Investigations

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Requirements of Quality Assurance Systems Concerning the Fabrication of Equipment for Nuclear Facilities

Abstract: The article discusses requirements formulated in document Gs-r-3 issued by the International Atomic Energy Agency and requirements specified in the Nsq-00 (Nqsa) and Nqa-1(Asme) standards concerning quality assurance related to deliveries of components and services for nuclear power plants.

Keywords: nuclear power plant, quality assurance system, Asme, Afcen, requirements

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Introduction

On the basis of the assumptions of the Polish Nuclear Energy Programme (pnep) of 28 .01.2014, the first nuclear power plant in Poland should come into existence sometime in 2024. Potential suppliers of nuclear technology include Areva (eprtm), Ge Hitachi (abwr) and Westinghouse (ap1000), although Kepco (apr1400) and Aecl (acr-1000) also still remain in play. Regardless of the nuclear technology supplier, companies intending to deliver equipment, build structures and provide services during the construction of nuclear power plants must take into consideration the necessity of developing and implementing appropriate quality assurance systems based on Iaea gs-r-3 guidelines and satisfy at least the requirements of standard Iso 9001 supplemented with specific requirements contained in standards Nqa-1 or Nsq-100.

Primary Quality Assurance Systems in Nuclear facilities

The primary guidelines concerning requirements related to quality assurance systems in nuclear facilities have been developed by the International Atomic Energy Agency (iaea) in document gs-r-3 *The Management System for Facilities and Activities – Safety requirements*. On the basis of the above named iaea guidelines, countries providing nuclear technologies (Usa, France, Russia, South Korea, China and Japan) have developed their own regulations and standards used when building and operating nuclear power systems. Such regulations and standards are also used in the countries where nuclear technologies are delivered. The most commonly used quality assurance systems are French and American (Fig. 1).

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IAEA GS-R-3 **ASME NQA-1** **NSQ-100**

Fig. 1. Standards and guidelines concerning quality assurance systems

In France, the organisation responsible for developing regulations concerning the design, construction (production), operation and tests of components used in nuclear power plants, is AFCEN. This organisation is the association of nuclear facilities companies whose scopes of activities include technical aspects used when designing, building and operating nuclear power plants. AFCEN has developed codes RCC-M, RCC-CW, RCC-MRX, RCC-C, RCC-E, RSE-M and ETC-F, including requirements connected with infrastructure, mechanical and electric equipment, resistance to high temperature and fire as well as requirements concerning surveillance, inspection and testing. In addition to design, technical and documentation-related requirements, the regulations mentioned above include requirements related to quality assurance systems based on document IAEA GS-R-3 and standard ISO 9001:2008.

The National Quality Standard Association (NQSA), a non-profit organisation, was founded in France in 2011. The association was established in response to the demand of the nuclear facilities market for increased awareness in the supply chain in relation to the culture of safety in the nuclear facilities sector and for high quality products and services. NQSA was created by AREVA (a company delivering nuclear technologies) and Bureau Veritas (a classification company), SGS, Alstom, World Nuclear Association, Rolls-Royce, Eskom, Rosatom Overseas and Mitsubishi Heavy Industries. Within the scope of its activity, NQSA has developed standards related to quality assurance systems in nuclear facilities NSQ-100 *Nuclear Safety and Quality Management System – Requirements*. The current version of this document has been based on standard ISO 9001:2008, yet it is extended by including requirements connected with safety and quality assurance in nuclear facilities, which in turn are based on primary nuclear facilities regulations such as documents GS-R-3:2006, AFCEN RCC-M [5] and RCC-CW [6] issued by the International Atomic Energy Agency (IAEA). According to the authors of the document, standard NSQ-100 also includes 18 quality assurance criteria for nuclear power plants, formulated in 10 CFR Appendix B to Part 50 [7], valid in the USA.

As regards the United States of America, regulations related to quality assurance when building and operating nuclear power plants as well as when generating nuclear energy in the USA are primarily specified by the American Code of Federal Regulations (CFR), in Title 10 *Energy*, and particularly in Annex B to

Part 50 of the Title *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*. The regulations have been developed by the Nuclear Regulatory Commission (NRC) and therefore are applied only in the USA. Criteria specified in Annex B include the organisation, quality assurance system, surveillance over design, surveillance over purchase-related documentation, instructions, procedures and drawings, surveillance over documents, the inspection of purchased materials, equipment and services, the identification and inspection of materials, parts and components, surveillance over special processes, inspections, check tests, surveillance over testing and measuring equipment, handling, storage and shipment of products, the status of inspections and tests, handling non-conforming products, corrective actions, quality records and audits. On the basis of the above named criteria of 10 CRF Appendix B to Part 50, ASME (American Society of Mechanical Engineers) has developed standard NQA-1 *Quality Assurance Requirements for Nuclear Facilitiy Applications* also used outside the USA and specifying requirements directly related to the development and implementation of quality assurance programmes applied when choosing the location, designing, building, operating and closing down a nuclear power plant. These requirements must be rigorously satisfied as they concern all activities affecting the quality and operational safety of all components and equipment in a nuclear power plant.

Requirements IAEA GS-R-3

Requirements related to quality management systems, contained in the document issued by the International Atomic Energy Agency, concern all areas related to nuclear facilities, i.e. nuclear power plant infrastructure, activities related to sources of radiation, the storage of radioactive waste, the transport of radioactive materials, activities connected with protection against radiation, as well as all activities which may result in the exposure of humans or the environment to radioactive radiation. The purpose of the guidelines contained in the above named document is to ensure that a quality management system, used in any of the cases mentioned above, does not duplicate requirements formulated in other documents and integrates the related requirements in an appropriate manner, which in turn should increase personnel awareness as regards safety and personnel role at the various level of the organisation. The integration should concern safety aspects, health protection, quality and economic aspects. Requirements contained in GS-R-3 constitute the basis for developing a quality management system used by companies intending to actively participate in the construction of a nuclear power plant, including sub-suppliers of other companies active in this sector.

This standard emphasizes the importance of a culture of safety and the grading of requirements. Nuclear safety culture is knowledge and a way of thinking about nuclear energy safety (about challenges, chances and threats in this area), manners of the sense of safety and responding to its lack (behaviour), the behaviour and operation of entities and their collaboration with other entities, affecting individual safety and that of other entities. A management system should be used in a manner promoting and supporting the culture of safety through the following:

- ensuring the understanding of key aspects of safety culture inside the organisation,
- providing resources by means of which the organisation supports individuals and teams in the safe and effective performance of tasks, taking into consideration the interaction between individuals, technology and organisation,
- supporting an air of education and asking questions at various levels of the organisation,
- providing resources used by the organisation in order to permanently develop and improve its safety culture.

Another important requirement as regards the shape and structure of a quality management

system is a so-called gradual approach. In each stage of the supply chain, the organisation should classify products (activities) in order to distinguish individual elements of the system, activities relevant to safety as well as activities significantly affecting the final quality of a product (service). The classification of elements or activity relevant to safety should be based on the analysis of the effect of a potential defect/damage or malfunction on the safe operation of a delivered product. The receiver of a product (service) should accept such a classification. It is necessary to adjust appropriate gradual approach to the classification; such a gradual approach should include requirements at the level of quality management, inspection, surveillance and surveillance over documentation. Requirements concerning individual levels should be appropriately documented. The above named classification and gradual approach could also concern special processes such as welding and heat treatment.

Document IAEA GS-R-3 specifies requirements related to the involvement of the organisation management in the planning, establishment, implementation, assessment and improvement of a quality management system. The document also specifies requirements concerning organisation resources, giving extra emphasis to safety and personnel awareness as well as to ensuring appropriate personnel competence, adequately to undertaken activities. The document describes in detail requirements concerning the management of processes (establishing, monitoring, specifying and analysing risks, input and output data), inspection results, documents and surveillance over records. In addition, the document presents general requirements related to measurements, analyses and improvements. Most of these requirements are similar to, yet less detailed than those found ISO 9001:2008. Document GS-R-3 has been used as the basis for the development of the French standard NSQ-100; the requirements of the latter are presented below in more detail.

Standard NSQ-100

NQSA has disseminated standard NSQ-100 and promotes its application, performs regular revisions of the standard and certifies companies for compatibility with the requirements of the standard as well as companies certifying other businesses. In addition to the standard, there are many guidelines facilitating the understanding of individual regulations of the standard and the implementation of the system.

Standard NSQ-100 aims to develop a so-called culture of quality and safety in the entire supply chain related to the market of nuclear power generation as well as to ensure that supplied products or provided services are characterised by appropriate quality, meet customer requirements and satisfy related regulations. The standard also aims to unify requirements of quality management systems to a degree enabling the application of the standard at each level of a supply chain worldwide.

Requirements of standard NSQ-100 can be implemented in each company delivering products or providing services for the purposes of nuclear facilities. These requirements supplement national regulations or regulations of national regulatory bodies. If the requirements of the above named standard are contradictory in any aspect, national regulations or regulations of national nuclear inspection bodies (in Poland – the National Atomic Energy Agency) should prevail. Because of the fact that the version of standard NSQ-100 being discussed supplements standard ISO 9001:2008; presented below are only these requirements which have not been described in the ISO standard.

As regards requirements concerning the **quality management system**, in contrast to ISO 9001, the documentation of the system should be available in a language understood by personnel connected with the implementation of a specific project. Quite often, the documentation is developed in a foreign language (for a given organisation). Therefore, in order to ensure the proper implementation of

requirements specified in related documents, it is necessary to determine which of these documents (procedures, instructions, inspection schedules etc.) should be prepared in two languages.

Many items of standard NSQ-100 give emphasis to safety aspects. Also in the Quality Manual (or other quality-related documents) it is necessary to specify appropriate requirements related to the specific character of activities performed within nuclear facilities projects. In addition to requirements specified in ISO 9001:2008, the document prepared by NQSA requires that there should be a list of personnel creating, revising and accepting quality documents. It is also necessary to appoint persons developing and altering documents containing requirements related to quality or procedures, instructions or drawings. Each such action must be fully authorised. In addition, it is necessary to develop a procedure of surveillance over regulations created by sub-suppliers. Requirements concerning the contents of the system and documentation as well as requirements concerning the **responsibility of the top management** are convergent with requirements of ISO 9001. The most important changes in standard NSQ-100 in this chapter are concerned with issues related to the safety of a product or service used for the purposes of nuclear facilities. Within their own involvement, the management should ensure the widespread understanding of safety culture and safety-related activities in the organisation as well as ensure resources for the development and improvement of safety culture. This objective can be achieved by organising specialist courses, permanently informing (inside the organisation) about the importance and specific character of the environment connected with nuclear facilities as well as by emphasizing the importance of complying with regulations and satisfying specific requirements (e.g. safety-related). Quality policy should also be safety-oriented. When planning the quality management system, it is necessary to take nuclear safety into consideration. All changes in the organisation should be classified in relation to their effect on safety and each change should be appropriately justified.

Resources of the organisation requiring management include not only personnel, infrastructure and work environment but also knowledge and information. In accordance with requirements of standard NSQ-100, the organisation personnel involved in the manufacturing of a product or providing a service should be trained as regards the meaning and importance of activities as well as possible consequences for nuclear safety resulting from mistakes or improperly performed actions. The above named trainings should be documented. For each position it is necessary to develop specific requirements concerning the scope of knowledge and skills providing necessary competence of personnel. Such requirements may concern educational background, participation in specific training, training related to a specific position/work station, occupational knowledge (technical, IT, knowledge of regulations, standards and foreign languages), behavioural skills and professional experience. The standard requires that workers be assessed in relation to developed criteria; evaluation results should be recorded and stored. Such evaluation records could take the form of a personalised table where a given person is subjected to evaluation in relation to criteria developed for a given position.

All activities connected with the **manufacturing of a product** or providing a service should be planned in detail. In the first place, it is necessary to formulate requirements concerning the product, taking into consideration such aspects as the functioning of the product, its reliability, maintenance, nuclear safety, aspects of health and safety at work and environmental protection during the production, operation and maintenance as well as environmental requirements concerning parts and materials used

in the production. It is also necessary to properly perform the **management of product changes** (i.e. any structural changes or changes in the process of manufacturing affecting the quality and operation of a given product). If appropriate, it is necessary to develop procedures related to putting the product into operation, and even define resources indispensable for the operation and maintenance of the product. The most important changes in relation to ISO 9001:2008 include requirements concerning **risk management** and **configuration management**. It is necessary to perform the analysis of risks, including internal factors (i.e. inside the organisation), external factors and the specific character of manufactured products. In accordance with the requirements of the standard, it is necessary to establish and define risks present in every stage, determine the probability of risk occurrence, its consequences and the level of acceptance. The risk and related consequences should be appropriately graded (in relation to the importance and effect on project implementation, safety and product quality). It is also necessary to properly communicate risks in the supply chain and undertake actions aimed to minimise specific risks. Each chapter of standard NSQ-100 contains guidelines explaining how to understand individual regulations of the standard and presents exemplary actions. Also in terms of risk management, there are guidelines how to assess, classify and reduce risks. The guidelines and the standard are available on a free of charge basis at the NQSA website.

Configuration management includes technical and administrative activities aimed to create and maintain product configuration and control its changes throughout the active life of a product. Configuration management constitutes part of a procedure concerned with the controlling of changes and refers to all products. Configuration management objectives include the identification, tracking and protection of project products. The standard requires that product configuration be defined and the process of configuration management be planned, controlled and audited.

As regards **processes related to clients**, the organisation should specify requirements established by the customer, requirements of legal regulations and standards, in particular those including nuclear safety aspects, applying to a given product. The supplier should create a (documented) list of parts and activity types classified as important for safety (ISF) and important for the quality of a finished product as well as define a quality management level, surveillance level and documentation-related requirements. The manner of classification should be consistent with a gradual approach. Such requirements concern all sub-suppliers in the supply chain and are delegated "down the chain" if sub-suppliers provide products or services classified as important for safety or important for the quality of a finished product. Nuclear safety aspects include primarily the culture of safety, gradual approach, importance of products and services for safety as well as the observance of appropriate regulations. If there are no standards related to a given product, it is necessary to observe regulations formulated by a related regulatory body or, if there are no such regulations, to develop and approve a new standard or technical specification. The review of customer requirements should include the assessment and confirmation of project (product or service) feasibility as well as risks related to the safe manufacturing, construction, testing, start-up and operation of a product.

Standard NSQ-100 contains specific requirements concerning the **process of purchasing** products (or services) directly affecting nuclear safety or the quality of a finished product. An organisation is responsible for the compatibility of purchased products with related requirements even if products have been purchased from a supplier designated by the manufacturer. Each person involved in the process of purchasing along the entire supply chain should undertake

appropriate measures in order to prepare purchase-related input data in a manner ensuring that customer requirements will be transferred to the supplier. The supplier should also know requirements of standard NSQ-100 or other requirements (as the case may be) resulting from existing regulations. At each level of the supply chain, the supplier should ensure whether the requirements have been taken into consideration and used so that the purchased product could be accepted by the buyer.

An organisation should assess and select suppliers on the basis of their ability to provide products consistent with requirements. It is necessary to define a process and determine the scope of responsibility for approving the status of purchased products and changes in the status (who and when decides that a given product satisfies related requirements). In addition, the organisation should define activities concerning purchases of commercial grade items, i.e. products, systems, services and structures relevant for safety but not designed and manufactured in accordance with requirements of a document under discussion or, in other words, items, whose design and manufacturing processes do not require inspections when designing and manufacturing are performed. It is necessary to periodically assess suppliers and keep a record of assessment processes. The scope of assessment concerning product or service providers is significantly wider than that specified in the requirements of ISO 9001:2008. Assessments are usually performed using the TQRDC method (Technical, Quality, Responsiveness, Delivery, Cost) taking the following aspects into account:

- technical aspects of product manufacturing (assessment of documentation and production process),
- quality management system along with the culture of safety,
- supplier's adaptability to the changing environment (requirements, design/structural changes etc.),
- timely deliveries,
- price.

In every stage, an organisation may request a supplier for consent to perform an audit and supervise key stages of product manufacturing. The organisation should develop detailed information concerning products or services to be purchased and submit this information to the supplier. Documents specifying products to be purchased should include requirements concerning a quality management system with particular attention paid to safety culture, technical and design requirements, requirements related to contents of documentation to be submitted along with products, the specification of spare parts and the possibility of ordering and purchasing such spare parts as well as all other requirements concerning, e.g. non-conforming products, the necessity of informing about changes in organisation processes (e.g. a change in the location of a production plant, changes in manufacturing technologies etc.). It is also necessary to inform the supplier that they may need to make available all rooms/areas of key importance in terms of production to representatives of the organisation, inspectors of independent third parties or representatives of nuclear regulatory bodies. Documents including requirements for subcontractors should be inspected before being delivered by competent personnel (inspection records). All changes in documents should be supervised.

The organisation should plan and run **production** as well as provide **services** in supervised conditions. In addition to requirements specified in ISO 9001:2008, supervised conditions should include evidence that all activities connected with production, inspection and/or surveillance have been completed as planned, documented and approved by appropriate personnel. Planning should also include the development of processes used in the management and monitoring of activities and products important for safety (IFS). As regards planning, processes should identify points of interoperational control subjected to inspection as it may

be impossible to perform such inspection at later stages of implementation.

The organisation should establish and document processes of inspection and surveillance. In accordance with regulations of the standard, the inspection consists in the verification of the compatibility of a product with related requirements through monitoring and measurements, whereas the surveillance consists in ensuring such compatibility through monitoring and observation (wider notion). It is necessary to define methods of inspection and surveillance, plan appropriate activities and delegate appropriately qualified personnel to such activities. It is necessary to keep a record of such activities.

As regards **corrective actions**, there are additional requirements concerning a documented procedure and requiring the following:

- providing a supplier with requirements concerning corrective actions if it has been ascertained that the supplier is responsible for the incompatibility of a product with related requirements,
- defining specific action if previous corrective actions have proved ineffective,
- identifying other products inconsistent with requirements and resulting from an ascertained non-compliance.

It is necessary to store records of performed corrective actions in order to ensure that all stages of planned actions have been performed. As regards **preventive actions**, it is also necessary to develop a documented procedure identifying requirements (apart from those defined in ISO 9001:2008) concerned with the securing of appropriate resources for the implementation of preventive actions. Sources of potential non-compliances can be determined using the experience of other organisations (information exchange), available technical knowledge, research results and best practice.

A process of certifying a quality management system for compatibility with requirements of standard NSQ-100 is similar to a certification process for compatibility with requirements of standard ISO 9001:2008. NQSA has developed a document specifying requirements for a Certification Body and an organisation wishing to obtain a certificate of compatibility with requirements of NSQ-100. This document is entitled *General requirements – Certification process for suppliers* and is published at the NQSA website. A certification process involves an audit performed at the organisation and including the analysis of documentation and an audit performed on site. Audit activities are performed by auditors of a Certification Body. Until today, an NQSA Certification Body has not been established in Poland. Therefore, at the initial stage, auditors will probably be representatives of the parent body from France. A certification audit is performed every three years. In the meantime, two surveillance audits should take place. Audit principles, the selection of auditors, the scope of an audit, handling major and minor non-compliances, audit report and documents for submission to a Certification Body are similar to those specified in principles of an audit for compatibility with requirements of ISO 9001:2008. Certain differences are concerned with audit duration (due to the necessity of inspecting areas related to nuclear safety) and in documentation subjected to an audit (particularly as regards surveillance audits). In addition to documentation, a Certification Body should be provided with information about the volume of sales (and types of products) for purposes of nuclear facilities in a period subjected to assessment. A certificate remains valid for 3 years; afterwards a recertification audit should be performed.

Quality Assurance System NQA-1

Standard NQA-1 has been developed by ASME on the basis of a mandate granted by ANSI (American National Standards Institute). The standard takes into consideration industrial experience and the present state of awareness as regards requirements related to quality assurance in order to safely and efficiently use

nuclear energy and supervise the processing of radioactive materials. The standard is focused on achieving specific goals, emphasizes the involvement of individuals and organisation management in order to meet quality objectives, and concentrates on the practical use of individual quality assurance-related requirements. According to definition 10 CFR Appendix B to Part 50, quality assurance includes all scheduled and systematic activities ensuring that a product, structure, system or a component will function properly. Quality assurance includes quality control, i.e. all activities connected with the determination and verification of physical properties of materials, structures, components or systems. This, in fact, constitutes methods of controlling and qualifying materials, structures, components or systems in accordance with specific requirements. Standard NQA-1 specifies requirements directly connected with the development and implementation of quality assurance programmes used when choosing the location, designing, building, operating and closing down a nuclear power plant. These requirements must be rigorously satisfied as they concern all activities affecting the quality and operational safety of all components and equipment in a nuclear power plant. In contrast to the process approach, used in European quality management systems, standard NQA-1 is based on an approach taking into consideration safety aspects at each level and in every stage of the construction or operation of a nuclear power plant. The regulations specified in the standard state that at each stage it is necessary to provide objective evidence that a finished product meets requirements of appropriate technical specifications and other valid regulations. Presented below are 18 criteria constituting the primary requirements of standard ASME NQA-1.

Requirement 1 – Organisation

As regards organisational aspects, it is necessary to define a scope of responsibility for the development and implementation of a quality assurance programme. It is necessary to document an organisational scheme, the scope of responsibility and manners of communication for all activities affecting quality (preferably in the quality manual). Persons assigned with responsibility for the defining and measuring of a quality assurance system should be appropriately qualified and licensed to perform their duties and have direct access to the top management of the organisation. In the event of endangered safety, the scope of qualifications/rights of persons responsible for the operation of the system should be sufficiently extensive to enable undertaking necessary actions regardless of costs.

Requirement 2 – Quality Assurance Programme

A quality assurance programme should be planned, documented, implemented and maintained in accordance with requirements specified in NQA-1. It is necessary to develop and implement written procedures concerning all actions and parts (of products) to which they refer. Being part of the programme, such procedures should ensure the control of all activities affecting quality (proportionally to their importance). The programme should ensure the monitoring of all activities for the satisfaction of requirements and specified acceptance criteria in a manner making it possible to explicitly prove that activities affecting quality are performed satisfactorily. The quality assurance programme should be established at the earliest possible stage of project implementation.

The programme must enable planning and undertaking all qualification-affecting activities in controlled conditions. Such conditions include appropriate equipment and environmental conditions as well as ensuring that initial conditions have been defined and satisfied for each activity. The quality assurance programme should ensure appropriate processes for each special inspection, testing equipment, tools and skills necessary in order to verify quality and

satisfaction of specified requirements. In addition, it is necessary that personnel responsible for assigned activities be appropriately informed and trained.

Requirement 3 –Design Control

A design process should be appropriately defined and supervised; a design must be verified. It is necessary to define appropriate design-related input data ensuring a proper design process, define individual stages of the process and verify the design process result by persons other than those participating in the design process. The verification of the design using a special software programme is acceptable. Input data should be carefully selected, documented and subjected to inspection and approval. Input data should be detailed to an extent ensuring proper decision-making during a design process and an efficient design process. Input data should enable the verification and assessment of changes in a design (if any). A design process should be scheduled in sufficient detail enabling the final verification, i.e. whether the design has satisfied specific requirements formulated at the initial stage. It is necessary to define and select all necessary standards and regulations as well as verify and approve the selection. It is necessary to review, select and accept design methods, materials, parts and equipment in relation to intended applications. The design should be analysed (reviewed) for completeness and compatibility with input data. It is necessary to develop and approve related documentation.

Requirement 4 – Procurement Document Control

A supplier should provide products, commercial grade items or services on the basis of documentation developed and submitted by the organisation. The documentation should include an appropriate structural design and all other requirements necessary for ensuring the quality of purchased products or services. If necessary, a supplier should have used a quality assurance programme following the requirements of NQA-1. Purchase-related documents should include all necessary information making it possible to deliver products or provide services in accordance with requirements. The above named documents should at least contain the following:

- scope of works performed by the supplier or a precisely specified scope of delivery,
- technical requirements, in particular regulations, standards, codes, procedures and instructions containing provisions for provided products, commercial grade items or services, along with the range of necessary tests and inspections enabling the determination of whether related acceptance criteria have been met,
- requirements concerning the quality assurance system, appropriate for the importance and complexity of purchased products or services,
- requirements concerning the assessment of the supplier's infrastructure in order to perform audits,
- requirements concerning documentation to be developed and submitted by the supplier,
- determination of methods for handling non-compliances,
- list or spare parts or wearable parts.

Requirement 5 – Instructions, Procedures and Drawings

The standard requires that all activities affecting quality be performed in accordance with documented instructions, procedures or drawings containing quantitative and qualitative acceptance criteria. These documents must be approved before their use. Information contained in such documents should make it possible to ascertain whether results of activities and products meet specified requirements.

Requirement 6 – Document Control

The development, issue or changes in documents specifying quality requirements or describing activities affecting quality (instructions,

procedures, drawings etc.) should be supervised in a manner ensuring the use of appropriate documents. Such documents should be approved and accepted for use by personnel designated for this purpose. The inspection of documentation should include the identification of documents, verification whether appropriate documents are used as intended for this purpose (control of distribution), overview of documents for their completeness and usability as well as verification whether the inspection has been approved by authorised personnel. Changes in documentation, except for minor changes, should be subjected to the same surveillance as the process of documentation development and distribution.

Requirement 7 – Control of Purchased Items and Services

The process of purchasing commercial grade (i.e. commercially available) goods, products, elements and services should be supervised in accordance with requirements formulated in NQA-1. Surveillance over this process should include the assessment and selection of supplier/providers (source), assessment of objective quality evidence provided by suppliers, inspection and audit performed at suppliers' as well as the inspection of provided goods or services. Surveillance over purchases should also include the verification of documentation provided by a supplier for consistency with requirements specified in purchase-related documentation.

Prior to submitting products for acceptance, the supplier on their own should verify whether the goods satisfy the requirements specified in the purchase-related documentation. Verification should be documented. In special cases, if required by related regulations or contractual provisions, documents should be available on the nuclear plant construction site before the installation or start-up of the product. The standard also specifies handling commercial grade items. If such items are used, it is necessary to undertake at least the following actions:

- technical assessment in order to verify whether these items can be used safely,
- confirmation whether these items satisfy related requirements,
- identification of key properties, including acceptance criteria,
- determination and documentation of methods used for assessing the satisfaction of acceptance criteria.

In addition, suppliers of the above named items should be subjected to assessment and selection.

Requirements 8 – Identification and Control of Items

The quality assurance programme should include the determination of inspection methods ensuring that proper items/components have been used or installed. It is necessary to ensure the entire identification and traceability of individual components. Elements should be identifiable and traceable from the moment of acceptance (purchase, manufacturing etc.) until their installation and use. Identification should be concerned with a specific document related to a given element, e.g. design or construction documentation. If a given element is subjected to divisions, each separate part should be provided with a permanent designation which should not be removable by surface treatments. If related standards or regulations require, an item should be entirely traceable up to the grade of material, number of heat, lot and batch (as regards, e.g. sheets and filler metals for welding and brazing). In terms of elements of specific active life, it is necessary to ensure that an element exceeding its use-by-date should not be used in the construction.

Requirement 9 – Control of Special Processes

The quality assurance system according to NQA-1 requires surveillance over special processes, i.e. those used for welding, heat treatment and NDT. If need be, surveillance over special processes should involve the use of instructions, procedures, drawings, check lists or other measures.

Instruction or procedures concerning special processes should specify necessary personnel qualifications and requirements related to surveillance over equipment. Instructions (procedures) should specify conditions necessary for the proper performance of processes (technological parameters, equipment) and acceptance criteria arising from related standards or regulations.

Requirement 10 – Inspection

A quality assurance system should involve scheduling inspection activities aimed to verify the compatibility of products or services with related requirements as well as to ensure the constant compatibility of these products or services with related requirements during operation. It is necessary to specify characteristics subjected to inspection; inspection results should be documented. Inspection activities should be performed by appropriately qualified personnel, other than those directly related to the manufacturing of a product or to the providing of a service. Requirements concerning characteristics and manners of inspection should include requirements specified in the design documentation or in other documents approved by the personnel or organisation executing a given design-based project. If there are any specific stoppage points, outside which no actions without the previous consent expressed by a previously designated organisation representative should be performed, such points should be indicated in the documentation related to inspection activities. Inspection activities should also be performed when manufacturing a product or providing a service if it is necessary to verify the quality and check whether specific requirements in individual stages have been met. If possible, automatic monitoring and measurements can be used.

Requirement 11 – Test Control

Check tests are tests performed, e.g. when collecting data concerning the location of a power plant or design input data. Check tests are also concerned with products or software programmes as it is necessary to schedule and perform tests aimed to demonstrate the usability of the above named products or software programmes for specific applications. It is necessary to specify characteristics subjected to tests as well as testing methods. Test results should be documented. Before the commencement of tests, it is necessary to define requirements and acceptance criteria both for components (products) and software programmes. Depending on needs and types of products, such tests can include prototype qualification tests, production tests, pre-installation tests, design tests and operational tests. Tests of software programmes include, among other things, verification tests of design software. All check tests should be supervised and performed in appropriate conditions and equipment. Results should be characterised by appropriate accuracy enabling acceptance-related decision-making. Records of check tests should include the name of an element or software programme (or computer component) being tested, date of test, manner and procedure, test results and information about approval as well as activities undertaken in the event of a non-compliance.

Requirement 12 – Control of Measuring and Test Equipment

The organisation should supervise testing and measuring equipment. In order to ensure the accuracy of measurements, each item of equipment used in activities affecting quality should be calibrated or inspected at specific intervals. The activities mentioned above should be performed following appropriate national or international standards using certified equipment. Measurement equipment should be supervised. It should be ensured that equipment not inspected in due time has not been used for tests or measurements. Equipment should be appropriately designated in order to explicitly identify its status.

Requirement 13 – Handling, Storage and Shipping

It is necessary to ensure that products are handled properly in each stage of their manufacturing. In addition, it is necessary to undertake actions aimed to prevent damage to or loss of products. Handling, storage and shipment (transport) should be performed in accordance with specific operating instructions, existing standards or regulations. In specific cases, special manners of transport or storage (containers, absorption of shocks etc.) and special environmental conditions (atmosphere, humidity, temperature) may be required. Such conditions must be specified and ensured; their satisfaction should be verified and documented. If special manners of transport are needed, personnel responsible for such activities should be appropriately qualified.

Requirement 14 – Inspection, Tests and Operating Status

For each manufactured element, it is necessary to define the status of inspection and tests. Such a status should be designated on the element and in related documentation. The purpose of such an approach is to ensure that all tests and inspections in all individual stages have been performed and that a product failing to satisfy related requirements has not been installed or otherwise utilised. The manner of status designation should ensure its explicit identification (tag, stamp, label etc.). The licence of personnel to designate the status and its changes should be clearly defined. It is also necessary to designate (using appropriate indicators) the operational status of systems and components of nuclear infrastructure.

Requirement 15 – Handling of Non-Conforming Items

A product failing to satisfy specific requirements should be separated and monitored in order to prevent its unintended use or installation. Monitoring should ensure product identification, documentation, evaluation, separation and instructions concerning its further handling as well as notification of companies interested in the product. A non-conforming product should be stored in a properly indicated area intended for this purpose until a decision concerning the further handling of this product has been made. If, due to the size or weight of the product or because of limited access, it is not possible to store such a product in a special area intended for this purpose, it is necessary to take other measures ensuring that the product will not be used in an unintended manner.

It is necessary to define the range of responsibilities and qualifications in relation to the assessment of such a product and decisions concerning its further handling. It is necessary that the delegation of responsibility related to further processing, supply, installation or operation of a non-conforming agreement should be made in writing. Personnel performing such activities should be properly qualified, aware of product-related requirements and have access to all necessary information.

Requirement 16 – Corrective Actions

Conditions compromising quality (i.e. reasons for non-compliances according to ISO 9001) should be identified and corrected as soon as possible. Actions aimed to identify, determine reasons and correct conditions adversely affecting quality should be documented and reported at an appropriate level of the organisation. The effectiveness of corrective actions should be verified.

Requirement 17 – Quality Assurance Records

Standard NQA-1 requires surveillance over quality records. Surveillance over such records should be conducted along with scheduled stages of product manufacturing. Quality records should constitute documented evidence that a product or service satisfy specified

requirements. Requirements related to surveillance over records and a related scope of responsibility should be documented. The primary requirement concerning records is related to their legibility. Records should reflect all activities related to a given product (stages of production, inspection and tests) or provide necessary information about a product or service in individual stages. Requirements related to records should be specified in documentation such as purchase-related documents, design specifications, testing procedures and process procedures. Records are valid if stamped, dated and signed by appropriate persons or otherwise authenticated. Electronic documents also should be authenticated in a manner explicitly specifying their validity.

Requirement 18 – Audits

The organisation should carry out audits in order to verify whether the quality assurance system is consistent with the requirements and whether the criteria of the system implementation have been satisfied as well as in order to verify the operational efficiency of the system. Audits should be performed, in accordance with a related written procedure, by personnel who have not been directly responsible for areas and activities subjected to the audit. Audit results should be documented (reports) and presented at the appropriate management level. Audits should be planned in a manner taking into consideration the status and importance of audited processes and areas as well as results of previous audits. Personnel performing an audit (or an external organisation) should hold appropriate qualifications. The audit team is selected prior to the commencement of an audit. The team can be composed of one or more persons, one of whom should always perform the function of a lead assessor. During an audit, evidence should be assessed for the satisfaction of specific requirements. If an audit team ascertains the existence of conditions requiring fast corrective actions, such a fact should promptly be reported to the top management of the organisation. An audit should be followed by a report summarising results and describing detected non-conformances in detail. Personnel responsible for an area subjected to an audit should promptly undertake corrective actions and inform a person conducting the audit about these actions in writing. It is necessary to verify the effectiveness of corrective actions.

Summary

The conducted analysis of the primary quality assurance-related standards revealed that regardless of a document being considered, when selecting the location, designing, constructing and operating a nuclear power plant it is necessary to implement scheduled and methodical actions in order to satisfy the end product-related quality requirements. It is also of utmost importance to ensure the highest reliability and safety at each and every stage of nuclear power plant development. Each analysed standard concerning quality assurance systems in nuclear facilities emphasizes that the primary criterion governing the selection of equipment and technologies is the effect on the safety of nuclear power operation, its personnel as well as that of nearby residents and environment surrounding a nuclear power plant.

A condition for the implementation of a quality assurance system consistent with NSQ-100 or NQA-1 is the previous implementation of a quality management system according to ISO 9001:2008. Experience of the system operation increases the awareness of the fact that the quality assurance system in nuclear facilities emphasizes the permanent striving for the improvement of procedures and regulations by drawing conclusions form regularly conducted analyses and audits (system improvement). This process must help both a single worker and entire teams carry out their tasks effectively. In particular, the system should give particular emphasis to the acquisition of experience, advancement of knowledge as well as

the constant development and improvement of safety culture. Therefore, the system should enable workers to contribute to the improvement of procedures and processes. It is also of utmost importance to emphasize the fact that a quality assurance system developed according to the analysed regulations should, at every stage, provide objective evidence confirming the satisfaction of specific requirements. For this reason, it is crucial to know such requirements (e.g. technical requirements) and develop methods enabling the documentation of the effective satisfaction of these requirements.

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