

Radiation and Nuclear Safety Authority

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Guide YVL A.1, Regulatory oversight of safety in the use of nuclear energy

1 Introduction

National legislation on the use of nuclear energy, the key parts of which include the Nuclear Energy Act (990/1987), Nuclear Liability Act (484/1972), Nuclear Energy Decree (161/1988) and Radiation and Nuclear Safety Authority Regulations on the Safety of a Nuclear Power Plant (STUK Y/1/2018), Emergency Arrangements (STUK Y/2/2018), Security (STUK Y/3/2016) and Disposal of Nuclear Waste (STUK Y/4/2018), presents procedures connected to the licence process of the use of nuclear energy, which serve as the basis of the requirements of this Guide and which are referred to in this Guide.

Legislation on the decommissioning licence (Nuclear Energy Act and Decree) was updated in late 2017. The licensee shall submit to STUK with the decommissioning licence application the documents referred to in Section 36a of the Nuclear Energy Decree. Decommissioning licence applications are not anticipated in the coming years, so the updated legislation concerning the decommissioning licence shall be considered in the next update to Guide YVL A.1.

Legislative amendments that entered into force in 2017 did not bring significant changes to the national licence process. Experiences during the construction of the Olkiluoto 3 nuclear power plant unit and lessons learned from the Fukushima accident in 2011 have influenced the review of the licence process and safety requirements both in national legislation and in the oversight of the Radiation and Nuclear Safety Authority. The requirements concerning the preparation and submission of documents also take into account the procedures for electronic services (Act on Electronic Services and Communication in the Public Sector 13/2003).

The IAEA's IRRS (Integrated Regulatory Review Service) review conducted at STUK in autumn 2012 was taken into account in the preparation of the Guide. As regards this Guide, the recommendations of the review focused on the development of STUK's inspection activities and on presenting the connection between nuclear safety requirements and STUK's radiation safety and emergency preparedness guides in the regulations.

The Guide includes three annexes that supplement and specify the requirements:

- Annex A "Documents to be submitted to the Radiation and Nuclear Safety Authority in connection with an application for a decision-in-principle and the licensing process" lists the documents to be submitted to STUK for approval or for information in connection with an application for a decision-in-principle and the licensing process, and specifies the content requirements for documentation.
- Annex B "Submission of documents to the Radiation and Nuclear Safety Authority" specifies the requirements concerning the submission of documents. The requirements concerning electronic services are new.

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- Annex C “Nuclear liability arrangements” presents and specifies the requirements concerning nuclear liability arrangements. Guide YVL D.2 “Transport of nuclear materials and nuclear waste” presents requirements for descriptions of nuclear liability insurance and transfer of responsibilities as a part of the plan for transporting nuclear materials and commodities.

The Guide’s nuclear safety requirements are also supplemented with requirements presented in other field-specific YVL Guides. The field-specific YVL Guides in question are referenced where appropriate.

2 Scope of application

Guide YVL A.1 provides a summary of the obligations imposed on the licence applicant and the licensee, as well as the regulatory oversight to be taken by STUK in processing a licence application for the use of nuclear energy and at the different stages of the design, construction, commissioning, operation and decommissioning of a nuclear facility.

3 Justifications of the requirements

The requirements of the Guide are primarily based on legislation, and the relevant section is indicated in the requirement. The justifications of the requirement are presented below only if it is necessary to clarify the understanding of the requirement or if the requirement has not direct legal basis.

3.1 Justifications of the requirements by topic

3.1.1 Chapter 3.2 Preparations for applying for a construction licence

Requirement 305. *An organisation issued with a Government decision-in-principle for the construction of a nuclear power plant shall submit to STUK for information the requirements pertaining to the safety design and licensing of the plant specified in the invitation to tender.*

The requirement aims to ensure that national safety requirements concerning the design and licence process of a nuclear facility are sufficiently made known to the plant supplier candidates already during the tender stage. The documents are requested to be submitted to STUK for information.

Requirement 306. *An organisation issued with a Government decision-in-principle for the construction of a nuclear power plant shall submit to STUK for information the auditing programme pertaining to the plant supplier candidates.*

The requirement aims to ensure that the audit programme for plant supplier candidates is sufficient in consideration of national nuclear safety requirements. This also supports STUK’s own preparation for oversight of the project. The audit programme is submitted to STUK for information.

Requirement 307. *An organisation issued with a Government decision-in-principle for the construction of a nuclear facility shall submit to STUK for information a plan for*

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the preparations made by the organisation in view of filing an application for a construction licence.

The requirement aims to ensure that an organisation preparing for the construction licence stage has sufficient competence and sufficient resources to process tenders and apply for a construction licence. The plan is requested to be submitted to STUK for information.

3.1.2 Chapter 3.12 and Annex B Submission of documents to the Radiation and Nuclear Safety Authority

Requirement 374. *The licensee shall assess the acceptability of safety-significant products. The licensee shall, in particular, ensure that the safety requirements pertaining to the product concerned are met, with due consideration given to any other information available that can be used for assuring safety. With regard to the depth and extent of the acceptability assessment, due consideration shall be given to the significance of the product in terms of nuclear and radiation safety, as well as to its technical complexity, novelty and uniqueness. Those conducting the acceptability assessment shall be independent of the product's design and implementation.*

Requirement 375. *The licensee shall duly review the conformance of the documents pertaining to safety-significant products before submitting the documents to STUK. To demonstrate this, the licensee shall, at a minimum, provide the following information in the submitted document:*

- *the licensee's justified assessment of the product's acceptability;*
- *the scope and extent of the licensee's in-house inspection;*
- *the due execution of the process (e.g. design process) defined for the generation of the document concerned, including due execution of the verification and validation stages defined for the process; and*
- *the fulfilment of the safety requirements in the design documentation: the licensee's description on how the requirements of the YVL Guides, reference standards and any prior decisions on the matter issued by the Radiation and Nuclear Safety Authority have been met. If any non-conformances are detected in the due fulfilment of the safety requirements, their acceptability shall be justified in detail.*

Definition of 'product': *Product shall refer to a result of a process. Examples of products include a nuclear facility, plant modification, system delivery, single component or part thereof, plan or design, processed material, or information product. A service is not a product.*

The requirement aims to ensure that the licensee has assessed the acceptability of the product and the product documents' conformity to requirements in its own organisation sufficiently comprehensively, independently and with justifications, and has confirmed the appropriateness of the process specified for producing the document, fulfilment of safety requirements and acceptability of any non-conformances with safety requirements. The requirement was added to the YVL Guide based on the experiences gained during the construction of the new nuclear power plant.

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The licensee's justified assessment of the acceptability of the product may be included in a separate summary of justifications document, safety assessment, suitability assessment or covering letter on a case-by-case basis.

Guides YVL E.3 "Pressure vessels and piping of a nuclear facility", YVL E.6 "Buildings and structures of a nuclear facility", YVL E.8 "Valves of a nuclear facility", YVL E.9 "Pumps of a nuclear facility", YVL E.10 "Emergency power supplies of a nuclear facility" and YVL E.11 "Hoisting and transfer equipment of a nuclear facility" present more detailed requirements for the summary of justifications to be submitted as an annex to the construction plan, and Guide YVL E.5 "In-service inspection of nuclear facility pressure equipment with non-destructive testing methods" for the summary of justifications to be submitted as an annex to the in-service inspection and qualification documents.

In connection with plant and system design, according to Guide YVL B.1 "Safety design of a nuclear power plant", the licensee is expected to prepare a preliminary safety assessment independent of the designer and submit it as an annex to a safety-significant design document being submitted to STUK for approval. Requirement 375 of Guide YVL A.1 is also considered fulfilled when the licensee's own safety assessment is supplemented with the information required by requirement 375.

Requirement 377. *If the licence applicant or licensee submits confidential information to STUK, the document concerned shall be duly marked as confidential, and the necessary precautions shall be taken accordingly when the document is submitted. The request for confidential processing shall be made in the covering letter.*

STUK assesses the need for documents to be treated as confidential on a case-by-case basis in accordance with the principle laid down in the Act on the Openness of Government Activities (621/1999).

Requirement A5. *Report on quality management during construction*

Under Section 35 of the Nuclear Energy Decree, the license applicant shall submit a description of quality management during the construction of the nuclear facility. The description shall present the license applicant's organisation, significant plant supplier organisations, these supplier's scope of supply and overall descriptions of organisations' management systems. The description shall show on general level the systematic procedures adhered to by the organisations involved in the design and construction of the nuclear facility in their operations affecting quality.

The license applicant's project plan for the construction stage, complete with the project's human-resource and quality plans, organisational development plans and risk management plans related to safety and quality, shall be submitted to STUK for information.

Additionally, the quality plans of the nuclear plant supplier, suppliers of nuclear fuel, control rods and principal components and equipment, and design organisations shall be submitted to STUK for information. STUK may, at its discretion, request that the

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quality management documents of other organisations involved in the facility project to be submitted to STUK for information as well.

The general requirements pertaining to the management system and quality management are specified in Guide YVL A.3.

The licence applicant's lifecycle phase affects the fulfilment of the requirement. A licence applicant with a facility in operation and an appropriate management system for it must probably prepare a quality plan supplementing the management system for a new construction project, whereas the management system of the organisation of a completely new licence applicant may be consistent with a quality plan connected to the construction phase. The licence applicant must assess and propose actions and descriptions that fulfil the aim of the requirement, i.e. nuclear and radiation safety and quality management during the construction phase.

Requirement B08. *STUK performs a pre-inspection on the documents to ascertain that the form and content of the document are in compliance with the requirements set out in the YVL Guides. If the pre-inspection indicates that a document requires substantial additions or corrections, it will be returned to the licence applicant without closer scrutiny. If so, STUK will suspend the processing of the document, notify the licensee or licence applicant of this and demand that the party concerned provide the requested additional information by the set date. If the shortcomings are negligible, a normal request for clarification will be made.*

In the pre-inspection of a document submitted for approval, STUK pays attention of ensure that the document is appropriate and fulfils the requirements of YVL Guides.

Requirement B11. *The documents shall be clearly structured.*

For example, when a preliminary inspection document for a modification is drawn up, the purpose of the modification, its technical implementation, the assessment of its safety significance, the related analyses and calculations and the conclusions drawn from them shall be clearly separated from one another.

Requirement B16b. *The licensee shall report to STUK for information any delays to its self-reported deadlines, similarly to what is described in requirement B16a, because they have influenced STUK's previous processing.*

When the licensee sends documents to STUK for approval (or for information), STUK makes a decision based on the information presented in the documents and other official documents concerning the matter. The content of the decision and the requirements presented therein are influenced by what the licensee presents in its documents in regard to the matter. If the licensee presents a plan for the implementation of a matter, it serves as a partial basis for the decision and influences the requirements recorded in the decision. If the licensee has convincingly assured that it will, for example, implement a matter within a specific time period, STUK may not need to present a requirement regarding the matter if the actions and time limits can be considered sufficient.

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Therefore, plans presented by the licensee are by nature in the same position as requirements presented by STUK in its decision, so they are treated as the conditions of a decision. For this reason, STUK must receive notice in case of changes to the plans or time limits which were presented by the licensee in its documents and which influenced the content of the decision. Because they are not nominally requirements presented by STUK, it is not necessary to apply for a time extension for them as it would be for deviations from the time limits of requirements presented by STUK.

However, STUK must be notified with an official letter for information if plans that served as the basis of a decision change in terms of content or if there are delays from a previously presented implementation schedule. Based on such documents submitted for information, STUK can take the matter into its approval processing, if necessary, and present its view of the acceptable procedure in its decision.

4 International provisions concerning the scope of the Guide

International literature connected to the scope of application of the Guide:

- WENRA (Western European Nuclear Regulators Association) Reference Levels Issue P: Periodic Safety Review
- IAEA Safety Standards Series SSG-25, Periodic Safety Review of Nuclear Power Plants, published 2013
- IAEA Safety Guides, Functions and Processes of the Regulatory Body for Safety, GSG-13, September 2018.

5 Impacts of the Tepco Fukushima Dai-ichi accident

The Fukushima accident did not result in new requirements in this Guide.

6 Needs for changes taken into account in the revision

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.

Annex B to the Guide has been updated to correspond with current practices. The update takes into account, for example, electronic services.

The Guide and, in particular, its Annex A.3 "Application for an operating licence" have also been further specified based on experience received in connection with reviewing an operating licence application. A requirement concerning a descriptions of the licensee's safety culture and leadership during operation to be submitted with the operating licence application has been added to the Guide.

The requirements of the Guide do not contain any possibilities for administrative burden reduction.