developed in other jurisdictions – these are used as guidance in situations not explicitly covered by CNCAN regulations and guides**



New Regulatory Requirements on Human and Organizational Factors

Acting upon the lessons learned from the Fukushima Daiichi accident and from the safety reviews performed, CNCAN issued 2 new regulations that include requirements on human and organizational factors:

- **Nuclear safety requirements on the response to transients, accidents and emergency situations at nuclear power plants (2014)**
- **Requirements on the nuclear safety policy and on the independent nuclear safety oversight (2015)**

The new regulation on accident management and on-site emergency preparedness and response for NPPs provides requirements on:

- objectives, principles and factors to be taken into account for the response to transients, accidents and emergency situations on-site;
- transient and accident scenarios to be addressed (including severe accidents)
- emergency situations to be covered by the on-site emergency response plan and emergency response procedures;
- the minimum number of staff with necessary qualifications to manage all scenarios required by the regulation (including combinations of events and scenarios in which multiple units on site are affected by accidents initiated by extreme external events beyond the design basis of the plants);
- facilities and equipment to be available for accident management and on-site emergency response, including in situations caused by extreme external events;
- habitability analyses to demonstrate de feasibility of human actions for severe accident management;
- development, validation and documentation of the technical basis for the procedures, taking into account human factors;
- configuration management in relation to the procedures and systems credited for accident management and emergency response;
- training programs and exercises;
- use of operational experience for the improvement of accident management

The new regulation on the nuclear safety policy and on the independent nuclear safety oversight applies to all licensees and applicants for a license for the phases of construction, commissioning and operation of nuclear installations (including nuclear power plants) and provides requirements on:

- **the objectives and scope of the licensees' nuclear safety policy, its dissemination and implementation;**
- **reporting of abnormal conditions;**
- **safety conscious work environment;**
- **periodic self-assessments and independent assessments of safety culture;**
- **the objectives and scope of independent nuclear safety oversight - "internal regulator" (to identify the processes and activities that are not effective in preventing problems with impact on nuclear safety and to support the formulation of recommendations for corrective and improvement actions);**
- **the organizational unit and the qualifications and competence of the personnel in charge of performing independent nuclear safety oversight as an exclusive and full-time job (this personnel will be licensed by CNCAN);**

- **Examples of requirements:**

The personnel responsible for the independent nuclear safety oversight shall:

- ***have the necessary qualifications and technical competences in compliance with the requirements of this regulation;***
- ***have access to the nuclear installations and to the personnel, management and execution activities, documents and records necessary for performing the oversight;***
- ***have access to all the information necessary for maintaining and improving continuously their knowledge of the nuclear safety requirements, internal and external operating experience, good practices in the nuclear industry and the research activities relevant for nuclear safety;***
- ***be independent from cost and planning considerations;***
- ***not be involved in the performance or verification of the activities subject to evaluation;***
- ***have access to the highest level of management in the licensee's organization, for communicating the results of the oversight work and of the recommendations arising from it.***

- **Examples of requirements:**
- ***The personnel responsible for the independent nuclear safety oversight shall be selected such as to fulfill the following requirements:***
  - ***shall have adequate basic technical education;***
  - ***shall have a minimum of 10 years of experience in the activities of the respective nuclear installation or of a similar nuclear installation, in operation, engineering and / or nuclear safety analyses; an experience of less than 10 years, but of more than 5 years, can be accepted on an exceptional basis, if compliance with the competence provisions in the regulation is demonstrated;***
  - ***shall have completed a specific training course or program on independent nuclear safety oversight, accepted by CNCAN.***
- ***The personnel responsible for the independent nuclear safety oversight shall be licensed by CNCAN. Permits will be issued for 5 years periods, with the possibility of being renewed.***

- **Examples of requirements:**

The personnel designated to be part of the organizational unit responsible for the independent nuclear safety oversight shall meet the following competence requirements:

- ***be knowledgeable of the design basis, nuclear safety analyses and the operational limits and conditions of the respective nuclear installations;***
- ***be knowledgeable of the operation modes and of the operating procedures of the nuclear installations, both procedures for normal operation and emergency operating procedures;***
- ***be knowledgeable of the processes, activities and documents of the organization that are important for nuclear safety;***
- ***be knowledgeable of the nuclear safety requirements established in the regulations and licenses issued by CNCAN and in the international codes and standards applicable, including the licensing basis for the respective nuclear installations;***
- ***be knowledgeable of the good practices in the nuclear industry at international level in the area of nuclear safety;***
- ***have interpersonal and communication skills, strategic thinking, skills for coordinating, planning and organizing work, observation skills, attention for details, questioning attitude and critical spirit.***

- **Examples of requirements:**
- ***The independent nuclear safety oversight shall cover all the aspects relevant for nuclear safety, including the following:***
  - ***the compliance with the requirements in the applicable regulations, standards and codes;***
  - ***the compliance with the operational limits and conditions;***
  - ***the reliability and the performance of the systems, structures, components and equipment with nuclear safety functions;***
  - ***the implementation of the dispositions from the inspection reports issued by CNCAN and of the recommendations resulting from self-assessments, internal audits, external reviews and from the root cause analyses for events;***
  - ***the way in which the licensee uses the internal and external operating experience, results of the research activities and the good practices at international level for improving the nuclear safety performance of the nuclear installation and of its organization.***

Regulatory Oversight

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

1) **Human factors in design – consideration of human factors in design is reviewed as part of the regulatory assessment of design modifications for the existing nuclear installations (or as part of the regulatory assessment of the overall design, in case of a new reactor);**

2) **Human factors in safety analyses - considerations of human performance are reviewed as part of the regulatory assessment of deterministic and probabilistic safety analysis i.e. as regards**

   - **the assumptions made in the analyses regarding human actions,**
   - **the time when they are performed,**
   - **the probability of human error,**
   - **the conditions in which the actions are to be performed,**
   - **the "habitability" analyses, etc.**

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

3) Human factors in procedures - procedures for normal operation as well as emergency operating procedures are subject to regulatory review and human factors considerations are part of the assessment e.g.

- **format and style of the procedures,**
- **place keeping,**
- **compatibility with the number of staff and the environment in which they are to be used,**
- **validation of operation and maintenance procedures,**
- **validation of emergency operating procedures, including feasibility of various actions in different locations – Main Control Room, Secondary Control Area, local panels, etc., validation of minimum shift complement,**
- **legibility of printed procedures, etc.**

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

4) Operational performance - human performance considerations are reviewed as part of the following activities:

- **the examination of control room and shift supervisors on the full-scope simulator, for licensing purposes;**
- **the interview of plant managers, for licensing purposes;**
- **the analysis of significant events which have human factors as a contributing cause;**
- **the observation of various activities of the operating staff, such as shift-turnover, performance of testing and maintenance activities, training activities;**
- **the assessment of training and qualification programs and procedures;**
- **the assessment and inspection of human resources management (staffing, selection and recruitment, promotion, succession planning);**
- **the assessment of organizational changes planning and implementation;**
- **the implementation of fitness-for-duty**

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

5) **Emergency planning and preparedness - considerations of human factors are reviewed as part of the regulatory assessment and inspection of emergency response plans, procedures and arrangements; this includes:**

- **use of lessons learned from major nuclear and industrial accidents to improve emergency arrangements;**
- **observation activities during emergency response exercises;**
- **use of experience from exercises to improve emergency response plans and procedures and emergency preparedness training.**

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

6) Organizational structure and staffing of the licensee – the regulatory reviews focus on

- **the assessment of the staffing needs;**
- **the procedures for recruitment and for training and qualification of staff;**
- **licensees' self-assessments on the sufficiency and adequacy of the staffing; succession planning is also reviewed;**
- **changes to the organizational structure or resources require regulatory approval before implementation and monitoring after the implementation**

The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

7) Management system and its processes – the management system manuals and procedures of the licensees, their management, core and support processes are reviewed, audited and inspected by CNCAN; the reviews cover the self-assessment and independent assessment processes, the use of operational experience feedback and the management of non-conformances and corrective actions.

8) Safety conscious work environment – starting with September 2015, CNCAN has explicit regulatory requirements on the licensees' obligation to encourage staff to report concerns without fear of repercussions/retaliation, to resolve such concerns and to provide feedback to the staff that raised the issues

9) Implementation of the nuclear safety policy – CNCAN has new explicit regulatory requirements on the establishment, communication, display and implementation of the nuclear safety policy

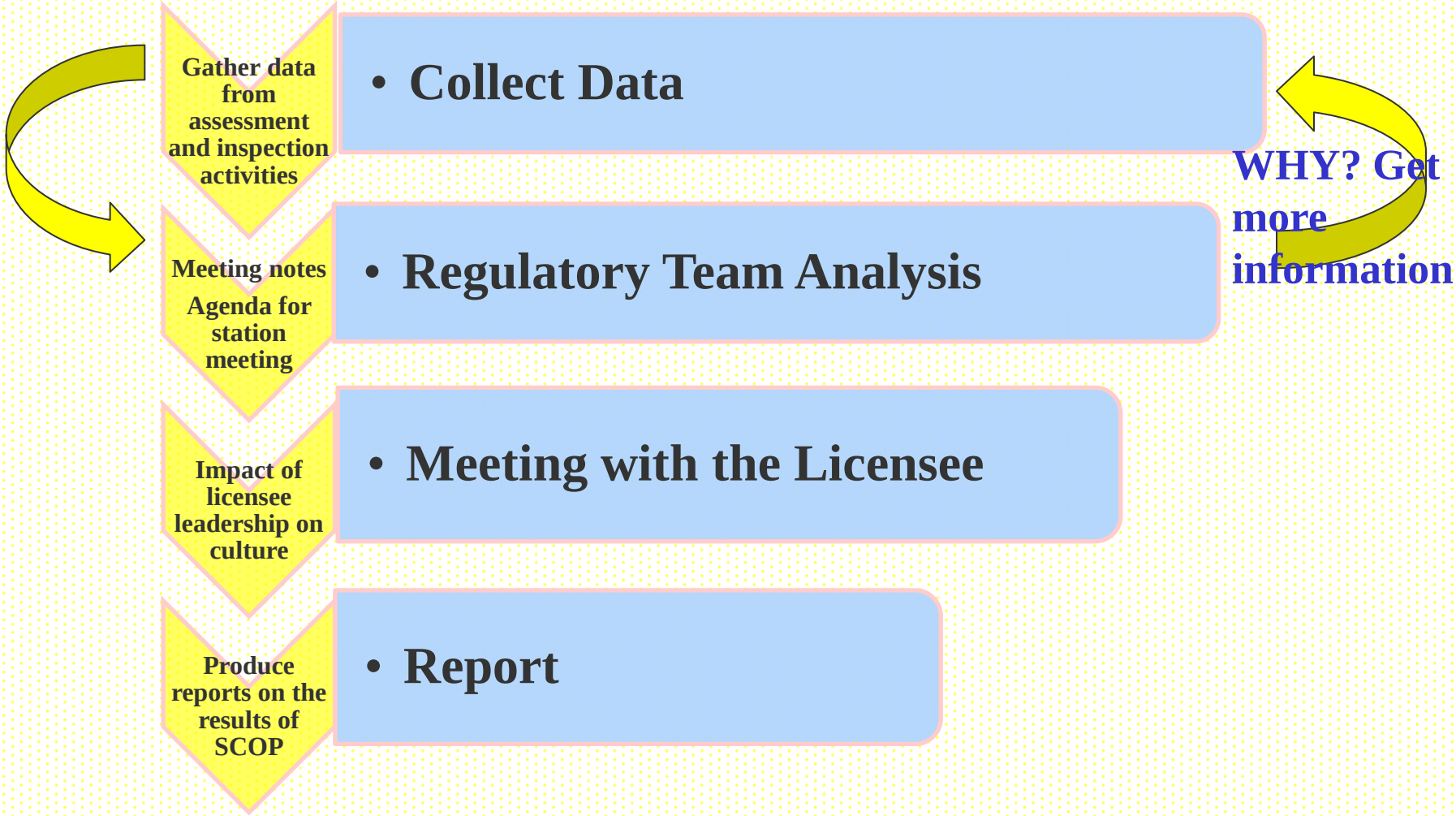
The regulatory oversight exercised by CNCAN (National Commission for Nuclear Activities Control) in the areas of human and organizational factors covers the following :

10) Implementation of the internal independent nuclear safety oversight – CNCAN has new requirements on the independent nuclear safety oversight within licensees' organization ("internal regulator")

11) Nuclear safety culture – the regulatory oversight of safety culture has been formalized in a Safety Culture Oversight Process (SCOP), with detailed guidance for the assessors and inspectors, based on the 37 safety culture attributes in the IAEA safety guides

- The establishment of a Safety Culture Oversight Process (SCOP) started in 2010 following a recommendation from the 4th Review Meeting of the CPs to the Convention on Nuclear Safety
- The SCOP procedure and guidelines have been reviewed and revised in 2015
- SCOP is a structured process for the identification, collection and review of data relevant to the safety culture in licensees' organisations
- SCOP is applicable primarily in the regulatory assessment and inspection activities for organizations responsible for the construction, commissioning, operation or decommissioning of nuclear installations
- The procedure supplements the current regulatory assessment and inspection procedures

Description of the Safety Culture Oversight Process (SCOP)



- General criteria for identifying data potentially relevant to safety culture:
  - issues which, in the opinion of the staff, are directly related to one of the safety culture attributes
  - all findings that constitute deliberate non-compliance with license conditions and / or regulations and / or requirements of the management system of the licensee
  - all findings that indicate a mismatch between the declared policies and organizational values ("espoused values") and the current state of affairs, including procedures, behaviours, state of equipment, etc. ("artefacts").

- IAEA GS-G-3.1 establishes a set of 37 attributes corresponding to the 5 safety culture characteristics ; SCOP uses these 37 attributes
- All information gathered from inspection and assessment activities, from meetings with the licensees, can be relevant for safety culture (one of our assumptions)

- Generic data sources, examples
- policy documents, procedures describe safety-related processes and activities;
- self-assessment guidelines; self-assessment reports and safety performance indicators for various processes;
- results of (quality) management system audits and reviews, reports from external reviews;
- previous inspection reports;
- records of past events and corrective actions implemented;
- interviews with licensee's during the inspections;
- observations during common meetings;
- observation of activities in the field

- SC Attributes can be assessed through:
  - Review of documentation
  - Interviews
  - Direct observation
- Detailed guidelines are provided for the assessment of the safety culture attributes
- For each safety culture attribute the detailed guidelines include, as applicable:
  - regulatory expectations relevant to the attribute;
  - documentation to be reviewed;
  - questions to be asked;
  - observations to be made;
  - elements necessary for considering an attribute fulfilled;
  - warning flags.

A safety culture oversight database is being put together , with this structure:

Identification number	Unique identification number for the observed safety culture issue
Date	The date when the safety culture issue was observed
Nuclear installation	The identification on the nuclear installation were the issue was observed
Area	The functional area in which the safety culture issue was observed
Finding	Description of the finding
Safety Culture Characteristic	.....
Safety Culture Attribute(s)	..... (maximum 5, the most relevant)
Basis	Basis for considering the finding as a safety culture issue; any information needed during the assessment process
Associated documents	Inspection report, review report, minutes of the meeting, as applicable

Regulatory Influence

What regulators see and hear

- Regulators *see artifacts*.
- Regulators *are aware of the espoused values and principles* (these are usually set in licensees' policies, goals and strategies).
- Regulators *may discover / hear some of the basic assumptions* in the discussions/interviews with the licensees' personnel and in the root cause analysis reports for events.
- Basic assumptions are (like) root causes. Apparently unrelated non-conformances or events may have their root causes in shared basic assumptions

What regulators do

- Regulators *set requirements on some the artifacts* or *directly influence some of the artifacts*.
- Regulators review and inspect the artifacts (procedures, processes, practices, programs, behaviors, state of structures, systems and components, organizational changes, resources, etc.) and take enforcement actions in cases of non-compliance with requirements.
- Regulators may observe patterns, including improvement in licensees' performance as well as signs of declining safety performance.
- Regulators review and *may influence the espoused values and principles* when they review licensees' policies, goals and strategies.
- Regulators may discover underlying/basic assumptions or may seek to discover them if they observe discrepancies between espoused values and artifacts; *may have some influence over some basic assumptions*.
- Regulators *can and should identify discrepancies between the espoused values and the artifacts* and should then question the basic assumptions of the licensees.

- **Aware that the culture of the regulator influences the safety culture of the licensees, CNCAN started to define its own organizational culture model and identifying the elements that promote and support safety culture**
- **This action will also address a recommendation received from the 6th Review Meeting of the Contracting Parties to the Convention on Nuclear Safety, to have assessments of the safety culture of the regulatory authority**
- **A limited exercise for a safety climate survey has been implemented for CNCAN staff involved in the regulatory review and inspection activities for nuclear installations. The same 37 attributes of a strong safety culture promoted by the IAEA have been used, in a slightly adapted form, also for the safety climate survey for CNCAN staff.**

① Strongly disagree ② Disagree ③ Neither agree, nor disagree ④ Agree ⑤ Strongly agree ⊗ Not applicable

1. In my organization, the high priority given to safety is shown in documentation, communications and decision making (A.1) ① ② ③ ④ ⑤ ⊗

.....

12. Management ensures that there are sufficient competent individuals. (B.5) ① ② ③ ④ ⑤ ⊗

Strategy and further work

Starting with July 2014, Romania has a National Strategy for Nuclear Safety and Security, which was officially approved by the Government and by the Supreme Council of National Defense. The strategy includes a policy statement with nuclear safety and security principles, including the ten fundamental safety principles outlined in the IAEA SF-1 Publication, and takes account of the relevant provisions of the IAEA GSR Part 1 Publication.

The strategy includes objectives, associated directions for action and concrete actions for promoting nuclear safety culture in all the organizations in the nuclear sector.

The progress with the implementation of this strategy with regard to nuclear safety culture so far consists of:

- new regulatory requirements on human and organizational factors and improved regulatory oversight of safety culture;
- promotion of the principles and attributes of a healthy nuclear safety culture, based on the documents issued by INPO and WANO;
- training activities for improving awareness and understanding of nuclear safety culture and of the factors of organizational culture that support or undermine safety culture;
- development of a safety culture model for the regulators' organization

Work will continue with the implementation of the new regulations and with the regulatory inspections and reviews aimed at verifying compliance, as well as with the training activities aimed at improving awareness and understanding of how the elements of organizational culture influence nuclear safety.