REGULATION REGARDING EQUIPMENT PROCUREMENT PROCESS AND APPROVAL OF MANUFACTURERS FOR NUCLEAR FACILITIES

SECTION ONE
Purpose, Scope, Basis, Definitions and General Considerations

Purpose and scope

ARTICLE 1 – (1) The purpose of this Regulation is to establish the provisions for; the procurement process of all equipment used in nuclear facilities; the permit necessary to be obtained by the Owner to initiate the procurement process; documents to be submitted with the permit application; manufacturing notification; manufacturing approval and documents required for this approval; matters regarding approval of manufacturers taking part in the procurement process of equipment important to safety; as well as regulatory inspections and sanctions to be implemented in the procurement process.

(2) This regulation covers equipment manufacturers and the procurement process of equipment used in nuclear facilities.

Basis

ARTICLE 2 - **(1)** This regulation has been prepared based on the;

a) Subparagraph (e) of first paragraph of Article 4 of Turkish Atomic Energy Authority Act no 2690 dated 13/7/1982,

b) "Decree on Licensing of Nuclear Installations" dated 19/12/1983 and issued in the 18256 numbered Official Gazette.

Definitions

ARTICLE 3- (1) Within the context of this regulation:

a) Hold point means the stage in the work at which the progress of a particular work is stopped before or during implementation of this work as necessitated by such quality related activities as review, examination, control and verification, planned by the Owner and/or determined by the Authority.

b) Equipment means all systems and components constituting the nuclear facility,

c) Manufacturer: Legal person involved in the manufacturing of equipment important to safety and used in a nuclear facility,

d) Quality Management System: Management system needed to manage and control an organization in terms of quality,

e) Owner: Legal person recognized by the Authority to establish a nuclear facility.

f) Authority: Turkish Atomic Energy Authority,

g) Nuclear safety inspector means a person authorized and appointed to carry out nuclear safety inspections on behalf of the Authority in order to determine whether individuals authorized to carry out certain activities by the Authority fulfills relevant requirements and authorization conditions.

h) Nuclear safety inspections: Inspection activities carried out in nuclear installations from the beginning of site studies until the end of decommissioning, to provide high level of safety assurance that all activities are carried out safely and that nuclear safety objectives and related authorization conditions are met.

i) Equipment important to safety: Equipment, that the failure of which may cause exposure of site personnel or public to radiation exceeding the predetermined levels, or that prevents escalation of anticipated operational occurrences into accidents or mitigates accident consequences,

j) Nuclear facility: All types of facilities that produce, process, use, retain, reprocess or store nuclear materials in quantities where nuclear safety need to be taken into account by the decision of the Authority

Dated 28/05/2015 and issued in the 29369 numbered Official Gazette.

k) Witness point: The stage in the work at which inspectors from the Authority carry out observations by being present in the location physically to gain information during the work of quality activities of the Owner,

l) Procurement: All activities including purchase against remuneration or for free, manufacturing, verification on source, acceptance tests and factory assembly tests of a particular product.

m) Procurement management system: The system which includes management and inspection mechanism, organization, coordination and procedures ensuring the quality and adequacy of product or service during the procurement process of raw materials, finished or semi-finished goods, services etc.

n) Decree: "Decree on Licensing of Nuclear Facilities" published in the Official Gazette no:18256, dated 19/12/1983.

General considerations

ARTICLE 4 - (1) In order to initiate procurement process for equipment to be used in a nuclear facility, a permit for initiation of procurement shall be obtained in accordance with provisions of this Regulation.

(2) Manufacturing of the equipment, which is within the scope of this Regulation shall be initiated after limited work permit is obtained by the Owner in accordance with article 17 of the Decree. However, manufacturing of equipment important to safety which has long procurement period may be initiated prior to this permit provided that the provisions of this Regulation are fulfilled.

(3) To initiate manufacturing of equipment important to safety, manufacturing notification shall be submitted to the Authority. For equipment important to safety whose manufacturing is required to start before limited work permit due to long procurement process, manufacturing approval shall be obtained from the Authority.

(4) If deemed necessary, the Authority may participate in the manufacturing inspections and might demand required information and documents to carry out nuclear safety inspections for equipment other than those important to safety.

(5) the Owner need to have the construction license in order to use, and assemble the equipment during the construction of the facility.

(6) Only manufacturers approved by the Authority in accordance with this 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.

(7) The Authority, if deemed necessary, inspects manufacturers and their sub contractors taking part in the procurement process including the Owner.

(8) Application documents for approval, permit or notification in accordance with this Regulation shall either be original or notarized copy of original. . If the original document is not in Turkish or English, a Turkish or English translation made by a certified translator shall be submitted to the Authority together with the original document.

(9) By granting permits or approvals or carrying out inspections, the Authority shall not be held responsible for the actions of the Owner or approved manufacturers and shall not share their responsibilities.

SECTION TWO
Equipment Procurement Process

Procurement permit

ARTICLE 5 - (1) To obtain procurement permit, the Owner shall apply to the Authority with procurement system documents defined in the quality management system and bank receipt stating that service fee for procurement permit has been paid.

(2) The Authority assesses the application within thirty (30) working days with regard to whether the procurement process of the Owner is clearly and adequately defined or not. If

necessary, this period may be extended by the Authority and the extension is notified to the Owner in written form.

(3) As a result of the assessment of the Authority, if deficiencies, non-compliances or inadequacies are found in the submitted documents, additional information and documents may be requested from the Owner. The time required for the Owner to provide the requested information and documents is added to the evaluation time cited in the second paragraph.

(4) In case the application is deemed adequate, procurement permit is granted by the Authority. In the attachment of the procurement permit, permit conditions determined by the Authority are listed.

(5) Before initiation of procurement, the Owner which has the procurement permit shall notify to the Authority by submitting a procurement plan prepared on equipment basis as well as a list of equipment constituting each unit including their safety, quality and seismic classification.

Manufacturing notification

ARTICLE 6 – (1) The Owner shall submit a notification to the Authority for each equipment important to safety at least two (2) months before the manufacturing begins. A single notification may be submitted for more than one equipment.

(2) The notification shall be supplemented with:

a) The copies of the approved contract and technical requirements (the financial information may be omitted),

b) A list of regulations, codes and standards to be applied to the manufacture process and regulations and standards indicated in this list,

c) A copy of Manufacturer Approval Certificate which is obtained in accordance with the provisions of this Regulation,

d) Quality plan approved by the Owner which is prepared by the manufacturer and which also includes inspections to be implemented by the Owner on the equipment; and procedures as mentioned in the plan and all related documents such as examination and test plans.

e) The Accreditation certificate which shows that the test, examination and supervision organizations involved in equipment manufacturing process has been accredited by Turkish Accreditation Agency or national accreditation organizations listed in the Mutual Recognition Agreement of International Accreditation Forum.

(3) The Authority plans nuclear safety inspections including hold points and witness points of equipment manufacturing and notifies the Owner in ten (10) days about the plan. If necessary, this period may be extended by the Authority and this extension is notified to the Owner in written form.

Manufacturing approval

ARTICLE 7 – (1) 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. A joint application can be made for more than one equipment.

(2) Following documents shall be submitted with the application to the Authority for each equipment:

a) Documents required for manufacturing notification as defined in Article 6 paragraph 2,

b) Limiting conditions that determine the equipment design and the design basis consisting of numerical values of limiting conditions,

c) Design information indicating that the equipment is within the design basis,

d) A report that demonstrates the ability of equipment to fulfill its safety function.

(3) The Authority assesses the documents submitted with the application in three (3) months in terms of design basis regarding equipment and adequacy of safety functions. If necessary, this period may be extended by the Authority and this extension is notified to the Owner in written form.

(4) As a result of the assessment of the Authority, if deficiencies, non-compliances or inadequacies are found in the submitted documents, the Authority demands the Owner to eliminate the deficiencies or to provide additional information and documents. The time period that takes the Owner to eliminate deficiencies, non-compliances and inadequacies is added to the Authority's assessment period.

(5) As a result of the Authority's assessment, if deficiencies, non-compliances and inadequacies are not found or if the determined deficiencies, non-compliances and inadequacies have been resolved, manufacturing approval is granted. The Authority makes a written notification about nuclear safety inspection plans including hold points and witness points to the Owner in the attachment of the manufacturing approval.

(6) The assessment cited in the 3rd paragraph do not replace the assessment which will be carried out for Construction License and does not imply approval of the equipment design in any way.

Responsibilities of the Owner regarding procurement process

ARTICLE 8 – (1) The Owner shall obtain procurement permit in order to initiate procurement process and submits the required manufacturing notifications and obtains manufacturing approval.

(2) The Owner shall ensure that all measures are taken in manufacturing facilities to enable t manufacturing inspections to be conducted as planned by the Authority and shall ensure that the manufacturer incorporates the information on nuclear safety inspection plans of the Authority to its manufacturing plan.

(3) The Owner shall approve all design drawings constituting the basis for manufacturing of each equipment and shall keep a copy of them in the nuclear facility site. Additionally, the Owner shall ensure that all necessary documents and records regarding procurement process of each equipment are prepared and shall keep these documents and records in the nuclear facility site or in the headquarter of the Owner until the nuclear facility is released from regulatory control. These documents and records shall be open to access and inspection of the Authority and shall be presented to the Authority when requested.

(4) The Owner shall ensure that ability of equipment to fulfill its safety functions within the determined design limits is controlled and guaranteed by means of analyses, assessments or tests.

(5) During the manufacturing process, the Owner shall ensure that the equipment is manufactured in compliance with its design by means of all necessary controls and inspections.

(6) During procurement process, the Owner shall include a provision in the contracts stating that manufacturers and their subcontractors agree to the inspection rights of the Authority.

(7) The Owner shall inspect the manufacturing process and carry out the acceptance of equipment. The Authority does not participate in this acceptance process but may participate as observer if it deems necessary.

(8) The Owner shall require its manufacturers and their subcontractors to have a certified quality management system.

(9) In selection of test, examination and supervision organizations, the Owner shall consider conditions that the organization has no corporate relation with the equipment manufacturers and designers and that the organization has a certified quality management system, similar work experience and adequate number of qualified expert staff.

(10) Following documents are, as a minimum, records and documents that are obligatory to be kept by the Owner for each equipment regarding the procurement process:

a) Final design documentation including as-built technical drawings,

b) Conformity certificates,

c) Inspection and test results,

d) Non-conformity reports and corrective action reports,

e) Procurement records,

f) Storage, transportation, installation and testing instructions,

g) Operation and maintenance manuals,

h) Operation limits and conditions,

(11) If any of the records and documents cited in the previous paragraph is not applicable to the equipment, it may be omitted provided that the omission is justified and the Authority finds this justification acceptable.

SECTION THREE
Approval of manufacturers

Documents required for application regarding approval of manufacturers

ARTICLE 9 – (1) Manufacturers who are willing to take part in the equipment procurement process shall obtain approval from the Authority. In order to obtain the approval, manufacturers shall apply to the Authority with a petition that includes the documents listed below. The Authority may demand additional documents from the manufacturers if necessary.

a) Official documents indicating that the manufacturer conducts active and registered commercial activities,

b) Documents indicating persons authorized to represent the organization and statement of signature or signature circulars of these persons,

c) Manufacturer's ISO 9001 Certificate or a Quality Management System Certificate which is valid on the international level,

d) A document taken from Turkish Accreditation Agency certifying that the quality management system document of the manufacturer has been given by a certification agency that is either accredited by Turkish Accreditation Agency or by an accreditation agency which is present in the Mutual Treaty of International Accreditation Forum,

e) 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,

f) Equipment list requested to be within the scope of approval,

g) A report detailing 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.

h) Bank receipt of authorization fee,

i) If exist, authorization certificates from other countries' regulatory authorities about related activities.

Application Assessment

ARTICLE 10 – (1) Application is assessed in thirty (30) working days with regard to adequacy of the manufacturer to carry out the activity for which application has been made considering the information in the application documents. If necessary, this period may be extended by the Authority and this extension is notified to the Owner in written form. During application assessment stage, the authority, if deemed necessary, may conduct on-site audits or inspections. When any deficiency, non-compliance or inadequacy is found as a result of assessment or inspection, the applicant manufacturer is demanded to resolve the issue within a given time specified by the Authority. If the issue is not resolved at the end of this period, an extension may be granted upon the request of manufacturer. At the end of this process, if the issue is not resolved, the application is denied and the application fee is not returned.

Manufacturer Approval Certificate

ARTICLE 11 – (1) After review and assessment carried out by the Authority, manufacturer approval certificate is provided to the manufacturer whose application is found to be adequate for approval.

(2) Manufacturer approval is granted for a five (5) year term.

(3) Approval conditions including a list of equipment within the scope of the approval is given to the Owner as complementary attachment to the manufacturer approval certificate.

Extension of validity of Approval

ARTICLE 12 – (1) Approved manufacturers willing to validity of their certificate at the end of approval period shall apply to the Authority with petition and bank receipt at least two (2) months before end of approval period. If any application document is different from the original s, manufacturers shall attach the updated documents to the renewal application.

(2) Manufacturer approval certificate's validity is extended for 5 (five) years if the application has been found to be adequate. Applications, which are found to be inadequate are denied and the authorization fee is not returned.

(3) Manufacturers, which did not apply for extension before the end of validity period, lose their right to extension and shall reapply in accordance with the provisions of this regulation.

Expansion of scope of approval

ARTICLE 13 – (1) Approved manufacturers willing to change the approved equipment list, shall submit to the Authority an application with the following documents:

a) All documents of cited in Article 9, that need to be updated with change in the scope of equipment, From the documents cited in Article 9, those required to be renewed and/or added for equipment asked to be included in the approved scope,

b) Bank receipt of the authorization fee,

(2) Manufacturers with an approval certificate that needs extension within 6 months, cannot apply for expansion of scope

(3) Application for scope expansion is assessed by the Authority in thirty (30) working days. If needed, this period can be extended and this extension is notified to the Owner in written form.

(4) After review and assessment, if the application is found to be inadequate, or if for some other reason approval certificate loses its validity during the assessment, application is denied and the service fee is not returned.

(5) For applications, found to be adequate as a result of review and assessment , scope of approval is expanded by the Authority

Responsibility of approved manufacturers

ARTİCLE 14 – (1) Approved manufacturers are responsible for the quality of its work and product and/or ensuring efficiency of the quality management system related to manufacturing activities. However, this responsibility does not eliminate or reduce the responsibility of the Owner.

(2) Approved manufacturers shall comply with approval conditions during the validity period of approval.

(3) Approved manufacturers shall take all measures to ensure Authority's inspections to be conducted as it was planned without a delay in the related facilities.

(4) Approved manufacturers shall notify the Authority about all organizational and infrastructural changes that may require amendment to the approval conditions.

(5) Approved manufacturers shall keep all records and reports regarding the activities which are within the scope of this regulation during validity period of the approval.

SECTION FOUR
Inspections and Sanctions

Inspections

ARTICLE 15 – (1) The Authority performs nuclear safety inspections related to equipment manufacturing under the provisions of "The Regulation of Nuclear Safety Inspections and Enforcement" published in Official Gazette no: 26642, dated 13/09/2007.

(2) To conduct inspections, the Authority sends nuclear safety inspectors to the Owner and manufacturers; and if necessary, to test, examination and supervision organizations. Staff of consultancy organizations of the Authority may also attend inspections.

(3) To conduct inspections of the Authority which are stated in inspection plan of the Authority and in hold and witness points determined by the Authority in submitted related quality plan, the Owner shall notify the Authority with an official letter at least fifteen (15) working days before start of related activity.

(4) To conduct nuclear safety inspections, an English and, if exists, a Turkish copy of the required documents shall be made available at the inspection point by the Owner or manufacturer.

(5) To conduct inspections without delay and to provide required communication, the Owner shall provide during the inspections an interpreter or staff having the ability to interpret spoken language to English or Turkish .

(6) Approved manufacturers are subject to nuclear safety inspections during validity period of the approval certificate. While performing their duties, nuclear safety inspectors have a right to access to the relevant documents, records, persons and facilities which are in the scope of approved activities.

Sanctions

ARTICLE 16 – (1) In the frame of violations of provisions of this Regulation, the Authority takes into consideration importance, urgency and severity of the violation in terms of nuclear safety to decide executive sanctions.

(2) During implementation of activities related to the nuclear facility by the Owner or approved manufacturer;

a) If it is understood that the Owner or the approved manufacturer no longer meets one or more than one conditions of the Regulation,

b) If non-compliances or deviations are found in evaluations and inspections,

a specified time period is given to the Owner or manufacturer to resolve the issue. If the issue is not resolved with corrective and preventive actions within this time period determined by the Authority, approval and permits given within the scope of related activity to the manufacturer or the Owner shall be revoked.

(3) During regulatory inspections, if the approved manufacturer or the Owner does not cooperate, does not give information and documents demanded or if it is found that the approved manufacturer or the Owner falsify documents or gives wrong information, the Authority may revoke the approval or permit.

(4) If approval or permit is revoked by the Authority for reasons cited in the second and third paragraphs, no application can be submitted by the Owner or the approved manufacturer on the same matter within two (2) months after the date the approval or permit is revoked.

SECTION FIVE
Miscellaneous and Final Provisions

PROVISIONAL ARTICLE 1 – (1) If the procurement process has already been started by the Owner on the date this Regulation enters into force, all documents necessary for issuing permit for initiation of procurement will be submitted to the Authority within three (3) months after this Regulation enters into force and responsibilities specified in Article 8 of this Regulation shall be fulfilled by the Owner.

(2) If procurement process of a particular equipment has already been initiated by the Owner when this Regulation enters into force, manufacturer of this equipment shall obtain manufacturer approval certificate within two (2) years after this regulation enters into force.

Dated 28/05/2015 and issued in the 29369 numbered Official Gazette.

(3) Within two (2) years after this Regulation enters into force, the Authority reserves the right to find equipment, which is produced by manufacturers not having the manufacturer approval certificate, inadequate.

Enactment

ARTICLE 17- (1) This regulation enters into force on the date of its publication in the Official Gazette.

Implementation

ARTICLE 18- (1) The provisions of this regulation are implemented by the President of the Authority.

Dated 28/05/2015 and issued in the 29369 numbered Official Gazette.