
Regulations in the Romanian nuclear industry

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- ❖ **CNCAN responsibilities**
- ❖ **Regulatory framework for design and construction of Nuclear Power Plants**
- ❖ **Licensing aspects of Cernavoda NPP U3&U4**
- ❖ **Regulatory Framework for Management Systems in Romania**



- ❖ **By Law CNCAN is responsible for:**
 - ❖ **Nuclear Legislation & Regulations**
 - ❖ **Nuclear Safety**
 - ❖ **Radiation Protection**
 - ❖ **Quality Assurance**
 - ❖ **Safeguards**
 - ❖ **Emergency Preparedness**
 - ❖ **Physical Protection**
 - ❖ **Nuclear and Radiological Security**
 - ❖ **Nuclear Liability**
 - ❖ **Transportation**
 - ❖ **Radioactive Waste Management**
 - ❖ **Operators Certification**
 - ❖ **International Treaties and Conventions**



- ❖ **CNCAN maintains regulatory control over:**
 - ❖ **Power reactors**
 - ❖ **Research reactors**
 - ❖ **Nuclear research and test establishments**
 - ❖ **Uranium mines and mills**
 - ❖ **Uranium refining and conversion facilities**
 - ❖ **Fuel fabrication facilities**
 - ❖ **Heavy water production facilities**
 - ❖ **Radioactive waste management facilities**
 - ❖ **Prescribed substances and items, and**
 - ❖ **Radioisotopes & ionising radiation applications**



- ❖ **CNCAN nominates the national focal points for:**
 - ❖ **Nuclear events (INES and IRS);**
 - ❖ **Safeguards reports;**
 - ❖ **Physical protection reports;**
 - ❖ **Illicit trafficking incidents with nuclear and radioactive material;**
 - ❖ **Import and export of strategic products;**
 - ❖ **Emergency notification;**
 - ❖ **Other specific activities that involve regulatory specific contacts with international organizations.**



Regulatory framework in nuclear industry



Main Laws governing the safety of nuclear installations:

- Law no. 111/1996 on the Safe Deployment, Regulation, Licensing and Control of Nuclear Activities, republished in the Official Gazette no. 552/27.06.2006
- Law no. 703/2001 on the Civil Liability for Nuclear Damage, published in Official Gazette, no. 818/19.12.2001

The complete list of laws, treaties, regulations, etc. related to the safety of nuclear installations and activities is provided on the **CNCAN web site**.



CNCAN Regulations



Regulatory framework

Licensing aspects

The current licensing practice for Cernavoda NPP is based on the provisions of the Law and of the regulations issued by CNCAN. The general requirements are specified in the Law.

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

Romanian regulations;

Limits and Conditions specified in the different licences;

IAEA Safety Standards and Guides;

WENRA Reference Levels

ICRP recommendations;

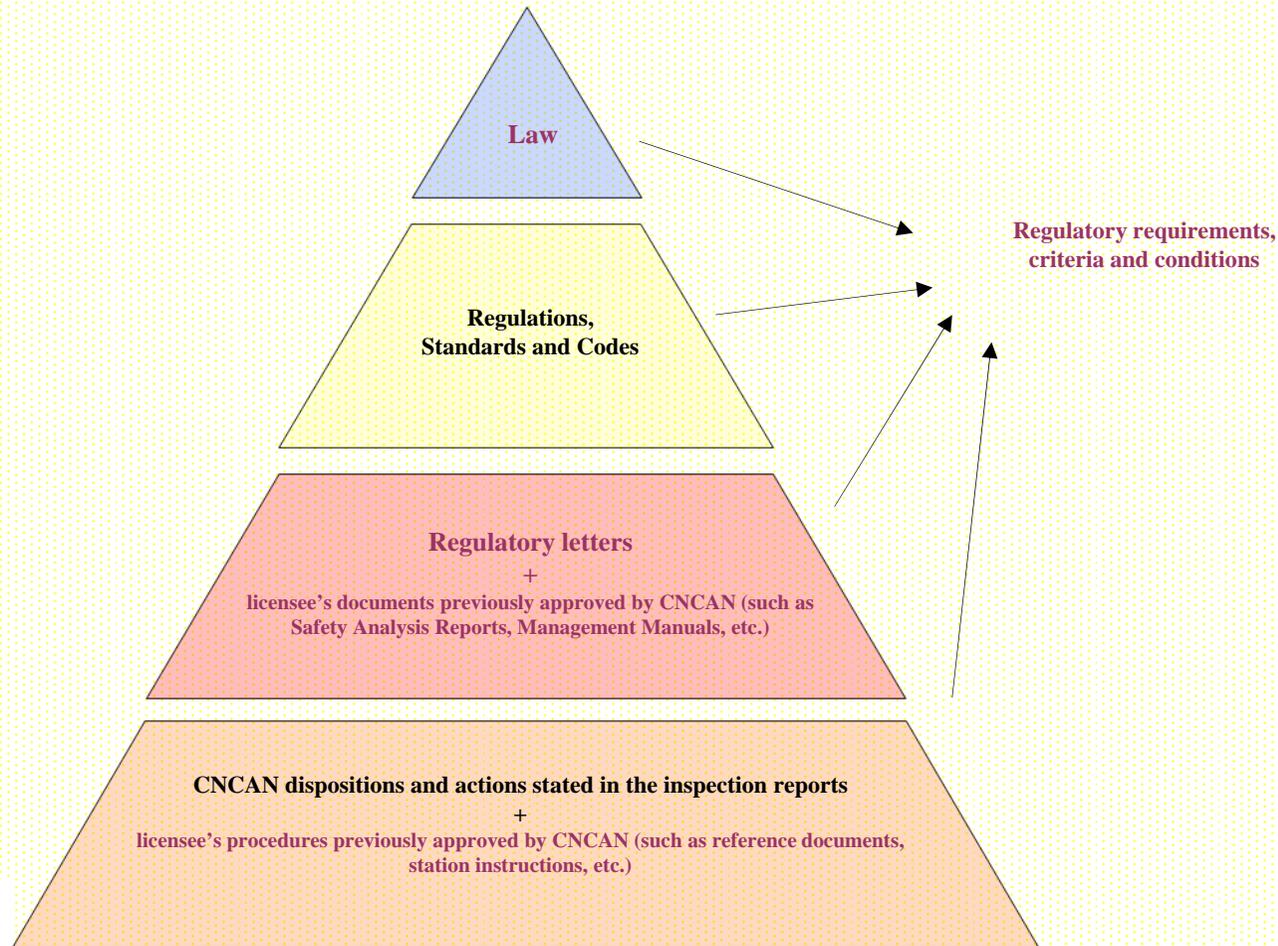
Regulatory documents developed by CNSC and US NRC;

Applicable Standards and Codes (CSA, ANSI, ASME, IEEE, etc.);

Safety related documentation produced by the licensee and approved or accepted by CNCAN (e.g. Safety Analysis Reports, Safety Design Guides, Design Manuals, reference documents, station instructions, operating manuals, technical basis documents, etc.)



Regulatory framework



Regulatory framework

Licensing aspects

The licences for nuclear installations are granted to legal persons, at their request, if they prove compliance with the provisions of the Law and specific regulations issued by CNCAN.

The licenses are applied for and issued, respectively, either simultaneously or successively, separately for each kind of activity or for each nuclear or radiological installation operating independently, in the property of the applicant.

The licensing of construction or operation phases for any nuclear or radiological facility may only take place if for the previous phases have been granted all the types of necessary licenses.



Regulatory framework

Licensing aspects

The installations or activities for which a licence has been granted are not transferable without the approval of CNCAN.

The main responsibilities of the licence holder are stated in Chapter III of the Law and are further detailed in the specific regulations issued by CNCAN and in the conditions attached to each license.

The articles 25 - 28 from the Law are particularly relevant to licence holders for activities directly related to nuclear power plants.



Regulatory framework

Licensing aspects

For a nuclear power plant, the licensing stages include:

- design;
- siting;
- construction;
- commissioning;
- trial operation;
- operation;
- repair and/or maintenance (as major refurbishment);
- modification (as major upgrades);
- preservation;
- decommissioning.

The civil construction activities of nuclear facilities shall be licensed by CNCAN in accordance with the provisions of CNCAN Order no. 407/2005.



Regulations used for site approval of the current NPP Units in Romania

- ❑ Nuclear Safety Requirements (NSR) - Nuclear Reactors and Nuclear Power Plants (1975)

based on the regulatory requirements of US NRC (10 CFR)

- ❑ Specific requirements for the quality management systems applied to the evaluation and selection of the sites for nuclear installations, NMC-03 (2003)

Main elements:

- ❑ Reactor design characteristics
- ❑ Population density and site area characteristics, including those of the exclusion area and the low population area
- ❑ Physical characteristics of the site, including seismic, meteorological, geological and hydrological data



Regulatory framework

Regulations used for licensing the design, construction and operational phases of the current NPP Units in Romania

- ❑ **General design criteria – Nuclear Safety Requirements (NSR) Regulation**

CANDU specific acceptance criteria:

- ❑ **“Requirements for the Safety Analysis of CANDU Nuclear Power Plants”, (C-6 rev.1, September 1999, issued by AECB);**
- ❑ **Requirements on Containment Systems for CANDU Nuclear Power Plants**
- ❑ **Requirements on Shutdown Systems for CANDU Nuclear Power Plants**
- ❑ **Requirements on Emergency Core Cooling Systems for CANDU Nuclear Power Plants**

endorsing the Regulatory Documents issued by Canadian Nuclear Safety Commission

- ❑ **USNRC Regulatory Guide 1.70 “Standard Format and Content of the Safety Analysis report for Nuclear Power Plants”**

complemented by

IAEA GS-G-4.1 “Format and Content of the Safety Analysis report for Nuclear Power Plants”



Development of nuclear safety regulations for new reactors

- ❖ During the period 2009 – 2010, CNCAN has reviewed and revised its nuclear safety regulation establishing general design criteria and requirements on siting for nuclear power plants.
- ❖ The revision led to the elaboration of two new regulations, “Nuclear Safety Requirements on Siting of Nuclear Power Plants” and “Nuclear Safety Requirements on Design and Construction of Nuclear Power Plants” published at the end of 2010.



Regulatory framework

The most important elements introduced by the new regulations on siting, design and construction of NPPs:

- ❖ the establishment of numerical nuclear safety targets / quantitative nuclear safety objectives;
- ❖ requirements on the consideration of severe accidents in the establishment of design bases and in the choice of site for nuclear power plants and on the analysis of severe accidents for demonstrating compliance with the quantitative nuclear safety objectives;
- ❖ formalised requirements on accident analysis, including on the way in which deterministic and probabilistic safety analyses should be used together in the design of nuclear power plants;



The most important elements introduced by the new regulations on siting, design and construction of NPPs (cont'd):

- ❖ detailed requirements on the format and contents of the safety analysis reports which need to be elaborated by the applicants for site and construction licenses;
- ❖ formulation of nuclear safety requirements for generic plant systems in a technology-neutral, function oriented manner, without prescribing technical design solutions;
- ❖ establishment of requirements on the safety classification of nuclear power plant systems, structures and components based on their safety importance, i.e. their contribution to ensuring the essential nuclear safety functions.



Cernavoda Units 3 and 4

- ❖ Pre-licensing activities for Cernavoda Units 3 and 4 are ongoing. In May 2011, CNCAN has approved the Licensing Basis Documents (LBDs) for Cernavoda NPP Units 3 and 4.
- ❖ The LBD includes all applicable regulatory documents, codes and standards, safety design requirements, the list of all the design basis events, safety analysis requirements, and the general requirements for the stages of construction, commissioning and operation. The applicable international safety standards and guides are also endorsed by means of the LBD.
- ❖ Approval of the LBD by CNCAN means that the proposed design is licensable.
- ❖ An application for a construction license for resuming construction of Cernavoda NPP Units 3 and 4 is expected in 2012.



Regulatory Framework for Management Systems in Romania



- ❖ According to the Law, a licence for the quality management system has to be obtained from CNCAN, as pre-condition for the issuance of the design/ siting/ construction / commissioning / operation / decommissioning licence.
- ❖ The licensing of the quality management systems is applied not only to the operators of nuclear installations but also to the suppliers of products and services for the nuclear installations.



Legal Basis of MS Licensing

Law No. 111/1996:

Art. 5 – (1), The Commission is empowered to issue regulations for ... quality assurance.

Art. 18. – (1), m), Licensee institutes and maintains a controlled quality management system, authorized by CNCAN.

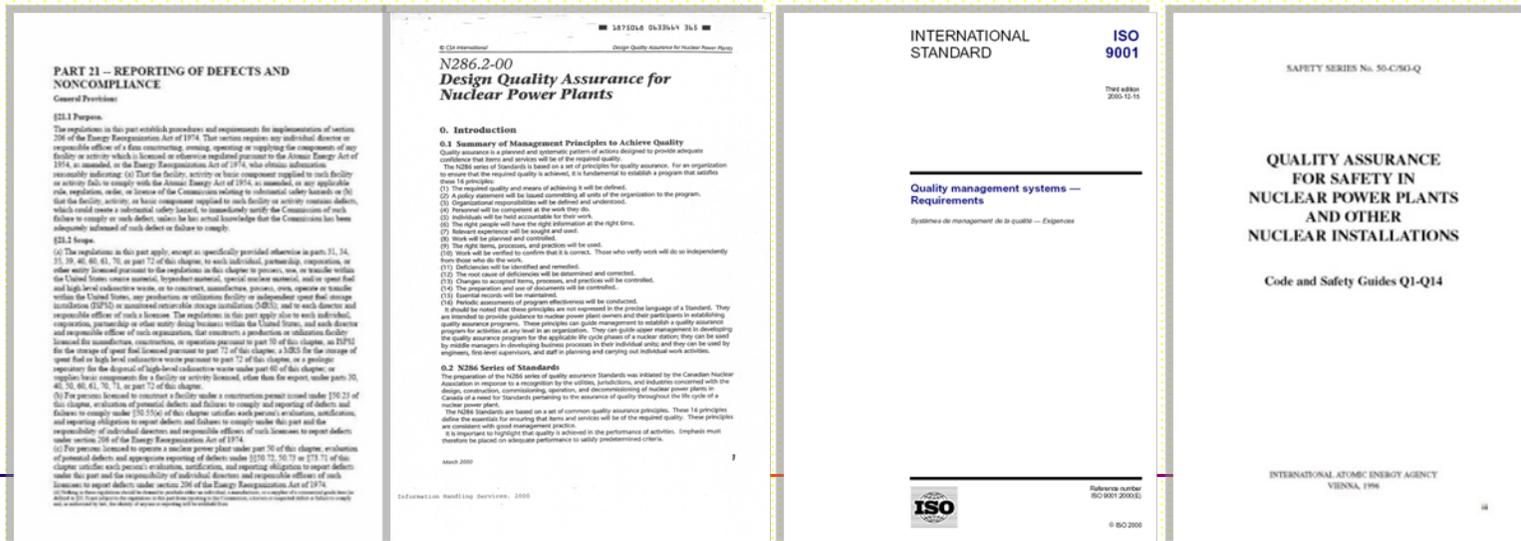
Art. 24. – (1) The quality management systems authorization in the nuclear field of the design, sitting, procurement, construction, assembly, commissioning, operation, decommissioning or conservation activities for products, services and systems classified as important for the nuclear installation safety shall be mandatory.



Quality Management System Regulations

The existing CNCAN MS Regulations are based on:

- IAEA Standard/Guide, Quality assurance for safety in nuclear power plants and other nuclear installations, code SS/50-C-SG-Q;
- ISO 9001:2000;
- CSA Canadian series standards codes N286 and Z299;
- US NRC 10 CFR Part 21 (Reporting of Defects and Noncompliance)
- Feedback from CNCAN oversight and Romanian environment.



Quality Management System Regulations

General requirements for quality management systems

The QMS of the applicant shall describe:

- ❖ Scope, objectives, means and methods to achieve the requirements;
- ❖ QA policy and commitment;
- ❖ Responsibilities;
- ❖ Training and qualification staff;
- ❖ Individual responsibilities;
- ❖ Control of interfaces;
- ❖ Use of feedback;
- ❖ Graded applicability of QA requirements



Quality Management System Regulations

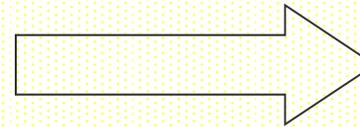
General requirements for quality management systems (cont.)

- ❖ Execution, planning and control;
- ❖ Verification;
- ❖ Control of nonconformities;
- ❖ Corrective actions;
- ❖ Document control;
- ❖ Records;
- ❖ Control of changes;
- ❖ Records;
- ❖ Self assessment;
- ❖ Audits

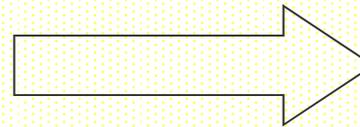


Quality Management System Regulations

Licensing of the quality management systems applied to the construction, operation and decommissioning of nuclear installations (NMC-01);

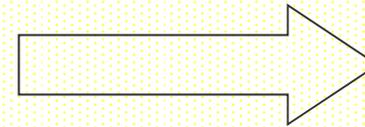


General requirements for quality management systems applied to the construction, operation and decommissioning of nuclear installations (NMC-02);

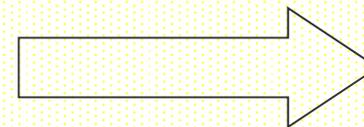


Quality Management System Regulations

Specific requirements for the quality management systems applied to the evaluation and selection of the sites for nuclear installations (NMC-03)

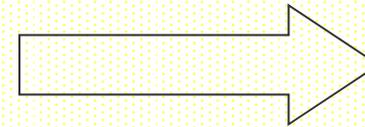


Specific requirements for the quality management systems applied to the research and development activities in nuclear field (NMC-04)

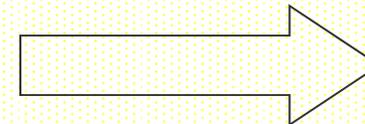


Quality Management System Regulations

Specific requirements for the quality management systems applied to the design of nuclear installations (NMC-05)

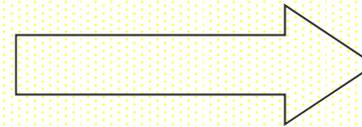


Specific requirements for the quality management systems applied to procurement activities for nuclear installations (NMC-06)

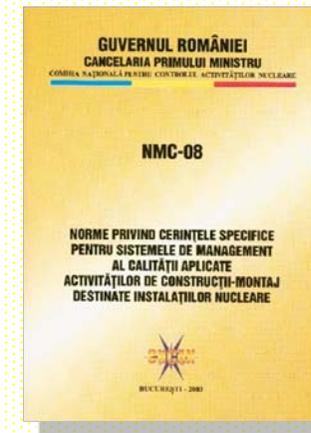
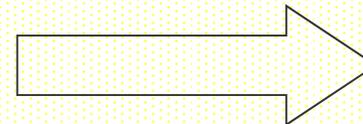


Quality Management System Regulations

Specific requirements for the quality management systems applied to the manufacturing of products and the supply of services for nuclear installations (NMC-07)

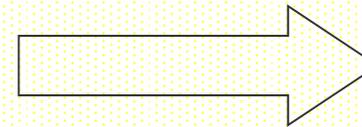


Specific requirements for the quality management systems applied to the construction and assembling activities for nuclear installations (NMC-08)

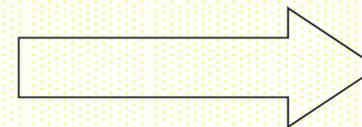


Quality Management System Regulations

Specific requirements for the quality management systems applied to commissioning activities for nuclear installations (NMC-09)

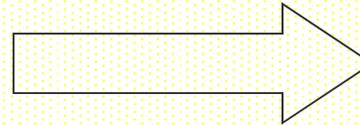


Specific requirements for the quality management systems applied to the operation of nuclear installations (NMC-10)

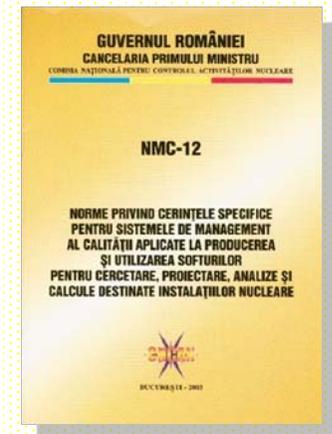
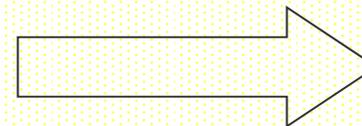


Quality Management System Regulations

Specific requirements for the quality management systems applied to decommissioning activities for nuclear installations (NMC-11)



Specific requirements for the quality management systems applied to the activities of producing and using software for research, design, analysis and calculations for nuclear objectives (NMC-12)



Revision of MS Regulations

- ❑ The revision of the set of 12 regulations on quality management systems, covering activities related to all the phases of the lifetime of nuclear installations, has started in 2007, to take account of the latest IAEA Requirements and Guides on Management Systems (GS-R-3, GS-G-3.1 and GS-G-3.5).
- ❑ Until the revision process will have been completed, the provisions of the regulations on QMS are in force and considered to be applicable also in the context of the integration of the management systems.



Future set of MS Regulations

MS Licensing Requirements (NMC 01)

General MS Requirements (NMC 02)

Specific MS Requirements on:

- Sitting (NMC 03)
- Research & Development (NMC 04)
- Design (NMC 05)
- Procurement (NMC 06)
- Manufacturing of products (NMC 07)
- Construction Installation (NMC 09)
- Commissioning (NMC 09)
- Operation (NMC 10)
- Decommissioning (NMC 11)
- Software (NMC 12)



- Norms on General MS Requirements (NMS 02)

- MS Licensing Requirements (NMC 01)
- Procurement (NMC 06)
- Manufacturing of products (NMC 07)
- Software (NMC 12)

Specific guide for application of regulation on General MS requirements
GSM-02.1

Specific guide for application of regulations on General MS requirements for NPPs, RR and Nuclear Fuel Plant GSM-02.2



Thank you!

