

# ***COMISIA NATIONALA PENTRU CONTROLUL ACTIVITATILOR NUCLEARE***

## ***NMC 09***

**Anexa la Ordinul Presedintelui CNCAN nr. 73 / 30.05.2003**

Norme privind cerintele specifice pentru sistemele de management al calitatii aplicate activitatilor de punere in functiune a instalatiilor nucleare

*Norms regarding specific requirements for the quality management systems applied to the commissioning activities of nuclear objectives*

**Appendix to CNCAN Order no. 73/30.05.2003**

**NORMS REGARDING SPECIFIC REQUIREMENTS FOR THE QUALITY  
MANAGEMENT SYSTEMS APPLIED TO THE COMMISSIONING ACTIVITIES  
OF NUCLEAR OBJECTIVES**

**CHAPTER I  
GENERAL**

**Purpose**

**Article 1.** (1) These norms are issued according to the provisions of Law 111/1996 regarding the safe development of the nuclear activities, with its subsequent modifications and completions, to establish the specific requirements for the quality management system applied to the commissioning activities of nuclear objectives.

(2) These norms are part of the norms regarding the quality management systems applied to nuclear objectives

**Scope**

**Article 2.** These norms shall be applied to the commissioning activities of:

- a) nuclear objectives;
- b) safety related structures, systems, equipment, components of nuclear objectives.

**Definitions**

**Article 3.** The definitions in Law 111/1996 regarding the safe development of nuclear activities, with its subsequent modifications and completions and of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives, shall also be applied to these norms.

## **CHAPTER II**

### **SYSTEM MANAGEMENT**

#### **Quality management system requirements**

**Article 4.** The organization responsible for commissioning activities that performs the commissioning activities shall establish, develop and maintain a quality management system that meets:

- a) the requirements of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives;
- b) specific requirements of these norms.

**Article 5.** The activities listed in article 2 can be performed by the responsible organizations only if their quality management systems are authorized by CNCAN for that activity, according to the norms regarding the authorization of the quality management systems applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

#### **Quality management systems**

**Article 6.** The organization responsible for commissioning activities shall develop and implement a quality management system to include all general methods of management, performance and assessment of the commissioning activities.

**Article 7.** The quality management system of the organization responsible for commissioning activities shall be integrated in the quality management system of the owner of the nuclear objective when the organization responsible for commissioning activities is part of its structure.

**Article 8.** The quality manual, that describes the quality management system applicable to the commissioning activities, shall be issued by the commissioning organization according to the provisions of the norms regarding the general requirements for quality management system applied to the construction,

1commissioning, operation and decommissioning of nuclear objectives, submitted to the acceptance of the owner and to the approval of CNCAN.

### **Quality policy**

**Article 9.** The management of the organization responsible for commissioning activities shall issue in written the quality policy regarding the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

### **Gradual application**

**Article 10.** The quality management system shall be applied gradually according to the importance to nuclear safety of the structures, systems, equipment and components commissioned, according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

**Article 11.** The gradual application shall be used for the following components of the quality management system:

- a) independent verification of the turnover of the construction-installation activities;
- b) the complexity of the stages and integration of tests;
- c) testing of individual components;
- d) detailing of the analysis regarding the commissioning tests;
- e) requirements regarding the records of the of the commissioning tests;
- f) reporting of the non-conformances to the designer;
- g) calibration requirements for the equipment installed;
- h) quantity and degree of details of the commissioning documents;
- i) audit and surveillance.

## **Organization and responsibilities**

**Article 12.** Organizing the commissioning activities shall be documented according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives. These documents shall describe the following:

- a) organizational structure;
- b) responsibilities of the functions involved;
- c) authority levels;
- d) internal and external interfaces.

**Article 13.** (1) The organization responsible for commissioning shall assign a person responsible for the commissioning activities.

(2) The person assigned shall have the necessary resources to meet his/her responsibility.

(3) A group shall be established with the commissioning responsibility, formed of different teams with the responsibility for performing the specific commissioning activities, with the authority to operate the structures, systems, equipment and components.

(4) For each of these activities, there shall be identified the personnel assigned with the corresponding responsibility to perform and document the activity.

**Article 14.** The organization responsible for commissioning activities shall nominate the person in the management of the organization who is responsible to establish, development and maintenance of the quality management system and to monitor the implementation status. This person shall meet all the requirements of the norms referenced in article 4, para. a).

**Article 15.** (1) The organization responsible for commissioning activities shall establish requirements for the separation between the construction, verification and audit activities.

(2) This separation shall ensure that no person can perform at the same time more than one of these activities.

**Article 16.** The organization responsible for commissioning activities shall establish the organizational entity responsible for the independent assessment of the quality management system, that shall meet the requirements of the norms referenced in article 4, para. a).

### **Personnel training and qualification**

**Article 17.** The personnel involved in the commissioning activities shall have the adequate training, qualification and competence to accomplish their assigned responsibilities and to understand the impact of their activity on nuclear safety.

**Article 18.** Personnel training program shall ensure that the performance of personnel required for performing commissioning activities are reached and maintained.

**Article 19.** The organization responsible for commissioning activities shall establish and document the qualification level for all persons involved in the execution, verification and audit activities and to ensure that the activities are performed by qualified personnel.

**Article 20.** (1) The qualification criteria for the technical personnel involved in commissioning activities shall be established according to the competence levels required for the activities to be performed.

(2) These criteria shall include the definition of the minimum training, experience, initial training and continuous training requirements.

**Article 21.** Records regarding personnel training shall be issued and maintained.

### **Individual obligations and responsibility**

**Article 22.** The management of the organization responsible for commissioning activities shall ensure that:

- a) the expected results are defined and communicated;
- b) the effective results are measured and compared to the expected ones.

**Article 23.** (1) The personnel of the organizational entity responsible for the independent assessment of the quality management system for commissioning activities shall have sufficient authority and freedom to organize to:

- a) identify the problems related to the implementation of the quality management system;
- b) initiate and recommend solutions to these problems;
- c) confirm the implementation and effectiveness of these solutions;

(2) The personnel of this organizational entity shall have access to that management level to ensure that the actions required for the implementation of the quality management system are met.

### **Control of interfaces**

**Article 24.** The management of the organization responsible for commissioning activities shall identify and control internal and external interfaces.

**Article 25.** The organization responsible for commissioning activities shall identify and control during the commissioning period the interfaces with the following organizations:

- a) interfaces with the owner of the nuclear objective, or his representative, as applicable;
- b) interfaces with the organization responsible for construction-installation activities;
- c) interfaces with the organization responsible for operation activities;
- d) assistance organization;
- e) interfaces with the suppliers;
- f) interfaces with the designer;
- g) interfaces with the organization responsible for selecting the site location;
- h) interfaces with CNCAN and other regulatory bodies.

**Article 26.** The documents describing interfaces shall be accepted by all interface participants.

## **Using feedback**

**Article 27.** Where applicable, the organization responsible for commissioning activities shall obtain the relevant information regarding quality and the previous commissioning experience from the owner of the nuclear objective and/or suppliers of equipment.

**Article 28.** (1) The organization responsible for commissioning activities shall establish measures to document the commissioning experience.

(2) The information regarding commissioning shall be maintained both during commissioning period, as well as during the whole life cycle of the nuclear objective.

**Article 29.** The measures established in article 28 shall ensure that the information in the commissioning documents or the information received from other stages of completion of the nuclear objective are analyzed and included in specific commissioning documents or the quality management system documents, as applicable.

**Article 30.** The organization responsible for commissioning activities shall establish measures to obtain the internal and external relevant information regarding the commissioning activity, as well as from other stages of the nuclear objective life cycle, in order to improve the activities of completion of future nuclear objectives.

## **Planning and control of activities**

**Article 31.** The organization responsible for commissioning activities shall plan the commissioning activities. The commissioning plans shall define the following:

- a) sequential scheduling of commissioning activities and their duration;
- b) resources allocated for each activity;
- c) verification activities;
- d) personnel responsible for the activity.

**Article 32.** The activities of commissioning, modification, replacement, preventive preservation and repair activities for structures, systems, equipment



and components during commissioning period shall be planned, approved and controlled.

**Article 33.** (1) When services from suppliers are used for the commissioning of structures, systems, equipment or components, the suppliers shall establish detailed plans of the activities to be performed and to obtain the approval of the organization responsible for commissioning.

(2) The organization ensuring the commissioning is responsible to coordinate the performance of these activities and is responsible for the quality of the activities performed by the supplier.

**Article 34.** The organization responsible for commissioning activities shall inform periodically CNCAN on the planning of commissioning activities and their implementation status.

### **Control of products, processes and procedures**

**Article 35.** The organization responsible for commissioning activities shall use only specified and accepted products, processes and procedures.

### **Verification**

**Article 36.** The organization responsible for commissioning activities shall implement verification activities to confirm that:

- a) the commissioning of the equipment has been performed according to documented procedures, with qualified and trained personnel;
- b) all operation parameters meet the specified criteria;
- c) all deficiencies have been found and solved;
- d) the analysis of the completion of commissioning stages has been performed according to the pre-established requirements.

**Article 37.** The management personnel, the personnel of the organization responsible for commissioning activities, at all levels, shall ensure and prove that the commissioning activities have been verified correspondingly.

**Article 38.** The verification activities shall be planned and sequentialized according to the commissioning activities and they prime to the production plans or schedules.

**Article 39.** The verification methods and acceptance criteria shall be described in commissioning procedures.

**Article 40.** The persons with responsibilities in the verification of commissioning activities shall:

- a) not verify the activities they performed;
- b) report to the hierarchical supervisor on all non-conformances found.

**Article 41.** (1) The planning shall be documented by commissioning procedures.

(2) The format, content and the approval method of commissioning procedures shall be described in a specific procedure issued by the organization responsible for commissioning activities, accepted by the owner and approved by CNCAN.

**Article 42.** The organization responsible for commissioning activities shall ensure the interface with the general designer / design authority to verify the results of the tests as per the design scope and meeting the design requirements.

**Article 43.** (1) The results of the commissioning tests shall be analyzed and approved by personnel qualified and authorized for the verification of the completeness of the tests performed and the confirmation that the products or activities are satisfactory.

(2) It is recommended that a representative of the design authority to participate to these analyses.

### **Non-conformances**

**Article 44.** The management of the commissioning organization shall take all the required measures to ensure that a history is kept regarding the non-conformances appeared during the commissioning period and that they have been solved before the corresponding commissioning activities are closed.

**Article 45.** (1) A nonconforming item can be used based on a conditional release.

(2) The authority of decision and the technical justification for using this product shall be documented.

**Article 46.** The identification, analysis and solving of non-conformances shall comply with the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

### **Corrective / Preventive Actions**

**Article 47.** The organization responsible for commissioning activities shall periodically analyze the information available from the non-conformance reports, nuclear safety analyses, commissioning completion assurance for the structures, systems and equipment, the internal audit reports or the audit reports of regulatory bodies, and to establish corrective actions that would lead to improving the effectiveness and performances of the commissioning activities.

**Article 48.** The organization responsible for commissioning activities shall establish and document a process to identify, monitor and control the corrective actions resulting from evaluating non-conformances, activities and processes, that would meet the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

### **Control of modifications**

**Article 49.** The permanent and temporary modifications to the accepted design, structures, systems, equipment, components, software, processes and practices shall be processed and documented by the responsible organization according to the provisions of the norms regarding specific requirements for the quality management system applied to design activities for nuclear objectives.

## **Document Control**

**Article 50.** The organization responsible for commissioning activities shall ensure the control of the following types of quality management system documents according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives:

- a) policy documents, program documents that describe the objectives and policy of the commissioning organization and the interfaces with the owner of the nuclear objective and with CNCAN. These documents shall be submitted to the approval of CNCAN.
- b) organizational documents that describe the managerial processes to meet the commissioning objectives and policy; these documents shall comply with the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.
- c) The detailed working documents that describe work activities, processes or execution sub-processes.

## **Control of records**

**Article 51.** The organization responsible for commissioning activities shall establish a documented system to identify, control and keep the records according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

**Article 52.** The organization responsible for commissioning activities shall establish, with CNCAN approval, and the owner of the nuclear objective or his representative shall accept the list of records to be issued during commissioning and their classification as permanent or non-permanent.

## **Quality management system assessment**

**Article 53.** The organization responsible for commissioning activities shall meet the requirements regarding self-assessment of the management according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

**Article 54.** (1) The responsible organization shall comply with the requirements regarding independent assessments according to the provisions of the norms regarding the general requirements for quality management system applied to the construction, commissioning, operation and decommissioning of nuclear objectives.

(2) The independent assessment shall include the following domains:

- a) interfaces;
- b) nuclear safety management;
- c) temporary modifications;
- d) implementation of identification methods;
- e) maintenance and cleanliness;
- f) identification of status of work;
- g) surveillance shifts system.

### **CHAPTER III**

#### **SPECIFIC COMMISSIONING REQUIREMENTS**

##### **Commissioning documentation**

**Article 55.** The organization responsible for commissioning activities shall ensure the commissioning documentation that identifies clearly the requirements, the objectives of the tests, the performance indicators, testing conditions and procedures, special equipment, personnel requirements, material resources, acceptance criteria and records to be issued.

**Article 56.** The commissioning documentation shall contain the following:

- a) commissioning procedures;
- b) commissioning completion schedules.

**Article 57.** (1) The commissioning documentation shall be revised to ensure the compliance with the design objective.

(2) On a case-by-case basis, a representative of the design authority and/or construction/installation organization can be included in the team to analyze the commissioning procedures.

(3) The analysis of the commissioning documentation shall be performed by competent persons, with access to information and capability of understanding the operation of the systems to be commissioned.

**Article 58.** The commissioning procedures shall contain:

- a) main objectives of the tests proposed;
- b) detailed instructions for the team performing the tests;
- c) specific nuclear safety requirements;
- d) information regarding emergency procedures, where applicable;
- e) tests limits and conditions;
- f) acceptance criteria;
- g) data collection methods.

### **Transfer of responsibilities**

**Article 59.** The organization responsible for turnover activities shall establish and document by interface procedures the transfer of responsibilities between:

- a) the construction-installation organization and the commissioning organization;
- b) the commissioning organization and the operation organization.

### **Activity in shifts**

**Article 60.** (1) The organization responsible for commissioning activities shall establish an official process of turn-over between shifts when the commissioning activities are executed in several shifts.

(2) The turn-over/receiving process shall include the issue of reports or registers to identify the status of the main systems being commissioned as well as the status of commissioning activities being executed.

(3) The shift turn-over process shall identify the persons involved, their responsibilities, the method of reporting the nuclear objective commissioning status, including the measures taken in case of abnormal circumstances or unavailability of personnel.

(4) Once with the nuclear fuel loading, the organization responsible for commissioning activities shall meet the provisions regarding specific requirements for quality management system applied to the operation of nuclear objectives.

## **CHAPTER IV REQUIREMENTS FOR ORGANIZATIONS PROVIDING TECHNICAL ASSISTANCE**

### **Control of design**

**Article 61.** The organization responsible for commissioning activities shall analyze, approve and validate the modifications appeared as a result of the commissioning activities before their implementation.

**Article 62.** According to the importance to the nuclear safety of the nuclear objective, the modifications in article 61 shall be submitted to the approval of the general designer / design authority and CNCAN.

### **Temporary modifications to structures, systems, equipment and components**

**Article 63.** The organization responsible for commissioning activities shall document and control the temporary modifications required for the tests on structures, systems, equipment and components.

**Article 64.** The temporary modifications shall be implemented based on an approved procedure that establishes the official method for registering and approval of the temporary modification, as well as the method to solve any problem that might appear in the process of implementation and return to the initial configuration.

**Article 65.** The temporary modifications that shall be transformed into permanent modifications shall be processed according to the design modifications control process in articles 61 and 62.

### **Identification of structures, systems, equipment and components**

**Article 66.** (1) The organization responsible for commissioning activities to ensure the unique identification of the structures, systems, equipment and components being commissioned.

(2) This identification shall be found in the commissioning documentation related to structures, systems, equipment and components and ensure that the commissioning records are retrievable as related to the equipment and components they refer to.

**Article 67.** (1) The identification of structures, systems, equipment and components in the commissioning period shall be kept during operation with no major modifications.

(2) For the components and systems installed temporarily during commissioning, the identification shall be different from that of the permanent components and systems.

### **Control of structures, systems, equipment and components**

**Article 68.** The organization responsible for commissioning activities shall ensure the control and to maintain a system of identification of the status of the systems, equipment and components during the commissioning period.

**Article 69.** The structures, systems, equipment and components shall be inspected in the moment of the transfer from the commissioning organization to ensure that the limits and deficiencies known are clearly identified in the transfer documents.

**Article 70.** The terminal points and the operation procedures for the equipment representing terminal points shall be identified.

**Article 71.** The structures, systems, equipment and components taken out of service shall be verified to ensure the correctness of their decommissioning.



**Article 72.** The commissioning personnel shall ensure that the structures, systems, equipment and components have been brought to the status requested by the design documentation, after the completion of the testing, maintenance or modification activities.

## **CHAPTER V HEALTH AND INDUSTRIAL SAFETY REQUIREMENTS**

### **Industrial safety**

**Article 73.** The organization responsible for commissioning activities shall establish industrial safety measures according to the industrial safety rules applicable at the national level.

### **Radiation protection**

**Article 74.** (1) The organization responsible for commissioning activities shall establish a system to monitor and control the radiation fields before the arrival of the nuclear fuel or other radiation sources in the nuclear objective, according to the specific regulations.

(2) In this purpose, all specific monitoring and control devices shall be available, and the personnel that would have access to the monitored areas shall be trained, qualified and authorized accordingly.

### **Emergency plans**

**Article 75.** The organization responsible for commissioning activities shall identify the emergency conditions that might appear during commissioning, as well as the organizational structure necessary to answer to diminish the effects.

**Article 76.** The resources and facilities necessary for emergency cases shall be made available before the associated installations or equipment with such emergencies are commissioned.

**Article 77.** The organization responsible for commissioning activities shall develop plans, scenarios and procedures to describe the emergency scenarios.

**Article 78.** (1) The personnel in the emergency teams shall be continuously trained regarding the requirements of the emergency plans and procedures by testing these plans and procedures, by periodical exercises and informing the population.

(2) The experience gained from the periodical drills shall be used to continuously improve the emergency plans and procedures.

## **CHAPTER VI PHYSICAL PROTECTION REQUIREMENTS**

**Article 79.** The organization responsible for commissioning activities shall establish a system to control the access as soon as the systems or equipment are commissioned to prevent them from being destroyed.

**Article 80.** Special access control measures shall be established according to the specific physical protection requirements before the delivery of the nuclear fuel to site, and after the delivery of the nuclear fuel, these shall be applied to all personnel, including visitors.

## **CHAPTER VII MAINTENANCE REQUIREMENTS**

### **Maintenance of components and systems**

**Article 81.** (1) The organization responsible for commissioning activities shall establish a maintenance and repairs program for the structures, systems, equipment and components that have been turned over for commissioning.

(2) This program shall include the following:

- a) type of maintenance activity;
- b) frequency of the activity;
- c) quality records for maintenance history.

## **Calibration of measurement and test devices**

**Article 82.** (1) The organization responsible for commissioning activities shall implement procedures to ensure that the measurement and test devices used for performing tests or collect data, are of the corresponding class, type and precision to prove the compliance with the requirements established by the execution documentation.

(2) The evidence of the measurement and test devices, as well as adequate records shall be kept to prove their metrological verification status.

**Article 83.** (1) The measurement and test devices shall be calibrated or verified as compared to measurement devices certified by recognized applicable national standards.

(2) Where no national standards exist, the basis used for calibration or verification shall be documented.

**Article 84.** (1) The organization responsible for commissioning activities shall maintain records of calibrations and verifications and shall ensure the traceability between the records regarding measurement and tests and the measurement devices.

(2) Where possible, marking or labels shall be applied on the measurement devices so that the verification / calibration status is known at any moment.

(3) If there is found an uncertain precision of a measurement device, or if that device is decalibrated, the responsible organization shall analyze whether the measurements and tests performed using that device are acceptable.

## **Housekeeping activities**

**Article 85.** The organization responsible for commissioning activities shall ensure the performance of the commissioning activities in controlled and documented conditions, so that adequate housekeeping of structures, systems, equipment and components is ensured.

**Article 86.** The organization responsible for commissioning activities shall take measures for the controlled storing of combustible waste resulting from the activities of cleaning systems and equipment.

## **Procurement of products and services**

**Article 87.** The supply of products and services shall be done according to the provisions of the norms regarding the specific requirements for quality management systems applied to procurement activities for nuclear objectives integrated in the quality management system for commissioning activities.

## **CHAPTER VIII MATERIAL CONTROL**

### **Receiving of equipment, components, materials and testing devices**

**Article 88.** (1) The organization responsible for commissioning activities shall take the required measures for the receiving inspection of products to determine the following:

- a) the products received do not present any damages;
- b) the packing and transport requirements have been met;
- c) identification and marking are complying with the requirements in the procurement documentation.

(2) The organization responsible for commissioning activities shall analyze the documentation received with the products to verify if:

- a) the products received have been fabricated, tested and inspected before delivery according to the procurement documentation;
- b) the requirements in the procurement documentation have been met;
- c) the fabrication history docket for the products with special quality requirements has been analyzed by the representative of the owner to ensure that the requirements of the commissioning activities procedures have been met.

**Article 89.** The products that have not been inspected by the manufacturer shall be inspected when received to verify the compliance with the procurement documentation requirements.

**Article 90.** The products found as not complying at the receiving inspection shall be identified and stored separately.

### **Handling and storage**

**Article 91.** The organization responsible for commissioning activities shall take all the measures for the control of handling and storage of products starting with their receiving, in order to prevent any loss or damage.

**Article 92.** (1) The organization responsible for commissioning activities shall issue handling procedures and instructions for each type of material, equipment or measurement device that might be damaged if handled incorrectly.

(2) Other products, that no specific handling procedures are requested, can be handled according to usual handling practices.

**Article 93.** The tools and devices necessary for the handling of products shall be inspected at pre-established intervals of time to determine their status.

**Article 94.** The products shall be stored according to the requirements for specific space and environment conditions.

**Article 95.** The storage areas shall be inspected periodically to verify the storage conditions and the integrity of the products stored.

**Article 96.** The organization responsible for commissioning activities shall ensure the transfer of structures, systems, equipment and components commissioned to the operation organization according to the provisions of the norms regarding specific requirements for quality management system applied to the operation of nuclear objectives.

**Article 97.** The organization responsible for commissioning activities shall issue specific procedures for the maintenance and control and preservation conditions for the structures, systems, equipment and components installed and taken over from the construction-installation activities and which are not yet commissioned.

## **CHAPTER IX**

### **TRANSITORY AND FINAL DISPOSITIONS**

**Article 98.** These norms are applicable within 60 days from the date of being published in Monitorul Oficial.

**Article 99.** (1) Until the term stated in article 98, the organizations responsible for commissioning activities in the nuclear field shall take all the necessary measures to implement the requirements of these norms into the activities performed.

(2) If the implementation of these requirements requires a revision of the quality management system documents, the revised documents shall be submitted to CNCAN for approval.