Radiation and Nuclear Safety Authority

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Guide YVL A.3, Leadership and management for safety

1 Introduction

It is the licensee's obligation to assure the safe use of nuclear energy. Assuring safety requires good safety management, safety culture and management system for ensuring the management of safety and quality. It is the management's duty to specify the objectives and ensure the achievement of these objectives. The intention of the management system is that the company meets these objectives that it has set. In this Guide, the requirements concerning the responsibilities of the management and risk management have been specified.

The definition of "safety" used in the Guide corresponds to the definition presented in requirement 110 of Guide YVL A.1 "Regulatory oversight of safety in the use of nuclear energy": *Nuclear and radiation safety comprises safety, security and emergency arrangements and nuclear safeguards at all stages of the use of nuclear energy.*

The 2015 version of standard ISO 9000 "Quality management systems. Fundamentals and vocabulary" no longer includes the definition for the Finnish word "johtamisjärjestelmä". Instead, the Finnish word "hallintajärjestelmä" is used for "management system". However, the word "johtamisjärjestelmä" is mentioned in the footnotes of the standard: *National footnote: The management system ("johtamisjärjestelmä") of an organisation may include different management systems ("hallintajärjestelmiä") such as the quality management system, the financial administration system and the environmental management system.* This Guide follows this outline.

The update of IAEA General Safety Requirements No. Part 2, "Leadership and Management for Safety", 2016 (IAEA GSR Part 2) has affected the content of this Guide. GSR Part 2 emphasises the responsibility for safety even more than before: not just the top management but the entire organisation, starting from the top management, is responsible for safety. Leadership refers to utilising the skills and capabilities of an individual to give employees and groups a direction and have an impact on their commitment to safety. Management refers to authorised actions to guide the organisation and ensure work performance.

The name of Guide YVL A.3 has been changed to better correspond to the changes of both the quality vocabulary and the emphasis of the IAEA. The previous name "Management system for a nuclear facility" has been changed into "Leadership and management for safety".

2 Scope of application

For an organisation applying for a construction or operating licence for a nuclear facility, or one constructing or operating a nuclear facility, Guide YVL A.3 "Leadership and management for safety" defines general safety and quality management

requirements affecting the leadership, safety culture and management system and their maintenance, assessment and improvement.

The requirements set forth in this Guide shall be applied at all the stages in the life cycle of a nuclear facility, and in all operations, of a nuclear facility in normal situations and in transients and emergencies, including any subsequent period of institutional control that may be necessary. The stages in the life cycle of a nuclear facility refer to siting, design, construction, commissioning, operation and decommissioning of the nuclear facility and final disposal of nuclear waste.

3 Justifications of the requirements

3.1 Chapter 1 Introduction

The chapter presents the starting points and grounds for Guide YVL A.3 “Leadership and management for safety”. The Guide is based on the Nuclear Energy Act (990/1987) and sections 6 and 25 of the Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018). IAEA GSR Part 2 has been implemented into this Guide during this guide update.

3.2 Chapter 2 Scope of application

Chapter 2 presents the scope of the Guide and its interfaces with other Guides. In addition to the licensee, the requirements also apply, to the appropriate extent, to the plant supplier and all safety-significant suppliers.

In the Guide, the aim has been to indicate, more clearly than in the previous version, which requirements only concern the licensee (the word “nuclear facility” or “licensee” has been added to these items). The words “organisation”, “management system” and “management”, on the other hand, refer to the requirement also being applied to suppliers. In this context, management refers to a person or group orienting and guiding the organisation. The Guide does not separate top management from middle management.

3.3 Chapter 3 Management system

Chapter 3 presents the general requirements concerning the management system. These include the general requirements relating to the planning, implementation, maintenance and continuous development of the management system, the requirements relating to safety culture, principles and policies, the assessment of the need for procedures based on safety significance (the graded approach principle) and the general requirements relating to the documentation of the management system.

The management system now describes more formally documented procedures. The management system shall describe in more detail, for example, the organisational structure and the responsibilities and authorities of the personnel. The management system shall include a description or a general part explaining how it has been built, what it is based on and what it contains. This requires that this part can be submitted to authorities and the changes are submitted for approval or information.

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

Requirements 301–309 are based on the WENRA requirements C:1.1, C:3.4, C:2.2, C:3.2 and C:2.1 and IAEA GSR Part 2 Req. 6 “Integration of the management system”. Requirement 301 includes the use of an integrated management system, while in the previous version, it was not mentioned in the guide but in the introduction. While IAEA documents have previously used the term “requirements”, they now use “elements” to refer to the parts of the management system. The word “requirement” has therefore been replaced by “procedure” in several items.

Requirement 306 is based on requirement 386 of Guide YVL A.1: *During the commissioning of a nuclear facility, the holder of the construction or operating licence shall, for its part, ensure that the documents submitted to STUK as provided in Sections 35 and 36 of the Nuclear Energy Act are duly kept up-to-date. The documents shall be supplemented based on the findings made during commissioning where necessary and the changes submitted to STUK in the same way as the original document*. Changes to the management system shall be submitted insofar as they have originally been approved.

3.3.2 Subsection 3.2 Safety culture

The organisation shall have a good safety culture. A good safety culture includes matters relating to decision-making, comprehensive analysis, working professionally and responsibly in good working conditions, mutual respect and trust in the organisation, an open atmosphere, etc. These measures are such that it might not be possible to provide instructions on them, but systematic and determined action is needed to achieve them.

The aim has been to clarify the safety culture requirements by incorporating the definition of a good safety culture into one item of this Guide. The requirements for the safety culture are based on IAEA GSR Part 2 Req. 2 “Demonstration of leadership for safety by managers”, Req. 12 “Fostering a culture for safety” and Req. 14 “Measurement, assessment and improvement of leadership for safety and of safety culture” and the WENRA requirements C:7.1–7.3. The requirements for the safety culture have also been specified in accordance with the IAEA Safety Guides GS-G-3.1 “Application of the Management System for Facilities and Activities” and GS-G-3.5 “The Management System for Nuclear Installations”. The consideration of the security culture has been included in the comprehensive idea of safety culture. Safety culture requirements concerning suppliers have brought from Guide YVL A.5 “Construction and commissioning of a nuclear facility”.

3.3.3 Subsection 3.3 Management of human and organisational factors

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. The management of human and organisational factors shall be integrated in the functions and processes. This requires new methods.

Requirements 319–321 are based on IAEA GS-G-3.1, item 2.2. The requirements concretise the requirement of regulation STUK Y/1/2018, Section 6 concerning the management of human factors relating to safety. Human and organisational factors shall be handled in the same context as technical matters in order to improve their consideration. This means that the assessment of human factors is part of the processes of, for example, plant modifications and other planning and development. The personnel shall identify the effects of human factors on work performance and the possibility of error. The organisation shall also possess special expertise on human and organisational factors.

3.3.4 Subsection 3.4 Safety and quality policy

The requirements for safety and quality policy are based on IAEA GSR Part 2 Req. 4 “Goals, strategies, plans and objectives” and WENRA A group requirements 1.1–1.5.

3.3.5 Subsection 3.5 Consideration of safety significance in the management system

The consideration of safety significance now requires more clearly than previously the consideration of the operation of the organisation (complex delivery, lack of experience, etc.). This shall be taken into account in the preparation of instructions and in training.

Requirements 326, 326a and 327 are based on IAEA GSR Part 2 Req. 7 “Application of the management system” (*the management system shall be developed and applied using a graded approach*) and the WENRA requirement C:2.1. Requirement 326a has been moved from Guide YVL A.5 because the requirement also applies to operating facilities. It describes the things to be taken into account when assessing the procedures needed to manage quality. In addition, the change to GSR Part 2 has been considered in which the assessment relating merely to the product has been extended to also concern the company and its operations. The words “operation” and “function” cover matters relating to the activities of individuals and organisations, and these concepts are broader than the functionality relating to an individual product.

In standard ISO 9000:2015, the word “product” only refers to a product, whereas previously, the definition also included services. The word “product” has now been replaced by the words “product and service” in several requirements. There was no wish to use the word “output”, used in the ISO standard to describe both concepts, in this Guide.

3.3.6 Subsection 3.6 Documentation of the management system

Requirements 328–330 are based on IAEA GSR Part 2 Req. 8 “Documentation of the management system” and the WENRA requirements C:2.2 and C:2.3. There is an added requirement to describe how the management system complies with the requirements of the authorities.

3.4 Chapter 4 Leadership for safety

Safety management requires that the significance of leadership in the direction of operations is emphasised more clearly. It also requires from the management a

different preparedness to work in a way that strengthens the commitment of the entire personnel. The management shall more openly justify their decisions and act as an example throughout the entire organisation and with stakeholders.

Chapter 4 presents the responsibilities of the management. Requirements are presented to both the licensee and the management of the nuclear facility as persons. This chapter also presents the requirements relating to responsible management and the requirements relating to the planning and monitoring of operations. Management refers to top and middle management. This is because top management can be understood very narrowly or broadly in different companies.

The requirements of the chapter are based on IAEA GSR Part 2 Req. 1 “Achieving the fundamental safety objective”, Req. 2 “Demonstration of leadership for safety by managers” and Req. 3 “Responsibility of senior management for management system” and the WENRA C:3 requirements.

3.4.1 Subsection 4.1 Licensee’s responsibility

Requirements 401–402 are based on the Nuclear Energy Act (990/1987), which emphasises the responsibility of the licensee. After the change in GSR Part 2, the requirements have been changed to focus more on safety because it is understood that the management system is a tool to achieve objectives. The aim of requirement 403 is to clarify the application of the procedures of the management system of a nuclear facility that is part of a group.

3.4.2 Subsection 4.2 Responsibility of the management

Requirements 404–406 are based on IAEA GSR Part 2 Req. 4 “Goals, strategies, plans and objectives” and the WENRA requirements C:1.1 and C:3.3. The management of a nuclear facility shall set the goals. The goals shall be made tangible, and plans to be followed shall be made for them. All these actions shall support the achievement of the safety and quality policy.

3.4.3 Subsection 4.3 Responsible manager of the nuclear facility

Requirements 407–410 on the responsible manager and his or her deputy are directly from Section 7 k of the Nuclear Energy Act (990/1987). Guide YVL A.4 “Organisation and personnel of a nuclear facility” provides more detailed requirements on the responsible manager.

3.4.4 Subsection 4.4 Planning and follow-up of operations

Requirements 411–413 are based on IAEA GSR Part 2 Req. 2 “Demonstration of leadership for safety by managers” and the WENRA requirements A:1.4, C:3.1 and C:4.1.

3.5 Chapter 5 Management of resources

Chapter 5 presents the requirements relating to the management of resources and the working environment.

3.5.1 Subsection 5.1 Resources

The management shall define which competences and resources shall be found inside the organisation and which ones can be outsourced. The organisation shall have adequate competence and clear procedures for the definition and management of outsourced services as well as for the assessment of operations and results. The outlines shall be made clear to everyone, and they shall be updated when necessary.

The requirements for the resources are based on IAEA GSR Part 2 Req. 9 “Provision of resources” and the WENRA requirements A:1.1, C:4.1 and C:5.5. The IAEA has changed the use of the word “resource” so that the word now describes many different things: people (number and competence), infrastructure, working conditions, knowledge and information, suppliers and also material and economic matters. In this Guide, however, it mostly refers to resources related to persons.

3.5.2 Subsection 5.2 Working environment

Requirement 510 is based on IAEA GSR Part 2 Req. 9 “Provision of resources” and the requirements of ISO 9001:2015 concerning the infrastructure and working environment.

3.6 Chapter 6 Procedures

The title of the chapter has been changed to better correspond to the structure of standard ISO 9001:2015. The chapter is called “Activities”, and one of its subsections is “Processes”. This does not mean abandoning process-like activities. Instead, the intention is to emphasise the definition and description of processes at the appropriate level. The IAEA publication emphasises the interaction between processes and their relationship to exterior processes. It does not include a strict description of “process flow” requirement any longer. Following the example of that publication, the previously included minimal requirement processes have been removed from Guide YVL A.3 as well.

Chapter 6 presents the requirements for processes and their implementation and development. Different YVL guides lay down more specific requirements on what functions a nuclear organisation shall include.

3.6.1 Subsection 6.1 Processes

Requirements 601–610 are based on IAEA GSR Part 2 Req. 10 “Management of processes and activities” and the WENRA requirements C:5.1 and C:5.2.

Requirement 611 has been removed as it is useless according to GSR Part 2. The names of the defined processes have no significance as long as they are suitable for the purpose of the activities. Other YVL guides also lay down requirements on what processes and functions an organisation shall include.

3.6.2 Subsection 6.2 Document management

Requirements 612–615 are based on IAEA GSR Part 2 Req. 8 “Documentation of the management system” and the WENRA requirements C:5.3 and C:5.4.

3.6.3 Subsection 6.3 Ensuring the conformity of products

Requirements 616–619 are based on IAEA GSR Part 2 Req. 11 “Management of the supply chain” and the WENRA requirements C:5.8.

3.6.4 Subsection 6.4 Control of records

Requirements 620–621 are based on IAEA GSR Part 2 Req. 8 “Documentation of the management system”.

3.6.5 Subsection 6.5 Purchasing and the management of the supply chain

Requirements 622–637 are based on IAEA GSR Part 2 Req. 11 “Management of the supply chain”, standard SFS-EN ISO 9001 and the WENRA requirements C:5.6, C:5.7, C:5.8 and C:6.5.

Suppliers of safety-significant products and services shall have in place a system that is certified or independently evaluated by an expert third party (for example, ISO 9001 or ISO 19443).

In accordance with the graded approach principle, SC 1 and 2 suppliers (products and services) shall, as a rule, have a nuclear field management system. The proof of a nuclear industry management system may be a certification of a nuclear industry management system or a written comparison on the fulfilment of the requirement level of Guide YVL A.3. Complementary procedures to ensure quality and safety can be presented in the quality plan for justified reasons.

The quality plan is a specification defining what procedures and related resources are applied to a particular item, who applies them and in what stage they are applied. The quality plan shall be made using a suitable method so that sufficient and uniform quality management procedures in the project or delivery can be ensured.

3.6.6 Subsection 6.6 Communication

The management system shall include the methods to communicate issues relating to nuclear safety, radiation safety and quality within the organisation and to interest groups. Changed and unexpected situations shall also be taken into account in communications. The organisation shall ensure that the employees are able to communicate work-related matters. Because of the requirement, it should be ensured that everyone has the opportunity to communicate using their native language or a language they are fluent in. In a multicultural environment, the communication capability of supervisors, in particular, shall be paid more attention to.

Requirements 641, 641a and 642 are based on IAEA GSR Part 2 Req. 5 “Interaction with interested parties”. Requirement 641a has been introduced from

Guide YVL A.5 because it applies to all nuclear facilities, especially if people with different native languages work together.

Communication needs of a very long duration may be related to the different stages of the nuclear facility's lifecycle. In these cases, it shall be ensured that the message is understood.

3.6.7 Subsection 6.7 Managing organisational changes

In accident investigations, it has been noted that many major accidents have originated from changes in the organisation. In managing organisational changes, it is important that risks have been assessed and they are responded to and prepared for.

Requirements 643–647 are based on IAEA GSR Part 2 Req. 6 "Integration of the management system", item 4.13. Detailed requirements pertaining to organisational changes are also specified in Guide YVL A.4. Guide YVL A.1 includes requirement 384: *If the licensee makes any changes to its organisation that are important in terms of safety, the management system shall be updated to reflect the changes made*.

3.6.8 Subsection 6.8 Project management

Requirements 648–651 present guidance in project management standards and IAEA instructions on the management system, such as GS-G-3.5 The Management System for Nuclear Installations (5.43–5.61). The licensee may define the procedures used in project management in its instructions. A developed and commonly known procedure can be considered a project management standard.

3.7 Chapter 7 Assessment and improvement

The chapter presents the requirements relating to the assessment and improvement of the management system. The requirements are based on the principle of continuous improvement, and similar procedures are included in all modern advanced management systems.

Requirements 701–707 are based on IAEA GSR Part 2 Req. 13 "Measurement, assessment and improvement of the management system" and the WENRA requirements A:3.1, C:6.3 and C:6.4.

3.7.1 Subsection 7.1 Monitoring and measuring processes

Requirement 708 is based on the WENRA requirement C:6.1.

3.7.2 Subsection 7.2 Self-assessment

Requirements 709–711 are based on IAEA GSR Part 2 Req. 13 "Measurement, assessment and improvement of the management system" and IAEA GSR Part 2 Req. 14 "Measurement, assessment and improvement of leadership for safety and of safety culture" and the WENRA requirements C:3.4 and C:6.1.

3.7.3 Subsection 7.3 Internal auditing and independent assessment

Requirements 712–715 are based on IAEA GSR Part 2 Req. 13 “Measurement, assessment and improvement of the management system” and the WENRA requirements C:6.1 and C:6.2. Approved certification has been added to **requirement 714** as an external assessment. Previously, it was unclearly presented among the auditing requirements in requirement 713.

In an approved certification of the quality system, the accreditation of the certification body is covered by an IAF Multilateral Agreement (MLA) or Mutual Recognition Arrangement (MRA) entered into by FINAS, and the accreditation of the certification body has been done against the requirements of standard EN ISO/IEC 17021. This was already a requirement, but now it is expressed more clearly. It should be checked that all supplier certifications comply with these requirements.

3.7.4 Subsection 7.4 Management review

Requirement 716 is based on IAEA GSR Part 2 Req. 13 “Measurement, assessment and improvement of the management system”.

3.7.5 Subsection 7.5 Non-conformances, corrective and preventive action

Requirements 717–720 are based on IAEA GSR Part 2 Req. 13 “Measurement, assessment and improvement of the management system” and the WENRA requirements C:6.5 and C:6.6.

3.7.6 Subsection 7.6 Improvement

Requirements 721–723 are based on IAEA GSR Part 2 Req. 13 “Measurement, assessment and improvement of the management system” and the WENRA requirement C:6.6.

3.8 Section 8 Oversight by the Radiation and Nuclear Safety Authority

Chapter 8 presents STUK’s regulatory activities concerning the management, safety culture and management system of the licensee.

3.9 Definitions and abbreviations used in the Guide

The key definitions have been assembled at the end of the Guide as a separate chapter, Definitions. When possible, the Guide uses quality terminology found in standard SFS-EN ISO 9000:2015, while also taking into account the IAEA terminology in some contexts.

According to standard ISO 9000:2015, “management system”, as used in the Guide, consists of different management systems.

The term safety culture shall refer to overall safety. There is only one organisational culture, in which safety, safety arrangements and nuclear safeguards are taken into account.

4 International provisions concerning the scope of the Guide

Guide YVL A.3 covers the requirements of IAEA General Safety Requirements, “Leadership and Management for Safety”, No. GSR Part 2 2016 (IAEA GSR Part 2).

Guide YVL A.3 takes into account some of the recommendations of IAEA Safety Standards Series No. GS-G-3.1 “Application of the Management System for Facilities and Activities”, Vienna, 2006. Most of this guide, however, is good background material for Guide YVL A.3.

Guide YVL A.3 also takes into account some of the recommendations of IAEA Safety Standards Series No. GS-G-3.5 “The Management System for Nuclear Installations”, Vienna, 2009. However, this guide also remains mostly background material for Guide YVL A.3.

Guide YVL A.3 takes into account “WENRA Reactor Safety Reference Levels A: Safety Policy and C: Management System, September, 2014”. Guide YVL A.3 covers these requirements.

Other international references are listed at the end of the Guide.

5 Impacts of the Tepco Fukushima Dai-ichi accident

The Guide covers the application of the management system in all usage situations including emergencies and disturbances. An efficient management system with its procedures may enable quicker intervention, for example, in decision-making chains, and it should also, for its part, ensure the efficiency of relaying information in accident situations. The update of GSR Part 2 has, for its part, taken into account the Fukushima accident in its requirements concerning management.

6 Needs for changes taken into account in the update

The needs for changes due to changes made to international and national laws/regulations and the change proposals made in connection with the preparation of the YVL Guide implementation decisions (SYLVI) together with others recorded in STUK’s change proposal database have been considered when updating the requirements. In addition, the possibilities to reduce the so-called administrative burden have been considered.

The 2016 update of IAEA strengthened the requirements relating to safety management and the continuous improvement of safety culture. The responsibilities and obligations of the management were checked with minor changes to the Guide. Changes relating to leadership were taken into account, and the definitions were updated. Expectations concerning behaviour were added for the entire personnel as regards safety culture.

On the standardisation front, the changes to the quality management system ISO 9000:2015 have created a need to review the definitions. The Guide follows the terminology of ISO 9000:2015 as far as possible.

In the update of the Guide, nuclear power-specific requirements for management systems of suppliers/manufacturers (for example, serially manufactured standard products and S/A components) were reassessed (requirement 629) and it was made easier to find requirements for suppliers. Thanks to these changes, the administrative burden was slightly reduced. Unclear items were also clarified. These unclarities concerned the control of the supply chain, the delivery of management system documents and the relationship between documents relating to quality.

Requirements of Guides YVL A.5 and YVL A.3 have been reviewed so that some overlapping requirements have been removed. Some of the requirements of Guide YVL A.5 are better suited to Guide YVL A.3, so they have been moved to this Guide. The scope of some of the moved requirements have been extended because Guide YVL A.3 covers normal operation, not just major modification or construction projects.