

MANAGEMENT SYSTEMS FOR NUCLEAR FACILITIES

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continues

As regards new nuclear facilities, this guide is valid as of 1 July 2008 until further notice. At operating nuclear facilities, and those under construction, the guide is enforced by a separate STUK decision. This guide replaces Guide YVL 1.4 issued on 20 September 1991.

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Authorisation

By virtue of the below acts and regulations, the Finnish Radiation and Nuclear Safety Authority (STUK) issues detailed regulations that apply to the safe use of nuclear energy and to physical protection, emergency preparedness and safeguards:

- section 55 of the Nuclear Energy Act (990/1987)
- section 29 of the Government Decision (395/1991) on the safety of nuclear power plants
- section 13 of the Government Decision (396/1991) on the physical protection of nuclear power plants
- section 11 of the Government Decision (397/1991) on the emergency preparedness of nuclear power plants
- section 8 of the Government Decision (398/1991) on the safety of a disposal facility for reactor waste
- section 30 of the Government Decision (478/1999) on the safety of disposal of spent nuclear fuel.

Rules for application

The publication of a YVL guide does not, as such, alter any previous decisions made by STUK. It is only after having heard those concerned that STUK makes a separate decision on how a new or revised YVL guide applies to operating nuclear power plants, or to those under construction, and to licensees' operational activities. The guides apply as such to new nuclear facilities.

When considering how new safety requirements presented in YVL guides apply to operating nuclear power plants, or to those under construction, STUK takes into consideration section 27 of the Government Resolution (395/1991), which prescribes that *for further safety enhancement, action shall be taken which can be regarded as justified considering operating experience and the results of safety research, as well as the advancement of science and technology.*

If deviations are made from the requirements of the YVL guides, STUK shall be presented with some other acceptable procedure or solution by which the safety level set forth in the YVL guides is achieved.

1 Introduction

Sections 6 and 6a of the Nuclear Energy Act (990/1987) provide that the use of nuclear energy must be safe; that it may not cause injury to people or damage to the environment or property; and that nuclear waste generated in connection with, or as a result of, the use of nuclear energy in Finland is to be handled, stored and permanently disposed of in Finland.

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, as 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).

The assurance of safety presupposes high quality operation from nuclear facility systems, structures, components and organisation as well as special attention being given to safety-significant matters.

The Government Resolution (395/1991) defines the following general principles:

- When designing, constructing and operating a nuclear power plant, an advanced safety culture shall be maintained which is based on the safety oriented attitude of the topmost management of the organisations in question and on motivation of the personnel for responsible work. This presupposes well organised working conditions and an open working atmosphere as well as the encouragement of alertness and initiative in order to detect and eliminate factors which endanger safety.
- Advanced quality assurance programmes shall be employed in all activities which affect safety and relate to the design, construction and operation of a nuclear power plant.

Quality assurance practices have developed such that today's quality assurance is part of the quality management system, which further is part of the organisation's management system.

The management system for a nuclear facility emphasises the consideration of both safety and quality in all of the organisation's operations. The management system ascertains the taking into consideration of safety-significant factors by combining systematic safety and quality management procedures.

Putting emphasis on safety factors in the management system is part of an advanced licensee safety culture. Its characteristics include management and personnel commitment to working in alignment with the management system and to continuous improvement of performance.

Responsibility for the nuclear facility's safety as well as for the planning, implementation, maintenance, functionality and effectiveness of the management system rests with the licensee.

The quality vocabulary in this guide is in accordance with SFS-EN ISO 9000:2005 [8].

2 Scope

This guide defines generic safety and quality management requirements affecting 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

The management system requirements set forth in this guide shall be applied at each phase in the lifetime of the facility and for the entire duration of activities in normal, transient and emergency situations, including any subsequent period of institutional control that may be necessary. For the facility, these phases usually include siting, design, construction, commissioning, operation and decommissioning.

The requirements set out in this guide apply, to the appropriate extent, to the vendor as well as design and expert organisations, testing and inspection organisations, component and materials manufacturers and other suppliers whose operations have a bearing on the safety of the nuclear facility.

3 Management system

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

A management system shall be planned and implemented to incorporate all the operations of an organisation, and it shall be continuously maintained and improved. The system shall be a well-balanced entity aligned with the goals of the organisation and shall ascertain the fulfilment of nuclear and radiation safety requirements. It shall be introduced through management-personnel co-ordination.

Organisational structure, and personnel responsibility and authority as well as decision-making procedures shall be defined based on their safety implications.

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

The safety significance of operations shall be considered in planning and implementing the management system and any modifications to it. The applicability of important modifications shall be assessed prior to their enforcement.

The management system shall oblige the entire personnel as well as the suppliers and partners in co-operation who work at the nuclear facility. Commitment to the goals of the management system and operation in accordance with the system shall be ensured.

There shall be a team of experts who are independent of operational activities and subordinate to the management. Their task is to assess matters with a bearing on the facility's nuclear and radiation safety, and their handling, and to issue recommendations pertaining to them.

The International Atomic Energy Agency (IAEA) has published a document containing requirements for the management system [9] to be taken into account in the management system. In addition, the IAEA has published several documents whose safety requirements are to be taken into account in the management system [10, 11, 12, 13, 14, 15 and 16].

The International Nuclear Safety Advisory Group (INSAG), active under the auspices of the IAEA, has published a report called Management of Operational Safety in Nuclear Power Plants [17] that can be utilised in developing the man-

agement system.

In addition to the above IAEA safety requirements, the design of the management system shall be based on international standards such as SFS-EN ISO 9000 [8], SFS-EN ISO 9001 [18], SFS-EN ISO 9004 [19] and ISO 14001 [20] as well as the guidelines OHSAS 18001 [21] and OHSAS 18002 [22] on the assessment of occupational health and safety at work.

3.2 Safety culture

The management system shall support those characteristics of the organisational culture that promote safety i.e. a good safety culture, and it shall support superiors, employees and work groups in achieving goals. By means of the management system, the nuclear facility's management shall express its commitment to safety. The procedures contained in the system shall strengthen a vigilant, questioning and initiative attitude at all levels of the organisation. The management system shall contain procedures for the identification and continuous promotion of safety culture.

There are several IAEA publications on safety culture that can be utilised in assessing and developing an organisation's safety culture [23, 24].

3.3 Safety and quality policy

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

Safety policy shall define safety as paramount in the licensee's operation and decision-making as well as the licensee's commitment to the development of nuclear and radiation safety. Safety policy shall also establish generic safety-related goals. Quality policy shall present quality-related generic goals and the management's commitment to high quality and its continuous improvement.

3.4 Grading the application of management system requirements

The nuclear and radiation safety related effects of products and activities shall be considered in defining requirements applicable to them. The requirements shall be determined by the safety significance of the products and activities such

that the quality requirements of products and activities most important to nuclear and radiation safety are the strictest and the actions carried out to ensure this the most extensive.

3.5 Documentation of the management system

The management system shall be documented. The documentation shall include a description of the management system and the organisational structure. Organisational policies, authorities and responsibilities, competence requirements, management and decision-making procedures and processes plus related guidelines shall be included. The structure of the management system's documentation and the mutual relationships of its parts shall be defined.

Quality and safety related procedures within the management system shall be defined in the Quality Manual.

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

4 Responsibility within the management system

4.1 Licensee responsibility

Responsibility for the management system rests with the licensee. The licensee shall see to it that operation complies with the requirements of the management system.

The licensee is responsible for ensuring that regulatory requirements and guides are complied with in connection with the procurement of products having a bearing on the nuclear and radiation safety of the nuclear facility,

4.2 Management responsibility

The nuclear facility's management is responsible for the nuclear facility's management system. They shall ensure that the management system is established, implemented and continually improved.

The nuclear facility's management shall designate someone from the management to

- co-ordinate the development and implementation of the management system
- look to the regular assessment and continual

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.

The management shall see to it that the representative in question has the position required by his task and adequate authority.

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

4.3 Responsible manager of the nuclear facility

It is the duty of the responsible manager of the nuclear facility to see to it that the rules and regulations as well as licence conditions pertaining to the safety of the use of nuclear energy, physical protection and preparedness arrangements as well as safeguards of nuclear materials are complied with. He shall be vested with the authority presupposed by his task. The structure and ways of action of the nuclear facility's organisation shall be established such that the responsible manager is able to attend to the duties defined in chapter 16 of the Nuclear Energy Decree. He shall organise the performance of work and flow of information such that he is continuously aware of all essential factors affecting the safety of the facility and that their handling is in line with their safety significance. The responsible manager shall be named a deputy who has up-to-date knowledge of the facility's operation and safety-significant factors.

4.4 Planning of operations

The nuclear facility's management shall establish strategies and ways of action as well as set goals that support the implementation of a safety and quality policy. The strategies and ways of action shall be unambiguous and consistent and the personnel shall be aware of them. Clear and time-bound plans of action and procedures for the achievement of the goals shall be in place.

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

5 Resource management

5.1 Resources

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

Immediate facility operations shall be taken care of within the licensee's organisation.

The organisation shall have adequate competence and clear procedures for the definition and management of outsourcing services as well as for the assessment of operations and outcome. The use of outsourcing services shall be systematic and controllable.

The nuclear facility's organisation shall be viable under all circumstances, including operational transients and emergencies. The organisation's structure, tasks, the number of necessary personnel, competence requirements and employment shall be planned in adequate detail during the facility's design phase already.

The personnel shall be competent to perform their assigned work. Their duties and the relevant competence requirements shall be determined. They shall have received appropriate training and their competence shall be suitably ensured. Training shall be provided to ascertain that they understand the consequences for safety of their activities.

In case of particularly safety-significant tasks, appropriate procedures shall be established to ascertain individual competence levels prior to the assumption of duties and at regular intervals thereafter. A procedure may consist of e.g. a written examination and a hands-on demonstration of competence.

Contracted personnel at the nuclear facility are subject, to the appropriate extent, to the same requirements as those permanently employed.

5.2 Working environment

The licensee shall ascertain that the working environment is in compliance with all requirements, the personnel has available the necessary facilities, work can be safely performed, and that the goals set for work can be achieved.

6 Process implementation

6.1 Developing processes

The processes of the management system shall be planned and implemented in a controlled manner. The development of each process shall ensure that requirements, interfaces and interactions with other processes as well as risks relating to operation 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 determined.

In the definition of processes and the activities contained in them, provision shall be made for human error in work performance. Processes shall be planned to identify and disclose possible errors as early in the process as possible.

Process implementation and effectiveness shall be continually followed and periodically assessed. Processes and guidelines shall be continually improved.

6.2 Process management

Responsibilities and procedures for process implementation, evaluation and development shall be determined process by process.

For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.

The work performed in each process shall be planned. It shall be carried out under controlled conditions using only approved instructions and procedures as well as appropriate working tools. Each individual shall be responsible for the quality of his work. He shall be given adequate training, tools and instructions prior to starting the work.

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

6.3 Management system processes

The processes of the management system shall be defined for each phase in the lifetime of a nuclear facility. In determining and establishing the processes, requirements specific to each phase shall be observed as regards i.a. documentation, guidance, management of interfaces, transfer of responsibilities, research and analysis as well as training.

The requirements and guidelines stated in the IAEA publications [9, 10, 11, 12, 13, 14, 15 and 16] shall be observed in determining and establishing processes for the various phases in the lifetime of the nuclear facility.

In all phases during the lifetime of the nuclear facility, the management system shall contain the generic processes presented in 6.3.1–6.3.6, which support safety and quality management.

6.3.1 Control of documents

Systematic procedures shall be in place for the control of documents. Document control shall cover documents needed in the operation of the facility and organisations, such as the nuclear facility's plant documentation as well as its design, construction, commissioning, operation and decommissioning documents. In addition, procedures and requirements for the documentation of operation and events as well as for the storage of documents shall be determined.

The document control procedures shall be described. They include, among other things, the specification, preparation, drawing up, review, approval, promulgation, revision, dissemination, archiving and disposal of documents. The documents to be kept permanently and temporarily plus their storage times shall be defined. The materials and recording methods used shall meet the requirements for long-time storage, if necessary. The document control system shall take into account data security requirements.

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

The documents to be updated and the updating procedures shall be determined, considering

the documents' safety significance and regulatory requirements. A document means a paper copy and other data storage formats.

6.3.2 Control of products

The requirement specifications of products shall be in conformity with applicable regulations, guides and standards.

Prior to a product's approval, implementation or commissioning, its conformity shall be assured by inspection, testing, verification and validation. The methods and tools used shall be suitable for their purpose.

Products must be identifiable to ensure their correct use. Where traceability is a requirement, control identifying the products shall be arranged, and this control shall be documented.

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

6.3.3 Control of records

Records shall be defined in the process documentation. They shall be specified, identifiable, readable and easily retrievable.

The retention times of records and associated specimens and test materials shall be defined. The media used for the records and the manner of recording shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.

6.3.4 Purchasing

Systematic procedures shall be in place for the purchasing of the systems, structures, components, supplies and services of the nuclear facility to ensure the conformity and validity of purchased products. The availability of products shall be ensured by the purchasing procedures.

Adequate quality requirements shall be established for products; and it shall be controlled that they are complied with and that an adequate quality level is achieved. Qualified personnel shall both determine the quality requirements for purchases and control suppliers. Systematic procedures shall be in place to define purchasing requirements and to resolve and report non-conformances.

Requirements concerning the choice of suppli-

ers and the selection procedures shall be defined. Suppliers shall be evaluated and selected on the basis of these procedures. Prior to the ordering of a product, the supplier's ability to deliver in compliance with the requirements shall be evaluated.

The meeting of the requirements set for products shall be ensured prior to commissioning. Product conformity shall be systematically monitored. The experiences gained shall be evaluated for possible further action and the suppliers shall be given feedback on them.

6.3.5 Communication

The management shall communicate to the personnel the importance of safety-related requirements and shall demonstrate their commitment to safety and to the implementation and continual improvement of the management system. The organisation's safety and quality policy shall be communicated to the personnel such that it is understandable and complied with.

The safety and quality policies of the licensee/nuclear facility shall be communicated to suppliers and subcontractors. The management shall see to it that the suppliers and subcontractors are familiar with the safety and quality policy, the related goals and the management system in general, and that they are capable of taking into account in their operation the expectations and requirements of the customer.

6.3.6 Managing organisational change

When developing the organisation's structure or ways of action it shall be ensured that the modifications implemented support the achievement of safety goals and that the process of implementation is controlled.

Objectives shall be set for organisational changes. The safety impact of the changes shall be assessed. The planning and implementation of the changes shall be proportioned to the outcome of the assessment.

An organisational change significantly affecting the organisation's operation shall be subjected to an independent evaluation.

In order to not endanger safety, the implementation of change shall be planned and controlled. The management shall ensure adequate communication during the various phases of

organisational change. The justification for and the manner of implementation of change shall be documented.

7 Assessment and improvement

The characteristics of an evolved management system are the gathering of information relating to quality of operation and safety management, active monitoring and analysis, regular self-assessment, independent assessment, and, based on these, a continual improvement of the management system and procedures.

When the timing of self-assessments, independent assessments and management reviews is defined, the object of assessment and its impact on nuclear and radiation safety shall be considered.

7.1 Monitoring

The effectiveness of the management system shall be monitored and measured to confirm ability of the process to achieve the intended results and to identify opportunities for improvement.

7.2 Self-assessment

Senior management and management at all other levels in the organisation shall carry out self-assessment to evaluate and improve performance of work and safety culture.

Self-assessment means that the organisation's own personnel evaluates performance of work or a process against pre-determined criteria.

The personnel shall be able to contribute to assessment and improvement and the feedback provided by them shall be collected and processed.

7.3 Independent assessment

The management system shall include requirements and procedures for the regular, independent assessment of the system's conformity, performance and effectiveness. The following in particular shall be assessed

- effectiveness of processes from the viewpoint of the achievement of goals and the realisation of strategies and plans

- results of work performance and management
- the organisation's safety culture
- quality of products.

These assessment may be conducted by an own organisational unit with sufficient authority and independence to discharge its responsibilities. Individuals participating in independent assessments shall not assess their own work.

In addition, the licensee shall periodically assess the functionality and coverage of the management system. The assessment team shall be composed of individuals whose duties do not include co-ordination of the management system's improvement and implementation, and the system's regular assessment.

For the improved effectiveness of the management system, assessments conducted by external independent experts shall be utilised.

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

In addition to the above, comparative assessment of the performance of work in relation to the company or concern's external organisations shall be conducted. Every now and then comparative assessment shall be applied to equivalent foreign organisations as well. Suitable indicators shall be employed for indicating development trends.

7.4 Management system review

The licensee and the nuclear facility management shall conduct a management system review at planned intervals to ensure the management system's continuing suitability and effectiveness. The reviews shall include an assessment of the opportunities for improvement and the need for changes in the management system, including quality and safety policy as well as safety and quality objectives. As input data for the reviews, the following shall be used: outputs from audits, assessment of processes, realisation of safety and quality goals, status of corrective and preventive actions, follow-up measures after previous management system reviews, suggestions for

improvement, and changes that could affect the management system.

7.5 Non-conformances, corrective and preventive actions

The management system shall contain procedures for the handling of non-conforming processes and products.

The conformity of processes and products to the specified requirements shall be monitored. The significance of potential non-conformances shall be evaluated. Their causes shall be identified and corrective and preventive actions to eliminate them shall be determined. The facility's structure, the procedures in use or the management system shall be improved, where necessary. The effectiveness of development projects that were launched to improve corrective actions and operation shall be systematically monitored and evaluated.

Every employee shall be given the opportunity to bring forth non-conformances and defects in products, performance of work and the management system, and to propose improvements as well as be informed about their handling. The management shall promote an open atmosphere that improves the identification and handling of non-conformances and needs for improvement.

There shall be guidelines on the handling of non-conformances, defects and improvement proposals as well as the making of records. Individuals assessing non-conformances shall be independent of the matters under scrutiny. They shall have adequate competence and a good knowledge of the matter assessed.

7.6 Improving the management system

The outcome of assessments conducted into the effectiveness, quality of performance and safety management of the management system shall be appropriately handled and, based on this, the necessary improvements shall be implemented without undue delay. The improvement plan shall incorporate allocation of the necessary resources.

The progress of improvement actions shall be monitored. Their completion and effectiveness shall be ascertained.

8 Oversight by STUK

8.1 General

The prerequisites for the use of nuclear energy are presented in the Nuclear Energy Act and Decree. In its statement on the construction and operating licence, STUK assesses the acceptability of the licence applicant's management system.

STUK controls the management systems of the licensee and the nuclear facility as well as their implementation and effectiveness by document review and by inspecting the operation of the licensee and other organisations subject to regulation by STUK.

8.2 Construction licence

In accordance with section 35 of the Nuclear Energy Decree (161/1988), the licence-applicant shall submit *a description of quality assurance during the construction of the nuclear facility, showing the systematic measures that are applied by the organisations that take part in the design and construction of the nuclear facility in their operations affecting quality*. In addition to the description, the licensee's quality manuals on the construction phase, which describe management system procedures relating to quality and safety management, are to be submitted to STUK for approval. The quality manuals of the vendor, of the suppliers of fuel and the most important components and equipment as well as of 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 for information.

In its statement on the construction licence STUK gives its opinion on the conformity of the management system.

8.3 Construction and commissioning

During the plant's construction and commissioning phase STUK controls the overall functionality of the licensee's management system and conducts inspections focused on different fields at its discretion. STUK also controls the evaluation of the management systems of suppliers and subcontractors and the supervision of their operation by the licensee and the organisation operating the nuclear facility. Inspection of sys-

tem functionality is contained in the periodic inspection programme during construction whose contents and schedule are determined by the plant's construction and commissioning schedule. The functionality of systems is evaluated during the review of documents submitted to STUK and during STUK's other regulatory activities.

Safety-significant revisions of quality manuals shall be submitted to STUK for approval prior to their introduction into use. Minor revisions shall be submitted to STUK for information before their introduction into use.

The outcome of the periodical assessment of the functionality and coverage of the management system, as required in subsection 7.3, shall be submitted to STUK for information.

8.4 Operating licence

In accordance with section 36 of the Nuclear Energy Decree, when applying for an operating licence for the nuclear facility, the licence-applicant shall submit *a quality assurance programme for the operation of the nuclear facility*. The licence-applicant shall submit to STUK for approval quality manuals on the operation of the nuclear facility that describe quality and safety management procedures within the management system.

The licensee's quality manual on nuclear fuel shall be submitted to STUK for approval in accordance with Guide YVL 6.3.

In its statement on the operating licence application STUK gives its opinion on the conformity of the management system.

8.5 Operation

During the plant's operation STUK controls the overall functionality of the management systems of the licensee and conducts inspections focused on different fields at its discretion. In addition, STUK controls the evaluation of the management systems of suppliers and subcontractors and the supervision of their operation by the licensee and the organisation operating the nuclear facility.

Inspections of the management system are contained in the periodic inspection programme. They deal with i.a. observations made by STUK during its inspections and review.

The functionality of the management system is assessed also during the review of documents

submitted to STUK and during other regulatory activities.

Safety-significant revisions of quality manuals shall be submitted to STUK for approval prior to their introduction into use. Minor revisions shall be submitted to STUK for information before their introduction into use.

The outcome of the periodical assessment of the functionality and coverage of the management system, as required in subsection 7.3, shall be submitted to STUK for information.

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