NÜKLEER DÜZENLEME KURUMU

Regulatory Control over Supply Chain For Nuclear Safety

Authorization of Nuclear Safety Related Equipment Manufacturers

5th MDEP Conference

Erdem ÇAKIR

Nuclear Regulatory Authority
Department of Nuclear Installations

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Legal & Regulatory Infrastructure
Nuclear Regulation Law

- **Law no. 7381 dated 05/03/2022, Nuclear Regulation Law**
  - Activities within the scope of this Law cannot be carried out without notifying the Authority or obtaining authorization from the Authority.
  - The Law determines the activities that require license, permission or authorization certificate from the Authority and the issues that need approval
  - Among the issues that require a certificate of authorization from NDK:
    (a) Manufacture of equipment determined by the Authority
    (d) Equipment manufacturers
- **Regulation -** Approval of Manufacturers for Nuclear Facilities

Regulatory Control over Supply Chain
Highlights

- Risks in nuclear industry are too high (accidents)
  - ITNS supply chain is very important
- Effects on nuclear safety
  - Nuclear safety related equipment manufacturing and manufacturers are subject to regulatory control due to their effects on nuclear safety
    → Starts from manufacturing
- Multiple control over manufacturing process
  - By Nuclear Regulatory Authority NDK
    - Control via the Owner (Manufacturing approval, inspections via QPs)
    - Control via Manufacturers (Authorization and inspections)
    - Nuclear Construction Inspection Organizations (Authorization and inspections)
  - By Others
    - Licensee's own inspections
    - Nuclear Construction Inspection Organizations inspections

Equipment Procurement Process
Licensee's Responsibility & Roles

- Safety culture of suppliers
  - Confirms that its suppliers, from which it purchases goods or services important for safety, have a culture of safety.
- Responsibility of Supply Management
  - Bears responsibility for the safety of the services or products it procures from external sources.
  - Manages the procurement process to determine the suppliers who will provide safety-important goods or services, to monitor and audit the supply chain, and to control and accept the service or product it receives, in order to ensure the achievement of safety objectives.
- Graded approach
  - The procurement process management of the Owner includes the arrangements regarding the selection, evaluation, auditing and qualifications of the suppliers, which are determined by the graded approach to ensure the adequacy of the service or product to be procured.
- In-house competence
  - to determine the scope of all outsourced products and services and standards that they have to comply with and assess that the outsourced products and services satisfy the safety requirements
- Acceptance of equipment
  - Inspect the manufacturing process and carry out the acceptance of equipment

Equipment Procurement Process
Related Regulation

- Regulatory control of nuclear safety related equipment manufacturing and the authorization process of the manufacturers are carried out within the framework of the:

  «*Regulation Regarding Equipment Procurement Process And Approval Of Manufacturers For Nuclear Facilities - 2015*»

- The Regulatory control can be addressed in two main section
  - With regard to Manufacturers;
    - Approval of Manufacturers
      - Extension of validity of Approval
      - Expansion of scope of Approval
    - Inspection of Manufacturers
  - With regard to Licensee;
    - Procurement permit
    - Manufacturing Approval  Manufacturing Notification
    - Inspections during manufacturing

Equipment Procurement Process
Approval of manufacturers

- Manufacturers of equipment important to nuclear safety are required to obtain approval from the NDK
- Only manufacturers approved by the Authority in accordance with the Regulation can participate in the procurement process of equipment important to safety.

⇒ Regulatory decision on implementation - Graded approach

  - First tier manufacturers
  - Manufacturers of materials and semi finished products

- Information and guidance on the NDK website

Equipment Procurement Process
Approval of manufacturers: Application documents

Documents Required for Approval Application includes (Article 9 of Regulation)

- Manufacturer's Quality Management System Certificate and Turkish Accreditation Agency letter regarding to QMS Certificate
- Quality manual and related procedures of the manufacturer
  - which include organizational structure, duties, authorizations and responsibilities of divisions, competence and qualification requirements for technical personnel and arrangements regarding procurement management and control system,
- Equipment list requested to be within the scope of approval,
- A report which details
  - types, properties and safety classification of equipment that are in the list,
  - list of regulations, codes and standards used in the manufacture of these equipment,
  - if exists certificates and stamps, information on the facility where manufacturing will take place,
  - adequacy of the infrastructure of manufacturer within the scope of the work to be carried out,
  - production system including software and past experience and tools of the manufacturer.
- If exist, authorization certificates from other countries' regulatory authorities about related activities.

Equipment Procurement Process
Approval of manufacturers: Evaluation of the Application

- The application is evaluated
  - in terms of the ability of the manufacturers to carry out the activity they apply for approval
- In the first stage, documents sent by the manufacturer are subject to detailed evaluation.
- On-site examination is carried out at the manufacturer's facility Next page
- Final evaluation is made on the findings determined in these stages

Equipment Procurement Process
Approval of manufacturers: On-site Examination

On-site Examination

- The on-site examination is carried out at the manufacturer's premises
  - on an appropriate date agreed with the manufacturer
  - 4-5 days of examination
- During the on-site examination, plant/workshop visits are made and interviews with senior management and technical experts are conducted.
- Important points
  - Documentation of activities (procedures) and implemantation records
  - Nuclear-specific expectations

Equipment Procurement Process
Approval of manufacturers: On-site Examination

Some of the topics which consists the on-site examination scope:

- **Safety culture, graded approach, CFSI – Commitments, leadership, overriding priorty of safety; trainings, practices..**
- Organizational structure, role, responsibilities and internal and external (customer, supplier…) communication
- Design control, engineering and planning
- Purchasing and supplier evaluation
- Manufacturing (manufacturing process, control of input materials, manufacturing control, packaging, storage, labeling, transportation, traceability ...)
- Welding, non-destructive testing, heat treatment etc.
- Laboratories (tests, calibration of test items etc.)
- Quality management system and quality assurance (management review, process management, internal and external audit, nonconformity control, corrective actions, risk management, continuous improvement, maintenance and repair, archive, human resources, customer satisfaction)
- Project management

Equipment Procurement Process
Approval of manufacturers

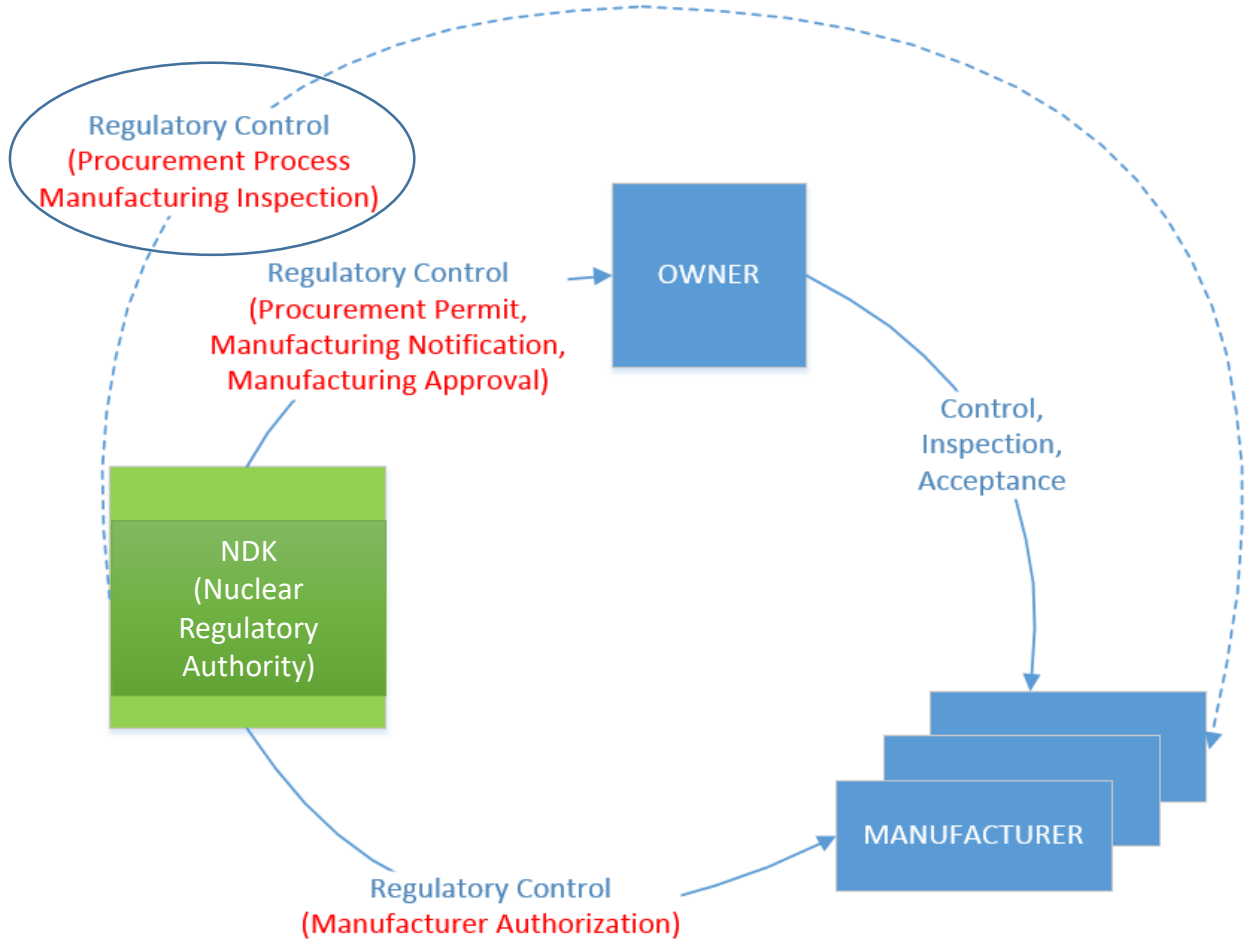
Finalization of Application assessment

- Any deficiency & non-conformity
  - Corrective actions & Update risks
- Sufficient application for approval
  - Manufacturer approval is given for a period of five (5) years
  - Approval is Project / Owner independent
- A total of 150 manufacturers have been granted manufacturer approval certificate.
- Nuclear safety inspections
  - During validity period of the approval certificate approved manufacturers are subject to inspections
  - During manufacturing process

Equipment Procurement Process

The process between the NDK, Licensee and the Manufacturer

The process figure indicates the regulatory control over Licensee and the Manufacturer



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THANK YOU

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Antalya