

REGULATORY CONTROL OVER MANUFACTURING

NUCLEAR SAFETY FORUM - II
Nuclear Regulatory Authority
Department of Nuclear Installations
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General Information & Legal Infrastructure

Regulatory Control over Manufacturing Highlights

- 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
 - Nuclear Regulatory Authority
 - Control through Owner
 - Control through Manufacturers
 - Other controls
 - By the Owner
 - By the Nuclear Construction Inspection Organizations authorized by the Authority

Legal Infrastructure – 1

Decree-law no. 702

- Decree-law no. 702 on 9 July 2018, nuclear regulatory body was established as Nuclear Regulatory Authority (NDK)
 - DL 702 contains provisions and requirements on general principles of safety, security and radiation protection
 - Authorizes NDK to regulate nuclear energy and ionizing radiation activities
 - Activities within the scope of the Decree Law cannot be carried out without authorization from NDK
 - The authorized persons are subject to the supervision of the Authority. The Authority may also inspect the contractor, subcontractor, supplier and sub-supplier of such persons

Legal Infrastructure – 2

Presidential Decree No:4

- The duties and responsibilities of NDK
 - The duties and responsibilities of NDK are defined on 15 July 2018 under “Presidential Decree on Organization of Institutions and Organizations Related, Affiliated and Associated with Ministries and Other Institutions and Organizations”, Presidential Decree No:4 (PD 4).
- Authorization required activities
 - Determination of the activities requiring authorization, approval, permission or license from the Authority

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Legal Infrastructure – 2

Presidential Decree No:4

- (1) The following are among the subjects that require authorization certificate or approval from the Authority:
 - ...
 - ...
 - ...
 - ç) Manufacturing and manufacturers of equipment specified by the Authority
 - d) Nuclear inspection organizations
- (2) Activities that require permission from the Authority include:
 - a) Preparation of the projected site for the construction of a nuclear installation, initiation of supply for the installation, performing the limited work before construction of the facility, construction of the installation, commissioning, decommissioning, re-start operation, performing changes related to safety and security in the installation.
 - ...
- (3) Activities to be licensed from the institution include:
 - a) To operate a nuclear installation, a radiation facility or a radioactive waste facility
 - b) To carry out radiation practices

Legal Infrastructure – 3

Regulation Regarding Equipment Manufacturing

- Regulation Regarding Equipment Procurement Process And Approval Of Manufacturers For Nuclear Facilities dated 2015
 - will be discussed in detail later in the presentation

Owner's Responsibility & Roles regarding Manufacturing

Regulatory Control over Manufacturing

Owner's Responsibility & Roles regarding Manufacturing

- Responsibility of SSCs
 - may supply design, manufacturing, etc. activities from suppliers as a service or product but the Owner is responsible for ensuring that the service or product provided is sufficient and in compliance with the legislation
 - bears the responsibility, in the context of safety and security, of all products or services procured from external sources
- Safety principles and quality standards
 - ensuring that structure, system and components and activities of the facility meet safety principles and quality standards
- Manages the procurement process
 - to identify suppliers particularly that will supply products or services important to safety, monitor and inspect the supply chain, and control and accept the service or product that it purchased
- Graded approach
 - to establish a system in direct proportion to the risks and hazards managed instead of requiring all suppliers to demand the same level of development

Regulatory Control over Manufacturing

Owner's Responsibility & Roles regarding Manufacturing

- Permit and approvals
 - to obtain procurement permit in order to initiate procurement process and
 - to submit the required manufacturing notifications and obtain manufacturing approvals
- 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
- Nuclear construction inspection organization
 - receive inspection services from the private legal entities authorized by the Authority for the inspection of the construction, manufacturing and installation processes of the structures, systems and components of the facility
- Acceptance of equipment
 - The Owner shall inspect the manufacturing process and carry out the acceptance of equipment

Regulatory Control over Manufacturing within the scope of main Regulation

Equipment Procurement Process

Main Regulation


- According to Article 787 of Paragraph 1 of the Presidential Decree no. 4
- 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»

Equipment Procurement Process

Scope of Regulation

The Regulation can be addressed in two main section

- With regard to Manufacturers;
 - Approval of Manufacturers
 - Extension of validity of Approval
 - Expansion of scope of Approval
- With regard to Owner;
 - Procurement permit
 - Manufacturing Approval  Manufacturing Notification

Equipment Procurement Process

Regarding to Manufacturers: 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. The Owner shall not sign contract with manufacturers which are not approved by the Authority.

 Regulatory decision on implementation - Graded approach

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

Equipment Procurement Process

Approval of manufacturers

ARTICLE 9 of Regulation - Documents Required for Approval Application includes

- Manufacturer's ISO 9001 Certificate or a Quality Management System Certificate
- Turkish Accreditation Agency letter regarding to Quality Management System 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 comprehensive evaluation of the application is carried out under Article 10 of the aforementioned Regulation. At this stage, documents sent by the manufacturer are subject to detailed evaluation.

The application is evaluated within thirty working days in terms of the ability of the manufacturers to carry out the activity they apply for approval, taking into account the information in the required documents.

On-site examination is carried out at the manufacturer's facility where the NDK deems it necessary. ➡ Detailed in next page

Equipment Procurement Process

Manufacturer: Approval of manufacturers

On-site Examination

- After the process of checking the application documents
- The on-site examination is carried out at the manufacturer's premises
 - on an appropriate date agreed with the manufacturer
 - within the time period and by the examination team determined within the scope of the application and the assessments made.
- During the on-site examination, field visits are made and interviews with senior management and technical experts are conducted.

Equipment Procurement Process

Approval of manufacturers

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

- Field visits
- General description of the manufacturer
- 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 incoming materials, manufacturing control, packaging, storage, labeling, transportation, traceability ...)
- Special processes (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
- Safety culture

Equipment Procurement Process

Approval of manufacturers

Finalization of Application assessment

- Detection of any deficiency & non-conformity as a result of the assessment or on-site examination
 - Preventive / corrective actions
- Sufficient application for approval as a result of the assessments, evaluations and on-site examination
 - Manufacturer approval is given for a period of five (5) years
 - Approval conditions including a list of equipment within the scope
 - Approval is Project / Owner independent
- Nuclear safety inspections
 - During validity period of the approval certificate approved manufacturers are subject to inspections

Equipment Procurement Process

Extension & Expansion of Approvals

Extension of validity of Approval

- Application at least two (2) months before end of approval period
- Different & changed documents from the originals
- 5 (five) years extension

Expansion of scope of approval

- Willing to change the approved equipment list
- new or updated documents related to equipment
- Not before 6 months prior to expire of approval

 A total of 43 manufacturers have been granted manufacturer approval certificate.

Equipment Procurement Process

Owner Stage 1: Permit for the procurement

- Application
 - Presenting the procurement management system documents and other necessary documents defined in the QMS
- Evaluation
 - Based on whether the procurement process is adequate (giving due consideration to nuclear safety) and clearly defined
- Permission
 - A procurement plan for each unit including equipment classifications before commencing procurement

➡ The permission was granted to Akkuyu Nuclear Company in 2015.


Equipment Procurement Process

Owner Stage 2: Manufacturing Notification

- Initiating the Manufacturing of the equipment
 - Manufacturing shall be initiated after limited work permit is obtained by the Owner.
 - However, manufacturing of equipment important to safety which has long procurement period may be initiated prior to this permit provided that the provisions of the Regulation are fulfilled. ➡ Next page
- If the permit for the procurement and the limited work permit exists
 - Owner notifies to the Authority at least two (2) months prior to manufacture for each equipment which is important to nuclear safety.
- The notification shall be supplemented with
 - the technical requirements, list of regulations, standards and guides to be applied to the manufacture process, copy of Manufacturer Approval Certificate, Quality plan approved by the Owner which is prepared by the manufacturer and the Accreditation certificate the test, examination and supervision organizations involved in equipment manufacturing process
- Next Step ➡ Manufacturing Inspections

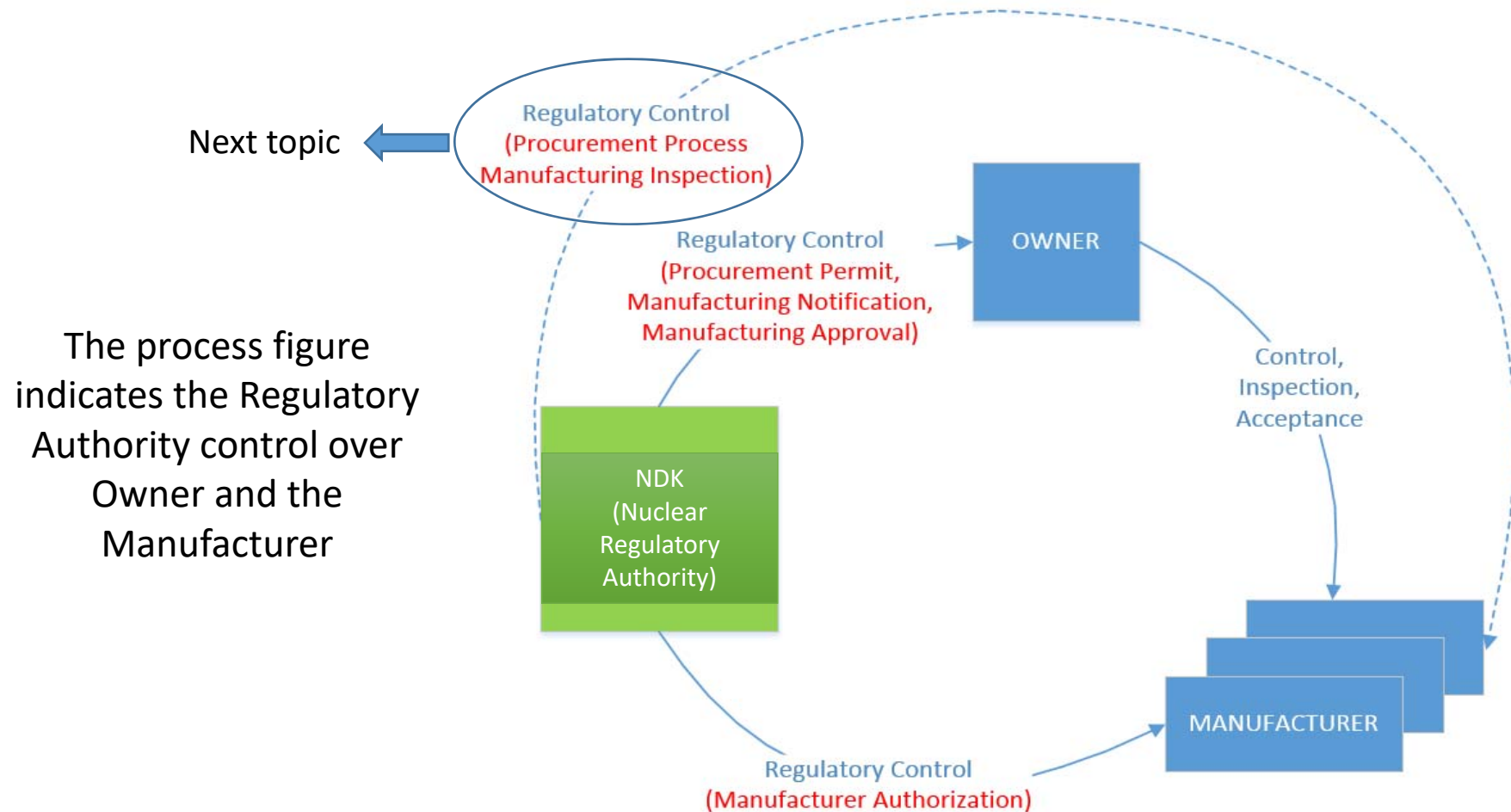
Equipment Procurement Process

Owner Stage 2: Manufacturing Approval

- For manufacturing of each equipment important to safety whose manufacture needs to start before obtaining limited work permit due to long procurement process
 - the Owner shall apply to the Authority to obtain manufacturing approval, instead of manufacturing notification.
- The Authority reviews documents with regard to design basis and safety functions adequateness.
- Next Step  Manufacturing Inspections

Equipment Procurement Process

The process between the NDK, Owner and the Manufacturer



THANK YOU

NUCLEAR SAFETY FORUM - II
Nuclear Regulatory Authority
Department of Nuclear Installations
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Ankara