RULEBOOK ON THE PERFORMANCE OF NUCLEAR ACTIVITIES

GENERAL PROVISIONS

Article 1

This rulebook regulates and governs the following matters:

1. Methods and deadlines for the submission of regular reports about the operation of nuclear facilities;
2. Conditions that must be fulfilled by persons who are professionally qualified to handle nuclear materials;
3. Method, types and frequency of control of measures defined in the integral quality management system for the performance of nuclear activities.

Article 2

Single expressions used herein shall have the following meaning:

1. *Traffic of nuclear materials* means the procurement, sales, import, export, transit and any other form of placing on the market of such materials;
2. *Use of nuclear materials* means the possession, production and storage of such materials, as well as operation with nuclear materials;
3. *Emergency* means any unintended event by the operator, including mistakes during operation, failures of equipment and accidents, as well as intentional activities by third parties, whose consequences or possible consequences are not negligible in the sense of protection and safety. The meaning of an emergency in the sense of consequences that can be caused is defined by International scale of nuclear and radiological events *INES* (*International Nuclear Event Scale*).

Article 3

The holder of the licence for the performance of nuclear activities (hereinafter licence holder) shall provide adequate financial assets to assure the conditions for nuclear safety when performing nuclear activities.

The licence holder shall provide a sufficient number of qualified staff with the corresponding level of education, training and additional training for all activities related to the safety of the nuclear facility and nuclear activities.

The licence holder shall provide adequate measures to ensure that human possibilities and limitations are taken into account for the entire time of operation of the nuclear facility and performance of nuclear activities.

Article 4

The licence holder shall take adequate measures to ensure that during all operations the exposure to ionizing radiation of employees and population is as

low as it is objectively achievable, so that it does not come to exposure that will exceed the permitted limits.

Article 5

The licence holder shall prepare Action Plan for the case of an emergency in the nuclear facility and during the performance of nuclear activities, which is the subject to periodical reviews and shall encompass all activities that must be executed in case of an emergency.

For new nuclear facilities, the plan referred to in paragraph 1 of this Article must be prepared and tested before the beginning of operation and approved by the Serbian Radiation Protection and Nuclear Safety Agency (hereinafter: Agency).

The licence holder must ensure that the population living in the surroundings of the nuclear facility is adequately informed about the activities and course of actions in case of an emergency in the nuclear facility.

Article 6

The license holder shall ensure that the license to operate the nuclear facility is based on appropriate safety analyses and operating programmes which prove that the facility's construction is compliant with the design and safety requirements.

The licence holder shall ensure that the following criteria are met:

1. Limitations and conditions derived from safety analyses, checks and working experience must be defined and revised for the need to identify safety limits during operation;
2. The operation, maintenance, inspection and control of the nuclear facility must be performed in accordance with approved procedures;
3. Response procedures must be established for events for which it is assumed that they could occur during regular operation as well as in emergencies;
4. All and any emergency that is important for the safety must be reported to the Agency within the legally stipulated period of time;
5. The radioactive waste generated during the performance of nuclear activities is reduced to the minimum, both in respect of the activities, as well as in respect of the volume, and procedures necessary for the treatment and storage of spent fuel and radioactive waste obtained from nuclear activities and located at the location of the nuclear facility must take into account the requirements for conditioning and disposal.

The license holder shall provide the necessary engineering and technical support in all areas important for nuclear safety during the performance of nuclear activities.

The license holder shall prepare a Programme for gathering and analysis of operational experience and ensure that the results are available and that the derived conclusions can be used in the exchange of experiences with other license holders, the Agency and international bodies and organizations.

TRAFFIC AND USE OF NUCLEAR MATERIAL

Article 7

Only the holder of the licence for the performance of nuclear activities (hereinafter: licence holder) can engage in the traffic and use of nuclear material.

The licence holder shall obtain a permit from the Agency for individual traffic of nuclear material.

At the request of the licence holder, the Agency shall issue the decision on the use of nuclear material.

The licence holder shall provide control of the stipulated conditions for the traffic and use of nuclear material and shall in a general act regulate the execution of such control, in particular the following:

1. Method of control;
2. Plan of the dosimetric supervision;
3. Action plan in case of emergencies in the traffic of nuclear material.

Article 8

The licence holder shall provide special storage and packaging for nuclear materials, which will assure the security of nuclear material, the protection of life and health of human beings and environmental protection.

Storage of nuclear materials, as well as their packaging, are constructed and maintained in accordance with the regulations and standards of the Republic of Serbia, technical regulations, recommendations and safety and security standards of the IAEA, as well as quality standards for products and services.

Article 9

The transport of nuclear materials is carried out in accordance with the regulations governing the transport of dangerous goods and international conventions and agreements on the transport of dangerous goods.

CONDITIONS THAT MUST BE FULFILLED BY PERSONS WHO WORK WITH NUCLEAR MATERIALS

Article 10

Nuclear materials on the market can be handled only by individuals who have at least completed secondary education in schools with electrical or mechanical engineering or chemistry orientation and two years of working experience, and are professionally trained for these tasks.

Article 11

Persons whose positions include tasks and duties of managing the operating process in the nuclear facility must fulfil the following requirements:

1. for tasks and duties of managing the research nuclear reactor, a university degree with a major in technical or mathematical/natural sciences is needed, as well as eight years of working experience, whereof at least five years on tasks in the research nuclear reactor;

2. for tasks and duties of managing the maintenance of technological, mechanical and electrical systems of the research nuclear reactor, managing shifts in the facility and tasks and duties of the research nuclear reactor operator a university degree with a major in technical or mathematical/natural sciences is needed, as well as five years of working experience, whereof at least three on tasks and duties in the research nuclear reactor;

3. for tasks and duties of managing the RAW management facility and managing the maintenance of technological, mechanical and electrical systems in the RAW management facility a university degree with a major in technical or mathematical/natural sciences is needed, as well as five years of working experience, whereof at least three in the nuclear facility.

Article 12

Persons who work in positions including tasks and duties of supervision of the operating process in the nuclear facility must fulfil the following conditions:

1. for tasks and duties of managing the radiation protection service in the nuclear facility a university degree with a major in technical or natural/mathematical sciences is needed, as well as five years of working experience, whereof at least three in the nuclear facility;

2. for tasks and duties of dosimetry in the nuclear facility employees must have secondary education degree from schools with electrical-technical, physical or chemical orientation and four years of working experience, whereof at least two in the nuclear facility.

Article 13

Persons who work in positions of executants in the operating process in the nuclear facility (hereinafter executants) must have at least completed secondary education in schools with electrical and mechanical, traffic or chemical orientation and two years of working experience, whereof at least one in a nuclear facility.

Article 14

Employed persons who perform jobs referred to in Articles 10, 11, 12 and 13 herein (hereinafter: employees) must be psychically and physically fit to perform these tasks and duties in accordance with the regulations governing this field.

PLAN AND PROGRAMME OF PROFESSIONAL TRAINING

Article 15

The licence holder is responsible for the professional training of employees.

The professional training of employees is done in compliance with the Professional Training Programme.

The Programme referred to in paragraph 2 of this Article encompasses experience from one's own practice, advice and experience of technology suppliers, standards and recommendations of the IAEA and of other international organisations dealing with nuclear energy and nuclear safety.

The programme must be renewed at the latest every four years, and it is necessary to provide the compliance of the programme with all amendments to regulations and standards that refer to the operation and maintenance of the nuclear facility.

The professional training programme and its amendments must be approved by the Agency.

Article 16

The Framework annual plan of professional training of employees is submitted by the licence holder to the Agency for consideration and adoption at least one month before the beginning of the calendar year. The framework annual plan of professional training must contain the following:

1. Number of employees for which professional training needs to be organised and the type of course;
2. Plan of courses per quarter.

Professional training of employees is done with basic courses and courses for knowledge renewal.

The licence holder shall provide basic courses to individuals who conclude an employment relationship for the first time for positions referred to in Articles 10, 11, 12 and 13 herein, whereby the basic course must be organised at the latest 3 months from the date when the employment relationship started.

Article 17

Upon completion of the basic training course and course for the knowledge renewal the employees must pass a qualification test (hereinafter: test).

The assessment of the test results for every employee is done by a commission consisting of four members. Two members are proposed by the licence holder and two are representatives of the Agency.

The grades in the test are "passed" and "failed". The grade "passed" is obtained by an employee who had more than 80% correct answers in the professional qualification test.

For the employee who got the grade "failed" after a completed basic course the commission will determine a new test date. However, this date cannot be before the expiry of three months from the date of the unsuccessful professional qualification check.

For the employee who got the grade "failed" after the completed course for knowledge renewal the commission will determine a new test date. However, this date cannot be before the expiry of one month from the date of the unsuccessful professional qualification check.

The employee who failed the test after the completed basic course or course for knowledge renewal can only move, load, unload and store materials under the supervision of professionally qualified persons, provided that he was previously made familiar with the method of such work, with dangers and with protection measures.

Article 18

The professional training programme for persons working with nuclear materials in traffic contains the following:

1. Basic principles of nuclear safety;
2. Instructions for normal operation and instructions for undertaking measures in emergencies;
3. Regulations for the protection from ionizing radiation.

Article 19

The pprofessional training programme for individuals who perform tasks and duties of managing the research nuclear reactor, managing the shift operating of the research nuclear reactor, managing the radiation protection service in the research nuclear reactor contains the following:

1. IAEA Safety Standards for the management of the research nuclear reactor;
2. Basics of the nuclear reactors' theory;
3. Basics of the nuclear reactors' technology;
4. Management of the nuclear reactor;
5. Procedures for handling the nuclear fuel of the reactor;
6. Procedures for RAW management;
7. Basics of the radiological risk assessment theory;
8. Instructions for procedures, working conditions and limits in normal procedure;
9. Action plan in case of accidents and in case of natural, nuclear and other large accidents, as well as in the case of war;
10. Integral system for quality management.

The professional training programme for persons who will perform tasks and duties of managing the maintenance of technological, mechanical and electrical systems of the research nuclear reactor, tasks and duties of operator of the research nuclear reactor and executant in the operating process contains:

1. Principles of the nuclear reactor functioning;
2. Basic principles of nuclear safety;
3. Instruments and management systems;
4. Components of the technological, mechanical and electrical systems of the nuclear reactor;
5. Instructions for normal operation and for taking measures in emergencies;
6. Procedures and regulations for the protection against ionizing radiation;
7. RAW management procedures;
8. Integral system for quality management.

The programmes referred to in paragraph 1 and 2 in this Article contain also practical training in the research nuclear reactor or its simulator.

Article 20

The professional training programme for persons who are to manage facilities for RAW management, manage the maintenance of technological, mechanical and electrical systems in facilities for RAW management, manage the radiation protection service in RAW management facilities and executants in the operating process in RAW management facilities shall contain:

1. IAEA standards for RAW management;
2. RAW treatment procedures;
3. Designed properties of the facility and its characteristics in the function of time during the use and after closure;
4. Instruments and supervision methods;
5. Instructions for normal operation and for actions in the case of accidental situations;
6. Procedures and regulations for radiation protection;
7. Procedures and regulations for radiological and nuclear safety;
8. Instructions in case of emergencies;
9. Integral system for quality management.

Article 21

The licence holder shall provide a periodic renewal of knowledge for persons performing tasks and duties referred to in Articles 10, 11, 12 and 13 herein once a year.

Article 22

The licence holder shall keep records of the professional training of employees. The records shall contain the following data:
1. Name and surname;
2. Unique master number of the citizen;
3. Date and place of birth;
4. Level of education and profession;
5. Date of start of employment in positions referred to in Articles 10, 11, 12 and 13 herein;
6. Date of completion, number of the diploma certificate and institution that issued the Diploma on additional training for the implementation of radiation protection measures;
7. Date of completion of the basic course, date when the test was done and grade obtained;
8. Date of completion of every subsequent course for knowledge renewal, date of test and grade obtained.

The licence holder shall submit the data about his employees to the Agency at the latest 15 days from the date when the change occurred. A change shall mean the following:
1. Conclusion of an employment relationship for positions referred to in Articles 10, 11, 12 and 13 herein;
2. Cessation of the employment relationship for positions referred to in Articles 10, 11, 12 and 13 herein;
3. Ban to perform tasks and duties relevant for nuclear safety and security.

ASSESSMENT OF THE NUCLEAR FACILITY'S SAFETY

Article 23

The nuclear facility has an acceptable level of safety, if it fulfils the following criteria:

1. Level of exposure to ionizing radiation of all persons in the facility, in all operating states of that facility is compliant with regulations about the radiation protection;

2. Level of exposure to ionizing radiation of individuals in the surroundings of the nuclear facility, due to regular operating discharges of radioactive effluents from the nuclear facility, is less than 1% of the value of the stipulated dose limit for an individual from the population;

3. Designed nuclear safety measures ensure that the probability of occurrence of a serious damage to the reactor core in existing nuclear facilities with a reactor is less than 1E-04 per year of operation of the nuclear facility;

4. In case of an emergency, with the probability of occurring once in the lifetime of the nuclear facility, the maximum dose for an individual is less than 5 mSv for the entire body and less than 30 mSv for the thyroid gland, and the collective dose is less than 1E-02 per man Sv, whereby the minimum dose value to which integration is performed is 0.05 mSv;

5. In case of an emergency, with the probability of occurring less than 1E-04 per year of operation of the nuclear facility, the maximum dose for an individual from the population is less than 0.25 Sv for the whole body and less than 2.5 Sv for the thyroid gland, and the collective dose is less than 1E-04 per man Sv, whereby the minimum value of dose up to which integration is done is 5 mSv.

The fulfilment of the criteria referred to in paragraph 1 in this Article is assessed based on the report on nuclear safety and other stipulated documentation, in accordance with IAEA standards.

INTEGRATED QUALITY MANAGEMENT SYSTEM

Article 24

The methodology for the development of quality assurance programmes for nuclear facilities is provided in Appendix 1 herein.

The Programme for the control of measures of the integrated quality management system may include one or more checks depending on the size, nature and complexity of the organization under review. These checks may have several objectives, and may include joint or combined tests.

Two or more organizations that perform the test can collaborate by performing joint tests as part of their testing programme.

The programme for the control of measures shall contain the following:

1. A series of internal checks encompassing the integrated quality management system in the entire organisation that performs nuclear activities, which are performed over the entire year;

2. Checks of potential suppliers of critical products (material and equipment for the construction and maintenance of the nuclear facility that must correspond in their quality to stipulated standards, technical norms, i.e. quality norms; the quality of services in the construction and maintenance of these facilities must also correspond to the stipulated norms), whereby the deadline for checks is 6 months before the mounting of such products;

3. Checks via a third party, implemented by the certification/registration body in order to certify/register and supervise the integrated system for quality management within the deadline foreseen in the agreement between the certification body and the orderer;

4. Extraordinary checks by the Agency and IAEA.

Records of the programme for the control of measures must be kept.

REPORTS ON THE PERFORMANCE OF NUCLEAR ACTIVITIES

Article 25

The holder of the licence for the performance of nuclear activities shall submit a report on operations to the Agency once a year, by the 1st March of the current year for the previous year.

The form and contents of the report referred to in the previous paragraph are defined in the safety report for the nuclear activity and approved with a licence by the Agency.

In case of violation of the operational conditions and limitations determined in the licence for the nuclear activity, or in case of an emergency the licence holder shall notify the Agency about the event without delay and shall submit an accident report to the Agency within 15 days from the event.

Article 26

The Agency may require from the licence holder to be notified of an emergency immediately and also to receive a report immediately.

The form and the contents of the report referred to in the previous paragraph are defined in the safety report.

The Agency may in extraordinary cases, when there is a doubt that there are deviations from the conditions defined in the licence, request a report from the licence holder about the conditions to which this doubt refers.

TRANSITORY AND FINAL PROVISIONS

Article 27

This rulebook shall enter into force on the eighth day from the date of its publishing in the "Official Gazette of the Republic of Serbia".

APPENDIX 1

METHODOLOGY FOR THE DRAWING UP OF THE QUALITY ASSURANCE PROGRAMME FOR NUCLEAR FACILITIES

Purpose and scope of the methodology

This regulation determines the principles, objectives and method for the drawing up of the quality assurance programme and for its implementation during preparatory works, project design, production, construction, putting into operation and during the operation of the facility, of system and components that are of importance for the safety of the nuclear facility. The quality assurance programme is applied to all activities affecting the quality, such as: study and research works, project and design planning, construction, handling and transport, storage, cleaning, assembly, testing, putting into operation, operation, inspection, maintenance, modifications, change of fuel and permanent cessation of operation of the nuclear facility. The quality assurance programme must be applied by all participants in the construction and use of the nuclear facility: architects, suppliers, contractors, operators and other legal entities and physical persons who participate in activities that affect the quality.

The user of the nuclear facility is responsible for the whole nuclear facility, as well as for the definition and implementation of the quality assurance programme. The user of the nuclear facility may assign to other organisations the task of determining and implementing the complete or part of the quality assurance programme, but he remains responsible for the realisation of the entire programme.

Quality assurance programme

The quality assurance programme is defined in accordance with the requirements defined in this regulation and is an integral part of the project of the nuclear facility. The programme must provide for the control of all activities that are related to the nuclear facility.

The quality assurance programme consists of the quality assurance plan and programme procedures that must be approved of accordingly. The plan defines the requirements, and the procedures and method to satisfy the requirements.

The management must provide for an efficient implementation of the quality assurance programme, compliant to time plans for the performance of activities related to the project, including here also the procurement of materials.

The programme must determine the organisational structure within which quality assurance activities are planned and implemented and also it must clearly designate the responsibilities and authorities of the staff and legal entities engaged in the project.

When determining the programme the technical aspects of the performed activities must be considered. The programme must contain items that ensure the identification and harmonization with technical regulations, standards, specifications and recognised practice.

Components, services and processes must be defined to which the quality assurance programme will be applied, but also adequate methods or degree of supervision and check for these components, services and processes. The programme must foresee the supervision and check of activities that influence the quality of components of services and processes, in the scope that is compliant with the level of importance of these activities for the safety of the nuclear facility.

The programme must also provide for the professional training of persons who perform activities that affect the quality.

In the programme the languages used in the documentation must be stated. Further, measures must be defined to ensure that the persons performing the quality assurance functions have good knowledge of the language in which the documentation is written. Translations of the documentation must be checked by competent persons. A verification of the translation's compliance with the original is necessary.

The programme must also ensure that activities affecting the quality are performed in accordance with written procedures, instructions and drawings. Instructions, procedures and drawings must encompass the adequate qualitative and quantitative acceptance criteria.

The procedures for the implementation of the quality assurance programme on planned and systemic basis for different stages of the project for the nuclear facility must be developed and documented by the legal person that is conducting these activities. The procedures must be checked and improved on a recurrent basis.

The management of the legal person responsible for the implementation of the programme must in certain intervals check the state and appropriateness of the parts of the programme for which it is responsible. Corrective actions must be taken within 30 days from the date when shortcomings in the programme were detected.

Organisation

A documented organisational structure must be established with clearly defined functional responsibilities, levels of responsibilities and lines for interior and exterior communications in relation to the management, guidance and execution of the quality assurance programme.

The organisational structure and divisions of tasks and duties must ensure the following:

1. Contractors must be responsible for their works, as well as for the achievement of the required quality;
2. The check of the harmonization of the required and achieved quality of works cannot be done by persons who are responsible for the execution of the works.

The authority and duties of legal entities and physical persons who are responsible for the implementation and check of the quality assurance programme, as well as for the implementation of other activities that influence the safety must be defined in writing. Physical persons and legal entities and organisations that implement tasks related to quality assurance must have sufficient authorities and organisational freedom to determine the problems and to initiate, propose or implement a solution. These physical persons, legal entities and organisations are competent for introducing supervising actions for the further processing, delivery or assembly of some component with shortcomings or component that does not satisfy the set criteria, until its adequacy is established.

Persons responsible for the efficient execution of any part of the quality assurance programme, regardless of the organisational structure, must have direct access to such levels of management that are needed for efficient quality assurance.

If there are contracts between several legal entities, the responsibility of each and every legal person must be clearly determined and the links and coordination between them must be secured with the help of corresponding measures. Communication must be established between the legal person and organisational groups that participate in activities that affect the quality. The transfer of basic information must be secured via corresponding documentation. The types of documents must be identified and a list for their distribution must be formed.

Plans must be drawn up for the selection and training of persons who carry out activities that influence the quality. Hereby, the plan of project activities must be respected in order to secure enough time for the selection, appointment and training of a necessary number of such persons.

Persons responsible for the carrying out of activities that affect the quality must be qualified based on their regular education, as well as based on their experience and expertise that is required for specific tasks. The programme and manner of education must be determined in such a way to secure that adequate expertise is achieved and maintained. The achievement and maintenance of expertise must be proved with a corresponding certificate in writing.

Control of documentation

The drawing up, review, approval and issuance of documents that are of importance for the execution and checks of works, such as instructions, procedures and drawings must be supervised.

Supervisory measures must include the identification of all physical persons or legal entities that are responsible for the drawing up, review, approval and issuance of documents that refer to activities which affect the quality. The legal person or physical person who performs the review and gives approval must have access to corresponding information on which the review or approval are based.

The system of issuance and distribution of documents must be determined by using the newest distribution list. Measures must be taken to ensure that participants will get familiar with the activities and use proper documents to implement these.

Amendments to documents must be reviewed and approved of in accordance with the documented procedure. For the documents' review, legal entities must have access to adequate information based on which approvals are issued, as well as adequate knowledge about the requests and intention of the original document. Changes to documents must be reviewed and approved by the legal entities that performed the review and gave the approval to the original document or other legal entities that were specially appointed to do this task. All individuals and legal entities to which the document refers must be timely informed about the review of the document and its actual status.

Control of the project planning

Measures of control must be determined and documented to secure that specified project requirements – stipulated conditions, project bases, regulations and standards – are properly transferred into the specifications, drawings, procedures or instructions. These measures must include provisions that will secure that levels of quality are specified and mentioned in the project documents.

Changes and deviations from the specified project requirements and levels of quality must be supervised. Also measures must be defined for the selection and review of all materials, parts, equipment and process that are important for the functioning of the system, component or construction.

Measures for the control of the project must be applied to items such as: protection against ionizing radiation, analysis of physical properties and stress (thermal, hydraulic, seismic), analysis of emergencies, compatibility of materials, accessibility for inspection during operation, maintenance and repair, depiction of acceptance criteria for the inspection and tests.

The project activities must be documented in order to enable them to be checked by professionals who are not included in the development of the original project.

Exterior and interior cooperation between organisations and organisational units that are working on the project must be documented in writing. The responsibility for every legal person and organisational unit must be defined in sufficient detail to encompass the preparation, review, approval, distribution and review of documents that include cooperation.

Methods must be determined for the exchange of project information, including changes, through the cooperation on the project. The exchange of information must be documented and supervised.

The measures of control of the project must secure the check of its adequacy (the review of the project, use of alternative calculation methods or execution of the adequate testing programme). The check of the project must be done by persons or groups who are not working on the original project. The checking methods must be determined by the responsible legal person, and the results of the check must be documented in the specified scope.

The programme of checking the adequacy of specific project characteristics must encompass the qualified testing of the prototype in most adverse conditions for specific project characteristics that are being checked. If this is not possible, the testing can be done under other conditions if the results can be transferred to the most adverse project conditions and if the adequacy for the specific project characteristics can be checked in that way.

A documented procedure must be secured for the implementation of project changes, including changes to the facility. The technical impact of changes must be carefully considered and the required actions must be documented. Changes to the project must go through the same measures of control as those applied to the original project.

The documents about changes must be checked and approved by the same groups or legal entities that are responsible for the review and approval of the original project documents, except when other legal entities are appointed for this. If other legal entities are appointed, they must have access to corresponding information and they must be competent in the specific project area and have adequate understanding of the original project requirements and intentions. Information in relation to the changes must be transferred to all persons and organisations that are engaged.

Control of the procurement

It must be established and documented that the stipulated requirements, project bases, standards, specifications and other requirements necessary to ensure the required quality are contained in the procurement documentation, or that they are referred to in the procurement documentation for elements and services.

The requests for procurement must, apart from other things, encompass also the following:

1. Description of the scope of work of the supplier;
2. Technical requirements specified in reference documents, such as regulations, standards, rulebooks, procedures, instructions and specifications in their last version with a description of components or services;
3. Requirements for testing, inspection and acceptance criteria, as well as all special instructions and requirements;
4. Securing access to the facilities and documents in order to perform advance checks and inspections, if necessary;
5. Identification of requirements for quality assurance and programme elements that are to be applied to components or services;
6. Identification of the requested documentation that should be prepared and submitted for review or approval to the buyer, such as instructions, procedures, specifications, notes on inspections and testing and other notes related to quality assurance;
7. Provisions for controlled distribution, safekeeping, maintenance and use of quality assurance records;
8. Reporting requirements about the approval of the decision on non-conformity;
9. Provisions that regulate the forwarding of requirements from the procurement documents to other producers and suppliers, including the buyer's access to their facilities and records
10. Provisions that specify deadlines for the submission of documents.

The basic consideration for the evaluation and selection of suppliers must be directed towards the assessment of his ability to deliver components or services in accordance with the requests of the procurement documents.

The assessment of the supplier includes:

1. The use of data about the quality in similar earlier deliveries;
2. Use of current records of the supplier about quality assurance, which are documented with qualitative or quantitative information that can be objectively assessed;
3. Assessments of the professional and technical abilities of the supplier, as well as his ability to deliver quality;
4. Assessment with the help of selected product samples.

The procured components and performed services must be controlled in order to harmonize them with the procurement documents. The control encompasses the proving of quality, inspection and check on site, as well as checks of products after the delivery.

Material samples are kept as needed for a certain time period at the agreed location and are controlled in order to provide the possibility for further testing.

The documented records for the procured components must correspond to the procurement documents and must be available in the nuclear facility before the assembly or use. These records must suffice in order to identify all requirements for the procured components. The records can be in the form of a written certificate that the component fulfils all requirements, provided that the fulfilment of the request can be checked.

Control of material

Measures must be determined to identify and control the quality of the components, including also partially constructed structures, according to the

requirements for the time of construction, delivery, installation and use. These measures secure the identification of the component at the time of upgrading, delivery, installation and use, with the help of a group number, part number, serial number or other adequate means, which can be placed on the element itself or contained in records accompanying this component. The requested documentation about the quality of the material must follow the elements in the process of production and installation.

The physical identification must be used to the largest possible extent. If the physical identification is impractical and insufficient, physical separation, procedural control or other adequate means are used for the identification.

Identification and control measures must be determined in order to prevent the use of defective or damaged material, parts or components in any place.

If labelling is used for identification, then the label must be clear, unique and indelible and must be applied in such a way so as not to affect the function of the element.

Labelling cannot be hidden by the processing of the surface or by a layer over it, except when the method identification has changed.

Measures must be established and documented for the supervision of the handling, storage and dispatch, which include the cleaning, packing and safekeeping of material and equipment in accordance with the determined instructions, procedures and drawings, in order to prevent damages, defects or loss. If necessary, for certain elements also special protection must be specified and procured.

Control of the operating process

Processes that affect the quality and that are used for and in the project planning, development, construction, testing, putting into operation and operation of the nuclear facility must be controlled in accordance with the specified requirements. If the regulations, standards, specifications, criteria or other special requests provide so, also measures must be determined and documented for qualified personnel to execute these processes by using qualified procedures and adequate equipment. For processes not encompassed in available standards or if the quality requirements exceed the requirements of existing standards, the necessary qualification of personnel, the procedures and equipment must be defined.

Control of tests and inspections

In order to check the compliance with the documented instructions, procedures and drawings, one must determine and implement a programme for the inspection of elements, services and activities that affect their quality. Such an inspection must be implemented by persons who are not directly in charge of the execution of the activities that are checked.

In the inspection it is also determined whether the checks, measurements and tests were conducted for every working operation for which it is necessary to assure the quality.

If the inspection of processed material or products is impossible or inadequate, an indirect control must be secured by monitoring the process methods, equipment and personnel.

The inspection and the indirect method of control must be implemented if this is necessary for complete control.

Points of detention after which work will not be continued without the approval of the appointed legal person or organisation, if such an inspection is necessary,

must be designated in adequate documents. Such an approval must be documented before work is continued after the designated point.

The inspection programme must be planned and implemented during the operation of the system, constructions and components and the results are assessed according to the tasks stipulated in the beginning stage. The testing programme must be established in order to secure the identification, carrying out and documentation of all tests necessary to prove that the facility, systems and components will work in a satisfying way. The testing programme encompasses all required tests and includes as necessary qualification tests for procedures and equipment, qualification tests of the prototype, tests before the assembly, pre-operation tests, tests for the first release into operation and operation tests.

All tests must be carried out in accordance with prescribed procedures. These procedures include among other: requirements and acceptance criteria specified in the project documents, method for the satisfaction of prerequisites for certain tests, method of satisfying the conditions of the environment and the necessary qualifications of persons performing the test and required gauging of the instruments. The results of the tests must be documented and assessed in order to satisfy the requirements of the test.

Measures must be determined that will secure that the tools, gauging meters, instruments and other equipment and devices for the inspection, measurements and tests, which are used to determine the compliance with the acceptance criteria, are right with regard to volume, type, accuracy and precision.

Devices for testing and measuring purposes that are used in activities affecting the quality must be controlled, gauged and adjusted in specified intervals or before their use in order to maintain the accuracy within the necessary limits.

When deviations from the prescribed limits are discovered, one must assess the importance of previous measurements and tests and reassess the acceptance of the tested elements. One must determine controls in order to secure the correct handling, storage and use of the gauged equipment.

The state of single components of the nuclear facility determined by means of tests and inspection is identified by using labels, stamps, plates, stickers, monitoring cards, inspection notes, physical locations or other adequate means that must show the acceptance or non-conformity of the components with regard to performed tests and inspections. The identification of the state of inspection and tests must be maintained, as needed for the time period of the production, assembly and operation of the components in order to secure the use, assembly or operation only of those components that are subject to the required inspection and testing.

Measures are determined to designate the operating status of the system and of components of the nuclear facility, e.g. the designation of valves and switches, in order to prevent unintended operation.

Control of non-conformity

Measures must be determined for the control of components that do not satisfy the requirements in order to prevent their incautious use or assembly. In order to supervise them, these components must be designated by hanging plates on them or by means of physical separation, whenever this seems practical. Measures must be determined, documented and implemented for the supervision of further processing, delivery or assembly of inadequate or damaged components.

Inadequate components must: be reviewed and accepted, rejected without any modifications, repaired or reworked, in accordance with documented procedures.

One must determine the responsibility and authority for the review and procedure for the inadequate component.

The end user must be notified about the acceptance of the inadequate component that deviates from the procurements requirements.

The description of changes, omissions or deviations that were accepted must be documented for the as-built state.

Corrective actions

The programme must provide for actions that must be undertaken to secure that conditions that damage the quality are identified for repair, such as failures, shortcomings, deviations, damaged or defective material and equipment, as well as other deficiencies.

For states with harmful impact on the quality, the programme must provide for determination of the reasons and corrective action that will prevent that such a condition will be repeated.

The identification of the condition with damaging impact on the quality, their cause and corrective action must be documented and the corresponding management must be notified thereof.

Documentation and recordkeeping

All quality assurance records foreseen in the programme must be done timely. The records represent an objective record of the quality and encompass the results of checks, inspections, tests, reviews of operations monitoring and analysis of materials and log of operation of the nuclear facility, qualification of the personnel, procedures and equipment, foreseen repair and other corresponding documentation. All records for quality assurance must be legible, complete and unambiguously recognisable, with regard to the element in question.

The time when the quality assurance record and the corresponding testing material were saved, as well as the number of copies, must be ascertained in writing. The system must require that sufficient documents are kept, that records are secured and insight into activities that affect the quality and the staring operating states must be described. The system must secure the identification, collection, development of an index, archiving, safekeeping, maintenance and disposal of documents. Documents must be saved in such a way that they can be easily found and maintained in the adequate ambience, so that damage to it or loss of it is prevented.

The time when the quality assurance documents, as well as the adequate testing material and samples were saved, must be ascertained in writing. Documents that identify correctly the actual state of components must be kept safe by the responsible legal person during the life cycle of the component from the production over the storage, assembly and facility. The safekeeping of other documents that do not refer to the entire life cycle of the component will be defined in accordance with the type of the document. Disposal of documents must be done in accordance with stipulated procedures.

Revisions

Measures must be taken for revision of the implementation and efficiency of the quality assurance programme. The system of planned and documented internal and external reviews must be implemented as necessary in order to confirm the compliance with all aspects of the quality assurance programme and to determine the efficiency of the programme.

Revisions are done in accordance with procedures in writing or with control lists. Legal entities responsible for reviews select and appoint qualified staff to perform the revisions.

The personnel must be independent from direct responsibility for the activities it is revising. In case of internal revisions, persons immediately responsible for the performance of activities that are subject to revision cannot be the revision executors. The results of the revision are documented and submitted to legal entities that are responsible for the area to which the revision refers. Additional action is taken in order to determine and remove deficiencies discovered during the revision.

Revisions must be planned based on the state and significance of the activities and must be implemented when one of the following conditions is fulfilled:

1. A systematic and independent assessment of the programme efficiency is necessary;
2. It is necessary to determine the suitability of the quality assurance programme of a contractor before an agreement or order is awarded;
3. After the contract award enough time has gone by for the implementation of the quality assurance programme and it can be determined that the legal person performs its functions adequately as defined in the quality assurance programme, regulations, standards and other contractual documents;
4. Significant changes took place in functional areas of the quality assurance programme, such as significant reorganisation or revision of the procedure;
5. There are doubts in the quality of the products or services due to deficiencies in the quality assurance programme;
6. It is necessary to check the implementation of requested corrective actions.