COMISIA NATIONALA PENTRU CONTROLUL ACTIVITATILOR NUCLEARE

NMC 02

Anexa la Ordinul Presedintelui CNCAN nr. 66 / 30.05.2003

Norme privind cerintele generale pentru sistemele de management al calitatii aplicate la realizarea, functionarea si dezafectarea instalatiilor nucleare

Norms regarding general requirements for quality management systems applied to the construction, operation and decommissioning of nuclear objectives

Attachment to CNCAN Order no. 66/30.05.2003

NORMS REGARDING GENERAL REQUIREMENTS FOR QUALITY MANAGEMENT SYSTEMS APPLIED TO THE CONSTRUCTION, OPERATION AND DECOMMISSIONING OF NUCLEAR OBJECTIVES

CHAPTER I
PURPOSE

Article 1. (1) These norms are issued in compliance with the provisions of Law no. 111/1996 regarding the safe development of nuclear activities, with its subsequent modifications and completions, to establish the general requirements for quality management systems applied to the construction, operation and decommissioning of nuclear objectives.
(2) These norms are part of the norms regarding quality management systems applied to nuclear objectives.

CHAPTER II
SCOPE

Article 2. These norms shall be applied by the responsible organizations to establish and develop quality management systems for any of the following activities:

a) design, site location, construction and installation, commissioning, operation and decommissioning as part of the construction, operation and decommissioning stages of nuclear objectives; activities of operational tests, preservation, maintenance, repairs and modifications of installations are considered stages of operation.
b) supply, research and development and fabrication of safety related structures, systems, equipment, components of nuclear objectives in art. 2 para. a) and the performance of their related services; the services include also the handling, transport, storing, cleaning, preservation, maintenance, repair, testing, inspection activities, as well as the activities of producing and using software.

CHAPTER III
DEFINITIONS

Article 3. (1) The following definitions shall apply to these norms:

a) definitions in Law 111/1996 regarding the safe development of nuclear activities, with its following modifications and completions;

b) definitions in Appendix 1;

c) definitions in EN ISO 9001 standard, 2000 edition, “Quality Management System. Requirements.”

(2) In case that the norms regarding quality management systems applicable for nuclear objectives call for different definitions applied to the same terms, the priority in using the definitions in para. (1) of this article is the following: a), b), c).

(3) The owner of the nuclear objective is hereinafter named owner.

CHAPTER IV
RESPONSIBLE ORGANIZATIONS

Article 4. (1) The owner shall establish, develop and maintain a quality management system during all life cycle stages of a nuclear objective, in compliance with the provisions in art. 10.

(2) The owner can delegate the responsibility of performing the specific activities of any stage of the life cycle of a nuclear objective to a participant to be nominated by the owner, without diminishing the responsibility of the owner in implementing the general quality management system.

(3) The owner shall ensure that the participants’ quality management systems meet the general requirements described in Article 11 and, according to the activity performed, the specific requirements described in Article 98.

(4) The participants’ quality management systems shall be reviewed and accepted by the owner.

Article 5. (1) The participants shall establish, develop and maintain their own quality management systems by complying with the general requirements described in article 11 and the specific requirements detailed in

the specific norms, presented in article 98, regarding the quality management systems for nuclear objectives, for the activities they are involved in and by also implementing requirements specific to other stages or activities they develop by association.

(2) The owner or the participants, as applicable, can sub-contract the performance of the activities in art. 2 para. b) to contractors.

(3) The owner or the participants, as applicable, shall ensure that the quality management systems of the contractors meet the general requirements described in these norms as well as the specific requirements described in the norms related to the quality management systems for the nuclear objectives, applicable to the contractor's domain of activity.

(4) The contractors' quality management systems shall be reviewed and accepted by the owner or participants, as applicable.

Article 6. The contractors shall establish, develop and maintain their own quality management systems by complying with the general requirements described in art. 11, as well as the specific requirements described in the norms presented in art. 98 regarding the quality management systems for nuclear objectives, applicable to the contractor's domain of activity.

Article 7. The activities listed in art. 2 can be performed by the responsible organizations only if their quality management systems for the respective activities are approved by CNCAN, according to the norms related the authorization of the quality management systems applied to the construction, operation and decommissioning of nuclear objectives.

Article 8. (1) The responsible organization shall nominate the person in the management of the organization responsible to establish, develop and maintain the quality management system and to monitor its implementation status. In the organizations that have quality management departments, the managers of these departments shall be the representatives of the management.

(2) The person responsible to establish, develop and maintain the quality management system and to monitor its implementation status shall have enough resources inside the organization to delegate the authority of performing the specific activities that derive from the applicable norms related to the quality management systems for nuclear objectives.

(3) The person responsible to establish, develop and maintain the quality management system and to monitor its implementation status shall have sufficient knowledge in the domain to be a graduate of a speciality course agreed by CNCAN.

Article 9. (1) The management of the responsible organization shall assign an organizational entity with the responsibility of evaluating independently the quality management system. The organizational entity responsible for the independent assessment of system efficiency shall:

a) have enough authority and organizational independence to fulfil its responsibilities;
b) analyze the efficiency of the management process and the adequate performance of the activities;
c) supervise the achievement of the goods and services quality;
d) promote the measures to improve the quality management system.

(2) The authority and independence of the organizational entities from para. (1) and of its personnel shall be clearly defined in writing. For this purpose, the organizational entity shall:

a) have access to the nuclear objective, to personnel, to the execution activities, to the documents and records necessary to assess the system;
b) be independent from the cost and schedule issues;
c) not to be involved in execution activities or in the verification of the assessed activities;
d) report to the appropriate level of management.

(3) The independent assessment shall be performed in a planned manner, through audits, review of documents, controls, inspections, tests, surveillance and other similar methods.

(4) The results of the independent assessments shall be taken into consideration by the management of the organization and, where necessary, measures shall be taken to improve the quality management system. The results of the implementation of such measures shall also be submitted to the independent assessment.

(5) The personnel performing the independent assessment shall have the technical capability and qualification necessary to analyze and review the

process to be assessed and shall not participate directly in the activities to be assessed.

(6) The personnel of the organizational entity with the responsibility to independently assess the quality management system shall be a graduate of a speciality course agreed by CNCAN.

CHAPTER V
GENERAL REQUIREMENTS FOR THE QUALITY MANAGEMENT SYSTEM

Article 10. The quality management system of the owner shall comply with the general requirements described in Chapters VI, VII, VIII, IX, X, XI, XV, XIX, XX, XXI and XXII.

Article 11. The quality management systems of the participants and contractors shall meet the general requirements described in Chapters VI, VII, …, XXI and XXII.

CHAPTER VI
QUALITY MANAGEMENT SYSTEM DEFINITION

Article 12. The quality management system shall define the objectives, means and methods to attain quality.

Article 13. The quality management system shall be described in a quality manual which shall be sufficiently detailed to prove that the requirements of these norms are complied with.

Article 14. The quality manual shall contain as a minimum the following:

a) the statement related to the owner’s quality policy;
b) scope of work;
c) description of the organization adopted to meet the quality management system objectives;
d) description of the main system functions according to the provisions of these norms.

Article 15. The quality management system shall be approved and assumed at the highest management level.

CHAPTER VII
QUALITY POLICY

Article 16. The owner shall issue a policy statement to express the commitment that the implementation and maintenance of the quality management system requirements represents an obligation for all its organizational entities during the whole life cycle of the nuclear objective.

Article 17. The participants shall issue a policy statement to express the commitment that the implementation and maintenance of the quality management system requirements represents an obligation for all their organizational entities in the development of the activities in their responsibility.

Article 18. The contractors shall issue a policy statement to express the commitment that the implementation and maintenance of the quality management system requirements represents an obligation for the period of performing the assigned activities.

CHAPTER VIII
ORGANIZATION AND RESPONSIBILITIES

Article 19. The responsible organizations shall establish measures to:

a) define and document the organizational structure, the functional responsibilities, the levels of authority inside the organizational entities;
b) ensure that the responsibilities of the organizational structures and of the individuals are effectively communicated and acknowledged;
c) identify external organizations that are potential suppliers of goods and services and that have to comply with the requirements in the applicable norms regarding the quality management systems for nuclear objectives;
d) identify the persons responsible to establish and implement the quality management system requirements;
e) ensure that the persons responsible to follow up and assess the effectiveness of the quality management systems report to the appropriate level of management with no financial or planning constraints;

f) ensure that the organizational structure responsible for the independent assessment of the quality management system has the necessary conditions to accomplish the assigned responsibility;
g) ensure the independence between the persons involved in the performance, verification or audit activities.

CHAPTER IX
PERSONNEL TRAINING AND QUALIFICATION

Article 20. (1) The personnel of the responsible organizations shall be selected based on competence criteria, defined according to their position, and the required level of competence shall be maintained in time.
(2) In order to meet the requirement in para. (1), the responsible organizations shall ensure that:
a) the qualification and training requirements are identified;
b) the personnel is periodically trained so that they have the competence to perform the assigned activities and to understand the impact of their activities on nuclear safety;
c) the training programs are permanently monitored and assessed;
d) the competence of the personnel is effectively verified and maintained;
e) records are kept related to the qualification, training and experience of personnel.

CHAPTER X
INDIVIDUAL OBLIGATIONS AND RESPONSIBILITY

Article 21. The responsible organizations shall take the necessary measures inside the quality management system to aware the personnel to assume the responsibility regarding the quality of the work performed.
In this scope, it is necessary that:
a) the expected results to be defined and communicated;
b) the effective results to be measured and compared with the expected ones.

CHAPTER XI
CONTROL OF INTERFACES

Article 22. The responsible organizations shall establish measures to ensure the effective communication and appropriate information regarding the activities developed by participants and contractors, so that the persons assigned to perform the activities have the correct information available at the right time.

Article 23. The responsible organizations shall ensure:

a) the identification and coordination of the information necessary to develop the activities;
b) the users' needs for information is defined;
c) the information is correct;
d) the users have complete information in due time.

Article 24. (1) The responsible organizations shall establish interfaces with the organizations involved in other stages or activities for the nuclear objectives, including the mechanism of communication and of using the previous experience.

(2) The responsible organizations shall establish interfaces with CNCAN. The procedures establishing these interfaces shall be approved by CNCAN.

Article 25. The responsible organizations shall administer the essential information to ensure that these are correct, actual, available in due time, understood and that they satisfy the requirements of the users.

Article 26. The responsible organizations shall ensure the control of interfaces, that shall include:

a) the circulation of information at the organizational interface boundaries;
b) establishing the procedures for the identification, review, approval, issue, distribution and revision of documents that are over the organizational boundaries.

CHAPTER XII
USING THE FEEDBACK

Article 27. The participants shall ensure a system to collect the information gained during the stages of the nuclear objective life cycle, so that the information is:

a) identified, obtained and delivered to the users;

b) assessed to be used to improve the performance of structures, installations, equipment and components, or of the requirements and practices used for design, procurement, construction-installation, operation, commissioning and decommissioning.

Article 28. The participants shall establish arrangements to ensure the change of experience with other organizations in the worldwide nuclear field.

CHAPTER XIII
EXECUTION PLANNING AND CONTROL

Article 29. The responsible organizations shall identify and plan the sequences, ensure the resources, assign responsibilities, define, control and verify the execution and verification activities.

Article 30. The activities shall be defined, planned, scheduled, assigned, controlled, verified and documented.

CHAPTER XIV
CONTROL OF PRODUCTS, PROCESSES AND PRACTICES

Article 31. The responsible organizations shall ensure that all requirements specified for the products, processes and practices used are met and, as often as necessary, to ensure their identification and traceability during execution.

Article 32. The participants and the contractors shall ensure the periodical metrological verification for the measurement and testing devices according to the laws in force. The requirements, methods, and the period of verification of the measurement and testing devices shall be defined in written procedures, and the results shall be recorded, indicating the verification status.

Article 33. The participants and the contractors shall ensure the appropriate conditions to maintain the products quality during their handling, storage and transport. These operations shall be performed according to written procedures that comply with the requirements stated by the manufacturer.

Article 34. The participants and contractors shall ensure that the performance of special processes, of verification and tests is performed by qualified personnel, by applying the qualified procedures. These procedures shall contain the required conditions, characteristics, equipment used, acceptance criteria, personnel qualification requirements, reports and records.

Article 35. (1) The goods, processes and services status shall be reported and submitted for approval to the owner.

(2) The owner shall periodically report to CNCAN the status of the construction, operation or decommissioning of the nuclear objective, according to CNCAN requirements.

CHAPTER XV
VERIFICATION

Article 36. The owner shall verify and confirm the activities performed by participants or contractors.

Article 37. The responsible organizations shall ensure that:

a) the verification activities are identified, planned and performed according to the specified requirements;
b) the methods of verification, extent, completion status, identification of verifiers and records of results are documented;
c) verification is made by other personnel that the one who performed the verified activity, and independent from this one.

Article 38. The production activities or the execution schedules shall not prime over the panned verification activities.

Article 39. Deviations from the planned verification activities shall be approved.

Article 40. Verification methods and acceptance criteria shall be described in procedures.

Article 41. The activities that require specific independent verification shall be identified to ensure that the results meet the specified requirements. Extending the verification can vary depending on the complexity of the activity and of the potential impact on nuclear safety.

Article 42. The verification activities shall be planned before starting the activity. As part of the planning of verifications, the following shall be identified:

a) what shall be inspected;
b) when the verification is to be done;
c) who will perform the verification;
d) verification methods and acceptance criteria.

Article 43. The activities management personnel shall ensure that the verification activities are performed and that any resulting non-conformance is solved.

Article 44. The personnel assigned for verifications shall meet the following requirements:

a) to be objective;
b) not to verify his own activity;
c) to report all non-conformances.

Article 45. The identity of the verifiers shall be found in the quality records.

CHAPTER XVI
CONTROL OF NON-CONFORMANCES

Article 46. The responsible organizations shall ensure that the structures, systems, equipment, components, documents, services or activities that are not meeting the requirements, named in this chapter nonconforming items, are treated as follows:

a) they are identified, documented and reported;
b) they are analyzed, the correction method is established, the corrective actions are implemented and verified, and the results are documented and recorded;
c) they are controlled to avoid their unauthorized using or implementation;

d) they are reported to CNCAN by the responsible organization, where required.

Article 47. The responsible organizations shall ensure that the responsibilities related to the verification and corrective processes are defined.

Article 48. The responsibilities for the disposition of the non-conformances shall be identified.

Article 49. When they exist, the non-conformances shall be identified during the following activities:

a) performing the works;
b) incoming inspections and tests;
c) surveillance, including monitoring;
d) procurement;
e) verifications and assessments;
f) CNCAN inspections.

Article 50. The nonconforming items shall be identified accordingly by marking, labelling or other methods and physically separated when possible. If physical separation can not be done, other measures shall be taken to prevent their use or installation. These requirements shall be detailed in the approved procedures.

Article 51. The non-conformance reports issued shall be sufficiently detailed to allow the review, assessment and appropriate disposition of the nonconforming items in the following categories: scrap, repair, rework, conditional acceptance, use as is.

Article 52. (1) In order to use a nonconforming item, the non-conformance shall be corrected or to prove that the non-conformance has become acceptable.

(2) The disposition in para. (1) shall be analyzed and approved in the same way as the initial specification.

Article 53. The further machining, installation or use of a nonconforming item shall be controlled based on a conditional release. The technical authority and justification for using the item shall be documented.

Article 54. The items repaired or reworked shall be re-inspected according to the applicable procedures.

Article 55. The review and assessment process shall ensure that corrective actions have been initiated according to requirements.

Article 56. (1) The participants and the contractors shall report to the owner and to CNCAN information regarding any deficiencies or non-conformances of structures, systems, equipment, components, documents, services and activities supplied that might affect the nuclear safety of the nuclear objective.

(2) In case that a deficiency or non-conformance is found later by the manufacturer through specific investigation methods or to other structures, systems, equipment, components, documents, services and activities developed in identical conditions, the reporting requirement in para. (1) remains valid even after the termination of the contract for the activities stated in article 2, during the whole life cycle of the respective structures, systems, equipment, components.

CHAPTER XVII
CORRECTIVE AND PREVENTIVE ACTIONS

Article 57. The participants and contractors shall establish measures to ensure that:

a) the significant non-conformances are analysed, their causes determined;

b) all causes are removed to prevent their recurrence.

Article 58. Corrective actions shall be documented and reported to the management levels and followed up to establish their effectiveness.

Article 59. The conditions that led to major or repeated non-conformances shall be:

a) analyzed to determine their causes;

b) corrected to prevent recurrence;

c) corrected within the specified timeframe limits;

Article 60. The responsibilities related to establishing and implementing appropriate corrective actions shall be identified.

Article 61. The persons responsible to analyze non-conformances shall have access to all relevant information. There shall be taken into consideration both the identified non-conformances, as well as the potential

ones, the root causes shall be analyzed and actions taken to prevent their recurrence.

Article 62. Corrective actions may result from the following activities, but not limited to these:

a) non-conformances;
b) internal audits;
c) external audits;
d) inspections and tests;
e) CNCAN audits and inspections.

Article 63. Preventive actions may include the following, but not limited to these:

a) changes of design, specifications, etc.
b) implementation of the requirements of procedures and working instructions;
c) modification of existing procedures or issue of new procedures;
d) withdrawal of damaged equipment for maintenance, calibration and metrological verification;
e) re-training and re-qualification of the personnel involved;
f) improvement of the quality management system.

Article 64. (1) The trends in the implementation of corrective actions shall be periodically assessed and reported to the management.

(2) The status of corrective actions that might affect the nuclear safety of the nuclear objective shall be periodically reported to the management of the organization in order to be disposed when these trends are negative.

CHAPTER XVIII
CONTROL OF CHANGES

Article 65. The responsible organizations shall ensure the control of changes to accepted items, processes and practices, so that:

a) permanent and temporary changes are verified and approved before their implementation;

b) verification and approval of changes is done by persons who have access to all initial information and requirements, who will assess the impact of the changes on the initial intents and requirements;
c) changes are documented;
d) all CNCAN approvals are obtained, where required.

CHAPTER XIX
DOCUMENT CONTROL

Article 66. (1) The responsible organizations shall ensure the control of the issue and use of documents to ensure that:
a) the documents and their use method are identified;
b) the documents preparation, review, approval, distribution and updating requirements are documented in a procedure;
c) the updated documents are available for users;
d) obsolete documents are withdrawn from use;
e) the modifications and updates of documents are identified in distribution lists and corresponding records;
f) CNCAN approvals are obtained, where required.

(2) The documents, including their modifications and revisions, shall be reviewed and approved by specially assigned personnel before their use.

(3) The modified documents shall be submitted to a process of review and approval as the initial documents. The personnel who ensure these reviews and approvals shall have relevant information in the domain and be aware of the requirements and purpose of the initial document.

CHAPTER XX
CONTROL OF RECORDS

Article 67. (1) The responsible organization shall identify, control and keep the records that:
a) are essential to prove that the products and services meet the specified requirements;

b) prove that the requirements of the quality management system are implemented correspondingly.

(2) The responsible organization shall identify and apply a record control system according to procedures, instructions, and other written documents.

(3) Individual responsibilities regarding records shall be established.

Article 68. The responsible organizations shall ensure that the records that prove the quality and the compliance to the specified requirements are maintained. In this purpose:

a) the records shall be identified;

b) the requirements regarding the keeping of records shall be identified;

c) the safe keeping of records for the period established shall be ensured;

d) the records shall be validated, legible, retrievable according to the product or activity they refer to;

e) to meet other regulatory requirements imposed by CNCAN.

Article 69. The owner shall ensure through periodical inspections that records are archived and stored so as to be protected against loss, damage or destroy.

Article 70. The records are classified into two categories: permanent and non-permanent.

Article 71. (1) The records that meet one or more of the following criteria are considered permanent records:

a) they have a proving value in demonstrating the safe operation capability;

b) they are necessary for the maintenance, rework, repair, replacement or modification of a product;

c) they can be used to establish the causes of an event, a malfunctioning or an unexpected operation;

d) they are required to ensure the basic information for periodical inspections;

e) they shall be used for the decommissioning of a product.

(2) Permanent records shall be kept during the whole life cycle of the nuclear objective or at least during the life cycle of the structure, system, equipment or component they refer to.

Article 72. (1) Non-permanent records are those records that do not meet any of the requirements in article 71, para. (1), but they are necessary as an evidence of performing the activities according to the specified requirements.

(2) Non-permanent records shall be kept for a minimum established period that would satisfy the requirements in the applicable codes, standards or regulations.

Article 73. (1) Measures related to the storing of records shall be established and documented in procedures. The procedures shall include at least the following requirements:

a) description of the storing area;
b) system used for receiving records;
c) rules regarding the access to the files of records and their control;
d) method of keeping, control and evidence of records that are released from the archive;
e) method of archiving corrected or supplementary records and of withdrawal of obsolete records;
f) measures related to the maintenance and periodic inspection of records so that their preservation and protection is ensured against loss, damage or destroy.

(2) There shall be ensured appropriate conditions to store the records to prevent their loss, damage or destroy.

(3) A security system shall be established to prevent the access of unauthorized persons to the storage area. The system shall ensure the security against steal or vandalism.

Article 74. (1) Measures shall be established and documented to ensure the documented transfer of records from the responsible organization assigned to develop the activity / execute the product to the responsible organization that delegated the responsibility, in line, up to the participant responsible for that construction, operation or decommissioning stage, as applicable.

(2) When transferring records, their reception, validation and registering shall be ensured for:

a) completeness;

b) complying with the contractual agreements regarding the transfer of documents;
c) corresponding physical status.

CHAPTER XXI
QUALITY MANAGEMENT SYSTEM ASSESSMENT

SUBCHAPTER I
SELF-ASSESSMENT

Article 75. The responsible organizations shall establish and implement a continuous assessment system of the effectiveness of the processes and activities they coordinate. In this scope, they shall establish assessment criteria and methods to determine:
a) how the organization objectives have been achieved;
b) how the nuclear and radiological safety objectives have been achieved;
c) the efficiency of the organization management system;
d) the involvement of the personnel of the organization in achieving the objectives;
e) the trends in the quality of the processes and the implementation of nuclear safety requirements;
f) the problems that appear in achieving the performances expected by the organization;
g) the corrective actions necessary to continuously improve the performance of the activities and of the nuclear safety requirements;
h) how CNCAN and other regulatory bodies requirements are implemented.

Article 76. (1) The responsible organization shall establish at the level of the organization management the performance indicators to measure in quantity the accomplishment of the expected performances.
(2) The performance indicators shall be communicated to the entire organization.

Article 77. The self-assessment shall be performed by all management levels, using the following methods:
a) surveillance, observation of coordinated processes and activities;

b) analysis of processes;
c) analysis of documents and records resulting from the processes;
d) continuous activity surveillance sessions to observe the activities performed by the subordinated personnel.

Article 78. The corrective actions or improvements proposed as a result of the self-assessments shall be included in the normal process of follow up and control of corrective actions.

Article 79. The self-assessment process shall be performed additionally to the normal audit process and not as replacement.

Article 80. Additionally to the self-assessment, the responsible organizations shall perform the official annual review of the quality management system. The analysis shall be led by the manager of the responsible organization.

Article 81. The results of the self-assessments shall be included in the annual reports regarding the effectiveness of the management system.

SUBCHAPTER II
INDEPENDENT ASSESSMENTS

Article 82. The quality management systems shall be independently assessed on behalf of the management to ensure:
a) the efficiency of the system in obtaining the satisfactory performances is determined;
b) the quality surveillance for products and services;
c) promoting the measures to improve the quality management system;
d) the assessment of meeting CNCAN regulatory requirements.

Article 83. (1) The independent assessment shall be done in a planned manner by internal and external audits, review of documents, controls, inspections, tests, surveillance and other similar methods;
(2) The independent assessment shall be focussed on the essential aspects in areas of activity and processes where problems have been found.

Article 84. The assessment frequency shall be sufficient to confirm that all requirements are continuously met.

Article 85. The results of the independent assessment shall be documented and reported to that level of management that has sufficient authority to solve any identified problems.

SUBCHAPTER III
AUDITS

Article 86. The responsible organizations shall apply a planned and documented audit system to confirm that the activities that affect quality are performed according to the quality management system requirements and the management system is effectively implemented.

Article 87. The audits shall be performed according to written procedures and audit checklists by personnel properly trained and qualified, who meets the following conditions:

a) does not have any responsibilities related to the performance of the audited activities;
b) did not perform the control of the audited activities.

Article 88. The auditors shall identify the audit scope and objectives, the requirements of the applicable documents, the activities to be audited and the departments involved.

Article 89. After finalizing the audit, the auditors shall ensure:

a) to promptly report to the appropriate management level on all deficiencies found during the audit;
b) to further confirm that all measures have been taken to eliminate the deficiencies and the corrective actions have been implemented to prevent their recurrence, where applicable.

Article 90. (1) Each deficiency shall be described in enough details to ensure that:

a) measures are established to eliminate the deficiency;
b) corrective actions are implemented to prevent the recurrence of the deficiency;

(2) The auditors can suggest corrective actions to be taken into consideration by the responsibles of the audited activities.

Article 91. The audited department shall plan the corective actions and to answer in writing, mentioning the actions taken and the date when these have been completed.

Article 92. The auditors shall report to the management about the answers received for each deficiency and implementation of the appropriate measures.

Article 93. The audit plans, audit reports and reports regarding the implemented corective actions shall be kept for a determined period.

Article 94. The audits shall be performed periodically with a frequency that would be sufficient to determine the compliance of the systems to the requirements and its efficiency. In case that the efficiency of the quality management system or of some of its parts in uncertain, the responsible organization shall supplement the planned audits with unplanned audits. The audits scope and scheduled date shall take into consideration the maturity of the quality management system, the construction, operation or decommissioning status of the nuclear objective and the activity developed.

Article 95. The responsible organization shall plan additional audits when problems are identified in implementing the quality management system requirements, when it is found that the system performance is low or when new procedures / processes / activities are introduced.

CHAPTER XXII
GRADUAL APPLICABILITY OF QUALITY REQUIREMENTS

Article 96. (1) The owner shall establish the list of safety related structures, systems, equipment and components in the nuclear objective and to classify them on a scale from one to four according to their importance for the nuclear safety and radiological risk related to their damage, according to the methodology in Appendix 2.

(2) The procedure for classifying and the list of structures, systems, equipment and components shall be submitted to CNCAN approval.

(3) The grouping into the four safety classes of structures, systems, equipment and components shall be done by the owner of the nuclear objective from the design stage.

(4) The owner shall send to the participants the list of safety related structures, systems, equipment, components, processes and services in the case of delegating the related activities.

(5) In the case that the participants contract the activities / fabrication of products to contractors, the participants shall inform the contractors about the safety class of established for the structure, system, equipment, component that the requested activity / products is related to and the class of applicability of the quality management system, established by this one if it was not established by the owner / designer according to the assigned safety class.

(6) The participants and the contractors shall issue specific procedures describing the different application of the quality management system requirements according to the safety class, procedures that shall be submitted to the approval of the owner / participants and to the approval of CNCAN. When issuing the procedures for the gradual applicability there shall be taken into consideration the methodology in Appendix 2, “Establishing the classes of gradual applicability of quality management system requirements for nuclear objectives”.

Article 97. (1) The gradual applicability of the quality management system developed by the responsible organizations shall ensure that the functional requirements and specification for structures, systems, equipment and components are met. The requirements regarding the gradual applicability of the system are increasing from class 4 to class 1.

(2) The gradual applicability of the quality management system shall be reflected in:

a) the managerial level giving the approvals;
b) the extension of the managerial assessment;
c) the level of detailing and review of documents;
d) the extension and type of verifications;
e) the frequency and depth of audits;
f) the extension of surveillance;
g) the extension of requested corrective actions;
h) the extension of the records kept;
i) the type and content of personnel training / qualification requirements;
j) the extension of material traceability requirements;

k) establishing the records issued and of those to be kept during the entire life cycle of the nuclear objective;

l) the level of using independent verifications;

m) the degree of detailing the process of identification, disposal and solving of non-conformances.

(3) In the gradual implementation of the quality management system requirements, the responsible organizations shall take into consideration the following factors:

a) complexity, uniqueness or recentness of the product, service or process;

b) necessity of processes, methods or special equipment for verifications or inspections;

c) difficulty in testing the functionality by inspections and tests after installation;

d) lack of information regarding the quality history of the product, service or process;

e) lack of standards regarding the product, service or process;

f) accessibility to the component for maintenance, in-service inspection or replacement after installation;

g) necessity of personnel special training.

CHAPTER XXIII
SPECIFIC REQUIREMENTS REGARDING THE QUALITY MANAGEMENT SYSTEM

Article 98. According to the activities developed, the quality management systems of the participants and contractors shall comply with the specific requirements from article 99 up to article 109.

Article 99. The norms regarding the specific requirements for quality management systems applied to the assessment and choosing the location for nuclear objectives contain specific requirements of the quality management system applicable for the nuclear objectives location studies.

Article 100. The norms regarding the specific requirements for quality management systems applied to the research-development activities in the nuclear field contain specific requirements of the quality management system

applicable for the research-development activities identified in all stages of construction, operation and decommissioning of the nuclear objective.

Article 101. The norms regarding the specific requirements for quality management systems applied to the design of nuclear objectives contain specific requirements of the quality management system applicable for engineering and design activities identified in all stages of construction, operation and decommissioning of the nuclear objective.

Article 102. The norms regarding the specific requirements for quality management systems applied to the procurement activities for nuclear objectives contain specific requirements of the quality management system applicable for the activities of procurement of goods and services for nuclear objectives.

Article 103. The norms regarding the specific requirements for quality management systems applied to the activities of fabrication of goods and supply of services for nuclear objectives contain specific requirements of the quality management system applicable for the activities of fabrication of goods and supply of services for nuclear objectives.

Article 104. The norms regarding the specific requirements for quality management systems applied to the construction-installation activities for nuclear objectives contain specific requirements of the quality management system applicable for construction-installation activities for nuclear objectives, including the reception of materials and equipment, their installation in the systems and structures, according to the design documents.

Article 105. The norms regarding the specific requirements for quality management systems applied to the activities of commissioning nuclear objectives contain specific requirements of the quality management system applicable for the activities of commissioning the equipment and systems of nuclear objectives to operate according to the design requirements.

Article 106. The norms regarding the specific requirements for quality management systems applied to the operation of nuclear objectives contain specific requirements of the quality management system applicable for activities of operation and maintenance of nuclear objectives, to ensure the operation in safe conditions.

Article 107. The norms regarding the specific requirements for quality management systems applied to the activities of decommissioning nuclear objectives contain specific requirements of the quality management system applicable for the activities of decommissioning the equipment and systems of a nuclear objective, from the moment of systems shutting down up to removing all risks.

Article 108. The norms regarding the specific requirements for quality management systems applied to producing and using software for research, design, analysis for nuclear objectives contain specific requirements of the quality management system applicable for the activities of design, development, modification, execution and configuration of software used for research, design, and nuclear and radiological safety analysis for nuclear objectives.

Article 109. Other specific norms regarding the quality management system for nuclear objectives issued by CNCAN.

CHAPTER XXIV
TRANSITORY AND FINAL DISPOSITIONS

Article 110. These norms are applicable within 60 days from the date of being published in Monitorul Oficial.

Article 111. (1) Until the term stated in art. 110, the owners, participants and contractors shall take the necessary measures to implement the requirements of these norms in the activities they develop.

(2) If the implementation of these requirements requires modifications to the quality assurance program documents, the revised documents shall be submitted to CNCAN for approval.

Appendix 1 to the norms regarding general requirements for quality management systems applied to the construction, operation and decommissioning of nuclear objectives

DEFINITIONS OF THE TERMS USED IN THE NORMS REGARDING GENERAL REQUIREMENTS FOR QUALITY MANAGEMENT SYSTEMS APPLIED TO THE CONSTRUCTION, OPERATION AND DECOMMISSIONING OF NUCLEAR OBJECTIVES

1. **Acceptance –** acceptance represents the admission or agreement on using a document / product / service based on the analysis of complying with certain prior established criteria.
2. **Nuclear accident –** nuclear accident means a nuclear event that affects the installation and causes the irradiation or contamination of population or environment over the limits accepted by the applicable regulations.
3. **Corrective action –** corrective actions represent measures taken and documented to determine the cause of deficiencies or non-conformances and to prevent their recurrence.
4. **Nuclear activity –** nuclear activity means any type of human practice that introduces radiation sources or means of additional exposal, leaving from the existing sources, thus increasing the exposal or the probability of exposal of persons or of the number of persons exposed.
5. **Locating** - locating means the process of selecting the adequate area for placing a nuclear objective, including the assessment and definition of related design basis.
6. **Quality management system review** – the quality management system review represents the periodical assessment of the effectiveness of the quality management system in the activities of construction, operation or decommissioning of nuclear objectives established in the quality policy.
7. **Design authority** – design authority represents the general designer or an organization or group inside an organization that received from the general designer and owner of the nuclear objective the right to develop designs or changes to the design.
8. **Beneficiary** – the owner represents the organization receiving a product or service.

9. **Calibration** – calibration means the comparison of two measurement instrument, devices, out of which one has the accuracy recognized and traceable in the national standards. Calibration is performed to detect, correlate, report or eliminate by adjustment any variation in the precision of the measurement instrument or device whose precision is not known.
10. **Life cycle of the nuclear objective or nuclear installation –** the life cycle of the nuclear objective means the assembly of different stages in the construction, operation or decommissioning of the nuclear objective, when the activities are oriented to accomplishing a certain objective, as choosing the site location, design, construction-installation, commissioning, operation and decommissioning of the nuclear objective / installation.
11. **Quality management system class –** the quality management system class represents the value established on a scale from one to four that establishes the extension of the quality management system of a responsible organization, according to the importance for the nuclear safety of structures, systems, equipment, components, processes and services the organization provides and the radiological risk resulting from their damage.
12. **Comisia Nationala pentru Controlul Activitatilor Nucleare (Nuclear Commission for Nuclear Activities Control) –** Comisia Nationala pentru Controlul Activitatilor Nucleare is the national authority for the authorization, regulation and control of activities in the nuclear field.
13. **CNCAN –** CNCAN means Comisia Nationala pentru Controlul Activitatilor Nucleare (Nuclear Commission for Nuclear Activities Control).
14. **Operation configuration –** operation configuration means the status in a certain moment of the structures, systems, equipment, components and software in the nuclear objective as compared to the specific operation documentation.
15. **Design configuration –** design configuration means that specific disposal of systems, structures, equipment, components and software defined by drawings / specifications and approved design calculation.
16. **Contractor –** contractor means any organization that develops activities for an owner or participant based on a contract.
17. **Design output –** design output represents all data resulting from the design process.

18. **Nuclear objective owner –** the nuclear objective owner represents the proprietary or the organization that administers the nuclear objective on behalf of the owner.
19. **Documentation –** documentation means the information and its support describing, defining, specifying or certifying activities, requirements, procedures or results.
20. **Organizational entity –** organizational entity means the organizational structure described and taken into consideration individually inside an organization.
21. **Assessment –** the assessment represents the activity of analysis of execution and control processes included in the quality management system to verify their capability to accomplish the objectives established.
22. **Operation -** the operation of the nuclear objective represents all activities developed since commissioning to decommissioning to accomplish the scope the nuclear objective was built for, including the activities of maintenance, repair, fuel loading/unloading and periodical inspection. The operation of the nuclear objective extends to the functional period of the nuclear objective and includes test operation and operation itself.
23. **Significant events -** significant events represent those events that might have an impact on nuclear safety, on personnel an on operation and that require analysis based on pre-established criteria.
24. **Fabrication -** fabrication represents the specific activities of executing equipment, components, parts and accessories. Fabrication does not include design.
25. **Essential information -** essential information means that basic information required to establish or develop some activities, without which an activity or a process can not be developed or if it does, the result of the activity or process is uncertain.
26. **Periodical inspection -** periodical inspection means:

a) Mandatory inspection of components performed at pre-established intervals after the commissioning of the nuclear objective, according to the requirements of Comisia Nationala pentru Controlul Activitatilor Nucleare (Nuclear Commission for Nuclear Activities Control);

b) General inspection program containing both inaugural inspection and the periodical inspection defined in para. a)

27. **Maintenance -** maintenance represents the activities to preserve, repair and verify the structures, systems, equipment and components so as to ensure that they accomplish their functions in good conditions. These activities include calibration, metrological verification, replacement and repairs.
28. **Stress limits** - the stress limits represent the force and limits of the intensity of the applicable force for the calculation loadings considered in the design specifications.
29. **Non-conformance -** the non-conformance represents a deficiency in the characteristics or documentation that makes the quality of a product or service unacceptable, undetermined or outside the specified requirements.
30. **Major non-conformance** - the major non-conformance represents the non-conformance appearing in a product, service or documentation with impact on nuclear safety, personnel protection or with a big economical impact.
31. **Norms regarding the quality management systems for nuclear objectives -** the norms regarding the quality management systems for nuclear objectives are the norms issued by Comisia Nationala pentru Controlul Activitatilor Nucleare (Nuclear Commission for Nuclear Activities Control) for the quality management systems of the organizations developing activities in the nuclear field.
32. **Operation -** operation is the term used to describe the activities developed by the personnel of the operating organization of the nuclear objective to start, maintain in operation and shut down the systems of the nuclear objective. This term excludes the maintenance activities or related technical and administrative services.
33. **Regulatory body -** regulatory body means a national organization competent in a certain domain to issue regulations, to authorize or to control the activities in that specific domain.
34. **Responsible organization -** responsible organization means the owner of the nuclear objective, the participants to the activities of construction, operation or decommissioning of the nuclear objective, as well as any other organization that receives by contract the right to develop activities for the nuclear objective, that meets the condition of being a Romanian or foreign legal person / entity, legally recognized in Romania, and that meets the requirements in the norms regarding the quality management systems for nuclear objectives.

35. **Participant -** participant means any organization assigned by the owner of the nuclear objective to develop on his behalf activities of construction, operation and decommissioning of the nuclear objective, and that shall establish, develop and maintain a quality management system according to the norms regarding the quality management systems for nuclear objectives.
36. **Operation personnel -** operation personnel means those persons especially assigned with the responsibility to operate the systems and equipment of a nuclear objective.
37. **Intervention plan -** the intervention plan represents the assembly of measures to be taken in the case of a nuclear accident.
38. **Intervention plan for emergency situations -** the intervention plan for emergency situations represents the assembly of measures especially established to take action in situations that have the risk of extension of the danger over the protection barriers of the nuclear objective.
39. **Qualified procedures -** the qualified procedures are the procedures verified based on a practical demonstration that proves that a certain activity developed based on that procedure has the established results.
40. **Temporary procedures -** the temporary procedures are those procedures used to describe activities developed for a limited period of time and under controlled conditions.
41. **Notification process -** the notification process is the process of the responsible organization to communicate / inform the Comisia Nationala pentru Controlul Activitatilor Nucleare (National Commission for Nuclear Activities Control) in order to participate at the mandatory hold / witness points established by the responsible organizations in the documents approved by Comisia Nationala pentru Controlul Activitatilor Nucleare (National Commission for Nuclear Activities Control).
42. **Special process -** the special process is that process whose result can not be examined directly, or in which the proofs generated during the process shall be used to verify the compliance. The correctness of the result of a special process depends on using the appropriate practices, qualified personnel and on the way of interpreting the result. Special processes include, but they are not limited to, welding, thermal treatment, cleaning, protective coating, concrete pouring, non-destructive examination and leak-tight tests.

43. **Products -** the products represent materials, equipment, components, subassemblies, subsystems, systems, structures, software and services.
44. **Commissioning -** commissioning is represented by the activities meant to prove that the equipment and systems are operating according to the limits of the design specifications at the moment of their putting into service.
45. **Terminal points -** the terminal points define the authority of operating some equipment in systems during commissioning at the interface between the organization responsible for construction-installation and the organization responsible for commissioning.
46. **Management representative -** the management representative is the person in the management of the organization responsible to establish, develop and maintain a quality management system and to monitor the status of its implementation. In big and medium organizations, the management representative is the quality management department manager and in small organizations, this responsibility can be held by one of the directors of the organization.
47. **Routine -** routine is the activity developed by the personnel of the responsible organization with a certain defined frequency and which is smaller than two weeks.
48. **Nuclear safety -** the nuclear safety represents the assembly of technical and organizational measures meant to ensure the safe operation of nuclear installations, to prevent and to limit their damaging and to ensure the protection of the personnel involved, of the population, of the environment and of the goods against irradiation or radioactive contamination.
49. **Safety related systems -** the safety related systems represent those structures and systems, and equipment and their components, which by their incapacity to operate according to their designed scope, have a potential impact on the radiological safety of the population or of the operation personnel of the nuclear objective.
50. **Surveillance -** the surveillance represents the continuous assessment and review of processes, procedures, records with the confirmation that the activity or conditions are complying with the specified requirements.
51. **Testing -** testing represents an element of the verification used to determine the capability of a product to meet the specified requirements and performed

thorough to a set of mechanical, chemical, environmental or functional conditions applied to the respective product.

52. **Surveillance tests -** the surveillance tests mean the performance of those steps necessary to determine that the structures, systems, equipment, and components continue to operate or that they are ready to operate to perform their functions according to the pre-established objectives.
53. **Unconventional tests -** the unconventional tests represent tests performed irregularly or that have not been performed before and that involve structures, systems, equipment or components which are under operation or that can be requested in case of emergencies and which are not in safe state during tests.

Appendix 2 to the norms regarding general requirements for quality management systems applied to the construction, operation and decommissioning of nuclear objectives

ESTABLISHING THE CLASSES OF GRADUAL APPLICATION OF THE QUALITY MANAGEMENT SYSTEM REQUIREMENTS IN NUCLEAR OBJECTIVES

CHAPTER I
ESTABLISHING THE SAFETY CLASS FOR STRUCTURES, SYSTEMS, EQUIPMENT, COMPONENTS

1. - A classification system between 1 and 4 is established for each system, structure, equipment and component in or for the nuclear objective.

2. - Class 1, 2 and 3 contain those safety related components of the nuclear objective with functions to prevent or decrease the consequences of postulated accidents that might cause an unacceptable risk for the health or safety of the population.

3. - Class 4 contains the components of the nuclear objective that are not included in class 1, 2 or 3, but whose damaging or operation at parameters different from the nominal parameters affect the capability of the installation to operate at the nominal parameters and which are not essential for a safe shutdown or for removing decay heat. The failure of these components of the nuclear objective does not put at risk the safety of the population.

4. - Class 1 contains those components that:

a) are part of the reactor cooling pressure vessel;

b) are used to perform the function to shut-down the reactor in any status of the installation;

c) maintain the geometry of the reactor core area or offer support to the reactor core area, and whose failure may result in an accident of deteriorating the reactor core area;

d) reactivity control mechanisms and systems to maintain an adequate reactivity safety margin;

5. - Class 2 contains those components that:

a) are necessary to maintain an adequate inventory of the reactor cooling agent after a leak of the cooling agent;

b) are part or an extension of the reactor containment;

c) are necessary to remove the decay heat of the reactor core area or that of the spent fuel bay and whose unique failure in any status of the installation may result in loosing a safety function, and those components that do not normally operate can not be actively tested during the nominal power operation.

d) In case of a unique failure may result in losing a safety function of other class 2 components;

6. - Class 3contains those components that are not part of class 1 or 2 and that:

a) are necessary in the process of overtaking the decay heat from the reactor core area or from the spent fuel bay;

b) their failure would lead to losing a safety function of other components (e.g. it could lead to losing the cooling of those components requiring cooling to meet their safety functions);

c) are an extension of the reactor cooling agent pressure vessel and have the capacity of being isolated from the pressure vessel, in any stage of normal operation of the reactor, by two valves, each of them being normally closed, or having the capacity of being remotely closed;

d) their failure would lead to the emission of radioactive materials in the environment and would lead to a calculated potential exposure at the termination of the exclusion area higher than 0,5 rem on the whole body (or its equivalent).

7. - The classification of each system, structure, equipment shall comply with a system similar to the one described in points 4-6, according to the impact in nuclear safety and radioprotection.

CHAPTER 2
ESTABLISHING THE CLASSES OF GRADUAL APPLICATION OF THE QUALITY MANAGEMENT SYSTEM REQUIREMENTS

1. - According to the nuclear safety class assigned to the structure, system, equipment and their components, the related activities are classified from the point of view of application into 4 different categories, according to the importance and impact of the activity on the nuclear safety as follows:

- class 1 - the activities might lead to an uncontrolled emission of radioactivity, as, for example: a pressure system component that can not be isolated;
- class 2 - non-conformance with the authorization / environmental protection requirements;
  - high risk of serious damage;
  - major radiological risk;
  - severe damage of the installation or losses in generating power
- class 3 - reduced physical integrity of the installation or small \losses in generating power;
  - minor radiological risk;
  - small risk of serious damage;
- class 4 - none of the above-mentioned risks are involved.

2. - In assigning the class, the following criteria shall be taken into consideration, each of them contributing in percentages between 0% and 20% of the total mark given to the system, structure, equipment, component, software, process or service they result from:

a) the complexity of the design and the difficulty in validating it; inexistence of standards regarding the product, service or process;

b) the complexity and difficulty of the execution process, the uniqueness or recentness of the product, service or process;

c) the complexity of the product characteristics;

d) the necessity of special processes, methods or equipment for verification or inspections; the difficulty of testing the functionality by inspections or testing after installation.

e) necessity of personnel special training.

3. - The economical impact of not performing the function that the system, structure, equipment, component, software, process or service was designed for, can be considered as an additional criterion in establishing the class.