STUK

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MANAGEMENT SYSTEM FOR A NUCLEAR FACILITY

1 INTRODUCTION 5

2 SCOPE OF APPLICATION 6

3 MANAGEMENT SYSTEM 6

3.1 Planning, implementation, maintenance, and improvement of the management system 6
3.2 Safety culture 7
3.3 Safety and quality policy 7
3.4 Grading the application of management system requirements based on safety significance 8
3.5 Documentation of the management system 8

4 RESPONSIBILITIES OF THE MANAGEMENT 8

4.1 Licensee's responsibility 8
4.2 Responsibility of the management of the nuclear facility 9
4.3 Responsible manager of the nuclear facility 9
4.4 Planning and follow-up of activities 9

5 MANAGEMENT OF RESOURCES 9

5.1 Resources 9
5.2 Working environment 10

6 PROCESSES AND FUNCTIONS OF THE MANAGEMENT SYSTEM 10

6.1 Developing and managing the processes of the management system 10
6.2 Management system processes 11
6.2.1 Document management 11
6.2.2 Product control 11
6.2.3 Control of records 11
6.2.4 Purchasing 12
6.2.5 Communication 13
6.2.6 Managing organisational changes 13
6.2.7 Project management 13

continues

With regard to new nuclear facilities, this Guide shall apply as of 1 December 2013 until further notice. With regard to operating nuclear facilities and those under construction, this Guide shall be enforced through a separate decision by STUK. This Guide replaces Guide YVL 1.4.

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7 ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM 14
7.1 Monitoring and measuring processes 14
7.2 Self-assessment 14
7.3 Independent assessment and internal auditing 15
7.4 Management review 15
7.5 Non-conformances, corrective and preventive action 15
7.6 Improving the management system 15
8 OVERSIGHT BY THE RADIATION AND NUCLEAR SAFETY AUTHORITY 16
8.1 General 16
8.2 Decision-in-principle 16
8.3 Construction licence 16
8.4 Construction and commissioning 17
8.5 Operating licence 17
8.6 Operation 17
8.7 Decommissioning 17
DEFINITIONS 18
REFERENCES 19
ANNEX QUALITY PLAN CONTENTS 20

Authorisation

According to Section 7 r of the Nuclear Energy Act (990/1987), *the Radiation and Nuclear Safety Authority (STUK) shall specify detailed safety requirements for the implementation of the safety level in accordance with the Nuclear Energy Act.*

Rules for application

The publication of a YVL Guide shall not, as such, alter any previous decisions made by STUK. After having heard the parties concerned STUK will issue a separate decision as to how a new or revised YVL Guide is to be applied to operating nuclear facilities or those under construction, and to licensees' operational activities. The Guide shall apply as it stands to new nuclear facilities.

When considering how the new safety requirements presented in the YVL Guides shall be applied to the operating nuclear facilities, or to those under construction, STUK will take due account of the principles laid down in Section 7 a of the Nuclear Energy Act (990/1987): *The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience, safety research and advances in science and technology.*

Under Section 7 r (3) of the Nuclear Energy Act, *the safety requirements of the Radiation and Nuclear Safety Authority (STUK) are binding on the licensee, while preserving the licensee's right to propose an alternative procedure or solution to that provided for in the regulations. If the licensee can convincingly demonstrate that the proposed procedure or solution will implement safety standards in accordance with this Act, the Radiation and Nuclear Safety Authority (STUK) may approve a procedure or solution by which the safety level set forth is achieved.*

Translation. Original text in Finnish.

1 Introduction

101. Under the Nuclear Energy Act (990/1987) [1] the licensee is responsible for the nuclear facility's safety as well as for the planning, implementation, maintenance, functionality, effectiveness, and continuous improvement of the management system.

102. Section 9 of the Nuclear Energy Act prescribes as follows: *It shall be the licensee's obligation to assure the safe use of nuclear energy.*

It shall be the licensee's obligation to assure such physical protection and emergency planning and other arrangements, necessary to ensure limitation of nuclear damage, which do not rest with the authorities.

A licensee whose operations generate or have generated nuclear waste (licensee under a waste management obligation) shall be responsible for all nuclear waste management measures and their appropriate preparation, as well as for their costs (waste management obligation).

103. The assurance of safety presupposes high quality operation from nuclear facility systems, structures, components, and organisations affecting safety as well as special attention being given to safety-significant factors and their interconnections. Safety, factors affecting safety, and the interconnections between the different factors form a system where the changing of one factor may have extensive consequences. Safety shall therefore be considered as a whole.

104. Under Section 28 of Government Decree (717/2013) [3], *when designing, constructing, operating, and decommissioning a nuclear power plant, a good safety culture shall be maintained. Nuclear safety shall take priority in all operations. The decisions and activities of the management of each organisation participating in the abovementioned activities shall reflect its commitment to operational practices and solutions that promote safety. Personnel shall be encouraged to perform responsible work and to identify, report and eliminate factors endangering safety. Personnel shall be given the opportunity to contribute to the continuous improvement of safety.*

Under Section 29 of Government Decree (717/2013), *organisations participating in the design, construction, operation, and decommissioning of a nuclear power plant shall employ a management system for ensuring the management of safety and quality. The objective of such a management system is to ensure that safety is prioritised without exception and that the quality management requirements correspond to the safety significance of the function. The management system shall be systematically assessed and further developed.*

The management system shall cover all organisational activities impacting the nuclear power plant's nuclear and radiation safety. For each function, requirements significant to safety shall be identified, and the planned measures described in order to ensure conformity with requirements. The organisational processes and operational practices shall be systematic and based on procedures.

Systematic procedures shall be in place for identifying and correcting deviations that are significant in terms of nuclear and radiation safety. [– –]

Corresponding principles are presented in Government Decree (736/2008) on the safety of the disposal of nuclear waste [4].

105. In the management system, the consideration of factors affecting the safety of a nuclear facility is ascertained by combining systematic safety and quality management procedures.

106. A good safety culture is characterised by a full commitment by the management and personnel to compliance with the management system and to the continuous improvement.

107. The quality vocabulary used in this guide complies with SFS-EN ISO 9000:2005 [5].

2 Scope of application

201. This guide presents the general requirements of safety and quality management that affect the contents, implementation, maintenance, assessment, and improvement of the management system of an organisation applying for a construction or operating licence for a nuclear facility or one constructing or operating a nuclear facility.

202. The management system requirements set forth in this guide apply to all the stages in the life cycle of a nuclear facility and for the entire duration of activities during normal operation, anticipated operational occurrences and accidents, and any subsequent periods of institutional control that may be necessary. Life cycle stages mean the siting, design, construction, commissioning, operation, and decommissioning of a nuclear facility and final disposal of nuclear waste.

203. The requirements of this guide apply, to the appropriate extent, to the plant supplier, suppliers contributing to nuclear fuel fabrication, safety-significant design and expert organisations, testing and inspection organisations, component and material manufacturers, and other safety-significant suppliers.

204. The requirements of this guide are specified in several other YVL Guides. Guide YVL A.4 sets forth detailed requirements for personnel and individual competence, and Guide YVL A.5 provides specified requirements for the management system of a construction project. Guide YVL A.6 sets forth requirements pertaining to the nuclear power plant's operating stage, Guide YVL A.7 presents requirements relating to the application of the PRA, Guide YVL A.11 specifies management system requirements pertaining to nuclear security, and Guide YVL A.12 specifies management system requirements for information security. Guide YVL B.1 specifies requirements related to the design of nuclear facilities for management systems and quality management. Furthermore, several field of technology-specific YVL guides establish detailed requirements for quality management, quality assurance, and quality plans.

3 Management system

3.1 Planning, implementation, maintenance, and improvement of the management system

301. A management system shall be planned and implemented to incorporate an organisation's operations, and it shall be continuously maintained and improved. The system shall be a well-balanced whole aligned with the goals of the organisation, which shall ascertain the fulfilment of nuclear and radiation safety requirements. The management shall promote ways for the entire personnel to participate in the implementation and continuous development of the management system.

302. In the management system, the organisational structure and the responsibilities, authorities, and decision-making procedures of the personnel shall be defined, taking into account their safety implications. The organisational structure shall be justified.

303. The management system shall contain procedures to identify, assess, and manage safety risks relating to the nuclear facility and its operation.

304. The management system shall contain procedures to identify and manage information security risks.

305. The safety significance of functions shall be taken into account when planning and implementing the management system or any modifications to it. The applicability of significant modifications shall be assessed prior to their execution, and the effect of such modifications shall be assessed and followed.

306. Safety-significant changes to the management system shall be submitted to STUK for approval before their implementation. Minor changes shall be submitted to STUK for information before their implementation.

307. The entire personnel, as well as the suppliers working at the nuclear facility, shall comply with the management system. Commitment to the goals of the management system and operation in accordance with the system shall be ensured.

308. Section 30 of Government Decree (717/2013) prescribes that *the licensee shall have a group of experts, independent of the other parts of the organisation, that supports the responsible manager and convenes on a regular basis to handle safety-related issues and issue recommendations thereon if necessary.*

309. The International Atomic Energy Agency (IAEA) has published a document containing requirements for the management system [6], which shall be taken into account when developing the management system and safety culture. In addition, the IAEA has published guidelines that supplement the requirements to support the assessment and development of the management system.

3.2 Safety culture

310. The management system shall support a good safety culture. In a good safety culture, safety is of primary importance, actions are prioritised based on their safety significance, the senior management and the entire personnel are committed to a high level of safety, the atmosphere is open and fosters a questioning attitude, safety is considered systemically, and safety is continuously improved.

311. The concept of safety culture shall be made concrete and communicated so that the personnel of the organisation share a common understanding of the importance of safety culture and its essential attributes and that everyone is able to identify, generally and in their own work, factors that strengthen and weaken nuclear and radiation safety as well as the safety culture.

312. The management shall define and promote the principles concerning safety culture that guide the personnel towards safety-conscious decision-making and conduct. Detailed requirements for manager roles in the reinforcement of safety culture are given in Guide YVL A.4 Organisation and personnel of a nuclear facility.

313. The management shall have available safety culture expertise in order to facilitate the development and maintenance of a good safety culture in the organisation.

314. The safety culture shall be improved in a target-oriented and planned way.

315. In addition to the systematic development of the safety culture, its strengths, weaknesses, and areas for improvement shall be identified in connection with operational events.

316. The importance of safety culture shall be continuously promoted and strengthened through regular communication.

317. The management system shall contain procedures to encourage the achievement of safety and quality objectives by the personnel, to facilitate continuous improvements, and to create an atmosphere that promotes openness.

318. The management system shall contain procedures to make the management aware of the state of the safety culture, changes to it and, in particular, the potential deterioration of the safety culture.

Management of human and organisational factors

319. The interaction between man, technology, and organisation affects safety. Systematic methods shall be incorporated in the management system in order to identify and manage human and organisational factors affecting safety.

320. Human and organisational factors shall be handled together with technical matters.

321. The personnel's individual competence shall be developed as regards the identification and management of human factors and potential errors.

3.3 Safety and quality policy

322. The management system for a nuclear facility shall contain a policy level statement on safety and quality based on the licensee's business idea.

323. The policy shall put safety first in the licensee's operation and decision-making. The policy shall also present the general objectives relating to safety and quality as well as the commitment to the improvement of nuclear and radiation

safety, good safety culture, high quality, and continuous improvement.

324. The organisation's safety and quality policy shall be communicated to the personnel so that it is understood and complied with.

325. The management shall see to it that the suppliers and subcontractors affecting nuclear and radiation safety are familiar with the safety and quality policy, the goals relating to the policies, and the management system in general. Furthermore, it shall be ensured that the suppliers and subcontractors are capable of taking into account in their operation the expectations and requirements of the customer. It shall be ensured in particular that the suppliers understand the safety significance of the products they supply.

3.4 Grading the application of management system requirements based on safety significance

326. The impact of products and activities on nuclear and radiation safety shall be identified and taken into account in defining the requirements set to them. The requirements shall be defined according to the safety significance of the products and functions so that the products and activities most important to nuclear and radiation safety are subject to the strictest quality requirements and quality assurance requirements and the most extensive measures for ensuring compliance with the requirements . The definition of the requirements shall also utilise the Probabilistic Risk Assessment (PRA) in accordance with Guide YVL A.7. The management system shall describe the application of the PRA and the principles of risk-informed decision-making.

327. Procedures for defining the quality requirements and quality assurance requirements for products and functions shall be documented in the form of instructions.

3.5 Documentation of the management system

328. The management system shall be documented. The documentation shall include a description of the management system and the organisational structure. Furthermore, the documentation shall include the organisational policies, authorities, and responsibilities, the requirements for individual competences and qualifications, the management and decision-making procedures, the processes and the related guidelines, and communication with the interest groups. The structure of the management system's documentation and the hierarchy of its parts shall be defined.

329. Procedures for quality and safety management shall be described and documented in the management system.

330. The language used in the management system shall be readable and readily understandable to the personnel.

4 Responsibilities of the management

4.1 Licensee's responsibility

401. Responsibility for the management system rests with the licensee. The licensee shall ensure that the operation complies with the requirements of the management system.

402. The licensee is obliged to ensure that the regulatory requirements and guides are complied with during the procurement of products having a bearing on the nuclear and radiation safety of the nuclear facility and that organisations contributing to the plant delivery or plant modifications understand and comply with the delivery-related requirements. The licensee shall communicate the requirements to the product suppliers by contractual means (contract documents) and ensure and control the fulfilment of the requirements throughout the entire supply chain.

403. The licensee shall assess and ensure the suitability of its parent company's procedures before their application at the nuclear facility.

4.2 Responsibility of the management of the nuclear facility

404. The nuclear facility's management is responsible for the nuclear facility's management system. The management shall ensure that the management system is established, implemented, assessed, and continuously improved. Furthermore, the management shall ensure that the operations comply with the requirements specified in the management system.

405. The nuclear facility's management shall designate an individual from the management with the responsibility and authority to

- co-ordinate the development and implementation of the management system
- attend to the regular assessment and continuous improvement of the management system
- report on the management system's functionality and development needs with an eye to safety and safety culture in particular
- resolve conflicts relating to the requirements and processes of the management system.

406. The nuclear facility's management shall demonstrate their commitment to safety as well as to the implementation and continuous improvement of the management system, and they shall communicate to the personnel the importance of safety-related requirements.

4.3 Responsible manager of the nuclear facility

407. Under Section 7 k of the Nuclear Energy Act, *the licensee shall appoint a responsible manager and his or her deputy* [– –] and further it is the responsible manager's task *to ensure that the provisions, licence conditions and regulations issued by the Radiation and Nuclear Safety Authority (STUK) concerning the safe use of nuclear energy, the arrangements for security and emergencies, and nuclear safeguards are complied with.*

408. Under the Nuclear Energy Act, a responsible manager shall have adequate authority as presupposed by his task. The nuclear facility's organisational structure and ways of working shall enable the responsible manager to attend to the duties defined in Section 7 k of the Nuclear Energy Act.

409. Performance of work and the flow of information shall be organised to make the responsible manager continuously aware of all the essential factors affecting the safety of the facility and that they are handled as required by their safety significance.

410. The responsible manager's deputy shall have up-to-date knowledge of the facility's operation and factors affecting safety.

4.4 Planning and follow-up of activities

411. The nuclear facility's management shall establish strategies and ways of working as well as set goals that support the implementation of a safety and quality policy. The strategies and ways of working shall be unambiguous and consistent, and they shall be communicated to the personnel. Clear plans of action and procedures as well as adequate resources shall be in place to achieve the goals.

412. The management system shall include procedures for the planning and follow-up of activities.

413. The set goals shall be measurable and their achievement shall be followed.

5 Management of resources

5.1 Resources

501. The licensee shall ensure the availability of adequate resources for the planning, carrying out, assessment, and continuous improvement of activities.

502. The management system shall have in place procedures for managing the information and individual competence in the organisation as a resource.

503. The management system shall have in place procedures for the coordination and control of the human resources of the line organisation and projects.

504. Direct operational activities of a nuclear power plant shall be taken care of within the licensee's organisation.

505. The organisation shall have adequate expertise and clear procedures for the definition and management of outsourced services as well as for the assessment of activities and outcomes. The use of outsourced services shall be planned and controlled.

506. The nuclear facility's organisation shall be able to function under all circumstances, including operational occurrences and simultaneous accidents at one or several plant units. Adequate personnel resources shall be ensured during prolonged accidents.

507. The organisation's structure, tasks, the number of necessary personnel, qualification requirements, and recruitment shall be planned already during the facility's design stage.

508. The management system shall include procedures to ensure that the personnel have the adequate individual competence and qualifications necessary in the tasks specified for them and that the personnel understand the safety implications of their work.

509. The contract personnel working at the nuclear facility are subject to the same requirements as the personnel employed by the facility.

5.2 Working environment

510. The licensee shall ascertain that the working environment complies with all the requirements, the personnel have the necessary equipment available, the work can be performed safely, and the goals set for work can be achieved.

6 Processes and functions of the management system

6.1 Developing and managing the processes of the management system

601. The processes of the management system shall be planned and implemented in a controlled manner. The development of each process shall ensure that the requirements, interfaces, interaction with other processes, and the risks relating to the activities have been identified and taken into consideration. The process flow and phases as well as the measurement and assessment procedures necessary for continuous improvement shall be specified and described.

602. The responsibilities and procedures for process implementation, evaluation, and development shall be specified process by process.

603. Written instructions shall be provided for process-related procedures and the manner of carrying out the activities. The possibility of human error in work performances shall be taken into account when defining the processes and the activities contained in them. The processes shall be planned so as to identify and disclose potential errors as early in the process as possible.

604. For each process, the necessary inspection, testing, verification, and validation phases, the acceptance criteria for each phase, and the responsibilities for the performance of the activities shall be specified. It shall also be specified if these activities are to be performed by individuals other than those responsible for the process.

605. The work performances shall be planned. Work shall be carried out under controlled conditions using only the approved instructions and procedures as well as the appropriate equipment. Each individual shall be responsible for the quality of his or her work. The personnel shall be given adequate training and instructions prior to starting work.

606. The management system shall have established procedures for the control of outsourced processes and activities.

607. Process implementation and effectiveness shall be continuously followed and periodically assessed. The processes and guidelines shall be continuously improved.

6.2 Management system processes

608. The management system processes shall be specified, and they shall be suitable for the relevant stage in the life cycle of the nuclear facility. They shall take into account radiation and nuclear safety as well as the co-ordination of security and emergency preparedness arrangements.

609. In defining and establishing the processes, the requirements specific to each stage shall be observed as regards, e.g., documentation, instructions, management of interfaces, transfer of responsibilities, research and analysis, and training.

610. The requirements and guidelines in the IAEA publications [6–15] shall be taken into account in defining and establishing processes for the different stages in the life cycle of the nuclear facility.

611. Throughout the life cycle of the facility, the management system shall include the generic processes described in 6.2.1–6.2.7 to support safety and quality management.

6.2.1 Document management

612. The documents shall be managed by systematic procedures. Document management shall cover documents needed in the operation of the facility and organisations, such as documentation for the nuclear facility as well as the documents for design, construction, commissioning, operation, decommissioning, and final disposal. In addition, procedures and requirements shall be defined for the documentation of activities and events and for storing and archiving the resulting documents. With regard to the documents pertaining to final disposal, additional attention shall be paid to maintaining the readability of the documents and their availability to different organisations even after a very long period of time.

613. The document management procedures shall be described. They include, among other things, the identification, preparation, drawing up, review, approval, implementation, revision, distribution, archival, and disposal of documents. The documents to be kept permanently or temporarily and their storage periods shall be defined. The materials and recording methods used shall meet the requirements for long-time storage and availability, if necessary. The document management system shall also take into account the information security requirements.

614. In drawing up, reviewing, and approving a document, the independence principle shall be applied. The drawing up, revision, review, and approval of a document shall be based on a defined authorisation. The management system shall guide the personnel towards the use of appropriate documents.

615. The documents to be updated and the updating procedures shall be specified, taking into account the documents' safety significance and regulatory requirements.

6.2.2 Product control

616. The requirement specifications of products shall conform with the applicable regulations, guides, and standards.

617. Prior to a product's approval, realisation, or commissioning, its conformity shall be assured by the necessary inspection, testing, verification, validation, and qualification. The methods and tools used shall be suitable for their purpose. Approval of the product documentation shall be attached to a product approval document.

618. Products must be identifiable to ensure their correct use. Where traceability is a requirement, a control procedure to identify products shall be arranged and documented.

619. Products shall be handled, transported, stored, maintained, and used according to instructions in order to avoid their damaging, loss, deterioration, or inadvertent misuse.

6.2.3 Control of records

620. The records generated during activities and the procedures pertaining to their management shall be defined. The records shall be specified, identifiable, readable, and easily traceable.

621. The retention times of records, associated test pieces, and testing materials shall be defined. The recording media, the manner of recording, and the storage conditions shall ensure readability for the duration of the retention period specified for each record. In specifying the retention period, the nuclear facility's life cycle and the long duration of nuclear waste management shall be considered.

6.2.4 Purchasing

622. Systematic procedures shall be in place for the purchasing of the nuclear facility and its systems, structures, components, supplies, and services so as to ensure the conformity and validity of the purchased products.

623. Systematic procedures shall be in place for defining the requirements for purchased products.

624. Adequate quality requirements shall be established for products and compliance with the quality requirements and achievement of the required quality level shall be ensured. There shall be adequately qualified personnel to specify the quality requirements and to control the products and suppliers.

625. Systematic procedures shall be in place for resolving and reporting deviations from the purchasing requirements.

626. The requirements for the selection of suppliers and the selection procedures shall be defined. These shall include the requirements pertaining to the supplier's management system and its quality management.

627. Appropriate procedures shall be in place for supplier assessment and selection. Records shall be kept of the assessments. Prior to ordering a product, the supplier's ability to deliver the product and the related documentation in compliance with the requirements shall be evaluated. Where necessary, a follow-up audit shall be used to ensure the supplier's capability to deliver a product compliant with the requirements prior to the commencement of manufacturing.

628. A list shall be kept of suppliers approved on the basis of assessment. The approval of suppliers of products important to safety shall be for a fixed duration only. The periods of validity shall be defined in the purchasing procedures.

629. Suppliers of safety-significant products shall have in place a management system that is appropriately certified or independently evaluated by a third party. In addition, the suppliers of products in safety class 1 and 2 shall comply with the management system requirements set forth in this guide. As necessary, the licensee may apply the procedure described in 630 with regard to suppliers that supply products related to structures or components in the safety class 2. The application of the procedure shall be justified.

630. The selection procedures shall define when a supplier referred to in 629 shall present a quality plan for the delivery, including the quality assurance procedures to complement its management system. The quality plan (see the annex) shall present the quality management procedures used for ensuring that the quality management requirements specified in the YVL guides and those set by the licensee are realised in the purchasing process.

631. The meeting of requirements set for products shall be ensured prior to commissioning. Product conformity shall be systematically monitored. The experiences of the product shall be evaluated for possible further actions and the supplier shall be given feedback on the product, where necessary.

632. The purchasing procedures shall define the conditions for the supplier's use of subcontractors and for the communication and relaying of requirements within the supply chain.

633. The management system shall define procedures for the licensee to ensure that, when purchasing sets of equipment involving several fields of technology, the contractual relationships and responsibilities within the entire supply chain are unambiguously defined.

634. The licensee is responsible for supervising all the suppliers in the supply chain. The licensee shall also incorporate the oversight rights of authorities into the supervision procedures.

635. For all purchases, the documentation to be attached to a product and control during product manufacture and implementation shall be defined. The control procedures shall be presented in supplier-specific delivery control plans.

636. The purchasing procedures shall contain procedures for the purchasing of type-approved, serial products for safety-significant components. The procedures shall define the validation of the suitability and conformity of the products as well as the documentation to be attached to the product.

637. Suppliers shall draw up a delivery-specific quality plan for the supply of safety-significant products. Through the use of a quality plan, it can be ensured that a product supplier has correctly understood the requirements of quality management applicable to the delivery and demonstrates that the supplier has in place procedures to fulfil the requirements.

638. A single quality plan may be used for all products that have the same quality management requirements and the same implementing organisations guided by the quality plan. In case of minor differences between the quality management objectives of different products, the differences may be specified in a shared quality plan.

639. The contents of a quality plan for deliveries is described in an Annex to this Guide. Field of technology-specific YVL guides set forth detailed requirements for the contents of quality plans and their submission to the Radiation and Nuclear Safety Authority. The standard ISO 10005, for example, can be applied to the drawing up of a quality plan.

640. The licensee shall have in place procedures to reliably prevent the purchasing of counterfeit and fraudulent products.

6.2.5 Communication

641. The management system shall include procedures and means for communicating matters related to nuclear and radiation safety, quality, and security and emergency preparedness arrangements within the organisation and to interest groups.

642. The life cycle stage of the nuclear facility shall be taken into account when planning and implementing communications.

6.2.6 Managing organisational changes

643. In developing the organisation's structure or ways of working, it shall be ensured that the changes implemented support the achievement of safety goals and that the implementation process is controlled.

644. Objectives shall be set for organisational changes. The safety implications of the changes shall be assessed. The planning and implementation of changes shall be proportioned to the outcome of the assessment. The different phases of a change shall be documented.

645. Organisational changes that significantly affect the organisation's operation shall also be subject to an independent evaluation.

646. The implementation of changes shall be planned and supervised. The management shall ensure adequate communication during the different phases of organisational change. The justifications for and method of implementing the changes shall be documented.

647. Safety-significant organisational changes shall also be evaluated after implementation. The evaluation verifies if the safety objectives set for the change are met.

6.2.7 Project management

648. The management system shall have documented procedures for project leadership, management, and progress assessment. There shall be a set of instructions for drawing up the project plan as well as the risk management, resource, and quality plan for the project.

649. A project shall be set up for the construction of new nuclear facilities, operating licence renewals, periodic safety assessments and, if considered necessary, plant modifications or other modification projects. The projects shall be described in a project plan and complemented, where necessary, with a project-specific resource, risk-management, and quality plan.

650. The project plans for modification projects important to safety, the associated human resource and quality plans, and the safety and quality-related risk management plans shall be submitted to STUK for information.

651. Project management shall comply with the applicable standards.

7 Assessment and improvement of the management system

701. The characteristics of an evolved management system are collecting information pertaining to the quality of activities and safety management, its active monitoring and analysis, and regular self-assessment, independent assessment and, based on these, continuous improvement of the management system and procedures.

702. The licensee shall ensure the systematic and continuous monitoring of safety indicators in order to ensure maintaining the level of safety and improving it where necessary.

703. In timing self-assessments, independent assessments, and management reviews, the object of assessment and its impact on nuclear and radiation safety shall be taken into account.

704. The licensee shall regularly assess the realisation of the safety and quality policy as well as the functionality and adequacy of the procedures related to ensuring safety in order to manage nuclear and radiation safety. The number of assessments shall exceed the number of periodic safety assessments.

705. Assessments of the management system shall be planned as a whole, and the coordination of the methods employed as well as the utilisation of the assessment results shall be systematic.

706. In order to support the assessment and improvement, domestic and international R&D pertaining to the management, development, and safety culture of organisations shall be followed.

707. The licensee shall conduct comparative assessment of operations in relation to organisations external to the company or group. Every now and then, a comparative assessment shall be applied in relation to equivalent foreign organisations as well.

7.1 Monitoring and measuring processes

708. The management system shall have in place procedures for the monitoring and measuring of processes and for the assessment of their functionality. The procedures ensure the capability of the processes to achieve the intended results and the identification of areas for improvement within processes.

7.2 Self-assessment

709. The management and all organisational levels shall carry out self-assessment in order to evaluate and improve the performance and the safety culture. Self-assessment means that the organisation's personnel evaluate their own work performances or processes related to their work against pre-defined criteria.

710. The organisation shall have in place a procedure for measuring the personnel's awareness of the significance and importance of their duties and of how the individuals affect the achievement of safety and quality objectives.

711. The personnel shall be able to contribute to the assessment and improvement process and their feedback shall be collected and processed.

7.3 Independent assessment and internal auditing

712. The management system shall include the requirements and procedures for regular, independent assessment of the system's conformity, performance, and effectiveness. Areas to be assessed in particular include the effectiveness of processes as regards the achievement of objectives and the realisation of the strategies and plans, the results of work performances and leadership, the organisation's safety culture, and the quality of products.

713. These assessments may be conducted by a unit within the organisation with sufficient authority and independence for discharging its responsibilities. Individuals participating in independent assessments shall not assess work for which they are responsible and they shall have expertise related to the object of assessment. The requirements of the standards ISO/IEC/EN 17021:2011, "Requirements for audit and certification of management systems" [16] and ISO 19011:2011, "Guidelines for auditing management systems" [17] apply to the assessor.

714. Assessments conducted by independent external experts shall also be used to improve the effectiveness of the management system.

715. The results of the periodic assessment of the functionality and coverage of the management system, as required above, shall be submitted to STUK for information.

7.4 Management review

716. The licensee and the management of the nuclear facility shall conduct a review of the management system at regular intervals in order to ensure the management system's applicability and effectiveness. The reviews shall include the objectives of the management system, including the safety and quality policy, that pertain to nuclear and radiation safety and quality as well as an assessment of opportunities for improvement and needs for change. As input data for the reviews, the following shall be used: the results of independent audits, process assessments, realisation of safety and quality objectives, status of corrective and preventive action, follow-up measures taken after previous management reviews, suggestions for improvement, and changes that could affect the management system.

7.5 Non-conformances, corrective and preventive action

717. The management system shall include procedures for the identification, processing, and handling of non-conforming processes and products.

718. The conformity of processes and products shall be monitored. The significance of any identified non-conformances shall be evaluated. Their causes shall be extensively studied and the necessary corrective and preventive action determined. The facility's structure, the procedures used, or the management system shall be improved, where necessary. The effectiveness of corrective actions and development projects for improving the operation shall be monitored and evaluated systematically.

719. Every employee shall be given the opportunity to report non-conformances and defects they observe in products, the performance of work, and the management system, to propose improvements, and obtain information about the handling of their propositions. The management shall promote an open atmosphere that facilitates the identification and handling of non-conformances and improvement needs.

720. There shall be guidelines on the handling of non-conformances, shortcomings, and proposed improvements as well as on producing associated records. The individuals assessing non-conformances shall be independent of the matters under scrutiny. They shall have adequate individual competence and good knowledge of the matter assessed.

7.6 Improving the management system

721. The licensee shall define, collect, and analyse appropriate information about its operation. This procedure helps demonstrate the applicability and effectiveness of the management system and identify areas for improving effectiveness.

722. The results of assessments of the effectiveness, quality of performance, and safety management of the management system shall be reviewed and the necessary improvements implemented systematically and in the order of importance without an undue delay. The action plans shall include provision of the necessary resources.

723. The progress of improvements shall be monitored. Furthermore, their completion and effectiveness shall be verified.

8 Oversight by the Radiation and Nuclear Safety Authority

8.1 General

801. The prerequisites for the use of nuclear energy are presented in the Nuclear Energy Act (990/1987) and Nuclear Energy Decree (161/1988) [1, 2]. In its statements on the construction and operating licences, STUK will assess the acceptability of the licence applicant's management system.

802. STUK oversees the management systems of the licensee and the nuclear facility as well as their implementation and effectiveness by document review, by observing operation, and by inspecting the operation of the licensee and the other organisations subject to STUK's oversight. STUK will assess the management system's functionality and coverage also on the basis of the results of assessments required under 7.3, which the licensee is responsible for. STUK may also obtain information in connection with other activities, e.g., by observing the training arranged by the licensee.

8.2 Decision-in-principle

803. Under Section 24 of the Nuclear Energy Decree, during the decision-in-principle stage, STUK may request for any reports it considers necessary.

804. Under Section 12 of the Nuclear Energy Act, STUK will draw up, at the request of the Ministry of Employment and the Economy, a preliminary safety assessment based on the application for a decision-in-principle. In its safety assessment, STUK will present any observations indicating insufficient prerequisites for constructing a new nuclear facility in accordance with the safety regulations of the Nuclear Energy Act. The assessment is based on Government Decrees [3, 4] issued under Section 7 q of the Nuclear Energy Act. In its safety assessment, STUK will also comment on the management system.

8.3 Construction licence

805. Under Section 35 of the Nuclear Energy Decree, the licence applicant shall submit a description of quality management during the construction of the nuclear facility, showing the systematic procedures adhered to by the organisations involved in the design and construction of the nuclear facility concerned in their operations affecting quality. In addition to this report, the licence applicant's construction quality manual, which describes the management system procedures related to quality and safety management shall be submitted to STUK for approval in accordance with Guide YVL A.1. According to Guide YVL A.1, the quality manuals of the plant supplier, fuel supplier, suppliers of the most important components and equipment, and the design organisations shall be submitted to STUK for information. STUK may also require, at its discretion, that the quality manuals of other organisations participating in the facility project be submitted to STUK for information. Furthermore, STUK will review the licensee's construction project plan and the related human resource and quality plans as well as the risk management plans related to safety and quality submitted to STUK for information.

806. In its statement to the Ministry of Trade and Industry concerning the construction licence application, STUK will give its opinion on the conformity of the organisations of the licence applicant and the construction project, as well as on the project management system.

8.4 Construction and commissioning

807. During the plant's construction and commissioning, STUK oversees the overall functionality of the licensee's management system and conducts, at its discretion, inspections focused on different fields of activity. STUK oversees the control, carried out by the licensee, of the suppliers' and their subcontractors' activities and the evaluation, also carried out by the licensee, of the functionality of their management systems. Inspection of system functionality is included in the periodic inspection programme during construction whose contents and schedule are determined by the construction and commissioning schedule of the facility. The functionality of the systems is also assessed during the review of documents submitted to STUK and during other regulatory work by STUK.

8.5 Operating licence

808. Under Section 36 of the Nuclear Energy Decree, when applying for an operating licence for a nuclear facility, the licence applicant shall submit a quality management programme for the operation of the nuclear facility. In accordance with Guide YVL A.1, the licence applicant shall also submit to STUK for approval the quality manuals concerning the operation of the nuclear facility, which shall describe the quality and safety management procedures of the management system. Based on these documents, STUK will review the conformity of the management system.

809. The licensee's quality manual concerning nuclear fuel shall be submitted to STUK for approval in accordance with Guide YVL A.1.

810. In its statement on the operating licence application to the Ministry of Employment and the Economy, STUK will give its opinion on the conformity of the licence applicant's management system.

8.6 Operation

811. During the operation of the nuclear facility, STUK will oversee the overall functionality of the management systems of the licensee and the organisation operating the facility and conduct, at its discretion, inspections focused on different fields of activity. Furthermore, STUK oversees the evaluation, carried out by the licensee and the organisation operating the nuclear facility, of the suppliers' and subcontractors' management systems and the control of operations.

812. Inspections of the management system are included in the periodic inspection programme. The inspections deal with, e.g., observations made by STUK during its previous inspections and reviews.

813. The functionality of the management system is also assessed during the review of documents submitted to STUK and during other regulatory work by STUK.

8.7 Decommissioning

814. During the plant's decommissioning, STUK will oversee the overall functionality of the licensee's management system and conduct, at its discretion, inspections focused on different fields of activity. Furthermore, the licensee and the organisation decommissioning the nuclear facility shall evaluate the management systems of suppliers and subcontractors and supervise their activities under STUK's oversight. Inspections of the functionality of the systems shall be included in the decommissioning inspection programme whose contents and schedule are determined by the decommissioning schedule of the facility. The functionality of the systems is also assessed during the review of documents submitted to STUK and during other regulatory work by STUK.

Definitions

Subcontractor

Subcontractor shall refer to a supplier that is not in a direct contractual relationship with the licensee or licence applicant.

Auditing

Auditing shall refer to a systematic, independent and documented process to objectively evaluate the audit evidence obtained to determine the extent to which the agreed auditing criteria are met.

Management system

Management system shall refer to a system that is used to establish policy and objectives and to achieve those objectives. (SFS-EN ISO 9000:2005)

Independent assessment of the management system

Independent assessment of a management system shall refer to an assessment performed by an internal or external party independent of the management, implementation and development of the item assessed. In general, independence can be demonstrated by indicating that the assessor is not responsible for the function being assessed.

Qualification

Qualification shall refer to a process to demonstrate the ability to fulfil specified requirements (corresponds to the qualification process of the ISO 9000 standard).

Validation

Validation shall refer to confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. (ISO 9000)

Individual competence

Individual competence shall refer to a person's knowledge and skills, suitability for his or her position, attitude towards and understanding of the safety significance of his or her work, and an ability to apply such competence to duties of safety significance.

Project

Project shall refer to a unique process consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources. (ISO 9000) Projects include for example construction projects of new nuclear facilities or plant modification projects launched to implement extensive modifications.

Process

Process is a set of interrelated or interacting activities which transforms inputs into outputs. (ISO 9000)

Competence

Competence shall refer to a demonstrated ability to apply knowledge and skills. (ISO 9000)

Supplier

Supplier shall refer to an organisation or person manufacturing or providing a product.

Product

Product shall refer to a result of a process (ISO 9000). Examples of products include a nuclear facility, plant modification, system delivery, single component or part thereof, plan or design, service, processed material, or information product.

Requirement

Requirement shall refer to a need or expectation of which a special mention is made, or one which is generally implied or obligatory. (ISO 9000)

References

1. The Nuclear Energy Act (990/1987).
2. The Nuclear Energy Decree (161/1988).
3. Government Decree on the safety of nuclear power plants (717/2013).
4. Government Decree on the safety of disposal of nuclear waste (736/2008).
5. SFS-EN ISO 9000:2005, Quality management systems. Fundamentals and vocabulary, 2005.
6. IAEA Safety Requirements, No. GS-R-3, The Management System for Facilities and Activities, August 2006.
7. IAEA Safety Requirements, No. GS-R-2, Preparedness and Response for a Nuclear and Radiological Emergency, November 2002.
8. IAEA Safety of Nuclear Power Plants: Design. No. SSR-2/1, February 2012.
9. IAEA Safety of Nuclear Power Plants, Commissioning and Operation Specific Safety Requirements, SSR-2/2, July 2011.
10. IAEA Safety Requirements, No. NS-R-3, Site Evaluation for Nuclear Installations, December 2003.
11. IAEA Safety Requirements, No. NS-R-4, Safety of Research Reactors, June 2005.
12. IAEA Safety Requirements, No. WS-R-1, Near Surface Disposal of Radioactive Waste, June 1999.
13. IAEA Safety Requirements, No. WS-R-5, Decommissioning of Facilities Using Radioactive material, October 2006.
14. IAEA Safety Requirements, No. GSR Part 5, Predisposal Management of Radioactive Waste General Safety Requirements, May 2009.
15. IAEA Specific Safety Requirements, No. SSR-5 Disposal of Radioactive Waste, May 2011.
16. ISO-IEC-EN 17021:2011, Conformity assessment. Requirements for bodies providing audit and certification of management systems, 2011.
17. ISO 19011:2011, Guidelines for auditing management systems, 2011.

ANNEX Quality plan contents

A01. A quality plan complementing the management system and pertaining to a delivery shall specify at least the following information

- responsibilities and obligations of the supplier as well as interfaces with other suppliers or organisations contributing to the delivery in question
- standards and guidelines to be complied with in the delivery
- potential division or phasing of delivery
- initial data of the delivery and the resulting documents and records
- reviews relating to delivery and its division or phasing, including the content of the reviews, performing party, acceptance criteria, and the responsibilities and decision-making procedures to be followed
- procedures for subcontractor supervision
- procedures for the management of the technical configuration and modifications
- delivery-specific processes of the supplier's management system and their potential delivery-specific additions
- grading of the quality assurance requirements in accordance with the requirement 326 of Guide YVL A.3
- updating procedures for the quality plan.