

**Nuclear Power Production & Development Company of Iran (NPPD)**

**Management System Requirements**

**for**

**Participated organization in Nuclear Power Plant lifecycle**

**MSRs**

**MSR-4700-01**

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DEFINITIONS

**Audit**

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

**Commissioning**

The process during which nuclear power plant components and systems having been constructed, are made operational and verified to be in accordance with design assumptions and to have met the performance criteria. It includes both non-nuclear and nuclear tests.

**Construction**

The process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment and the performance of associated tests.

**Corrective Action**

An action taken to rectify and eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence.

**Design**

The process and result of development of the concept, detailed plans, supporting calculations and specifications for a nuclear power plant and its components.

**Document Control**

Those measures established to control the preparation, review, release, issuance and deposition of documents such as design calculation, purchase orders, specifications, instructions, procedures and drawings, including changes thereto, which describe or documents activities affecting quality.

**Environment**

Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.

**Inspection**

Quality Control actions which by means of examination, observation or measurement determine the conformance of materials, parts, components, systems, structures, as Well as processes and procedures, with pre-determined quality requirements.

**Iranian Regulatory Authority (INRA)**

The Iranian Regulatory Authority (hereinafter INRA) is the independent national body authorized for regulating all stages of life cycle of NPPs (sitting, design, construction, commissioning, operation and decommissioning). The INRA is responsible for full state surveillance and control with regard to all matters relevant to radiation and nuclear safety in various phases of sitting, design, construction, commissioning, operation and decommissioning of NPPs.

**Item**

A general term covering structures, systems, components, parts or materials.

**Management System**

A single coherent management system in which all the components, parts of an organization in the areas of safety, quality, environment, health, security and economic are integrated to enable the organization’s objectives to be achieved.

**Manufacturing**

The process of fabrication of equipment and the performance of associated tests

**National Nuclear Safety Department (NNSD)**

The regulatory functions of INRA over nuclear facilities are performed by the National Nuclear Safety Department (hereinafter NNSD).

**Non-conformance**

A deficiency in characteristics, documentation or procedure which renders the quality of an item unacceptable or indeterminate.

**Participating organizations**

All Participating organizations assigned the responsibility for special activities relating to sitting, design, construction, commissioning, and operation and decommissioning of NPPs such as: sitting organization, design organization, construction organization, commissioning organization, operator (Subordinated Co. of NPPD Co. in stage of operation) and decommissioning organization.

**Siting**

The process of selecting a suitable site for nuclear power plant, including appropriate assessment and definition of related design bases***.***

**Suppliers**

Individuals or organizations under contract with participating organizations or NPPD Co. for furnishing items or services. This includes various levels or kinds of procurements undertaken by vendors, sellers, contractors, sub-contractors, fabricators and consultants.

**Systematic Approach to Training (SAT)**

An approach that provides a logical progression from the identification of the competencies required to perform a job to the development and implementation of training to achieve these competencies, and subsequent evaluation of this training.

**Testing**

The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operational conditions.

**Verification**

The act of reviewing, inspecting, testing, checking, auditing or otherwise determining and documenting whether items, processes, services or documents conform to specified requirements.

**Workplace**

Any physical location in which work related activities are performed under the control of the Participating organizations / suppliers.

ABREVIATIONS

|  |  |
| --- | --- |
| **AEOI** | Atomic Energy organization of Iran |
| **ALARA** | as Low as Reasonably Achievable |
| **BNPP-1** | Bushehr Nuclear Power Plant Unit-1 |
| **FSAR** | Final Safety Analysis Report |
| **IAEA** | International Atomic Energy Agency |
| **INRA** | Iran Nuclear Regulatory Authority |
| **MS** | Management System |
| **MSR** | Management System Requirements |
| **MSRs** | Management System Requirements |
| **N/A** | Non applicable |
| **NCR** | Non-conformance Report |
| **NNSD** | National Nuclear Safety Department |
| **NPP** | Nuclear Power Plant |
| **NPPD Co** | Nuclear Power Production and Development Company of Iran |
| **SAR** | Safety Analysis Report |
| **SAT** | Systematic Approach to Training |

1. **Introduction**
   1. Management system shall be established and implemented by all participating organizations / suppliers in the constituent stages of NPPs from siting to operation according to the requirements stipulated in this document.
   2. This document, to be considered as the minimum management system requirements, to design and establish MS, by all participating organizations / suppliers.
   3. The management system requirements shall be used to harmonize the management system aspects of the participating organizations / suppliers in siting, design, construction, commissioning and operation of NPPs and provide assurance that their assigned activities are performed in conformance with applicable codes, standards and regulatory requirements.
2. **Management system**

**General**

* 1. The MS shall be designed and implemented to ensure the organization’s objectives related to contractual obligation be achieved in a safe, efficient and effective manner.
  2. The Participating organizations / suppliers shall establish, implement, assess management system and keep it update. The main aim of the management system shall be to achieve and enhance safety goals and contractual obligation by:
* Bringing together in a coherent manner all the requirements for managing the participating organizations / suppliers which is called Management System (MS);
* Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements and contractual obligations are satisfied;
* Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.
  1. The MS shall provide a single framework for the arrangements and processes necessary to address all the contractual goals of the participating organizations / suppliers including safety, health, environment, security and quality based on the contract and its scope and obligations.
  2. The participating organizations / suppliers shall determine all the required processes adequately to address all requirements of the applicable regulations and standards and the organization’s management and technical practices with consideration of the requirements stipulated within this document.
  3. The Participating organizations / suppliers shall develop, implement and maintain a MS, fulfilling the MSR (G) and MSR (DE), MSR (CS), MSR (CM) based on the scope and obligation of the contract.
  4. Participating organizations / suppliers shall document own management system, including at least management system manual and management procedures which shall be sent to NPPD Co. for acceptance before starting the project based on the defined scope of the contract.
  5. Participating organizations / suppliers shall at least maintain all records and documents prior to the end of project, showing the implementation of management system and fulfilling the requirements during the project execution.
  6. The management system manual and management procedures of the participating organizations / suppliers shall be subject to periodic review (a maximum frequency of 18 months) to ensure their validity.
  7. The documentation of the management system (management system manual and management procedures) shall be developed in the official national language or/and English so it is easily understood, readily identifiable and available at the point of use.
  8. The management system manual shall contain as a minimum the following:
* The policy statements of the organization;
* A description of the management system;
* A description of the functional responsibilities, accountabilities, levels of authority;
* A description of the processes, processes map (model), the interaction and sequence of the all processes.
* Organizational structure.
  1. Management procedures shall be developed by the participating organizations / suppliers to cover all identified processes, explaining the purpose, scope, responsibilities and the description of each process and these documents shall be submitted to NPPD Co. for acceptance.
  2. The participating organizations / suppliers shall ensure that the management system of the its suppliers / main sub suppliers (based on the scope of the contract) are designed, established, implemented, assessed, maintained and improved and the documents shall be revised in 18 month after being accepted by NPPD Co.
  3. NPPD Co. shall have always the right to conduct participating organizations / suppliers system assessment at any time. In case of observing any non-conformance, participating organizations / suppliers shall prepare and fully implement the corrective action plans and present the obtained results to NPPD Co. for notification.
  4. Participating organizations / suppliers shall submit a report to NPPD Co., in at least 3 months intervals, stipulating the fulfilment of its own management system requirements and fulfilment the requirements of his suppliers / sub suppliers’ management system.
  5. Participating organizations / suppliers may delegate and/ or require suppliers / sub suppliers / or other organizational units to develop and implement all or part of the MS but shall retain overall responsibility for the implementation and effectiveness of system.
  6. The person in the most senior management position within Participating organizations / suppliers shall be responsible for establishing MS and enforcing its effective implementation.

**Interface**

* 1. The lines of internal and external interfaces shall be specified in the management procedure.

**Safety culture**

* 1. The management system shall be used to promote and support a strong safety culture by:
* Ensuring a common understanding of the key aspects of safety culture within the organization.
* Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization.
* Reinforcing learning and questioning attitude at all levels of the organization.
* Providing the means by which the organization continually seeks to develop and improve its safety culture.
  1. A common understanding by training of individuals of what is meant by safety culture shall be established. Training is one of the means by which individuals can achieve this understanding. Such training shall not be considered a one-off event but shall be provided regularly to all individuals, including senior management.

**Grading**

* 1. Participating organizations / suppliers shall provide a graded approach in application of MS requirements based on the relative importance of each item, service or process related to safety and documented as a management procedure for grading of application of the MS requirements.
  2. Application of MS requirements in the different aspects of all activities covering all stages of NPPs from sitting to operation shall be implemented by graded approach.
  3. The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:
* The significance and complexity of each product or activity;
* The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;
* The possible consequences if a product fails or an activity is carried out incorrectly.
  1. The most important factor in determining the grading is the effect of the malfunction or failure of an item on safety when put in service. Other factors for consideration include the following:
* Complexity or uniqueness of the item;
* Degree of standardization of the item;
* The need for special controls, administrative measures and surveillance over processes, methods and equipment;
* The degree to which compliance with design requirements can be demonstrated by inspection and test;
* Quality history (experience with performance and quality);
* Accessibility of the item, after installation in the plant, for maintenance, in-service inspection and replacement;

**3.** **Management responsibility**

**Management commitment**

* 1. The senior management of Participating organizations / suppliers is responsible and accountable for the planning and implementation of a management system that is appropriate to the Participating organizations / suppliers. Senior manager shall provide the individuals performing the work with the necessary information, tools, support and encouragement to perform their assigned work properly.
  2. Senior manager of Participating organizations / suppliers shall communicate the beliefs that underlie the organization’s policies through their own behavior and management practices. Participating organizations / suppliers shall share the management’s perception and beliefs about the importance of the management system and the need to achieve the policies and objectives of organizations.
  3. Management at all levels of Participating organizations / suppliers shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.
  4. Management at all levels of participating organizations / suppliers shall foster the involvement of all individuals in the implementation and continual improvement of the management system.

**Satisfaction of interested parties**

* 1. The expectations of interested parties including NPPD Co. and NNSD shall be considered by senior management of participating organizations / supplierss in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised.
  2. The process for the evaluation of the interested party satisfaction shall be determined, and the said process shall be documented as a management procedure and monitored.
  3. To consider and respond to the expectations of interested parties, participating organizations / suppliers shall:
* Identify its interested parties and address their expectations within the management system;
* Identify which of the interested parties’ expectations are to be satisfied and shall ensure that they are communicated throughout the organizations;
* Take an approach that ensuring safety overrides all other demands, especially in the event of contrary expectations on the part of different interested parties;
* Communicate the requirements throughout the organizations;
* Focus on improving processes to ensure value for the interested parties identified.
  1. The results of the assessment of satisfaction of the expectations of interested parties shall be used by participating organizations / suppliers as an input for the process of continual improvement of the management system.

**Statutory and regulatory compliance**

* 1. Senior management of participating organizations / suppliers shall ensure that organization has identified all applicable statutory and regulatory requirements that apply to its products, processes and activities, and it shall include in the management system the methods of complying with these requirements.

**Organizational policies and policy statement**

* 1. The policies of the participating organizations / suppliers, based on the scope and objectives of the contract, shall be as succinct as possible to enable them to be effectively communicated, understood, and consistently implemented. In addition, the following key information shall be communicated effectively for each policy:
* The meaning and purpose of the policy;
* The values and beliefs that relate to the policy;
* The commitment of senior managers to its implementation;
* The plans, standards, procedures and systems relating to its implementation and the measurement of performance;
* Additional factual information to promote the involvement and commitment of individuals;
* Comments and ideas for improvements;
  1. Based on scope and objectives of the contract, a single integrated policy statement or an integrated set of policy statements shall be developed by participating organizations / suppliers, and included in the management system manual of the participating organizations / suppliers, that contain as a minimum the following topics:
* Safety (including nuclear safety and health and safety of individuals);
* Quality;
* The environment;
* Change management;
* Security.

**Planning**

* 1. Goals, strategies, plans and objectives for satisfying contractual obligation of the participating organizations / suppliers shall be established. The methods for implementation and evaluation of the strategies shall be specified.
  2. Appropriate processes at various levels in the participating organizations / suppliers shall be specified to ensure that measurable objectives for implementing the goals, strategies and plans are established.
  3. Senior management of participating organizations / suppliers shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary.

**Organization, responsibility and authority for the management system**

* 1. Senior management of participating organizations / suppliers shall be responsible for the management system and safety and shall ensure that it is established, implemented, assessed and continually improved.
  2. Participating organizations / suppliers shall have an independent assessment unit.

**4. Resource Management**

**Provision of resources**

* 1. Senior management of the participating organizations / suppliers shall determine the amount of necessary resources and shall provide the resources to carry out the activities specified in the contract, delegated responsibilities of the Participating organizations / suppliers and to establish, implement, assess and continually improve the management system.

**Outsourcing**

* 1. Work may be contracted out to external organizations for reasons of economy or if a supplier is more competent to perform the work. This shall not be done contract by contract in a piecemeal fashion, but shall be based on an established management strategy for suppliers.
  2. When contracts are awarded for work to be carried out by individuals from a supplier / sub supplier, the participating organizations / suppliers shall ensure that there is no conflict between the work practices and standards of the supplier / sub supplier and their standards and practices.

**Involvement of individuals**

* 1. Senior management shall improve both the effectiveness and the efficiency of the organization and its management system by involving and supporting all individuals.

**Knowledge Management**

* 1. The knowledge of the participating organizations / suppliers shall be managed as a resource.
  2. A process for managing the knowledge shall be established, implemented, assessed and improved by the participating organizations / suppliers. This process shall be described in a procedure.
  3. Participating organizations / suppliers shall have an integrated, systematic approach to identifying, capturing, managing and sharing its knowledge and, in so doing, enabling groups of individuals to create new knowledge collectively to help achieve the objectives of the participating organization.

**Financial resources**

* 1. Resource management shall include activities by participating organizations / suppliers for determining the needs for, and sources of, financial resources. The control of financial resources shall include activities for comparing actual usage against plans and for taking necessary action.

**Human resources (Competence, awareness and training)**

* 1. Senior management of participating organizations / suppliers shall ensure that the necessary individual competences are available for the effective and efficient operation of the organization. Senior management shall evaluate both present and expected needs for competences against the competences already available in the organization.
  2. The personnel of participating organizations / suppliers shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.
  3. The qualification requirements for those personnel whose activities are affecting safety and quality shall be specified and satisfied by the participating organizations / suppliers.
  4. Participating organizations / suppliers shall establish the specific process for training, based on the Systematic Approach to Training (SAT) methodology and documented as a management procedure.
  5. Training plans shall be developed to ensure an adequate number of qualified staff is available to meet the needs of the organization and the contract.
  6. The training plans of participating organizations / suppliers shall be subject to ongoing review to determine their effectiveness and improvement.
  7. Training programs shall be established. The effectiveness of the training program shall be subject to review and periodic assessment performed in accordance with an appropriate procedure
  8. Management of participating organizations / suppliers shall ensure that personnel are familiarized with all relevant MS documents associated with their activities through training programs.
  9. Where required by codes, standards, specifications or other special requirements, personnel performing activities affecting quality, (e.g., non-destructive test personnel, welders and welding operators, etc.) shall be certified as per applicable codes, standards, etc.

**Infrastructure and the working environment**

* 1. Senior management of participating organizations / suppliers shall identify and establish the infrastructure necessary for safety and for achieving the organization’s objectives based on the scope and object of the contract.

**Working environment**

* 1. Senior management shall determine, provide, maintain and evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met.

**5. Process implementation**

**Developing processes**

* 1. The processes of the management system that are needed to achieve the participating organization / supplier's goals, shall be identified and their development shall be planned, implemented, assessed and continually improved.
  2. The identified processes shall be documented and categorized as management, supporting, and core processes and documented in a process description(s). Process descriptions shall include as a minimum the category, name, owner, relevant documents of the processes and sub-processes and be approved by the participating organizations / suppliers. Based on process description(s), the process map shall be developed and the interaction and sequence of all processes shall also be developed.
  3. Participating organizations / suppliers, based on developed procedure, shall monitor processes implementation and the results shall be documented,
  4. The processes shall be improved, as appropriate based on implementation results.
  5. The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.
  6. The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.
  7. The process description(s), process map, sequence and interactions of the processes shall be considered as essential parts of management system manual of the participating organizations / suppliers.

**Process management**

* 1. For each process the owner shall be given the authority and responsibility for:
* Developing and documenting the process and maintaining the necessary supporting documentation;
* Ensuring that there is effective interaction between interfacing processes;
* Ensuring that process documentation is consistent with any existing documents;
* Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
* Monitoring and reporting on the performance of the process;
* Promoting improvement in the process;
* Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the participating organizations / suppliers based on the scope and objectives of the contract.
  1. The control of processes contracted to external organizations shall be identified within the management system of participating organizations / suppliers. Participating organizations / suppliers shall retain overall responsibility when contracting any processes.

**Processes common to all stages**

### Control of documents

* 1. Documents shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned for this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.
  2. Changes to documents shall be reviewed and recorded and shall be subjected to the same level of review and approval as the documents themselves.
  3. A document control process shall be established and documented in a management procedure, to provide for the preparation, review, approval, issuing, distribution, revision and validation (where appropriate) of documents essential to the management, performance and assessment of work.
  4. The responsibilities of organizational units or individual shall be defined in the document control process.
  5. The types of documents to be controlled shall include, but shall not be limited to: documents that define the management system; safety requirements; work instructions; technical documents; assessment reports; drawings; data files; specifications; computer codes; purchase orders and related documents; and supplier documents.

**Control of records**

* 1. Participating organizations / suppliers shall establish a record control process and document it as a management procedure, to ensure that appropriate records are specified, prepared, reviewed, approved and maintained, as required by applicable codes, standards, specifications, and contract requirements to furnish documentary evidence of the quality of materials, equipment, and activities affecting quality in order to reflect completed work accurately.
  2. Participating organizations / suppliers shall generate and supply to, or hold for NPPD Co. the records, which are specified by applicable design specifications, procurement documents, construction procedures, test procedures, operational procedures or other documents based on the requirements of the contract.

**Control of product**

*General*

* 1. Specifications and requirements for products shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.
  2. Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products.
  3. The participating organizations / suppliers shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.
  4. NPPD Co. shall be notified by participating organizations / suppliers of any deviation in contractual requirements related to the product (cost, time, quality, and technical and safety issues). NPPD Co. is authorized to accept or reject the deviation and if the deviation is not accepted, the participating organizations / suppliers shall conduct related corrective actions.

*Inspection and testing for acceptance*

* *Grading*  
  1. The following specific activities as a minimum shall be graded in inspection and testing by participating ganizations/suppliers:
* The need for inspection and testing plans.
* The training and qualification of personnel carrying out inspections and testing
* The need to verify inspection and testing activities.
* The level and detail of information in inspection and testing procedures.
* The responsibilities for review and approval of inspection and testing documentation.
* The review of non-conformances.
* The requirements for record production and retention.
* *Inspection and testing stages* 
  1. Inspection and testing shall be carried out for all items at three identifiable stages based on the contractual requirements which are:
* Receiving Inspection and Testing
* In-process Inspection/Monitoring
* Final Inspection and Testing for Acceptance
* *Inspection and testing plans (QPs)* 
  1. Quality plans and time schedules shall be prepared by participating organizations / suppliers and handed over to NPPD Co. for acceptance.
  2. NPPD Co. has the right to add any additional control (witness, hold or sample) points to quality plans.
* *Testing* 
  1. Testing procedures shall define the test objectives and make provisions for ensuring that prerequisites for the given test have been met.
  2. Test results shall be documented and evaluated to ensure that testing requirements have been met.
* *Inspection and testing status* 
  1. Measures shall be established and documented by participating organizations / suppliers to identify inspection and test status of items.

### Measuring and testing equipment

* 1. Participating organizations / suppliers which use measuring and test equipment shall identify the relevant processes within MS and document it as a management procedure.
  2. Calibration results shall be recorded and maintained to provide objective evidence of calibration performance.

**Procurement control**

### General

* 1. A procurement process as a procedure shall be established within the MS of the Participating organizations / suppliers that meet the specified requirements based on the contract.
  2. Participating organizations / suppliers shall control procurement of items and services, for MS considerations, to the extent commensurate with importance of items or services to safety. The following procurement activities as a minimum shall be described by Participating organizations / suppliers within procurement control process:
* Procurement document preparation, review, distribution and change control;
* Selection of suppliers / sub suppliers;
* Bid evaluation and award of contract;
* Evaluation of supplier / sub supplier performance;
* Verification (surveillance, Technical review (inspection,…) or audit) activities of purchasers;
* Control of non-conformance, and follow up on corrective actions;
* Control of acceptance of item or service;
* Control of MS records;
* Audit of procurement activities;

### Grading

* 1. The following specific activities as a minimum shall be graded in procurement activities by organizations:
* The requirements for supplier assessment, evaluation and qualification.
* The scope and level of detail of the procurement specification.
* The need for and scope of supplier quality plans.
* The extent of responsible participating organization inspection, surveillance and audit activities.
* The scope of documents to be submitted and approved, and the records to be provided.
* The extent of records to be provided or stored and preserved.

### 

### Acceptance of item or service

* 1. Participating organizations / suppliers shall use any or a combination of the following methods for acceptance of an item or service from a supplier / sub supplier as the case demands.

### Acceptance by verification at source

* 1. Acceptance by verification at source shall be considered when the item or service:
* is vital to safety;
* is such that the characteristics are difficult to verify after delivery;
* is complex in design, manufacture or test;
* is supplied by the supplier / sub supplier who has been selected on the basis of his potential and is yet to prove his capability;

#### *Acceptance by receiving inspection*

* 1. Acceptance solely by receiving inspection is satisfactory when the items are:
* Relatively simple in design, manufacturing and test.
* Adaptable to standard or automated inspection and/or test of the end product to verify quality characteristics after delivery.
* Such receiving inspection does not require operations that could adversely affect the integrity, function or cleanliness of the item.
  1. Receiving inspection shall be coordinated with a review of the supplied documents.

#### *Acceptance by supplier/ sub supplier certificate of conformance*

* 1. Participating organizations / suppliers shall accept an item or service from a supplier / sub supplier on the sole basis of supplier / sub supplier's certificate of conformance stating that the specified requirements have been met. This can be done when the item or service is of simple design and involves standard materials, processes and tests.
* *Management system for suppliers* 
  1. Suppliers shall develop and implement a management system that meets the requirements established in this document.

**Communication**

* 1. A process for communication shall be identified and documented and monitored by participating organizations / suppliers.
  2. Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties.
  3. Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization.

**Managing organizational change**

* 1. An organizational change management process shall be identified and documented by the participating organizations / suppliers in a procedure based on scope of the contract. The process shall ensure that there is no degradation in the safety culture of the organization.
  2. Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.
  3. The implementation of such changes shall be planned, controlled, communicated, monitored, traced and recorded to ensure that safety is not compromised.
  4. The appropriate mechanisms for the feedback of information to monitor the effects of the changes and their implementation shall be communicated by participating organizations / suppliers to interested parties including NPPD Co..
  5. Changes to the organization affecting safety, the organizational structure, processes that impact contract requirements, and the interface with NPPD Co. shall be accepted by NPPD Co. prior to implementation.

**Project management**

* 1. The participating organizations / suppliers shall introduce to the NPPD Co. a project manager. Participating organizations / suppliers shall submit to NPPD Co. the relevant document for his assigned project manager to confirm his qualification.

**Work planning and control**

* 1. Work planning shall be provided with consideration of the scope of the contract.
* Shall identify the safety significance of the work processes;
* Shall identify and schedule the work necessary to perform;
* Shall identify the required objectives of work;
* Shall identify any requirements that are part of the work process.
* Shall ensure that the work is authorized to be carried out;
* Shall identify any workplace hazards and specify how they are to be mitigated;
* Shall clarify the personnel requirements to carry out the work safely and specify any special training needs that are a prerequisite for doing the work;
* Shall specify any reviews required upon completion of the work;
* Shall identify the required records.

Control and supervision of contractors

* 1. A process shall be developed by participating organizations / suppliers to control and supervise suppliers / sub suppliers who are carrying out work designated.

### Industrial safety

* 1. A process for health and safety with consideration of planning including (hazard identification, risk assessment and determining controls) and implementation and operation including (operational control, emergency preparedness and response) and checking including (performance measurement and monitoring) shall be determined, documented and monitored by participating organizations / suppliers.

### Protection of the environment

* 1. A process for protection of the environment with consideration of planning (environmental aspects, their impacts) and implementation (operational control, emergency preparedness and response) and checking (performance measurement and monitoring) shall be determined, documented and monitored by participating organizations / suppliers.

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### Protection against fires

* 1. Participating organizations / suppliers shall establish and implement a fire prevention and protection process to protect individuals and items. The fire prevention and protection process shall be appropriate to executive activities.

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### Identification of items

* 1. A process shall be established and implemented by participating organizations / suppliers to ensure that all items are uniquely traced.

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### Regulatory requirements

* 1. Participating organizations / suppliers shall ensure in appropriate manner that all regulatory and statutory requirements are identified and describe how they are implemented.

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### Information technology

* 1. A process shall be established by participating organizations / suppliers to control applicable software, based on the scope of the contract.

### Security

* 1. Participating organizations / suppliers shall establish, maintain and operate physical protection systems and appropriate security arrangements that could not jeopardize safety.

**6. Measurement, assessment and improvement**

**Monitoring and measurement**

* 1. The effectiveness of the management system with consideration of the scope and objectives of the contract and requirements stipulated in this document shall be monitored and measured by participating organizations / suppliers to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement. The Monitoring and measurement process shall be documented in a procedure.

**Assessment**

* 1. Assessment shall be performed to determine that management system requirements are met and that processes are adequate and effective and align with the NPPD Co. requirements by self and independent assessment.

Self-assessment

* 1. Participating organizations / suppliers shall implement self assessment process within their MS and document the process in a procedure. Participating organizations / suppliers shall conduct self assessments and the results shall be preserved by participating organizations / suppliers as the evidences of the requirements fulfillments and also at all other levels in organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.
  2. Self asessments shall be conducted at laest once every year by Participating organizations / suppliers.

Independent assessment

* 1. Independent assessments shall be planned, documented and conducted by participating organizations / suppliers to assure the effective implementation of MS and overall coordination and scheduling of assessment activities. Independent assessment shall be considered as a process within the MS by the participating organizations / suppliers and documented as a management procedure. The requirements associated with planning, implementation, evaluation, reporting and follow-up activities shall be considered during the development of the independent assessment process. The following types of independent assessment shall be considered by Participating organizations / suppliers in independent assessment process:

### Internal Audit

* 1. In order to ensure the fulfillment of its own management system requirements, participating organizations / suppliers shall plan to conduct the internal audits and the audit results shall be preserved by participating organizations / suppliers as the evidences of the requirements fulfillments.

### External Audit

* 1. Participating organizations / suppliers shall perform external audit of their suppliers / sub suppliers who are engaged in fulfillment of the Contract with NPPD Co. The frequency of audits shall be determined by factors such as the importance of items for safety and the performance of the contractors.
  2. NPPD Co. preserves the right to carry out external audits on the regular basis or occasionally as required. The participating organizations / suppliers shall provide NPPD Co. with suitable conditions for performance of such audits.

### Quality surveillance

* 1. Participating organizations/suppliers shall perform quality surveillance of work performance by themselves and by their suppliers / sub suppliers who are engaged in fulfillment of the Contract with NPPD Co..

### Technical review

* 1. Participating organizations / suppliers shall arrange for a review of the technical content of activities and processes of themselves and of their suppliers / sub suppliers who are engaged in fulfillment of the Contract with NPPD Co. with a view to improving the effectiveness of these activities or processes.
  2. NPPD Co. preserves the right to carry out any kind of the assessment activities on the on-going activity as required. The participating organizations / suppliers shall provide NPPD Co. with suitable conditions for performance of such technical review.

**Management system review**

* 1. A management system review shall be considered as a process and be documented as a management procedure. Participating organizations / suppliers shall perform a management system review at planned intervals at least annually to ensure the continuing suitability and effectiveness of the management system to the requirements of this documents and its ability achieve the objectives of the contract. The results of MS review shall be submitted to NPPD Co. for information.

**Non-conformances control, corrective and preventive actions**

### Control of Non-Conformances

* 1. Participating organizations / suppliers shall develop a specific process for non-conformance control and document it in a procedure.
  2. The following criteria shall be taken into account while determining significance of non-conformities:
* Failure to comply with regulatory requirements or licensing conditions as set by the regulatory body (NNSD);
* Failure of facility to accomplish a safety function, when required;
* A serious failure in the implementation of MS;
* Operation outside the scope of applicable quality program policies, procedures or instructions;
* An error in an approved and released design output document, which could have compromised a safety related function;
* A deficiency which, requires more than a routine analysis and correction;
* A repetitive deficiency for which previous corrective measures to prevent it have been ineffective;
* Failure to follow approved procedures or instruction;
* A repetitive or significant personnel error resulting from unclear or incorrect specifications, procedures or instructions;
* Failure to obtain required approvals to procedures and instructions;
* Violation of plant design limits;
* A deficiency which have an effect on plant or personnel safety;
* Unanticipated component, structures and system failure or malfunction;
* A repetitive or serious supplier deficiency detected during receiving, construction or operational activities, or activities such as source inspections and audits at the supplier facilities;
* Inadequate protection or storage of items during shipping, receipt, storage or construction which has resulted in sufficient deterioration of an item so as to adversely affect the safe operation of the facility;
* Repeated failure by Participating organizations / suppliers or individual to resolve by commitment date deficiencies;

### Corrective Action

* 1. Participating organizations / suppliers shall establish and document management procedure for corrective actions to preclude repetition of deficiencies/ conditions adverse to quality and safety.
  2. The following activities shall be described by participating organizations / suppliers within the process of corrective action:
* Deficiency/Adverse Conditions Reporting;
* Evaluation of Deficiency/Adverse Conditions;
* Planning, Scheduling and Implementing Corrective Action;
* Verifying the satisfactory completion of Corrective Action.

### Preventive Action

* 1. In the case of significant non-conformances/ deficiencies, participating organizations / suppliers shall determine and document the root causes and take appropriate preventive actions to preclude repetition of similar non-conformances/ deficiencies from occurring and to ensure and to improve project safety and performance.
  2. The status and effectiveness of all corrective and preventive actions shall be monitored and results shall be preserved.

**Improvement**

* 1. Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.
  2. A strategic objective of participating organizations / suppliers shall be the continual improvement of processes in order to enhance the organization’s performance.

**Appendix I Specific Management System Requirements for Design**

Introduction

1. The design organizations shall develop and implement a management system that meets the requirements established in items 1, 2, 3, 4, 5 and 6 of this document. In addition the following requirement mentioned in this Appendix shall be mandatory for the design organizations to comply with and adhere.
2. The objective to implement MS in design is to assure that the design from its conception to completion is carried out by appropriately trained and qualified persons and is examined and evaluated during its progress to assure fulfillment of design requirements, safety and performance, codes and regulatory requirements and of its capability to meet those set requirements.

Process implementation

General

1. The following requirements shall be applied by the design organizations in developing the design process or processes:

* All structures, systems and components that are important to safety, including software for instrumentation and control, shall be first identified and then classified on the basis of their function and their significance to safety.
* Design requirements, inputs, processes, outputs, changes, records and organizational interfaces shall be controlled.
* Design inputs shall be correctly translated to design outputs.
* Design changes shall be justified and shall be subject to design control measures commensurate with the original design.
* Interfaces among all organizations involved in the design shall be identified, coordinated and controlled.
* Design inputs, processes, outputs and changes shall be verified. Individuals or groups performing design verification shall be qualified to perform the original design. Those carrying out verification shall not have participated in the development of the original design (but they may be from the same organization). The extent of verification shall be based on the complexity, the associated hazards and the uniqueness of the design.
* Computer programs used in design shall be validated through testing or simulation prior to use, if they have not already been proven through previous use.
* Tests used to verify or validate design features shall be conducted in consideration of the conditions that simulate the most adverse operating conditions.
* Design verification shall be completed before the design output is used by other organizations, or is used to support other work such as procurement, manufacturing, construction.
* Design records, including the final design, calculations, analyses and computer programs, and sources of design input that support design output, shall be used as supporting evidence that the design has been properly accomplished.

1. The design process shall include the following activities:

#### Design initiation

* 1. The design process is initiated in support of a project for the construction of a new nuclear installation or modification to an existing plant and other nuclear structures, systems and components as needed. The overall specification of the scope and the initiation of design activities shall be carried out only after a review of the contracts, work orders and other such high level documents that require an organization to perform design activities. The planning and timing of design activities and milestones shall support the overall plan for the project.

#### Identifying design requirements

* 1. The design organizations shall establish all the key requirements for the design after conducting a review of applicable contracts, codes and standards, regulatory requirements, and laws and regulations.
  2. For the design of specific structures, systems and components, the applicable design parameters shall be covered in related design documents such as design requirements, design specifications and safety standards and guides on design by the design organizations.

#### Selection of the principal designer

* 1. The design organization shall identify who has responsibility for specifying the design requirements and approving the design output. The design organization may delegate all or parts of his responsibility to other organizations, but shall retain his responsibility, without prejudice to other organizations’ obligations and/or legal responsibilities.
  2. The responsibilities of the principal designer in any case at least shall include:
* Definition of the base requirements and specifications;
* Involvement in design reviews;
* Involvement in design verification;
* Approval of the detailed design;
* Review and approval of design changes at all stages;
* Control of interfaces;
* Review of relevant applications for non-conformances.
* Review and approval of MS for design.

#### Work control and planning

* 1. Design activities shall be carried out by the design organization in a logical planned sequence to ensure that the installation as designed can be safely, constructed, commissioned, operated and decommissioned.
  2. The design of the nuclear installation and of its structures, systems and components shall be organized by the design organization in discrete elements and work assignments that clearly specify the scope of the design, the activities for planning the design activities and the activities for preparing design documents.
  3. The design organization and its sub-contractors shall prepare design plan at the earliest opportunity before the beginning of design activities. Design Plan shall define the activities to be performed in manageable units (work breakdown structure).
  4. Plans used by the design organization in design shall include the following:
* The scope of the work, including work carried out by other organizations;
* All key interfaces with national and other relevant authorities, the design customer and other parties;
* The design methods including the consideration of human factors;
* Software requirements (software to be developed or software codes to be validated for use);
* Testing requirements, including qualification tests, prototype tests and seismic tests;
* Requirements for the review, verification and validation of the design;
* The production of design output documents such as maintenance manuals and operational procedures or instructions;
* Resource requirements, including, for example, the disciplines of specialists such as structural integrity and the resources required for design reviews;
* Any specific training requirements;
* A schedule of activities, specifically identifying those critical to the success of the design project (sometimes referred to as being on the critical path);
* Points at which checks of the design process will take place and the frequency of such checks.
  1. In addition to general planning requirements, the following aspects shall also be considered in design planning where applicable by the design organization:
* Procurement of components and materials;
* Availability of components and materials;
* Qualification of suppliers;
* Preparation and planning of tests;
* Acceptance and use of previously proven designs and components.

#### Design inputs

* 1. All relevant inputs that may affect the design directly or indirectly shall be considered by the design organization. The design input documentation include design requirements, design specifications, design guides and standards, documents on the analysis basis, documentation of technical specifications and flow sheets shall define the requirements to be met by the design. Design input documents shall be normally prepared, reviewed and approved by the design organization.
  2. Basic sources of design inputs are identified in contractual requirements, and by taking into account customer input and commercial considerations (including cost and marketability), design inputs shall be derived by the design organization from:
* Basic inputs that are available in the early stages of the design process as specified in relevant contracts and documents defining high level design requirements;
* Derived inputs that become available after the conceptual and detailed design progresses to a certain level.
  1. The design inputs shall include the following parameters, on the basis of their applicability to each particular installation and design activity:
* Basic inputs (independent of the conceptual design):
* Function of the installation, structure, system or component;
* Location and interfacing requirements;
* Performance requirements such as capacity, rating and output;
* Operational requirements under relevant conditions, such as start up, normal operation, anticipated operational occurrences, abnormal operation, accident and emergency, shutdown, standby, and consideration of the frequency of events;
* Environmental conditions, including wind, snow loading, consequences of rain and flooding and seismic events, and physical conditions such as conditions of temperature and humidity, the presence of airborne and other chemicals, and conditions of radiation, corrosion and erosion;
* Safety considerations, including risks to individuals, potential to cause physical damage, fire hazards and radiation hazards;
* Failure considerations, including consequences for safety, limiting the consequences of failure, the effect of failures on plant functions and on adjacent structures, systems and components, the function of standby equipment and the effects of adjacent failures;
* Standards, including mandatory and contractual codes and standards, and national and other relevant requirements;
* Security considerations;
* Safeguards considerations;
* Human factor considerations;
* Usability of equipment;
* Feedback from research and development;
* Consideration of previous designs and feedback of experience and lessons learned from purchasing, fabrication, construction, installation, commissioning, operation and decommissioning.
* Derived inputs (dependent on the conceptual design):
* Design requirements for specific disciplines, including:
* Structural aspects: loading, pressures, stress, supports and bracing;
* Mechanical aspects: vibration, speed and lubrication;
* Electrical aspects: voltage, power, regulation and insulation;
* Hydraulic and pneumatic aspects: flow, pressure, temperature, fluids, velocities, and suction and discharge heads;
* Chemical aspects: fluid chemistry, corrosion and erosion;
* Control and instrumentation: controls, alarms, ranges, stability and readability;
* Metallurgical and material aspects: protective coatings, welding, galling, wear, erosion and creep;
* Fabrication requirements, including constructability, size and weight, fabrication processes, quantity, interchange ability and spare parts;
* Installation requirements, including shipping, storage, installation, proof tests and running in plant at reduced loads;
* Commissioning requirements, including accessibility, tests and test equipment;
* Operational requirements, such as resource needs and the need for procedures and instructions;
* In-service requirements, including reliability, redundancy, accessibility, serviceability, maintenance and inspection;
* Engineering input data, including validity of reference data, test reports, analyses and in-service reports;
* Decommissioning requirements, including dismantling and decontamination.
  1. Sufficient detail shall be provided by the design organization in the design input documents to allow them to serve as a reference basis for making decisions, performing verification and validation for the conceptual and detailed design, evaluating design changes and setting up tests and criteria for commissioning.

#### Review of design concepts and selection

* 1. The design organization may examine one or more design concepts to evaluate the suitability and adequacy of various options to select the preferred approach. All design concepts selected in this manner shall be evaluated and documented.
  2. Such an evaluation of design concepts may include consideration of the feedback of previous experience from design, procurement, manufacturing, construction, installation, commissioning, licensing and operation. The preferred design concept shall be specified, documented and justified with supporting information by the design organization.

#### Selection of design tools and computer software

* 1. The design tools and computer software used in design, safety analysis, plant control, calculations and data management shall be selected by the design organization on the basis of their appropriateness and adequacy for application and use. All such tools and software shall be suitably qualified on the basis of applicable codes and standards. Tools and software used by the various design organizations shall be compatible to the maximum extent possible.
  2. Where computer software is used for analysis and for process control, appropriate measures shall be provided by the design organization for its verification and validation.

#### Conducting conceptual analysis

* 1. The need for a conceptual design analysis shall be evaluated by the design organization. Analyses, when required, shall be prepared on the basis of selected design concept(s). This is generally done for new, complex and first of a kind design of systems, structures or components that are critical to safety. Conceptual analyses documents may require submission and approvals depending on the applicable laws and regulations.
  2. The need for conceptual analyses, of the safety and environmental impact shall be determined and when required such analyses shall be prepared on the basis of optimum or preferred design concept(s) by the design organization.

#### Conducting the detailed design and production of design documentation

* 1. Calculations, analyses and studies shall be developed and documented by the design organization in sufficient detail and shall be controlled in such a manner that subsequent users of the design, in the various stages of the lifetime of the installation, can understand the design and make informed decisions. Inputs, assumptions, modelling, test and development work and results, safe operating parameters and envelopes, key acceptance criteria and parameters for commissioning tests, for example, shall all be documented.
  2. Design activities shall ensure that specified requirements are reflected into design outputs, such as:
* Design of the installation
* Design computer codes;
* Design specifications;
* Functional specifications.
  1. **A** suite of design documentation shall be developed by the design organization by establishing an overall ‘baseline’ listing of all key design documents on the basis of the requirements of the customer and of national requirements. This listing shall cover the design documents needed for the various activities at the installation in all stages.
  2. The baseline listing shall include the following:
* Design requirements and specifications;
* National and other relevant codes, standards, classifications and other criteria;
* Requirements for traceability;
* Requirements for purchasing, installation and maintenance;
* Critical characteristics of the design for which confirmation in commissioning is necessary;
* Operating limits and reliability and maintainability requirements for systems or equipment.

#### Safety analyses

* 1. Safety analysis is an important part of the design process that is carried out to examine the various postulated conditions, accidents and events that may affect the performance and operation of equipment, structures, systems and components at the installation. The necessary types and the extent of safety analyses shall be evaluated in the light of the governing codes and standards and regulatory requirements and, if required, the safety analyses shall be prepared on the basis of the selected design concepts by the design organization.
  2. Safety analyses shall be documented by the design organization in reports such as preliminary safety analysis reports (PSAR) and final safety analysis reports (FSAR) and in probabilistic safety analyses (PSA) which have been accepted by the NPPD Co. and NNSD. These reports shall be updated as required. All analyses shall cover the purpose, methods, assumptions, input and sources, computer modelling information, details of test and development work, results and key references. The selected tools for the safety analyses, such as computer programs, shall be verified and validated to confirm their suitability and adequacy for the types of analyses being performed.
  3. Design analyses and safety analyses shall establish an ‘envelope’ of configurations and operating limits for the plant, equipment, systems, structures and components that are acceptable for safe operation.

#### Carrying out design verification, review and validation

* 1. Individuals who did not perform the design activity or make decisions concerning the design being verified shall normally carry out design verification.
  2. The designer’s direct supervisor, or a qualified delegate, shall be responsible for confirming that the design work is correct, that the design meets the requirements, and that the verification activities have been properly completed. Those individuals carrying out verification and validation shall have access to sufficient background information and supporting information to gain an understanding of the design intent.
  3. At appropriate stages of the design, formal verification reviews shall be planned, conducted and documented by the design organization. Participants in these reviews shall include representatives of organizational units from the design organization concerned with the design stage under review and other individuals as necessary.
  4. The design organization shall carry out design verification based on established procedures, to ensure that all design requirements, including input requirements, planning and performance of the design process and interface controls have been satisfactorily met. The procedures shall provide the following:
* Designating competent individuals or groups to perform design verification other than those who performed the original design or supervised the original designer;
* Identifying and documenting the design verification methods, including design review and alternative calculation (at least one of which to be practiced);
* Evaluating the applicability of standardized and previously proven designs for present design inputs, including environmental conditions, considering known problems affecting the standardized design and their effect on other features;
* Verifying changes to previously verified designs, including evaluation of the effects of those changes on the overall design;
* Documenting the results of verification efforts in sufficient detail to allow for auditing the verification method after it has been completed so as to permit confirmation that the process has been properly implemented. The results shall identify checkers, verifiers and management approvals and the date;
* Taking measures to ensure that verification findings are implemented;
  1. Design verification is the process by which a design is evaluated to ensure compliance with the prescribed requirements. Design verification shall be performed by the design organization throughout the various design phases, including the phases of conceptual design, detailed design and safety analysis, to ensure that each design phase has reached a satisfactory level of completion before going on to the next phase.
  2. At the start of any design activity, the design organization shall specify activities to be carried out to verify each design or revisions to the design.
  3. The nature and extent of design verification shall be based on the following criteria:
* Importance to safety of the plant, equipment, structure, system or component;
* Exposure to economic risk;
* Complexity of the design;
* Consideration of human factors;
* Degree of standardization;
* Technical developments;
* Similarity to previously proven designs.
  1. When previously finished and verified designs are to be used for a new application, the design verification programme shall be limited to confirming that:
* The application of the design is correct;
* The analyses and design calculations are still valid.
  1. Acceptable design verification methods which have been used by the design organization shall include various methods of review such as:
* A review of the design by a group of peers ;
* Carrying out calculations using an alternative method;
* Verification by testing.
  1. The resulting verification output documents shall themselves be reviewed by the design organization to confirm their adequacy, validity and relevance to the design being verified.
  2. Design reviews shall be conducted by a group of experts in the subject matter that are led by a senior designer who has considerable experience in and a broad knowledge of the subject.
  3. At appropriate stages of the design, formal reviews of the design process shall be planned, performed and documented by the design organization to provide assurance that the output documents correctly and fully address the requirements such as functional, safety and regulatory requirements, and industry code and standards of the design specification.
  4. The principal designer shall determine the scope and extent of the review. As part of the review it shall be established that procedures have been followed and that designated individuals have participated in the review and that the results have been adequately documented and checked prior to the release of any design documents to the customer or organisation sponsoring the design project.
  5. The design review shall be such as to anticipate and identify potential problem areas and inadequacies and corrective actions shall be initiated to ensure that the final design meets the design intent.
  6. For performing design review a checklist shall be prepared and followed by the design organization addressing certain basic questions. These questions shall include but not be restricted to:
* Were design inputs correctly selected and incorporated?
* Have original design requirements been met?
* Is design output information complete?
* Were any assumptions made, are they adequately described and what is their basis?
* Was an appropriate design methodology used and were designated?
* Design standards followed?
  + - Is the design output reasonable when it is compared to the design input?
  1. Alternative calculations shall provide results, which are consistent with the original ones but not necessary, exactly the same results of the original calculation or analysis. (The permissible tolerances shall be identified, documented and approved by the authorized persons).
  2. Where alternative calculations are performed to verify the correctness of the original calculation, a design review shall be performed by the design organization to address the appropriateness of assumptions, design input data used, and the computer code or other calculation methods used.
  3. Qualification testing is used to verify the design of a system or component or a specific design feature of a prototype or a production unit by operating the item under controlled conditions and measuring and evaluating its performance. Organizations that performing qualification testing shall have a programme for qualification testing that meets the requirements of applicable standards.
  4. Test requirements shall be identified in a test specification document by the design organization. Test results shall be included in a test report. Test reports shall be reviewed for their validity and relevance to the test requirements against the acceptance criteria specified in the test specification document.
  5. Where computer programs and their associated documentation are part of the design output, such as computer programs for controlling the operation of safety systems or for monitoring or displaying reactor operation, they shall be subject to a set of verification and validation tests.
  6. Design validations shall be performed by the design organization on the final item under defined operation conditions such as commissioning or pre-operational testing. Design validation could also be carried out by the design organization throughout the various design phases, including the conceptual design, detailed design and safety analysis phases. Validation shall be conducted by the design organization on any subsequent changes to the design of systems and on new systems by using methods such as task based validation and user centered validation.

#### Design Models

* 1. The design organization shall use the suitable models to facilitate the design process as follows:
* To enable the feasibility of the design of structures and layout of critical areas to be established;
* To provide a physical and visual aid in the control and allocation of space for equipment, pipe work, services, separation and segregation of safety related plant components and systems, protection against and escape from hazards, and access for operation and maintenance;
* To identify potential problems/fouls and interfaces between buildings and plant components and systems;
* To co-ordinate interfaces between design suppliers;
* To provide an aid to construction planning and operator training;
  1. The design organization that uses physical or computer models shall ensure that changes to models are controlled in order to assure that they remain valid representations of the current configuration.

#### Management of the design and control of design changes

* 1. The design organization shall establish procedures for design changes to approved design and engineering documents, including field changes and shall include the following:
* Assuring that the impact of the change and the consequences to other design areas are carefully considered;
* Justifying changes after identifying and documenting the reasons for changes frequently resulting from such things as:
* Unsatisfactory qualification, preoperational or operational test results;
* Problems discovered during manufacturing/construction;
* Failures of structures, systems, or components to meet functional requirements;
* Disposition of non-conforming items;
* Changes in regulatory or other requirements;
* Operational experience;
* Design improvements;
  1. The design organization shall also provide records of design changes that it has introduced in the course of the design activities. All changes shall be reviewed by and shall be subject to the approval of individuals who have information and knowledge of the requirements and the intent of the original design.
  2. Design changes, whether initiated by the designers in the organization, or elsewhere at the installation, or by outside groups such as contractors, consultants, national or other relevant authorities or other interested parties, shall be identified (with the reasons for them) and shall be documented, reviewed, evaluated, verified and, where appropriate, validated. Documents affected by the change shall be identified. If the change is approved, the affected documents shall be revised and approved and then released. Activities affected by the change shall be verified.
  3. Permanent and temporary changes in the construction, commissioning and operation stages shall be documented, verified and approved by the design organization before they are implemented.
  4. Concessions provided to fabricators, installers, construction forces, and commissioning or operational groups that permit deviations from the design shall be controlled. The controls include methods for the identification of concessions and for the resolution, approval, issuing and filing of concessions.

#### Design outputs

* 1. The outputs of the design shall be provided by the design organization in a form enabling verification against the design input and shall be approved prior to release. The output documents shall at least cover the following:
* Design drawing;
* Technical specification and amendments;
* Safety evaluation;
* Design calculations and records of the checking of these calculations;
* Design reports;
* Approved design change requests;
* Design verification and validation reports;
* System descriptions;
* Technical analyses, evaluations and reports;
  1. The Design Outputs shall be controlled to ensure that:
* Meet the input requirements for design;
* Provide appropriate information for purchasing, manufacturing and construction;
* Contain or reference acceptance criteria;
* Specify the characteristics that are essential for the safe and proper working;

#### Drawings

* 1. The design organization shall establish procedures for preparation, modifying and controlling drawings. The following shall be covered by such procedures:
* Drafting office standards including standard drawing paper, standard drafting practices, and folding drawings;
* Standard symbols;
* Identification system such as drawing title and number;
* Checking methods;
* Requirements for review and approval;
* Issuance and distribution;
* Storage and control of originals or master copies;
* Revisions and control of obsolete documents;
* As-built drawings;
* Non-compliance with drawing requirements;
* Indication of status, such as preliminary revision or issue for construction;

#### Specification and Other Design Documents

* 1. The design organization shall establish procedures for preparation and control of specifications and other design documents such as installation instructions and commissioning and test procedures. The following shall be covered by such procedures:
* Format requirements;
* Identification system such as title and number;
* Indication of status, such as preliminary revision or issue for construction;
* Requirements for review and approval;
* Issuance and distribution;
* Storage and control of originals or master copies;
* Revisions;
* Non-compliance with specifications;

#### Interfaces

* 1. Interfaces shall be arranged and controlled by the design organization, and shall be agreed between all organizations involved in design activities.
  2. Procedures shall be developed for communication and interface control between technical disciplines within the design organization with other organizations involved in other stages of the NPP projects, to ensure their needs are taken into account
  3. Organizations communicating with the design organization shall identified as follows:
* Regulatory Authority.
* NPPD Co.
* Sitting Organization.
* Construction organization.
* Commissioning organization.
* Operating organization.

**Appendix II Specific Management System Requirements for Construction**

Introduction

* + - * 1. The construction organization shall develop and implement a management system that meets the requirements established in items 1, 2, 3, 4, 5 and 6 of this document. In addition the following requirement mentioned in this Appendix shall be mandatory for the construction organizations to comply with and adhere. The established management system shall describe the overall arrangements for the management, performance, assessment and improvement of the nuclear installation during construction stage which is included the requirements as mentioned in this Appendix.

Process implementation

*Construction*

* *General* 
  + - * 1. The processes for the construction stage shall be determined by the construction organization by reviewing the scope of construction activities derived from the specifications for the design of structures, systems and components, procurement documents and drawings, and construction work plans and schedules.
        2. The construction organization bears overall responsibility for their construction activities however the activities could be done by other organizations based on the contract.
        3. The construction organization shall assign the responsible person for construction activities.
        4. The individual appointed shall have access to the necessary resources within the construction organization to discharge the following responsibilities:
* Ensuring that construction work and work at the installation is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of the relevant requirements;
* Ensuring that construction work and work that is undertaken at the installation, including work by contractors, is coordinated, carried out and completed in accordance with planned programmes;
* Controlling access to the construction site.
  + - * 1. The following points shall be taken into account by the construction organization in construction activities:
  + The identification, preparation and control of procedures and work instructions;
  + Special equipment or materials;
  + Competent personnel;
  + Inspection hold points or hold points for the regulatory body;
  + Environmental considerations;
  + The validation at the end of construction of records that will be transferred to the commissioning or operation organization to be maintained for the lifetime of the installation
* *Construction plan*
  + - * 1. Construction activities shall be plannedby the construction organization. The plan shall specify:
  + The activities to be performed, in manageable units;
  + The planned sequential order and duration of these activities;
  + The resources allocated for each activity.
    - * 1. Whereas the construction organization shall retain the responsibility for coordinating and planning the overall construction of the nuclear installation, contractor shall be responsible for producing detailed plans of the work that they will be carrying out and for obtaining the construction organization’s approval of these plans.
* *Control of Construction activities*
  + - * 1. The construction organization shall establish methods and schedules for verification that specify the level of inspection and verification required.
        2. Construction activities carried out by contractors shall be performed on the basis of inspection and test plans, which shall be submitted to the construction organization for approval. The construction organization shall ensure that all design requirements and regulatory requirements are met during construction activities.
* *Verification of Construction activities*
  + - * 1. Before offering an item or service for acceptance, the supplier shall verify that all specified procurement requirements have been satisfied. Acceptance by the purchaser shall not absolve the supplier from the responsibility to provide products fit for purpose, nor shall it preclude the subsequent rejection of any product.
        2. The process shall be specified by the construction organization include arrangements to verify the completion of construction and installation activities.
* *Control of design information*
  + - * 1. Lines of communication and arrangements shall be established by the construction organization for the issue of design information among the organizations involved in design. Prior to issue, the construction organization shall ensure that the information being issued reflects the present conditions at the site. Particular attention shall be paid to the design information required at any off-site fabrication facility.
        2. A process shall be established by the construction organization to address queries from the supplier with regard to the design information issued. If the query may have an implication for safety in operation, it shall be addressed to the principal designer for a response.
        3. Changes from the design documentation made on site during the construction activities that have an impact on the design information shall be reviewed, designated for action, approved and validated by the owners’ representatives with design responsibilities and/or with the principal designer. Original design documentation shall be updated for design corrections or clarifications. A complete set of ‘as constructed’ drawings that includes approved changes from the baseline design shall be provided at the end of the construction phase.
* *Turn over from Construction to commissioning*
  + - * 1. Sufficient provisions shall consider by the construction organization to control and co-ordinate the handover of completed works from one subcontractor to another and to those responsible for commissioning of the nuclear power plant in order to maintain the integrity of the completed works. These provisions include the following steps:
  + Documentation related to the transferred items is reviewed by the construction organization for completeness and accuracy. Any non-conformance is identified and resolved, and it is ensured that the status of the items is clear;
  + NPPD Co. and Regulatory Authority shall be notified immediately on any non-conformance activity having negative impact upon safety;
  + When the construction and commissioning organizations are satisfied that the transfer can be accomplished, a joint check is carried out of the transferred items and the associated documents. Both parties sign formally to indicate transfer of responsibilities.
  + The construction organization together with Subcontractors shall develop and implement measures on control and coordination of handing-over-acceptance of finalized items and works, as well on transfer of responsibilities from one building organization to another and to commissioning organization. Said measures shall include: documented transfer of responsibilities, verification of transmitted documents, and identification of non-conformances, control and inspection by building, installation and commissioning organizations of transmitted to them items and respective documents.
* *Interfaces*
  + - * 1. Interface arrangements shall be agreed between the construction organization, suppliers and other organizational units performing the work. The interface arrangements shall be specified in writing and shall be included in procurement documents. In interfaces shall considered the following:
  + The construction organization with suppliers;
  + The construction organization with operating personnel, or the operating organization;
  + Suppliers with sub suppliers;
  + The construction organization with the design organization;
  + The construction organization with the site organization;
  + The construction organization with NPPD Co.;
  + The construction organization with the commissioning organization
    - * 1. The construction organization with the regulatory body.Following the award of subcontracts in the construction stage a start up meeting shall be convened between the supplier and the construction organization to establish that the supplier is fully aware of the construction organization’s requirements at least following:
  + Interface arrangements;
  + Methods of communication;
  + Documents and information to be submitted;
  + Housekeeping;
  + Site security;
  + Site training;
  + Industrial safety
  + The management system;
  + Oversight and supervision of sub-suppliers

Housekeeping and cleanliness

* + - * 1. Housekeeping and cleanliness shall be considered by the construction organization as an essential process to provide a clean workplace and to encourage a high standard of workmanship. The process shall include establishing, maintaining and enforcing standards for housekeeping and cleanliness that:
  + Prevent the contamination of items and individuals;
  + Minimize the risk of injuries;
  + Reduce the risk of occurrence of conventional accidents such as fires;
  + Protect open systems and equipment from pollution with foreign material during maintenance and modification;
  + Control the movement of materials, equipment, tools and individuals in and out of work areas;
  + Ensure that cleanliness inspections are performed immediately prior to reassembly of systems or components;
  + Encourage individuals to leave an area as clean as or cleaner than it was before they carried out activities in it

Handling, storage and Preservation

* + - * 1. It shall be ensured by the construction organization by means of a process for handling and storage that only the correct items are used at the installation. For this purpose, items shall be identified by organizations. Physical means of identification shall be used to the extent possible and the identification shall be transferred to each part of an item before it is subdivided.
        2. Provisions shall be made by the construction organization to prevent the damage, deterioration or loss of items. For this purpose, items shall be stored in a manner that provides for their ready retrieval and protection. Storage shall be controlled to prevent the deterioration of degradable material.
        3. Items removed from or placed into storage, including surplus material returned to storage, shall be promptly documented by the construction organization so that the store inventory is kept accurate. The store record system shall indicate the locations of materials and parts in all designated storage areas. Access to storage areas shall be controlled.
        4. The handling and storage process shall include arrangements for shelf life management.
        5. For critical, sensitive, perishable or high value items, special arrangements, such as the provision of protective enclosures, an inert gas atmosphere and moisture and temperature control, shall be specified by the construction organization and put in place. These measures may also be applied to installed items that are subject to extended out-of-service conditions.
        6. The handling and storage process shall also cover field storage of consumables such as lubricants and solvents to ensure that they are properly stored and identified by the construction organization.
        7. Items removed from storage shall be protected by the construction organization. In the handling of items, factors such as weight, size, certification and regular inspection of hoisting or lifting equipment, chemical reactivity, radioactivity, susceptibility to physical shock or damage, electrostatic sensitivity, sling location, balance points and method of attachment shall be considered. Special handling tools and equipment shall be provided, controlled and inspected periodically as necessary, to ensure safe and adequate handling

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