

REGULATORY CONTROL OF SAFETY AT NUCLEAR FACILITIES

1	GENERAL	5
2	Government resolution	5
2.1	Application and its processing	5
2.2	Documents to be submitted to STUK	6
3	Construction licence	6
3.1	Licence application and its processing	6
3.2	Documents to be submitted to STUK	6
4	Operating licence	9
4.1	Licence application and its processing	9
4.2	Documents to be submitted to STUK	9
5	Renewal of the operating licence and periodic safety	Y
	REVIEW	11
6	Other licences necessary for the use of nuclear en	ergy 12
6.1	General	12
6.2	Export licence	12
6.3	Transfer licence	13
6.4	Import licence	13
6.5	Transport licence	13
6.6	Licence for the possession and transfer of information	13
		continues

This Guide is in force as of 1 August 2006 until further notice. It replaces Guide YVL 1.1, issued on 27 January 1992.

Third, revised edition ISBN 952-478-121-2 (print) Dark Oy / Vantaa 2006

Helsinki 2006 ISBN 952-478-122-0 (pdf) ISSN 0783-232X ISBN 952-478-123-9 (html)

7	Construction and commissioning of a nuclear facility			
7.1	General	13		
7.2	Construction Inspection Programme	14		
7.3	Inspections and regulatory control required by YVL Guides			
8	Operation of a nuclear facility	17		
8.1	General	17		
8.2	Periodic Inspection Programme	17		
8.3	Inspections required by YVL Guides	18		
8.4	Control by STUK's resident inspectors	18		
9	SAFETY UPGRADING	18		
9.1	General principles	18		
9.2	Monitoring and analysis of operational events	18		
9.3	Operating experience gained abroad	19		
9.4	Safety research and commissions supporting regulatory control	19		
10	Modifications in a nuclear facility	19		
10.1	Structural modifications in a nuclear facility	19		
10.2	Modifications in the software used for safety assessment	20		
10.3	Changes in the licensee's organization	20		
10.4	Changes in the documents	20		
11	References	21		

Authorisation

By virtue of the below acts and regulations, the 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. After having heard those concerned, 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 account section 27 of the Government Decision (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 General

The Nuclear Energy Act (990/1987) [1] and Decree (161/1988) [2] provide the general basis for the use of nuclear energy and for its regulatory control.

In accordance with the Nuclear Energy Act, the use of nuclear energy constitutes operations subject to licence. A Government resolution, a construction licence, an operating licence and renewal of the operating licence are applied for from the Government. In accordance with the Nuclear Energy Decree, the licence applicant shall also submit an assessment report in accordance with the Act on Environmental Impact Assessment Procedure (468/1994) when applying for a Government resolution. The Radiation and Nuclear Safety Authority (STUK) will provide a statement about the environmental impact assessment programme and the assessment report.

In accordance with Section 9 of the Nuclear Energy Act, it is the licensee's duty to ensure the safety of the use of nuclear energy, and to see to the physical protection and emergency response and other arrangements necessary to reduce nuclear damage that do not rest with the authorities. The licensee bears primary responsibility for the safety of a nuclear facility. This also includes verifying that all organizations whose operations are closely linked to the nuclear facility have established policies in which nuclear safety takes first priority.

In accordance with Section 55 of the Nuclear Energy Act, the Radiation and Nuclear Safety Authority is responsible for regulatory control of the safe use of nuclear energy. Furthermore, STUK is responsible for regulatory control of the physical protection and emergency response arrangements and for safeguards of nuclear materials. Chapters 8 and 10 of the Nuclear Energy Act and Chapter 15 of the Nuclear Energy Decree deal with the obligations and supervisory rights vested in STUK as well as the regulatory control of the use of nuclear energy exercised by STUK. The Act (1069/1983) [3] and Decree (618/1997) [4] pertaining to STUK describe STUK's mission and organization.

The Advisory Committee on Nuclear Safety appointed by the Government operates in conjunction with STUK for the preparatory consideration of issues related to the safe use of nuclear energy. The Committee's duties have been defined in Decree (164/1988) [5]. The Committee issues statements about the licence applications for nuclear facilities and about other matters on STUK's request. If necessary, the Committee also makes suggestions within the scope of its duties.

This Guide gives a summary of the primary obligations imposed on the licence applicant/licensee and of STUK's control measures during the processing of licence applications for nuclear facilities as well as during the construction and operation of a nuclear facility. The regulatory control measures by STUK described in this Guide do not replace the obligation imposed on the licensee to take sufficient actions with a view to ensuring the safety. A nuclear facility refers to facilities defined in Section 3 of the Nuclear Energy Act. The Guide mainly concentrates on nuclear power plants, which in accordance with the definition given in Reference [1] mean a complex formed by reactor plants and other nuclear facilities located at the same plant site. The Guide concerns research reactors where applicable. This Guide does not deal with the decommissioning of a nuclear facility or the final disposal of operating waste and spent nuclear fuel.

'Quality' terminology in accordance with Standard SFS-EN ISO 9000 [6] is used in this Guide. The quality management system refers to the same issue as the term 'quality assurance programme' used previously; the term 'quality assurance programme' has been used, for instance, in nuclear energy legislation.

2 Government resolution

2.1 Application and its processing

The construction of a nuclear facility of great general significance requires a Government resolution that the construction of the facility is in the overall interest of society. In accordance with Section 15 of the Nuclear Energy Act, the Government resolution shall be submitted to Parliament for consideration, who may reverse the resolution as such or decide that it remains in force as given.

The regulations concerning the application for and consideration of a Government resolution have been given in Sections 12–15 of the Nuclear

Energy Act and in Sections 23–30 of the Nuclear Energy Decree. The application shall be supplemented with the documents listed in Section 24 of the Nuclear Energy Decree. The application may contain one option or several options for the plant site and plant type, on which a resolution will be subsequently taken.

In accordance with Section 12 of Nuclear Energy Act, STUK shall make a preliminary safety assessment of the application. In its safety assessment, STUK states whether any factors have arisen indicating a lack of sufficient prerequisites for constructing a nuclear facility as prescribed in Section 6 of the Act. The assessment shall be based on the Government Decisions [7, 8, 9, 10] issued under Section 81 of the Nuclear Energy Act. Furthermore, STUK takes a stand on the possibility of fulfilling other requirements laid down in legislation and YVL Guides as regards the issues to be reviewed by STUK.

2.2 Documents to be submitted to STUK

When applying for a Government resolution, descriptions of the facility options in question shall be submitted to STUK, in addition to the documents required in Section 24 of the Nuclear Energy Decree. The following information, i.a., shall be given about each facility option:

- a description of the facility and its reactor, primary circuit and containment as well as other safety systems
- references to the facilities that have served as models, and a summary of the most significant modifications compared with them
- a summary of the safety analyses carried out for the facility option
- general plans for the facility's implementation organization, the suppliers of the facility and its most important systems and components, as well as quality management of the implementation
- the licence applicant's own assessment of the opportunity to implement the facility option in question in accordance with the Finnish regulations.

STUK may request detailed information on each facility option at its discretion.

If Parliament ratifies the Government resolution, the licence applicant shall submit to STUK for information the safety-related design criteria used for the nuclear facility in the invitation for tenders.

3 Construction licence

3.1 Licence application and its processing

A construction licence for a nuclear facility shall be applied for from the Government. The application for a licence and its processing are dealt with in Sections 16, 17, 18, 19, 23, 24 and 25 of the Nuclear Energy Act and in Sections 31, 32, 35, 37, 37a, 38, 39 and 40 of the Nuclear Energy Decree. The application shall be supplemented with the documents listed in Section 32 of the Nuclear Energy Decree.

STUK issues a statement on the application for a construction licence. The statement is supplemented with a safety assessment. When preparing the safety assessment, STUK requests from the Ministry of the Interior a statement about the documents referred to in Section 35, Point 4, of the Nuclear Energy Decree concerning the physical protection and emergency response arrangements.

The preconditions for granting a construction licence are defined in Sections 18 and 19 of the Nuclear Energy Act. In its safety assessment, STUK takes a stand on the fulfilment of the requirements laid down in the relevant legislation and YVL Guides regarding the issues to be controlled by STUK.

The construction of a nuclear facility shall not begin, as far as the structures affecting nuclear safety are concerned, before the Government has granted the construction licence required by the Nuclear Energy Act for the facility. Beginning the formwork and reinforcing work of the safety-classified concrete structures at the building site is considered to be construction of this kind. If the manufacture of structures and components for the nuclear facility is begun before the construction licence is granted, the licence applicant shall apply for STUK's prior approval for commencing the work.

3.2 Documents to be submitted to STUK

When applying for a construction licence, the documents listed in Section 35 of the Nuclear Energy Decree, and other reports considered nec-

essary by STUK under Subsection 2 of Section 35 of the Decree shall be submitted to STUK for approval. STUK issues a statement about the construction licence application only after having approved essential parts of each of these documents by a separate decision. Requirements for these documents and specified instructions for their submission are given below.

Preliminary Safety Analysis Report

The purpose of the Preliminary Safety Analysis Report (PSAR) is to demonstrate that the factors affecting safety and the safety regulations have been adequately taken into account.

The PSAR shall include the following documents: a description of the nuclear facility's safety principles and design basis, as well as other design criteria and how these are met, a detailed description of the facility and the site, a description of the facility's operation, a description of the facility's behaviour in transient and accident conditions, a summary of the results of the Probabilistic Safety Assessment (PSA), and a report on environmental effects of the facility's operation. Guide YVL 2.0 gives the detailed requirements for describing safety-classified systems.

The Safety Analysis Report shall be primarily drawn up in Finnish. However, STUK may agree, on application, that certain parts of the safety analysis report to be defined separately could be submitted to STUK in some other language approved by STUK. An example of the contents of the Safety Analysis Report is given in Ref. [11].

The purpose of topical reports is to describe in detail on what kinds of experimental research and theoretical analyses the facility design is based. The reports may be related to the facility in question or to another facility of a similar type designed by the same supplier. In the PSAR, a reference shall be made to the topical reports that play a significant role in assessing the Safety Analysis Report.

Topical reports to be submitted concern, e.g., the fuel, reactor, reactor pressure vessel, safety systems and containment. These reports shall include research results important for design and describe in detail the calculation models used for design and the codes employed for computer analyses. Furthermore, they shall give the most significant results and conclusions.

The topical reports shall be submitted to STUK for approval in such a way that they can be dealt with during the consideration of the corresponding item in the Preliminary Safety Analysis report.

As far as nuclear power plants are concerned, requirements for the analytical methods and results of deterministic accident analyses are defined in Guide YVL 2.2.

Proposal for a Safety Classification Document

The Safety Classification Document shall include classification of the systems, structures and components important to safety of the nuclear facility on the basis of their functional and structural safety significance. In making the classification, the functions with which the systems, structures and components are linked shall also be considered.

The safety class affects the requirements set for the design, manufacture, installation, testing and inspections. STUK determines its regulatory control measures taken for each item on the basis of the safety class.

As far as nuclear power plants are concerned, requirements for the safety classification are given in Guide YVL 2.1. The safety classification shall be assessed with the aid of the PSA in accordance with Guide YVL 2.8.

Report on quality management during construction

The report shall describe the systematic procedures followed by the organizations involved in the design and construction of the nuclear facility in their operations that affect quality.

The quality manual of the construction licence applicant concerning the construction phase shall be submitted to STUK for approval.

The quality manuals of the facility's main supplier, building contractor, fuel supplier, suppliers of the most important components and equipment, and design organizations shall be submitted to STUK for information. If other organizations play a significant role in implementing the facility project, STUK also requests, at its discretion, their quality manuals for information.

Guide YVL 1.4 gives the general requirements for the management system linked with quality and safety management.

Plans for physical protection and emergency response arrangements

The purpose of physical protection is to prevent illegal acts against the nuclear facility. The preliminary physical protection plan shall include a plan for the security arrangements during the construction and operation of the nuclear facility. The plan shall cover both the structural protection of the facility and the administrative procedures.

Emergency response arrangements are aimed at limiting nuclear damage in the nuclear facility and its environment in the event of an accident. The preliminary emergency plan shall include a plan for the facility's own emergency response arrangements and their connection with emergency plans for which the authorities are responsible. The plan shall incorporate consideration of the emergency response arrangements in the facility design, and the administrative procedures.

Government Decisions [8] and [9] define the general requirements for the physical protection and emergency response arrangements of nuclear power plants. Detailed requirements have been laid down in Guides YVL 6.11 and YVL 7.4.

Plan for arranging necessary safeguards to prevent the proliferation of nuclear weapons

The purpose of nuclear material safeguards is to ensure that nuclear materials and other nuclear items will not be used to make nuclear weapons or other nuclear explosives. The plan for implementing the safeguards shall include the design data on the facility structure and the basic data on operation, as well as a description of how the nuclear material safeguards are meant to be managed in the facility.

The requirements for nuclear material safeguards and STUK's regulatory control measures are dealt with in Guides YVL 6.1, YVL 6.9 and YVL 6.10. Any permits linked with acquisitions are dealt with in Section 6 below.

Verification of the opportunities for regulatory control

In accordance with Section 35 of the Nuclear Energy Decree, the licence applicant shall describe and verify the arrangements for implementing the regulatory control by STUK both in Finland and abroad.

Design-phase Probabilistic Safety Assessment (PSA)

The design-phase PSA refers to a preliminary analysis of Levels 1 and 2 of the Probabilistic Safety Assessment (PSA). Level 1 of the PSA constitutes analysis of the probability of reactor core damage. The analysis of Level 2 assesses the amount, probability and timing of radioactive materials leaking from the containment.

As far as nuclear power plants are concerned, the purpose of the design-phase Probabilistic Safety Assessment is to demonstrate that the probabilistic design objectives stated in Guide YVL 2.8 are achieved. The Guide also gives requirements for the contents of the analysis.

Other reports

With regard to nuclear power plants, the licence applicant shall submit a report on fulfilment of the requirements laid down in Government Decisions 395–397/1991 and in the relevant YVL Guides. Correspondingly, with regard to other nuclear facilities, the licence applicant shall submit a report on fulfilment of the requirements set in the YVL Guides concerning the nuclear facility in question.

The licence applicant shall submit a preliminary description of the principles of managing the ageing of the facility. The description shall take account of all significant ageing and wear mechanisms, and potential degradation owing to ageing. The following information, i.a., shall be provided in the report:

- the general ageing management strategy for the facility and the prerequisites for its implementation
- provision for sufficient margins in designing the systems, structures and components important to safety to ensure that the systems, structures and components will be capable of fulfilling all the necessary safety functions throughout their operating lives
- how the facility layout ensures accessibility to the systems, structures and components to enable their inspection, maintenance and repair

- how the suitability and reliability of the systems, structures and components for all design basis operating and accident conditions are ensured during their acquisition
- how the availability of sufficient reference data on the systems, components and structures and on their operating conditions is ensured during construction and commissioning (testing)
- how the availability of knowledge related to ageing management and the expertise of the facility personnel are ensured as early as during the design, construction and commissioning (testing) of the facility.

The licence applicant shall submit to STUK for information the plan for the construction project of the nuclear facility, which describes the main stages of the project and the necessary official approvals, including the target schedules.

4 Operating licence

4.1 Licence application and its processing

An operating licence for a nuclear facility shall be applied for from the Government. The application for a licence and its processing are dealt with in Sections 16, 17, 20, 23, 24 and 25 of the Nuclear Energy Act and in Sections 33, 34, 36, 37, 38, 39 and 40 of the Nuclear Energy Decree. The application shall be supplemented with the documents listed in Section 34 of the Nuclear Energy Decree.

STUK issues a statement on the application for an operating licence. The statement is supplemented with a safety assessment. When preparing the safety assessment, STUK requests from the Ministry of the Interior a statement about the documents referred to in Section 36, Point 6, of the Nuclear Energy Decree concerning the physical protection and emergency response arrangements.

The preconditions for granting an operating licence are defined in Section 20 of the Nuclear Energy Act. In its safety assessment, STUK takes a stand on the fulfilment of the requirements laid down in the relevant legislation and YVL Guides as regards the issues to be controlled by STUK.

4.2 Documents to be submitted to STUK

When applying for an operating licence, the documents listed in Section 36 of the Nuclear Energy Decree, and other reports considered necessary by STUK under Subsection 3 of Section 36 of the Decree shall be submitted to STUK for approval. STUK issues a statement about the operating licence application only after having approved essential parts of each of these documents by a separate decision. Requirements for these documents and specified instructions for their submission are given below.

Final Safety Analysis Report

The general requirements for the Preliminary Safety Analysis Report also apply to the Final Safety Analysis Report. The Safety Analysis Report, including its accident analyses and topical reports, shall be based on the actual systems, structures and components of the nuclear facility. Guide YVL 2.0 gives the detailed requirements for describing safety-classified systems.

In addition to the information on the nuclear facility and the site, the Final Safety Analysis Report shall include descriptions of the facility commissioning and operation. Guide YVL 2.5 deals with requirements for the testing of nuclear power plants.

Probabilistic Safety Assessment

The Probabilistic Safety Assessment (PSA) shall include analyses in accordance with Levels 1 and 2, which are based on the actual systems, structures and components of the nuclear facility.

Guide YVL 2.8 defines the requirements for the Probabilistic Safety Assessment of a nuclear power plant.

Quality management system during operation

The operation-time quality management system shall describe the systematic procedures that are followed during the commissioning and operation of the nuclear facility in functions affecting quality and safety.

The tasks, authority and responsibilities of the licensee's organizational units, as well as the personnel's competence requirements shall be specified in a separate organization manual or a corresponding document, which shall be submitted to STUK for information.

Operational Limits and Conditions

The Operational Limits and Conditions shall determine the limits on the process parameters most important to safety, which are complied with in all operational states, as well as the limitations on the facility operation resulting from any component failure, or a deviation from a process parameter value. The Operational Limits and Conditions shall also set requirements for the tests and inspections important to safety by which the operability of the systems and components is periodically verified. Furthermore, the Operational Limits and Conditions shall determine the minimum number of personnel required for the different operational states of a nuclear power plant and define the release limits on radioactive materials.

The coverage and sufficient balance of the Operational Limits and Conditions of a nuclear power plant shall be verified in accordance with Guide YVL 2.8.

Summary programme for inservice inspections

The summary programme for in-service inspections shall define the periodic inspections of the components and structures important to safety to be carried out after commissioning. The programme shall contain the items scheduled for inspection, including the scopes, methods and periods of inspection.

Guide YVL 3.8 gives the requirements for inservice inspections of nuclear power plants and contents of the necessary qualification.

Report on physical protection and emergency response arrangements

The plans for physical protection and emergency response arrangements shall take account of the facility rooms, systems and components as well as the structure and areas of responsibility of the facility's operating organization.

The requirements for the contents of a physical protection plan have been defined in Guide YVL 6.11 and in STUK's separate supplementary decisions.

As far as nuclear power plants are concerned, the requirements for the contents of an emergency plan have been given in Guide YVL 7.4.

Report on arrangement of the necessary safeguards to prevent the proliferation of nuclear weapons

The report shall constitute a manual concerning the accounting and control system of nuclear materials.

Guide YVL 6.9 gives the requirements for the accounting and control system of nuclear materials.

Administrative rules

In accordance with Section 122 of the Nuclear Energy Decree, the administrative rules shall determine the duties, authority and responsibilities of the designated responsible manager of a nuclear facility, his/her deputy and the rest of the personnel needed for operation of the nuclear facility.

Environmental radiation monitoring programme

The environmental radiation monitoring programme shall describe the systematic measures taken to monitor the occurrence of radioactive materials in the vicinity of the nuclear facility from which they originate. Measures in accordance with the programme shall be initiated early enough before the facility is commissioned to enable assessment of the facility's environmental effects.

As far as nuclear power plants are concerned, the requirements for the environmental radiation monitoring programme have been presented in Guide YVL 7.7.

Other reports

With regard to nuclear power plants, the licence applicant shall submit a report on fulfilment of the requirements laid down in Government Decisions 395–397/1991 and in the relevant YVL Guides. Correspondingly, with regard to other nuclear facilities, the licence applicant shall submit a report on fulfilment of the requirements set in the YVL Guides concerning the nuclear facility in question.

To make provision for the ageing of the facility, a plan shall be presented for how the design and qualification of the components and structures, their operation and operating experience, in-service inspections and tests, and maintenance are integrated so as to form a comprehensive ageing management programme. All significant ageing and wear mechanisms and potential degradation owing to ageing shall be identified to provide a basis for the plan. In addition, the following information shall be provided to support the plan:

- provision for sufficient margins in designing the systems, structures and components important to safety to ensure that the systems, structures and components will be capable of fulfilling all the necessary safety functions throughout their operating lives
- how the facility layout ensures accessibility to the systems, structures and components to enable their inspection, maintenance and repair
- how the suitability and reliability of the systems, structures and components for all design basis operating and accident conditions have been ensured during their acquisitions
- how the availability of sufficient reference data on the systems, components and structures and on their operating conditions has been ensured during construction and commissioning (testing)
- how the availability of knowledge related to ageing management and the expertise of the facility personnel have been ensured.

5 Renewal of the operating licence and periodic safety review

In accordance with Section 24 of the Nuclear Energy Act, the licence, excluding the construction licence, shall be granted for a fixed term. When the length of the term is considered, particular attention shall be paid to ensuring safety and to the estimated duration of operations. [--]. In applying for renewal of the operating licence for a nuclear facility that is being operated, the procedure to be followed is in general the same as in applying for an operating licence for a new

nuclear facility. The renewal of the operating licence always involves a periodic safety review of the facility.

Legislation has not prescribed the length of the term fixed for an operating licence. The term proposed by the licensee in its application can be justified on the basis of the ageing and planned future operation of the nuclear facility in question. If a licence is granted for a significantly longer term than ten years, STUK requires that the licensee carry out a periodic safety review of the facility and request its approval from STUK within about ten years of receiving the operating licence or of conducting the previous periodic safety review. STUK sets, by a separate decision, a deadline for submitting the periodic safety review for approval. For a separate periodic safety review, STUK shall be provided with similar safety-related reports as in applying for renewal of the operating licence.

The renewal of the operating licence and the periodic safety review are mainly based on the documents referred to in Section 36 of the Nuclear Energy Decree. They shall be continuously updated, and the updated versions shall be regularly submitted to STUK. When applying for renewal of the operating licence, the documents may be submitted to STUK only insofar as they have been amended since the previous updates. Furthermore, the application shall include a summary of the most significant changes to the documents after the granting of the valid operating licence and a description of the documents' updating status.

The licensee shall also submit a periodic safety review of its own concerning the safety status of the nuclear facility, potential areas of development and maintenance of the safety. This assessment shall include the following documents:

- with respect to nuclear power plants, a report on fulfilment of the requirements laid down in Government Decisions 395–397/1991 and in the relevant YVL Guides, and, correspondingly, with regard to other nuclear facilities, a report on fulfilment of the requirements set in the YVL Guides concerning the nuclear facility in question
- a summary of the renewed safety analyses and conclusions drawn from their results

- experience of the facility ageing and ageing management
- a description of the licensee's safety culture and safety management
- with respect to nuclear power plants, a report on the actions required in Section 27 of Government Decision 395/1991 and on the consequent plant improvements
- a report on compliance with any terms of the operating licence
- a summary of fulfilment of the requirements laid down in Section 20 of the Nuclear Energy Act.

The report on the safety culture shall include the assessment methods, conclusions from the current status and effects within the operating licence period, and the measures aimed to upgrade the safety culture. In assessing and upgrading the safety culture, the expertise acquired in both organizational studies and practical nuclear safety shall be put to good use.

In making its own periodic safety review, the licensee shall verify that the safety factors proposed in the IAEA's guide in question [17] have been taken into account to a sufficient degree in the safety review and other licence application documents.

When renewal of the operating licence is being applied for, STUK submits a statement on the application to the Ministry of Trade and Industry, and provides the statement with its own safety assessment. STUK takes a decision of approval on the separate periodic safety review required from the licensee and provides it with STUK's own safety assessment.

6 Other licences necessary for the use of nuclear energy

6.1 General

In accordance with Section 24 of the Nuclear Energy Decree, the holder of a construction licence or an operating licence for a nuclear facility is also entitled, on the basis of these licences, to possess, produce, handle, use and store at the facility site the nuclear materials and nuclear wastes as well as the materials, devices and equipment referred to in Appendix A of this Decree that are needed for operation of the nuclear facility or result from this operation. On the other hand, a separate licence is required for the transport of nuclear materials and nuclear wastes and for the import, export and transfer of all the products mentioned above, unless the operation has been separately exempted from licence (Sections 11–22 § of the Nuclear Energy Decree). The export of information related to the above-mentioned products also requires a licence, unless the export has been exempted from licence in accordance with the Nuclear Energy Decree or the Council Dual Use Regulation (EC No 1334/2000, amendment 1504/2004) [12]. The possession, import and transfer of information require a licence only if the information is subject to any particular safeguards obligation (Section 1 of the Nuclear Energy Decree).

6.2 Export licence

In addition to the Nuclear Energy Act, the export of nuclear products is controlled by the Council Dual Use Regulation (EC No1334/2000) [12]. The Dual Use Regulation supplements the regulations issued in the Nuclear Energy Decree.

Category 0 of Annex I of the Council Dual Use Regulation defines the materials, devices and information to which the regulation applies. The export of these products outside the EU and the intra-Community transfers (transfers within the EU) require a licence granted by the Ministry of Trade and Industry or STUK. Non-sensitive nuclear materials (depleted and natural uranium and uranium with a maximum enrichment factor of 20%) and information related to them are an exception: no licence is needed for their intra-Community transfers.

The licence shall be applied for from STUK, and the application shall contain the information required in Section 54 b of the Nuclear Energy Decree. In addition, the application shall include the form in accordance with Annex III of the Council Dual Use Regulation filled in where applicable.

The export of nuclear wastes is prohibited with certain exceptions (Section 6 a of the

Nuclear Energy Act). The export is allowed for research purposes, and in this case the licence application shall be submitted to STUK. The licence may be granted for a maximum of three years at a time.

6.3 Transfer licence

A licence for the transfer of nuclear materials and other nuclear items as well as nuclear waste is granted by STUK, from which the licence is also applied for. The application shall give the information required in Section 48 of the Nuclear Energy Decree. In the event of export, no separate transfer licence is needed (Section 21 of the Nuclear Energy Decree).

6.4 Import licence

The Ministry of Trade and Industry or STUK, depending on the product and the country of destination, grants an import licence for nuclear materials and other nuclear items as well as nuclear wastes. The licence is always applied for from STUK, and the application shall contain the information required in Section 53 b (nuclear materials and other nuclear items) and/or Section 55 d (nuclear wastes) of the Nuclear Energy Decree. Only small amounts of nuclear wastes for research purposes may be imported.

6.5 Transport licence

A separate licence is needed for the transport of nuclear materials and nuclear wastes, unless the transport has been exempted from licence (Section 17 of the Nuclear Energy Decree). A transport licence in Finland and through Finnish territory is granted by STUK, to which the licence application is also submitted. The regulations concerning a transport licence have been issued in Chapter 8 of the Nuclear Energy Decree.

6.6 Licence for the possession and transfer of information

A separate licence is needed for the possession and transfer of information, if the information is subject to particular safeguards obligations. The licence is applied for from STUK (Section 71 of the Nuclear Energy Decree). Detailed regulations concerning the licence and its application have been issued in Chapter 11 of the Nuclear Energy Decree.

7 Construction and commissioning of a nuclear facility

7.1 General

In accordance with Section 123 of the Nuclear Energy Decree, the licensee shall designate a responsible manager and his/her deputy for the construction and operation of a nuclear facility. These persons shall have approval from STUK for this job. A responsible manager and a deputy shall also be appointed for the transport of nuclear materials and nuclear waste, if the transport requires a licence in accordance with the Nuclear Energy Act. The qualifications required of the responsible manager have been defined in Section 125 of the Nuclear Energy Decree. In accordance with Section 129 of the Nuclear Energy Decree, the licensee shall also appoint persons who are responsible for emergency response arrangements, physical protection and safeguards of nuclear materials. Only persons who have received STUK's separate approval for their specific jobs can be appointed to these duties. The above-mentioned persons shall be appointed before the construction begins.

In accordance with Section 108 of the Nuclear Energy Decree, the different phases of construction of a nuclear facility may be begun only after STUK has, on the basis of the documents mentioned in Section 3.2 above and other detailed plans and documents it requires, verified in respect of each phase that the safety-related factors and safety regulations have been given sufficient consideration.

Review of the structure and equipment designs can be begun after STUK has found that the system-level design data of the system concerned are sufficient and acceptable. This assessment may take place as part of the review of the Preliminary Safety Analysis Report or as reviews of the separate system-specific descriptions, which are subsequently added to the Final Safety Analysis Report.

Approval of the Preliminary Safety Analysis Report by STUK is one of the preconditions for STUK's statement favouring the granting of a construction licence. During construction, STUK approves the necessary detailed designs for the systems, structures and components. As far as nuclear power plants are concerned, detailed information on the requirements for system descriptions has been provided in Guide YVL 2.0 and in YVL Guides of specific technical areas. The Final Safety Analysis Report approved by STUK is a precondition for STUK's statement favouring the granting of an operating licence.

In accordance with Section 109 of the Nuclear Energy Decree, STUK controls the construction of the facility in detail. The purpose is to ensure that the conditions stated in the construction licence, the regulations for pressure equipment and the approved plans referred to in Section 3.2 above are complied with and that the nuclear facility is constructed in other respects in accordance with the regulations issued on the basis of the Nuclear Energy Act. In particular, the control is aimed to verify that working methods ensuring high quality are employed for the construction.

Section 60 a of the Nuclear Energy Act requires that the manufacturers of nuclear pressure equipment and the inspection and testing organizations that exercise control have received STUK's approval. In accordance with Section 113 of the Nuclear Energy Decree, non-destructive testing of the structures and components of a nuclear facility may only be carried out by a testing organization and a tester approved by STUK. The procedures linked with these approvals have been described in Guides YVL 1.3 and YVL 3.4.

7.2 Construction Inspection Programme

The purpose of STUK's Construction Inspection Programme is to verify that the operations of the construction licensee ensure high-quality construction and implementation in accordance with the approved designs while complying with the regulations and official decisions concerned. In particular, the Construction Inspection Programme assesses and controls the following issues:

- the licensee's general operations with a view to constructing the facility
- detailed procedures in the various fields of technology implemented for constructing the facility
- dealing with safety matters and consideration of safety in management procedures

- the licensee's expertise and use of expertise
- quality management and quality control.

The Construction Inspection Programme is divided into two main levels: the upper level assesses the licensee's main operations, such as project management and resources management, project control, dealing with safety issues and project quality management. The next level, known as the operation level, assesses, e.g., project quality assurance, training of the operating personnel, inspection procedures, utilization of the PSA, document management, radiation safety, and structure and component-specific inspections in the various fields of technology. Furthermore, the emergency response arrangements during construction, physical protection, fire protection and nuclear waste treatment are included in the Construction Inspection Programme within the scope STUK considers necessary.

In addition to the above-mentioned inspections, of which the licensee is informed in advance, STUK carries out inspections without prior notice at its discretion.

7.3 Inspections and regulatory control required by YVL Guides

STUK controls the construction project, quality management of the construction and the licensee's safety work with the aid of inspections at its discretion. The inspections pertain, e.g., to the following issues:

- project management and control
- organization; training, competence and adequacy of the personnel
- dealing with safety matters
- implementation of quality management as a whole and in the different sectors
- control exercised by the licensee concerning the implementation of quality management by the licensee itself, the facility contractor and their subcontractors.

Buildings and concrete and steel structures

STUK controls the design, manufacture and installation of the buildings and concrete and steel structures important to safety. The control includes

• pre-inspection of structures

- inspections at the construction site concerning the readiness to begin work
- inspections concerning manufacture
- construction inspections of steel structures
- commissioning inspections.

The safety class of structures is taken into account when determining the scope of control and setting the requirements. The requirements for and control of concrete and steel structures have been described in Guides YVL 4.1 and YVL 4.2. Fire protection at nuclear facilities is discussed in Guide YVL 4.3.

Only organizations and persons in their employ that have been granted approval by STUK are allowed to carry out inspections and expert duties subject to licence relating to concrete and steel structures. Guides YVL 1.3 and YVL 4.1 deal with these duties and the approval procedures.

Components

STUK controls the design, manufacture and installation of pressure equipment and other mechanical components of nuclear facilities. The control includes

- inspection of the construction plans for components
- approval of the manufacturers and testing organizations
- inspections concerning manufacture
- construction inspections
- installation inspections
- commissioning inspections.

The safety class of components is taken into account when determining the scope of control and setting the requirements. On the licensee's application, STUK may approve a separate testing organization to carry out specified control duties. The requirements for and control of mechanical components have been described in Guides YVL 1.3, YVL 1.14 and YVL 1.15 and in YVL Guides of series 3 and 5. Guide YVL 3.0 describes the principles of pressure equipment control.

Guide YVL 3.4 presents the requirements for the approval of manufacturers. Only organizations and persons in their employ that have been granted approval by STUK are allowed to carry out inspection and testing duties subject to licence relating to mechanical components. Guide YVL 1.3 deals with these duties and the approval procedure.

STUK controls the design, manufacture and installation of electrical and instrumentation and control equipment of nuclear facilities. The control includes review of the suitability assessment, inspections concerning manufacture and installation to be conducted at STUK's discretion, and commissioning inspections.

The safety significance of the component concerned is taken into account when determining the scope of control and setting the requirements. The requirements for and control of electrical and instrumentation and control equipment have been described in Guides YVL 5.2 and YVL 5.5. Guides YVL 7.9 and YVL 7.10 give the requirements for radiation protection of nuclear facility workers and monitoring of occupational exposure. Other requirements and control concerning the radiation protection and environmental monitoring of a nuclear facility are discussed in guides of the YVL 7 Guide series.

Nuclear fuel

In accordance with Sections 114 and 115 of the Nuclear Energy Decree, STUK controls that the nuclear fuel is designed, manufactured, transported, stored, handled and used in compliance with the valid regulations.

The nuclear fuel licensing procedure and STUK's regulatory control measures for nuclear power plants have been described in Guide YVL 6.1.

Guides YVL 6.2, YVL 6.3, YVL 6.4, YVL 6.5, YVL 6.7 and YVL 6.8 give the requirements for the design, manufacture, transport, handling, storage and use of nuclear fuel.

Preparations for operation; organization and training

In accordance with Section 119 of the Nuclear Energy Decree, STUK controls that the organization operating the facility is appropriate and adequate and that the persons involved in the use of nuclear energy meet the competence requirements and that they are given proper training. Development and training of the operating organization shall begin early enough during the construction of the nuclear power plant (YVL 2.5).

When reviewing the administrative rules and organization manual referred to in Section 4.2 above, STUK assesses the appropriateness and adequacy of the licence applicant's organization and the qualifications required.

In accordance with Section 128 of the Nuclear Energy Decree, the operator of the facility systems in the main control room of a nuclear facility shall have STUK's approval for this job.

The requirements for the nuclear power plant operator licensing and the training of personnel have been defined in Guides YVL 1.6 and YVL 1.7.

Pre-operational testing

The purpose of the pre-operational testing of a nuclear facility is to demonstrate that the facility has been constructed and operates as designed. The testing consists of the following stages:

- system performance tests
- fuel loading and pre-criticality tests of the reactor systems
- making the reactor critical and low-power tests
- power tests.

STUK controls the testing of a nuclear facility by reviewing the general testing plans and programmes, by watching the tests at the nuclear facility and by reviewing the documents of test results.

The operation of a nuclear power plant is considered to begin when the loading of nuclear fuel into the reactor begins. The reactor loading requires that the Government has granted an operating licence and that STUK has approved the application concerning fuel loading and the reports on the reactor and fuel behaviour in the first operating cycle.

To ensure that the nuclear facility complies with the regulations applied to it, STUK verifies, in accordance with Section 20 of the Nuclear Energy Act, before the fuel loading that

 the documents linked with operation of the facility, referred to in Section 36 of the Nuclear Energy Decree, are acceptable in all respects

- the instruction manuals concerning operation of the facility, including instructions for accidents and transients, are adequate
- the organization operating the nuclear facility is appropriate and adequate
- the persons involved in the use of nuclear energy meet the competence requirements
- the persons designated as responsible manager for the facility operation and as his/her deputy have received STUK's approval
- there is a sufficient number of licensed operators at the facility
- for operation of the facility, persons who have received STUK's approval have been appointed to see to the emergency response arrangements, physical protection and safeguards of nuclear materials
- the commissioning inspections of the facility systems, structures and components have been carried out with acceptable results
- the results of system performance tests are acceptable insofar as it has been possible to perform the testing without the reactor
- pre-service inspections of the structures and components have been completed
- physical protection and emergency response arrangements are sufficient
- the necessary control to prevent the proliferation of nuclear weapons has been arranged appropriately
- the licensee of the nuclear facility has arranged indemnification regarding liability in the case of nuclear damage as prescribed.

The reactor may be made critical and brought to a higher power level in accordance with the decisions taken by STUK.

When the testing has finished, the holder of the operating licence shall assess the results of the testing as a whole. The testing results shall be used to assess, for instance, whether any changes in the Final Safety Analysis Report and in the operational limits and conditions are needed. On the basis of this assessment, the licensee shall make the necessary changes in the operational limits and conditions and in the Final Safety Analysis Report, and submit them to STUK for approval.

Guide YVL 2.5 deals with regulatory control of the testing of nuclear power plants.

8 Operation of a nuclear facility

8.1 General

Regulatory control of the safety of nuclear facilities in operation contains official inspections, which can be divided into four categories as follows:

- periodic inspections, which STUK has specified and recorded in the facility-specific periodic inspection programme
- inspections required by YVL Guides which the licensee is obliged to request as part of the measures carried out at the facility or which STUK conducts at its discretion
- control by local inspectors at nuclear power plants
- safety assessment on the basis of operating experience and safety research as well as other information obtained after the granting of the operating licence.

To support the regulatory control, STUK requires the submission of both fixed-term and event-specific reports. The requirements for reporting have been given in Guide YVL 1.5. The reports are used, on the one hand, to prepare the inspections and, on the other hand, to assess the safety-enhancing measures and to monitor the safety level in general.

The licensee shall annually submit to STUK for information the insurance policies concerning nuclear liability arrangements. It is STUK's duty to verify that the licensee has fulfilled the prescribed obligations concerning the nuclear liability of nuclear facilities. Guide YVL 1.16 deals with the nuclear liability arrangements.

In addition to the regulatory control of nuclear facility operation, STUK maintains its preparedness to act in emergencies of the facility. In an emergency, STUK acts as the authority controlling accident management and as an expert body giving assistance to the authorities in charge of the rescue services.

Linked with prevention of the proliferation of nuclear weapons, nuclear facilities are responsible for safeguards of nuclear materials in accordance with the obligations imposed by the international agreements Finland has signed. The licensee is responsible for nuclear material accounting and shall report on the events connected with safeguards of nuclear materials and on changes in the inventory to STUK and the European Commission in accordance with Guides YVL 6.9 and 6.10 and the Commission regulation No. 302/2005 [18]. STUK, the IAEA and the EU carry out inspections relating to nuclear materials and other nuclear items at the facility site. To enable these inspections, the licensee shall grant the inspectors access to the areas in question.

8.2 Periodic Inspection Programme

The inspections included in the Periodic Inspection Programme concern the licensee's operations that are important to safety. The objective of the Periodic Inspection Programme is

- to verify that the facility is operated and maintained in accordance with the regulations, design criteria, and instructions issued in the licensee's quality management system;
- to assess the licensee's operations with a view to maintaining and upgrading safety, the consideration of safety in the management procedures, implementation of the licensee's self-assessments, and active utilization of the gathered experience at all organizational levels;
- to acquire information to provide a basis for directing and enhancing STUK's regulatory control.

The Periodic Inspection Programme is drawn up by STUK and its contents are reviewed annually. The programme and the procedures to be followed in its implementation are described in STUK's internal guide. This guide and the necessary amendments to it are forwarded to the licensees of the nuclear facilities under control for information.

The inspection programme of nuclear power plants is divided into three main levels. The uppermost level assesses the level and efficiency of the licensee's safety management. Inspections of the next level concern, e.g., the assessment and upgrading of safety, the facility operation and maintenance, and the different sectors of

protection operations. The lowest level covers inspections of operations in the specific fields of technology. The inspection programmes of other nuclear facilities have been drawn up taking account of their special features with regard to nuclear and radiation safety.

8.3 Inspections required by YVL Guides

Inspections required by YVL Guides consist of inspections that the licensee is obliged to request as part of the measures carried out at the facility or which STUK conducts at its discretion.

The operation of a nuclear facility includes operations that may not be begun before STUK has given its approval for the operation concerned. STUK's decisions are required, for instance, in the event of modifications made at the facility.

Requirements and obligations concerning inspections required in YVL Guides are described in several YVL Guides.

Inspections required by YVL Guides cover the following issues:

- competence of the personnel
- inspections concerning operational events
- outage planning and implementation
- refuelling of the reactor
- in-service inspections in accordance with Guide YVL 3.8
- in-service inspections of registered pressure equipment
- modifications, repairs and preventive maintenance
- · start-up of the facility after annual outage
- procurement and use of nuclear fuel
- safeguards of nuclear materials
- exemption of nuclear waste from regulatory control.

Guides YVL 1.8 and YVL 1.13 deal with the requirements for and control of outages as well as modifications, repairs and preventive maintenance at nuclear power plants.

8.4 Control by STUK's resident inspectors

The duty of resident inspectors is to control operation and maintenance of nuclear power plants at the plant site. This includes, for instance, monitoring the licensee's operating and maintenance activities.

9 Safety upgrading

9.1 General principles

In accordance with Section 27 of the Government Decision (395/1991), operating experience from nuclear power plants as well as results of safety research shall be systematically followed and assessed.

For further safety enhancement, actions 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.

The assessment and upgrading of nuclear power plant safety does not end in the granting of the operating licence but also continues during operation. This is necessary for the following reasons:

- Operating experience reveals issues to which adequate attention has not been paid.
- Safety research increases understanding of the effects of plant ageing and organizational factors, and enhances opportunities to anticipate transient and accident sequences more accurately.
- Nuclear power plant technology continues to develop, and so it is appropriate to replace out-of-date components with new, improved equipment.
- General views of the safety level to be sought after and, consequently, the safety requirements change over time.

On the basis of safety assessment made during operation, both the licensee and STUK assess the need and opportunities to upgrade safety.

If new research findings and operating experience are considered to be significant for safety and require, for example, modifications to existing structures or operation of nuclear facilities, STUK evaluates and ensures that the licensee has launched the required studies and assessments as well as implementation of the necessary measures.

9.2 Monitoring and analysis of operational events

Operational events at a nuclear power plant may include single transients or observations but also recurrent or common cause failures. On the basis of the reports required from the operating organization and STUK's own inspection findings, STUK sets up an investigation team to analyse a certain event, if necessary. The specific duty of the team is to find out the root causes of the event and set the objectives for corrective measures.

Guide YVL 1.11 deals with the licensee's operations with a view to assessing and utilizing operating experience.

9.3 Operating experience gained abroad

In addition to operational events at the Finnish nuclear facilities, STUK monitors events at foreign facilities. STUK receives event reports through international organizations (IAEA, OECD) and directly from the regulatory authorities of various countries. STUK forwards the reports to the licensees for information. STUK also reviews the reports systematically. This means that STUK assesses, by each Finnish facility separately, whether measures upgrading safety should be taken on the basis of the lessons learned. Furthermore, STUK follows the licensees' measures to monitor and assess the operating experience gained abroad (see YVL 1.11).

9.4 Safety research and commissions supporting regulatory control

STUK participates in international work on upgrading nuclear and radiation safety both by means of preparation of standards and research within international organizations as well as through the exchange of information and co-operation with the regulatory authorities of other countries.

STUK is involved in international and domestic research work. Comparative analyses and studies are also needed to support the handling of licensees' applications; STUK mostly orders them from independent research institutes.

The licensees report on research work of their own and on the monitoring of research findings in accordance with Guide YVL 1.5 in their annual reports. STUK verifies that the licensees' operations fulfil the requirements laid down in Section 27 of the Government Decision (395/1991).

10 Modifications in a nuclear facility

10.1 Structural modifications in a nuclear facility

In accordance with Section 112 of the Nuclear Energy Decree, if the licensee intends to carry out modifications in the nuclear facility systems or structures, in nuclear fuel or in the way the facility is operated, and these modifications would have an effect on safety and would involve changes in the plans or documents approved by the Radiation and Nuclear Safety Authority (STUK) the licensee shall obtain an approval from STUK for these modifications before they are carried out. I = -1.

If facility systems, structures and components previously covered by STUK's approval procedure require modifications after commissioning of the facility, the planned modifications shall be submitted to STUK for approval before their implementation. If the facility modifications involve changes in the conditions set in the granted operating licence or in the criteria adopted when granting the licence, the facility modification shall be handled in accordance with Section 25 of the Nuclear Energy Act, to the extent applicable, following the same procedure as when the operating licence was granted.

At the site of a nuclear power plant, there are usually other nuclear facilities. These include, e.g., facilities required by nuclear waste management. If the construction of such a facility has been taken into account in the operating licence conditions of the nuclear power plant, no separate Government licensing procedure is needed. Otherwise, the necessary licences are determined in accordance with Section 6 of the Nuclear Energy Decree. If it is a question of a nuclear facility of considerable general significance referred to in Section 11 of the Nuclear Energy Act, a Government resolution that Parliament has ratified is also needed.

Guide YVL 2.0 gives the requirements for the contents of documents concerning system modifications of nuclear power plants. In addition, other YVL Guides deal with requirements for the contents of documents concerning technology

field-specific modifications. Guide YVL 1.8 discusses modifications of systems, structures and components.

When making modifications to the facility structure, the licensee shall assess which of the facility documents shall be updated to correspond to the changed situation.

10.2 Modifications in the software used for safety assessment

The safety of a nuclear facility is assessed and justified before commissioning and during operation with the aid of various tests and analyses. Testing and measuring equipment and computer software are used for this purpose. The results of tests and analyses are usually described in the Final Safety Analysis Report or the attached topical reports and, with regard to maintenance as, e.g., maintenance reports. The accuracy and reliability of safety assessment depends, e.g., on the software used for the work and on the data used as the basis for calculations.

If the procedures or the software used for safety assessment or the data used as the basis for the assessment are modified, the significance of the modifications for safety shall be assessed and documented.

When making modifications to the procedures for facility safety assessment, the licensee shall assess which of the facility documents shall be updated to correspond to the changed situation.

10.3 Changes in the licensee's organization

If the licensee makes changes in its organization, the administrative rules and/or the organization manual shall be updated to correspond with the changes made. The updated administrative rules shall obtain STUK's approval before they are brought into use. The significance of an organizational change is based on the safety significance of those functions on which the change has an effect. The effect of significant changes on safety shall be assessed, and this assessment shall be submitted to STUK as a part of the updated administrative rules and/or organization manual.

When making organizational changes, the licensee shall also assess which documents other than those mentioned above shall be updated to correspond to the changed situation.

10.4 Changes in the documents

In accordance with Section 112 of the Nuclear Energy Decree, if the licensee intends to carry out modifications in the nuclear facility systems or structures, in nuclear fuel or in the way the facility is operated, and these modifications would have an effect on safety and would involve changes in the plans or documents approved by the Radiation and Nuclear Safety Authority (STUK) the licensee shall obtain an approval from STUK for these modifications before they are carried out. The licensee must see to it that the documents mentioned in Sections 35 and 36 are revised accordingly.

The licence applicant shall ensure that the documents in accordance with Section 35 of the Nuclear Energy Decree, submitted to STUK for a statement about the construction licence, are kept up to date as the processing of the construction licence application progresses. The licence applicant shall particularly see to the updating if, during the official procedure, the applicant obtains new information that is important to safety or if the licence applicant wants, for some other reason, to change the plans for the nuclear facility referred to in the application. During the preparation of its licence statement, STUK requires supplements to the documents at its discretion. STUK ascertains the acceptability of these documents by separate decisions before submitting its statement about the construction licence application to the Ministry of Trade and Industry.

During construction and commissioning, the holder of the construction licence shall correspondingly ensure that the documents submitted to STUK, referred to in Sections 35 and 36 of the Nuclear Energy Decree, are kept up to date. If the changes pertain to the documents mentioned in Section 35 of the Nuclear Energy Decree, STUK announces its decision on them as part of its regulatory control during construction. During the preparation of its licence statement about the operating licence, STUK requires supplements to the documents at its discretion. With regard to the documents mentioned in Section 36 of the Nuclear Energy Decree, STUK ascertains their acceptability by separate decisions before

submitting its statement about the operating licence application to the Ministry of Trade and Industry.

During operation, particularly the safety classification document of the nuclear facility and the documents approved as part of STUK's processing of the application for an operating licence, referred to in Section 36 of the Nuclear Energy Decree, shall be kept up to date. In updating the documents, the changes shall be submitted to STUK for approval. The documents may be brought into use only after STUK has approved them.

Certain documents are an exception to the procedures described above. They are dealt with as follows:

- 1. On the basis of its own approval procedure, the licensee may bring into use such minor changes in the construction and operation quality manual that are insignificant for safety of the nuclear facility. The changed documents shall be forwarded to STUK for information. The licensee's assessment of the safety significance shall be recorded, including justifications.
- 2. Amendments to the Final Safety Analysis Report shall be collected and forwarded to STUK once a year, if STUK has received, for instance, during preliminary inspection of the modification, the corresponding information that will be added to the Safety Analysis Report owing to the modification.
- 3. Instructions for operation of the facility (e.g. instructions for operation, maintenance, transients, accidents and working methods) may be updated and brought into use on the basis of the licensee's own approval procedure. The amended instructions shall be forwarded to STUK for information.

If necessary, STUK issues instructions, by a separate decision, on how to update the documents referred to in Sections 35 and 36 of the Nuclear Energy Decree and on how to forward them to STUK.

Instructions for the documents to be submitted in electronic form are given in Guide YVL 1.2.

11 References

- 1. Nuclear Energy Act (990/1987).
- 2. Nuclear Energy Decree (161/1988).
- 3. Act on the Radiation and Nuclear Safety Authority (1069/1983).
- 4. Decree on the Radiation and Nuclear Safety Authority (618/1997).
- 5. Decree on the Advisory Committee on Nuclear Safety (164/1988).
- SFS-EN ISO 9000, Quality Management Systems. Fundamentals and Vocabulary, 2001.
- 7. Government Decision on the general regulations for the safety of nuclear power plants (395/1991), 14 February 1991.
- 8. Government Decision on the general regulations for physical protection of nuclear power plants (396/1991), 14 February 1991.
- 9. Government Decision on the general regulations for emergency response arrangements at nuclear power plants (397/1991), 14 February 1991.
- 10. Government Decision on the general regulations for safety of the final disposal facility for operating waste from nuclear power plants (398/1991), 14 February 1991.
- 11.IAEA Safety Guide GS-G-4.1, Format and Content of the Safety Analysis Report for Nuclear Power Plants, 2004.
- 12. Council Regulation (EC) No. 1334/2000. Setting up a Community regime for the control of exports of dual-use items and technology.
- 13. Convention on Nuclear Safety (Finnish Treaty Series 74/1996).
- 14.Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, IAEA Safety Standards Series No. GS-R-1.
- 15. Safety of Nuclear Power Plants: Design, IAEA Safety Standards Series No. NS-R-1.
- 16.Safety of Nuclear Power Plants: Operation, IAEA Safety Standards Series No. NS-R-2.
- 17.IAEA Safety Guide NS-G-2.10, Periodic Safety Review of Nuclear Power Plants, 2003.
- 18. Commission Regulation No. 302/2005 on the application of Euratom safeguards, 8 February 2005.