

REGULATORY OVERSIGHT OF SAFETY IN THE USE OF NUCLEAR ENERGY

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continues

This Guide shall apply as of 1 December 2013 until further notice. This Guide replaces Guides YVL 1.1, YVL 1.2 and YVL 1.16. With regard to operating nuclear facilities and those under construction, this Guide shall be enforced through a separate decision to be taken by STUK.

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| First edition | ISBN 978-952-309-034-7 (print) Kopijyvä Oy 2014 |
| Helsinki 2013 | ISBN 978-952-309-035-4 (pdf) |
| | ISBN 978-952-309-036-1 (html) |

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Authorisation

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

Rules for application

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

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

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

1 Introduction

101. The general basis for the use of nuclear energy and the requirements pertaining to its safety are laid down in the Nuclear Energy Act (990/1987) and Nuclear Energy Decree (161/1988).

102. The general safety requirements for the safe use of nuclear energy are laid down in Chapter 2 a of the Nuclear Energy Act.

103. According to Section 7 q of the Nuclear Energy Act, more specific general safety regulations for the use of nuclear energy are laid down in the Government Decree on the Safety of Nuclear Power Plants, the Government Decree on the Security in the Use of Nuclear Energy, the Government Decree on Emergency Arrangements at Nuclear Power Plants, and the Government Decree on the Safety of Disposal of Nuclear Waste.

104. The prerequisite for ensuring the safe use of nuclear energy is that the safety requirements specified in statutes, provisions and official guidelines are understood and complied with at all stages of the use of nuclear energy, and that all parties concerned are committed to abiding by them.

105. Except for the use of nuclear energy exempted from licence requirements under Chapter 3 of the Nuclear Energy Act, the use of nuclear energy constitutes operations subject to licence. All applications for a decision-in-principle concerning a nuclear facility, licences for a nuclear facility, including the construction licence and the operating licence and its renewal, as well as a licence for mining and milling operations aimed at producing uranium or thorium, are to be submitted to the Government. Other applications for licences pertaining to the use of nuclear energy are to be submitted to the respective licensing authority specified in Section 16 of the Nuclear Energy Act.

106. The licensee's obligations are set forth in Section 9 of the Nuclear Energy Act. *It shall be the licensee's obligation to assure safe use of nuclear energy. This obligation cannot be delegated*

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

107. The legal basis for the regulatory control of the safe use of nuclear energy exercised by STUK is laid down in Section 55 of the Nuclear Energy Act as follows: *The Radiation and Nuclear Safety Authority (STUK) is responsible for the supervision of safe use of nuclear energy. In addition, STUK shall be responsible for attending to the supervision of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons.*

The legal basis for the obligations and supervisory rights vested in STUK is laid down in Chapters 8 and 10 of the Nuclear Energy Act and Chapter 15 of the Nuclear Energy Decree.

108. The legal basis for the preparatory work pertaining to the safe use of nuclear energy and nuclear security arrangements at the Advisory Committee on Nuclear Safety and Advisory Committee on Nuclear Security is established in Section 56 of the Nuclear Energy Act. The advisory committees appointed by the Government operate in conjunction with STUK. The committees issue statements on the licence applications concerning the use of nuclear energy, regulations concerning the safe use of nuclear energy and nuclear security arrangements, and other matters as requested by STUK.

109. In addition to the national legislation, the use of nuclear energy is governed by the Treaty establishing the European Atomic Energy Community [15], the regulations of the European Commission and of the Council, and a number of treaties related to the nuclear energy sector.

110. Nuclear and radiation safety comprises safety, security and emergency arrangements and nuclear safeguards at all stages of the use of nuclear energy. All the aforementioned are necessary for attaining the shared goal of protecting people, society, the environment and future

generations from the harmful effects of ionising radiation. Safety, security and emergency arrangements, and nuclear safeguards all involve the common principle of assuring a level of safety as high as reasonably achievable. In the use of nuclear energy, safety, security and emergency arrangements, and nuclear safeguards measures shall be aligned by utilising similarities between them whilst avoiding potential conflicts as far as practicable.

2 Scope of application

201. This Guide provides a summary of the obligations imposed on the licence applicant and the licensee, as well as the regulatory control measures 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 and decommissioning of a nuclear facility.

202. Detailed nuclear safety requirements for the different stages of the use of nuclear energy are specified in the other relevant YVL Guides addressing the subject concerned.

203. This Guide applies to nuclear facilities, i.e. nuclear power plants; research reactors; facilities performing extensive disposal of nuclear waste; and facilities used for the extensive fabrication, production, use, handling and storage of nuclear material or nuclear waste.

204. The Guide also provides a summary of the safety control related to other uses of nuclear energy. Such other uses of nuclear energy include mining and milling operations aimed at producing uranium or thorium; the possession, manufacture, production, transfer, handling, use, storage, transport and import of nuclear materials and nuclear waste; the export of nuclear waste; and the possession, manufacture, assembly and import of other nuclear use items.

205. The exports, brokering and transit of nuclear use items is governed by the Council Regulation setting up a Community regime for the control of exports, transfer, brokering and transit of dual-

use items [20] and the national act on the control of exports of dual-use items [4]. The Ministry for Foreign Affairs is the authority responsible for the export control of nuclear use items. Nuclear safeguards and the related requirements are specified in Guide YVL D.1 Regulatory control of nuclear safeguards.

206. The Guide provides a summary outline of the procedure whereby an inspection organisation may file an application for accreditation in order to serve as an authorised inspection body approved by STUK, and the procedure whereby the licensee may request approval for the licensee's in-house inspection organisation.

207. To ensure radiation safety in the use of nuclear energy, the Regulatory Guides on radiation safety (ST Guides) issued by STUK are also applicable in addition to the YVL Guides. Examples of ST Guides applicable to the use of nuclear energy include Guides ST 7.1 through 7.5 discussing the monitoring of radiation doses, and Guide ST 5.7 discussing shipments of radioactive waste and spent nuclear fuel.

3 Requirements related to licensing

3.1 Applying for a Government decision-in-principle

301. A precondition for any construction of a nuclear facility of considerable general importance is a Government decision-in-principle issued pursuant to Section 11 of the Nuclear Energy Act, establishing that the construction project is in line with the overall good of society.

302. The provisions and instructions pertaining to applying and processing the decision-in-principle are laid down in Chapter 4 of the Nuclear Energy Act and specified in greater detail in Chapter 4 of the Nuclear Energy Decree. An application for a decision-in-principle shall be accompanied by the documents required under Section 24 of the Decree. The application may propose a single option or several options for the facility site and facility type for final selection.

303. Pursuant to the Nuclear Energy Decree, when applying for a Government decision-in-principle, the licence applicant shall submit an assessment report drawn up in accordance with the Act on Environmental Impact Assessment Procedure, accompanied by the coordinating authority's statement on the assessment report.

304. In addition to the attachments required under Section 24 of the Nuclear Energy Decree, the documents specified in Section A.1 of Annex A to this Guide shall also be submitted to STUK for information when an application for a Government decision-in-principle is filed. STUK draws up a preliminary safety assessment at the request of the Ministry of Employment and the Economy, for which purpose it may, at its discretion, request more details on each plant project.

3.2 Preparations for applying for a construction licence

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.

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.

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

308. Under Section 9 of the Nuclear Energy Act, an organisation preparing to construct and operate a nuclear facility shall have adequate procedures in place for ensuring that the other organisations involved in its operations comply with the radiation and nuclear safety requirements pertaining to the use of nuclear energy.

309. Prior to the issuance of a construction licence by the Government, the organisation shall, for the purpose of commencing the fabrication of structures or components related to the safety of the nuclear facility concerned, request from STUK a review and approval of the plans and designs concerning said structures or components as provided in Section 55(5) of the Nuclear Energy Act. Based on the decision given by STUK, the fabrication of components and structures requiring an exceptionally long period of time to complete may be commenced before the construction licence is granted. Under Section 55(5) of the Nuclear Energy Act, *no work related to structures affecting nuclear safety may, however, be commenced at the plant site before the construction licence has been granted.* Guide YVL A.5 discusses the starting of structural manufacturing and manufacture of materials and the preparation of the plant site before the construction licence is granted.

310. For the purpose of nuclear safeguards, the organisation issued with a decision-in-principle for the construction of a nuclear facility shall submit to the European Commission and STUK the preliminary design information of the new facility within 60 days of the date when the decision-in-principle on the nuclear facility is adopted by Parliament. More detailed requirements are specified in Guide YVL D.1.

3.3 Applying for a construction licence for a nuclear facility

311. An application for a construction licence for a nuclear facility shall be filed with the Government. Provisions on filing and processing the licence application are set out in Sections 16, 17, 18, 19, 23, 24, 25, and 25a of the Nuclear Energy Act, and Sections 31, 32, 35, 37, 37a, 38, 39, and 40 of the Nuclear Energy Decree. An application for a construction licence shall be accompanied by the information required under Section 32 of the Nuclear Energy Decree.

312. The preconditions for granting a construction licence are specified in Section 19 of the Nuclear Energy Act.

313. When an application for a construction licence is filed, the documents listed in Section 35 of the Nuclear Energy Decree shall be submitted to STUK for approval. Any other reports deemed necessary by STUK under Section 35(2) of the Decree shall, as a rule, also be submitted for approval. These documents are listed in Section A.2 of Annex A to this Guide.

314. According to Section 55(5) of the Nuclear Energy Act, *the structures and components inspected and approved by the Radiation and Nuclear Safety Authority may only be used for the construction of a nuclear facility if they are in conformance with the construction licence.* The licence applicant shall provide a summary of the decisions on components and structures issued pursuant to Section 55(5) of the Act and their conformance to the documents included in the application for a construction licence. The licensee shall eliminate any discrepancies before the components and structures are used for the construction of a nuclear facility.

315. Under Section 7 k of the Nuclear Energy Act, the licensee shall designate a responsible manager and his or her deputy for the construction of the nuclear facility. The qualifications required of the responsible manager of a nuclear facility are specified in Section 125 of the Nuclear Energy Decree. Detailed requirements pertaining to the responsible manager are specified in Guides YVL A.4 and YVL A.5. The responsible manager and his or her deputy shall be proposed to STUK for approval when an application for a construction licence is filed.

316. The licensee shall appoint for the construction of the nuclear facility persons who are responsible for ensuring emergency arrangements, security arrangements and nuclear safeguards activities at the facility, and assign deputies for them as provided in Section 7 i of the Nuclear Energy Act. Approval of the individuals proposed to the aforementioned duties shall be requested from STUK. Detailed requirements pertaining to the responsible persons are specified in Guides YVL A.4, A.11, C.5 and D.1.

3.4 Activities during the construction of a nuclear facility

317. According to Section 108 of the Nuclear Energy Decree, *the various phases in the construction of a nuclear facility cannot be commenced until the Radiation and Nuclear Safety Authority (STUK) has, on the basis of the documents mentioned in Section 35 and other detailed plans and documents, ascertained for each phase that all safety-related factors and safety regulations have been given sufficient consideration.*

318. According to Section 60 a of the Nuclear Energy Act, *the Radiation and Nuclear Safety Authority (STUK) approves manufacturers of nuclear pressure equipment for their duties and inspection organisations, testing organisations and qualification body for duties pertaining to the control of pressure equipment, steel and concrete structures, and mechanical components at nuclear facilities within the scope determined by the Radiation and Nuclear Safety Authority. The Radiation and Nuclear Safety Authority supervises the operation of such an inspection organisation, testing organisation, and qualification body.*

319. Pursuant to Section 60 a of the Nuclear Energy Act, the inspection organisation shall file an application with STUK for a licence to carry out inspection duties in the capacity of an authorised inspection body. The requirements pertaining to an authorised inspection body are specified in Guide YVL E.1.

320. The licensee shall file an application with STUK or an authorised inspection body or the approval of the necessary detailed plans and designs of the structures and components. The general division of inspection responsibilities is specified in Guide YVL E.1.

321. The licensee shall file an application for the approval of the manufacturer of nuclear pressure equipment as specified in Guide YVL E.3.

322. According to Section 113 of the Nuclear Energy Decree, *non-destructive testing of a nu-*

clear facility's structures and components relevant to nuclear safety may only be carried out by a testing organisation approved by the Radiation and Nuclear Safety Authority. The requirements pertaining to the aforementioned approvals are specified in Guide YVL E.12.

323. The licensee shall file an application with STUK for an in-house inspection organisation a qualification body, and non-destructive testing (NDT) organisations for safety class 1 and 2 components and structures. More detailed requirements are specified in Guides YVL E.1, E.5 and E.12.

324. Guide YVL E.1 lists the device- or structure-specific inspections that the licensee must request from STUK or an authorised inspection body approved by STUK.

325. In the event that a safety deviation is observed in the inspections carried out during the construction of a nuclear facility by STUK or an authorised inspection body the licensee shall remedy the situation (Chapter 10 of the Nuclear Energy Act).

326. For the purpose of nuclear safeguards, the licence applicant shall declare to the European Commission and STUK the basic technical characteristics (BTC) of the new nuclear facility as provided in Commission Regulation 302/2005 as soon as possible, but in any event no later than 200 days prior to the estimated date of receipt of the first shipment of a nuclear material. The licence applicant shall supplement and update the basic technical characteristics as they are defined in more detail. More detailed regulations are specified in Guide YVL D.1.

3.5 Applying for an operating licence for a nuclear facility

327. An application for an operating licence for a nuclear facility shall be filed with the Government. Provisions on filing and processing the licence application are set out in Sections 16, 17, 20, 23, 24, and 25 of the Nuclear Energy Act, and Sections 33, 34, 36, 37, 38, 39, and 40 of the Nuclear Energy Decree. The application shall be

accompanied by the documents listed in Section 34 of the Decree.

328. The preconditions for granting an operating licence are specified in Section 20 of the Nuclear Energy Act.

329. When an application for an operating licence is filed, the documents listed in Section 36 of the Nuclear Energy Decree, as well as any other reports deemed necessary by STUK under Section 36(3) of the Decree, shall be submitted to STUK for approval. These documents are listed in Section A.3 of Annex A to this Guide.

330. Under Section 7 k of the Nuclear Energy Act, the licensee shall designate a responsible manager and his or her deputy for the operation of the nuclear facility. The qualifications required of the responsible manager of a nuclear facility are specified in Section 125 of the Nuclear Energy Decree. Detailed requirements pertaining to the responsible manager are specified in Guide YVL A.4. The responsible manager and his or her deputy shall be proposed to STUK for approval when an application for an operating licence is filed.

331. According to Section 7 i of the Nuclear Energy Act, the licensee shall designate persons responsible for ensuring emergency arrangements, security arrangements and nuclear safeguards activities at the nuclear facility, and assign deputies for them. Detailed requirements pertaining to these positions and tasks are specified in Guide YVL A.4, A.11, C.5 and D.1. Approval of the aforementioned responsible persons and their deputies shall be requested from STUK for each specific duty or position.

332. According to Section 7 i of the Nuclear Energy Act, the licensee shall request approval from STUK for the operators working in the control room of a nuclear facility. Detailed requirements pertaining to nuclear facility operators and the approval procedure are specified in Guide YVL A.4.

333. The licence applicant shall provide the Ministry of Employment and the Economy with the general data concerning the nuclear waste

management of the nuclear facilities being commissioned and the estimated radioactive releases arising from their operation that, under Article 37 of the Euratom Treaty [15], are required to be communicated to the European Commission. Where possible, this information shall be submitted one year in advance but no later than six months prior to the issuance of a licence for new operations generating radioactive releases or nuclear waste, or prior to the commencement of the decommissioning of a nuclear facility. The European Commission has given recommendation 2010/635/Euratom on the submission of this information [21].

3.6 Commissioning of a nuclear facility

334. Section 110 of the Nuclear Energy Decree requires that *the various phases in the commissioning of a nuclear facility cannot be commenced until the Radiation and Nuclear Safety Authority (STUK) has determined, [– –], for each stage, that sufficient attention has been paid to factors influencing safety, and regulations concerning safety.*

335. The licensee is required to demonstrate that the systems, structures and components of the nuclear facility being commissioned, as well as the facility as a whole, have been constructed to operate as designed, and that the licensee has a sufficient organisation and instructions in place. Detailed requirements pertaining to commissioning are specified in Annex A to Guide YVL A.5.

3.7 Bringing nuclear fuel into a nuclear facility and commencing its operation

336. Section 20 of the Nuclear Energy Act sets out the general preconditions for granting an operating licence and stipulates that *operation of the nuclear facility shall not be started on the basis of a licence granted:*

1) until the Radiation and Nuclear Safety Authority (STUK) has ascertained that the nuclear facility meets the safety requirements set, that the physical protection and emergency planning are sufficient, that the necessary control to prevent the proliferation of nuclear weapons has been arranged appropriately, and that the licensee of the nuclear facility has, as provided, arranged indemnification regarding liability in case of nuclear damage; and

2) until the Ministry of Trade and Industry has ascertained that provision for the cost of nuclear waste management has been arranged in accordance with the provisions of Chapter 7.

337. Before any fresh nuclear fuel is brought into the nuclear power plant, the licensee shall ascertain that the systems and components related to the safe handling, storage and monitoring of nuclear fuel are operable; and that the radiation protection, security and emergency arrangements necessary for the use of nuclear material are in place. A precondition for the commencement of bringing in fresh nuclear fuel is that STUK has ascertained the licensee's preparedness to safely receive fresh nuclear fuel as provided in Section 110 a of the Nuclear Energy Decree and accepted the other plans and designs concerning the handling and placement of fuel with regard to the transport batch concerned. Guides YVL A.11, C.5 and D.2 set out detailed requirements for security and emergency arrangements and for the transport of nuclear fuel.

338. A necessary prerequisite for the commencement of the loading of nuclear fuel on the basis of the licence granted is that STUK has ascertained that the prescribed preconditions are satisfied as provided in Section 20(2) of the Nuclear Energy Act, and approved the application concerning fuel loading and the reports on reactor and fuel behaviour during the first operating cycle. Detailed requirements for taking nuclear fuel into use are specified in Guides YVL E.2 and A.5.

339. The use of a spent nuclear fuel interim storage and encapsulation plant is deemed to commence when the outer cover of a shipping or transfer cask is opened. A necessary prerequisite for the removal of the cover is that the Government has granted an operating licence and STUK has ascertained the fulfilment of the prescribed preconditions as provided in requirement 336 above and approved the other plans and designs concerning the handling and placement of fuel with regard to the shipment or transport batch concerned.

340. The use of a final disposal facility is deemed to have commenced when the transport of nu-

clear waste into the facility is commenced. A prerequisite for the commencement of the use is that the Government has granted an operating licence and STUK has ascertained the fulfilment of the prescribed preconditions as provided in paragraph 336 above and approved the plans and designs concerning the handling and placement of the spent nuclear fuel included in the transport batch concerned.

3.8 Operation of a nuclear facility

341. According to Section 7 a of the Nuclear Energy Act, *the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience, safety research and advances in science and technology.*

342. According to Section 7 e of the Nuclear Energy Act, *compliance with requirements concerning the safety of a nuclear facility shall be proven reliably. The overall safety of the facility shall be assessed at regular intervals.*

343. Section 3 of the Government Decree on the Safety of Nuclear Power Plants (717/2013) lays down general requirements for the assessment and verification of the safety of a nuclear power plant.

The assessment and verification of the safety of the operation of a nuclear power plant is discussed in Chapter 6 of the Decree as well as in the YVL Guides setting out requirements applicable to the plant's entire lifecycle. The conduct of operations is specifically addressed in Guides YVL A.6, YVL A.7, YVL A.8, YVL A.9, YVL A.10 and YVL B.3, and in Guides YVL E.3 and E.5 concerning the in-service inspection of pressure equipment.

344. General requirements and instructions for ensuring the safe operation of a spent nuclear fuel encapsulation plant and final disposal facility and other nuclear waste facilities are specified in Section 18 of the Government Decree on the Safety of Disposal of Nuclear Waste (736/2008), and in Guides YVL D.3 and D.5.

345. Under Section 7 of the Nuclear Energy Act, *sufficient physical protection and emergency planning as well as other arrangements for limiting nuclear damage and for protecting nuclear energy against illegal activities shall be a prerequisite for the use of nuclear energy.*

346. According to Section 7 l of the Nuclear Energy Act, *arrangements for security during the use of nuclear energy shall be based on threat scenarios involved, and analyses of the need for protection.*

347. The security arrangements during the operation of a nuclear facility shall also comply with the requirements laid down in the Government Decree on the Safety of Nuclear Power Plants (717/2013), the Government Decree on the Security in the Use of Nuclear Energy (734/2008), and Guides YVL A.11 and YVL A.12.

348. During the operation of a nuclear power plant, provisions shall be made for accidents and events impairing safety through emergency arrangements. Requirements concerning emergency arrangements are presented in the Government Decree on Emergency Arrangements at Nuclear Power Plants (716/2013) and in Guide YVL C.5.

349. During the operation of a nuclear facility, the licensee shall file an inspection request with STUK in respect of all items for which an inspection is required. Such items are specified in the YVL Guides relevant to the respective field of technology, and in requirement 425 of chapter 4.7 of this Guide.

350. The licensee shall annually submit to STUK for information the insurance policies concerning nuclear liability arrangements. Nuclear liability arrangements are discussed in detail in Annex C to this Guide.

351. In accordance with Section 9 of the Nuclear Energy Act, *a licensee whose operations generate or have generated nuclear waste (licensee under a waste management obligation) shall be responsible for all nuclear waste management measures and their appropriate preparation, as well as for their costs (waste management obligation).*

Section 28 of the Nuclear Energy Act, Sections 74 and 75 of the Nuclear Energy Decree, and Guide YVL A.9 provide detailed regulations concerning the implementation of the waste management obligation, as well as reporting during use.

3.9 Renewal of the operating licence for a nuclear facility and periodic safety review

352. The procedure to be followed when an application for the renewal of an operating licence for a nuclear facility currently in operation is filed is the same as that for filing an application for an operating licence for a new nuclear facility. The renewal of the operating licence always involves a periodic safety review of the facility.

According to 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.* [– –].

The length of the term of the operating licence is not defined in the legislation. In the application, the licensee shall make a proposal for the length of the term, justified by, among other things, the condition of the nuclear facility concerned and its foreseen operation. In the event that a licence to operate the nuclear power plant is granted for a term considerably longer than ten years the licensee shall carry out a periodic safety review on the facility, and submit it to STUK for approval within approximately ten years of the date when the operating licence was granted or the previous periodic safety review was carried out. The periodic safety review of nuclear waste facilities shall be carried out every 15 years. If the time limit of an operating licence granted for a nuclear facility extends beyond 10 years, or that for a nuclear waste facility beyond 15 years, the licensee shall, in its application, propose a periodic safety review for the operating licence period.

353. For the purpose of conducting a periodic safety review during the operating licence period, STUK shall be provided with safety-related reports similar to those provided when an application for the renewal of an operating licence is filed. These reports shall also include the licen-

see's assessment of the current safety status of the nuclear facility concerned, potential improvements, and the maintaining of safety in future. Requirements pertaining to these documents are specified in Section A.4 of Annex A to this Guide.

354. Before drawing up the reports related to the periodic safety review, the licensee shall submit to STUK for information a plan pertaining to the methods of assessment and the reports drawn up in connection with the assessment. Instructions for carrying out the periodic safety review are provided in the IAEA Safety Standards Series, Specific Safety Guide No SSG-25, Periodic Safety Review of Nuclear Power Plants [29].

3.10 Decommissioning and nuclear waste management of a nuclear facility

355. In fulfilling its nuclear waste management obligation and making provision for the costs involved, the licensee shall abide by the requirements laid down in Chapters 6 and 7 of the Nuclear Energy Act, and Chapters 12 and 13 of the Nuclear Energy Decree. Supplementary requirements are specified in the Government Decree on the Safety of Disposal of Nuclear Waste, as well as in Guides YVL D.3, YVL D.4 and YVL D.5.

356. The licensee shall plan the decommissioning of the nuclear facility in accordance with the general requirements laid down in Section 7 g of the Nuclear Energy Act. Guide YVL D.4 sets out detailed requirements for the decommissioning of a nuclear facility.

3.11 Other licences and declarations pertaining to the use of nuclear energy

357. An application for a licence pursuant to the Nuclear Energy Act shall be filed for the following operations, unless the operations concerned have been specifically exempted from licence requirements under Chapter 3, Sections 10 c through 22 of the Nuclear Energy Decree:

- mining and milling operations aimed at producing uranium or thorium;
- the possession, manufacture, production, transfer, handling, use, storage, transport and import of nuclear material;

- the possession, manufacture, production, transfer, handling, use, storage, transport, export and import of nuclear waste;
- the possession, production, assemble, transfer and import of materials, devices, equipment and technology referred to in Appendix A to the Nuclear Energy Decree;
- the export and import of ores containing uranium or thorium.

358. A licence application shall be filed for the possession, transfer and import of technology if the technology concerned is subject to a particular safeguards obligation.

359. The export of nuclear materials and other nuclear use items is governed by the Act on the control of exports of dual-use items and the Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items [20]. The licensing authority is the Ministry for Foreign Affairs. Nuclear materials that are simultaneously nuclear waste are an exception. The export of these materials is governed by the Nuclear Energy Act, and the licensing authority is STUK.

360. Under Section 7 k of the Nuclear Energy Act, *the licensee shall appoint a responsible manager and his or her deputy: [– –]*

3) for mining and milling operations aimed at producing uranium or thorium; and (25 March 2011/269)

4) for the possession, manufacture, production, handling, use, storage and transport of nuclear materials and nuclear waste, if a separate licence is required for these operations.

361. Under Section 20 of the Nuclear Energy Decree, the holder of a construction licence or an operating licence for a nuclear facility is also entitled, by virtue of these licences, to possess, produce, handle, use and store at the facility site the nuclear materials, nuclear wastes as well as the materials, devices and equipment referred to in Section 8 of the Decree that are necessary for the operation of the nuclear facility or result from its operation, and to possess, produce and assemble technology concerning them at the

facility site and the licensee's other locations. A separate licence is required for the transport of nuclear materials and nuclear wastes, and for the import and transfer of all the items and products mentioned above.

362. The export and import of nuclear wastes is prohibited, subject to certain exceptions (Sections 6 a and 6 b of the Nuclear Energy Act). In these exceptional cases, the licence application shall be submitted to STUK for approval. The licence may be granted for a maximum of three years at a time. The import or export of nuclear waste is subject to an approval procedure conducted with foreign authorities as specified in Council Directive 117/2006 [16], due to which the application shall be submitted to STUK in advance on a timely basis as provided in Guide ST 5.7 issued by STUK.

363. The licence for the possession, fabrication, production, handling, use and storage of nuclear materials and nuclear wastes (operating licence), as well as for the possession of other nuclear use items and the transfer and import of all the aforementioned items and products shall be applied for from STUK. The reports and information required under the Nuclear Energy Decree (Chapters 6, 7 a – 7 c, 11) shall be stated in the application.

364. A separate transfer licence is not required for the export of nuclear materials, nuclear waste and other nuclear use items; instead, a notification concerning the transfer shall be submitted to STUK as provided in Section 21 and Chapter 17 of the Nuclear Energy Decree. However, a notification is not required for a transfer related to the export of technology.

365. A separate licence is required for the transport of nuclear materials and nuclear wastes, unless the transport has been exempted from the licence (Section 17 of the Nuclear Energy Decree). A licence for transport within and through the territory of Finland is granted by STUK, with which the licence application shall also be filed. The regulations pertaining to a transport licence are laid down in Chapter 8 of the Nuclear Energy Decree. The detailed requirements pertaining

to the transport of nuclear materials and nuclear wastes are specified in Guide YVL D.2. Transports for which no licence is required shall be notified to STUK as provided in Section 17 and Chapter 17 of the Decree.

366. A licence for mining and milling operations aimed at producing uranium or thorium, the amount of uranium or thorium produced being in excess of 10 tonnes a year, is granted by the Government. If the annual amount of uranium or thorium produced falls short of 10 tonnes, the licence application shall be filed with STUK. The application shall include the information and reports required under Sections 61 and 62 of the Nuclear Energy Decree. Additionally, the applicant is required to submit to STUK the documents specified in Section 62 a of the Decree and ensure that these documents are kept up-to-date at all times.

367. The extraction, mining and milling and processing of uranium and thorium, with the exception of exploratory extraction or similar processing, is also subject to the environmental impact assessment procedure (EIA procedure). The assessment report, complete with a statement thereon from the coordinating authority, shall be enclosed as an annex to the licence application (Section 62 a of the Nuclear Energy Decree).

368. Under Section 21(2) of the Nuclear Energy Act, a necessary prerequisite for the commencement of the use of nuclear energy within the meaning of paragraph 357 of this Guide is that STUK has ascertained, when the operations so require, that the use of nuclear energy is in accordance with the stipulated safety requirements; that the security arrangements and emergency response systems are sufficient; that the necessary control to prevent the proliferation of nuclear weapons has been appropriately arranged; and that the required arrangements are in place regarding liability for nuclear damage.

369. As regards mining and milling operations aimed at producing uranium or thorium, the licensee is required to comply with the general safety requirements set out in the Nuclear Energy Act. The detailed requirements are laid

down in a Government Decree (under preparation) and in Guide YVL D.6.

370. The European Commission and STUK shall be provided with the general data referred to in Article 37 of the Euratom Treaty concerning any mining and milling operations aimed at producing uranium or thorium and any other use of nuclear energy that may generate significant amounts of radioactive releases or nuclear waste. Where possible, this information shall be submitted one year in advance, but no later than six months prior, to the issuance of a licence for new operations generating radioactive releases or nuclear waste. The European Commission has given recommendation 2010/635 on the submission of this information [21].

371. For the purpose of nuclear safeguards, anyone engaged in operations subject to the Nuclear Energy Act is required to submit the prescribed information and declarations to the European Commission and STUK [22]. Requirements pertaining to the above are specified in Guide YVL D.1.

3.12 Submission of documents to STUK

372. The documents to be submitted to STUK are specified in Finnish nuclear legislation and in the YVL Guides. Requirements pertaining to the structure, content and method of delivery of the documents to be submitted to STUK are specified in Annex B. For the purposes of this Guide, a document means not only a hardcopy written or visual presentation, but also an electronic document within the meaning of the Act on Electronic Services and Communication in the Public Sector.

373. When electronic data transmission methods are used, STUK shall be consulted with regard to the procedures to be complied with when submitting documents. STUK will then provide the licensees with instructions and procedures concerning the submission of electronic documents by issuing a separate decision to that effect.

374. The licensee shall assess the acceptability of documents concerning safety-important products prior to their submission to STUK. 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 authors of the documents.

375. The conformance and acceptability of the documents pertaining to safety-significant products submitted to STUK shall first be duly reviewed by the licensee's in-house organisation. To demonstrate this, the licensee shall, at a minimum, provide the following information in the summary of justifications included in the document:

- 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 STUK have been met. If any non-conformances are detected in the due fulfilment of the safety requirements, their acceptability shall be justified in detail.

376. The licence applicant's or licensee's management system shall have the necessary responsibilities, authorities and procedures defined for the due management and processing of the documents and their submission to STUK. The procedures shall, in particular, ensure that no confidential information is disclosed in connection with its processing and submission, and that the information reaches STUK without undue delay.

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. STUK assesses the need for such 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).

3.13 Modifications and changes to a nuclear facility, organisation and safety documents

378. According to Section 112 of the Nuclear Energy Decree, *if the licensee intends to carry out modifications to the nuclear facility systems, structures, nuclear fuel or the way the facility is operated that influence safety and involve changes in the plans or documents approved by the Radiation and Nuclear Safety Authority (STUK), the licensee shall obtain approval from STUK for such modifications before they are carried out. The licensee shall ensure that the documents mentioned in sections 35 and 36 are revised accordingly.*

379. The requirements pertaining to the content of the documents concerning modifications to a nuclear power plant and its systems are specified in Guide YVL B.1, and those pertaining to the content of the modification documentation in the YVL Guides relevant to the respective field of technology. Requirements pertaining to more extensive plant modification and commissioning projects are specified in Guide YVL A.5.

380. If the design or implementation of any systems, structures or components – or the entire nuclear facility – previously subjected to STUK's approval procedure is deemed to require modification, approval for such modification shall be requested from STUK before any of the modifications are implemented.

381. If, following the commissioning of the nuclear facility concerned, any of its systems, structures or components previously subjected to STUK's approval procedure are deemed to require modification, the modification plans shall be submitted to STUK for approval before their implementation.

382. If the plant modifications involve changes to the conditions imposed for the construction or operating licence issued for the nuclear facility concerned, or to the criteria on which the issuance of the licence was based, the modification shall be handled in accordance with Section 25 of the Nuclear Energy Act, following, where applicable, the same procedure as when the construction or operating licence was granted.

383. In the event that a nuclear facility extension or modification relevant to nuclear safety is commissioned based on the conditions of an existing operating licence, the documents specified in Annex A related to the application for an operating licence shall be submitted to STUK for approval. Approval for the commissioning of such extension or modification shall be requested from STUK as provided under Section 20 of the Nuclear Energy Act.

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. When making organisational changes, the licensee shall also assess which documents other than those mentioned above shall be updated to reflect the changed situation. Detailed requirements pertaining to organisational changes are specified in Guide YVL A.4.

385. If the assessment and verification methods, software or reference data used in the safety assessment of a nuclear facility are modified, the safety significance of the modifications shall be assessed and documented, and the facility documents updated to reflect the changed situation.

386. 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.

387. During the operation of a nuclear facility, the documents approved by STUK in connection with the processing of the application for an operating licence as provided in Section 36 of the Nuclear Energy Decree shall be kept up-to-date at all times. In updating the documents, the changes shall be submitted to STUK for approval. The changes may only be put to use after STUK has approved them.

This procedure may only be derogated from in the following cases:

1. The licensee may, based on its own approval procedure, introduce such minor changes to the management system used during construction and operation that are of no significance with regard to the safety of the nuclear facility concerned. The revised documents shall be submitted to STUK for information. The assessment of the safety significance of the change, complete with reasoning, shall be recorded.
2. The licensee may, based on its own approval procedure, put to use the updates to the Final Safety Analysis Report as soon as they have been submitted to STUK for approval if the procedure for updating the safety analysis report has been specified in connection with the pre-inspection documents already submitted, or the changes made are minor, or the implementation of the change did not require processing by STUK. Amendments to the Final Safety Analysis Report may be collected and forwarded to STUK once a year if, for example, STUK has received the corresponding information concerning the amendment to the safety analysis report during the preliminary inspection of the modification, or the changes to the safety analysis report are minor.
3. Updates to the classification document, if the amendments concerned were approved in connection with the preliminary design documents, shall be submitted to STUK for information.
4. Plant instructions pertaining to the operation of the facility such as operating, maintenance, transient and accident operating procedures may be updated and put into use based on the licensee's own approval procedure. The re-

vised instructions shall be submitted to STUK for information.

5. The licensee may, based on its own approval procedure, put into use updates of the probabilistic risk assessment (PRA) as soon as they have been submitted to STUK for processing as specified in Guide YVL A.7.

Where necessary, STUK will issue instructions, by means of 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 submit them to STUK.

388. According to Section 112 a of the Nuclear Energy Decree, *if the licensee intends to carry out modifications to mining and milling operations that influence safety and involve changes in the documents approved by the Radiation and Nuclear Safety Authority, the licensee shall obtain approval from the Radiation and Nuclear Safety Authority for such modifications before they are carried out. Correspondingly, any measures related to the decommissioning of a mine or a milling facility that influence radiation safety shall be approved by the Radiation and Nuclear Safety Authority. The licensee shall ensure that the documents mentioned in Section 62 a are revised accordingly.*

4 Regulatory oversight by the Radiation and Nuclear Safety Authority

401. STUK's supervisory rights are set forth in Section 63 of the Nuclear Energy Act.

402. In support of the processing and oversight of the licence applications, STUK shall, at its discretion, commission comparative analyses and expert opinions from independent research institutions or expert organisations.

4.1 Assessment of the application for a decision-in-principle

403. According to the Act on Environmental Impact Assessment Procedure, the Ministry of Employment and the Economy acts as the coordi-

nating authority insofar as nuclear facilities are concerned. STUK contributes to the EIA procedure by issuing its statement on the assessment programme and report to the ministry.

Under Section 24 of the Nuclear Energy Decree, the application for a decision-in-principle for a nuclear facility project shall be accompanied by, among other things, an assessment report concerning the environmental impact of the foreseen facility. STUK will take the report into consideration when preparing its preliminary safety assessment for the Government in respect of the application for a decision-in-principle.

404. Under Section 12 of the Nuclear Energy Act, STUK is responsible for drawing up a preliminary safety assessment on the application for a decision-in-principle, stating its opinion on the prerequisites for constructing the nuclear facility concerned. In its safety assessment, STUK states whether any factors have arisen indicating a lack of sufficient prerequisites for constructing a nuclear facility in a manner that satisfies the requirements laid down in the Nuclear Energy Act. The assessment draws upon the Government Decrees issued under Section 7 q of the Nuclear Energy Act.

4.2 Processing the construction licence application for a nuclear facility

405. STUK issues a statement on the construction licence application for a nuclear facility to the Ministry of Employment and the Economy, attaching to the statement its safety assessment, evaluation of the documents required under Section 35 of the Nuclear Energy Decree as well as the statement from the Advisory Committee on Nuclear Safety.

406. When preparing the safety assessment, STUK requests a statement from the Advisory Committee on Nuclear Safety and from the Ministry of the Interior on the reports concerning security and emergency arrangements referred to in Section 35(4) of the Nuclear Energy Decree.

407. The preconditions for granting a construction licence are specified in Sections 18 and 19 of the Nuclear Energy Act. In its safety assessment,

STUK gives an opinion on the fulfilment of the requirements laid down in the relevant legislation and YVL Guides with regard to the issues to be reviewed by STUK.

408. STUK will not give its statement on the application for a construction licence until it has approved each of the documents specified in Section A.2 of Annex A to this Guide in their essential parts by issuing a specific decision to that effect, with the exception of the licensing plan submitted for information.

409. As part of the review of the construction licence application for a nuclear facility, STUK also conducts inspections and assessments related to the operations of the licence applicant, the plant supplier, and any organisations involved in the project whose work can be deemed to have major implications for safety. These inspections and assessments focus on the management system of the organisation concerned, in particular the organisation of operations and management of resources, competence management, quality management procedures, management of non-conformances and security of information systems.

410. STUK assesses and issues decisions on the applications filed by the licence applicant concerning the individual proposed as the responsible manager during construction of the nuclear facility and his or her deputy, as well as on the applications concerning the individuals proposed as the persons responsible for emergency and security arrangements and nuclear safeguards and their deputies.

411. Under Section 58 of the Nuclear Energy Act, STUK is required to provide a statement on the local detailed plan being drawn up for the area intended as the site of a nuclear facility.

4.3 Regulatory control of the construction of a nuclear facility

412. Under Section 109 of the Nuclear Energy Decree, STUK oversees the construction of a nuclear facility in detail. The purpose of regulatory control is to ensure that the conditions stated in

the construction licence, the regulations pertaining to pressure equipment and other components and structures, and the approved plans and designs are complied with, and that the nuclear facility concerned is constructed in compliance with the regulations issued under the Nuclear Energy Act. The regulatory control exercised by STUK during construction is discussed in detail in Guide YVL A.5.

413. STUK oversees the construction of nuclear facilities by means of a Construction Inspection Programme. The purpose of the Construction Inspection Programme is to verify that the holder of the construction licence has operations in place to ensure high-quality construction and implementation in accordance with the approved plans and designs, while complying with the applicable regulations and regulatory decisions. The following, in particular, are assessed and controlled under the Construction Inspection Programme:

- the licensee's operations as a whole with a view to constructing the facility;
- the detailed procedures in various fields of technology used for implementing the facility;
- the due consideration given to safety aspects in management procedures;
- the licensee's expertise and use of expertise; and
- quality management and quality control.

414. In addition to the inspections of which the licensee is notified in advance, STUK may, at its discretion, also carry out unannounced inspections as well as so-called reactive inspections in response to events and deviations.

415. If STUK detects a safety deviation in the construction of a nuclear facility, it will require remedial action through the use of the procedures specified for this purpose in Chapter 10 of the Nuclear Energy Act.

4.4 Processing the operating licence application for a nuclear facility

416. STUK issues a statement on the operating licence application for a nuclear facility to the Ministry of Employment and the Economy, at-

taching to the statement its safety assessment, its evaluation of the documents required under Section 36 of the Nuclear Energy Decree, and the statement from the Advisory Committee on Nuclear Safety.

417. When preparing the safety assessment, STUK requests from the Ministry of the Interior a statement on the documents referred to in Section 36(7) of the Nuclear Energy Decree concerning the security and emergency arrangements.

418. In its safety assessment, STUK gives an opinion on the fulfilment of the requirements laid down in the relevant legislation, construction licence and YVL Guides with regard to the issues falling under its regulatory responsibilities.

419. STUK will not give its statement on the operating licence application for a nuclear facility until it has approved each of the documents specified in Section A.3 of Annex A in their essential parts by issuing a specific decision to that effect.

420. If the time limit of an operating licence granted for a nuclear facility extends beyond 10 years, or that for a nuclear waste facility beyond 15 years, STUK will, in its statement, propose a date for the periodic safety review to be conducted during the operating licence period.

4.5 Commissioning

421. STUK oversees the commissioning of a nuclear facility by reviewing the commissioning plan and pre-operational testing programmes, by witnessing the tests conducted at the nuclear facility concerned, and by reviewing the trial run result reports. The detailed requirements pertaining to the pre-operational testing and its regulatory control are specified in Guide YVL A.5.

422. STUK conducts commissioning inspections for mechanical components, structures and electrical and I&C systems as provided in the YVL Guides relevant to the respective field of technology.

4.6 Verification of readiness for commissioning

423. STUK will review the licensee's application regarding the readiness to receive nuclear fuel to the nuclear facility and carry out an on-site inspection to verify this.

424. STUK will ascertain that the prescribed safety requirements are met as provided in Section 20(2) of the Nuclear Energy Act following the issuance of the operating licence for the nuclear facility. Such ascertainment is a necessary prerequisite for the commencement of operation of the nuclear facility. At this inspection, STUK will verify that the requirements set out in the legislation, official regulations, operating licence conditions and the decisions issued by STUK are duly satisfied, and that the nuclear facility can be safely started. Among other things, the inspection will address the following items to ensure that

- the documents related to the operation of the facility, referred to in Section 36 of the Nuclear Energy Decree, are acceptable and up-to-date in all respects;
- the instruction manuals concerning the operation of the facility, including the operating procedures for accidents and operational occurrences are up to the required standard;
- the organisation operating the nuclear facility is appropriate and sufficiently extensive;
- the persons involved in the use of nuclear energy meet the applicable qualification requirements;
- the person designated as the responsible manager for the operation of the facility and their deputies are duly approved by STUK;
- there is a sufficient number of licensed operators at the facility;
- persons and their deputies, duly approved by STUK, have been designated to assume responsibility for emergency and security arrangements, and nuclear safeguards;
- the commissioning inspections of the facility systems, structures and components have been successfully carried out;
- the results of system performance tests are acceptable insofar as it is possible to perform pre-operational testing before the loading of nuclear fuel into the reactor;

- standard non-destructive tests have been successfully carried out on structures and components in accordance with Guide YVL E.5;
- the security and emergency arrangements are up to the required standard;
- the required controls to prevent the proliferation of nuclear weapons have been put in place; and
- the required arrangements are in place regarding the licensee's liability for nuclear damage.

4.7 Regulatory control of the operation of a nuclear facility

425. Regulatory control of the safety of nuclear facilities in operation include official inspections and supervision carried out by STUK, which can be divided into four categories as follows:

- periodic inspections specified and recorded by STUK in the facility-specific periodic inspection programme;
- inspections by STUK required under YVL Guides which the licensee is obliged to request as part of the measures carried out at the nuclear facility, or which STUK may conduct at its discretion;
- regulatory oversight exercised by resident inspectors; and
- safety assessment based on operating experience, safety research and other information obtained after the granting of the operating licence.

426. STUK oversees the operation of nuclear facilities by means of the Periodic Inspection Programme. The purpose of the inspection programme is to verify that the actions taken by the licensee ensure the safe operation of the nuclear facility in compliance with regulations and regulatory decisions. STUK will specifically notify the licensees of the inspections to be carried out under the annual plan. The findings of each inspection and any requirements arising from them will be entered in the inspection protocol.

427. Additionally, STUK may carry out extraordinary or unannounced inspections, inspections to supplement the Periodic Inspection Programme, as well as so-called reactive inspections in response to events and deviations.

428. The inspections to be carried out in response to the licensee's inspection request are specified in the individual YVL Guides.

The inspections required at nuclear power plants under YVL Guides address the following items:

- the planning and implementation of outages;
- the refuelling of the reactor;
- non-destructive in-service inspections required under Guide YVL E.5;
- in-service inspections of registered pressure equipment and other components and structures;
- modifications, repairs and preventive maintenance;
- start-up of the power plant after the annual outage;
- the procurement and use of nuclear fuel;
- the nuclear safeguards;
- security arrangements; and
- the clearance of nuclear waste from regulatory control.

429. In exercising regulatory control, STUK makes use of the periodic and event-specific reports filed by the licensee. The general requirements pertaining to reporting are set out in Guide YVL A.5 with regard to construction and commissioning; in Guide YVL A.6 with regard to operation; in Guide YVL A.9 with regard to reporting; and in YVL A.10 with regard to the operating experience feedback process, as well as in the other YVL Guides relevant to the respective field of technology. The reports are used for preparing the inspections, assessing the safety-enhancing measures and monitoring the safety level in general.

430. Operational events at a nuclear facility may consist of single transients or observations as well as recurring or common cause failures, human errors or omissions. Based on the reports provided by the operating organisation and its own observations made during inspections, STUK may appoint an investigation team as appropriate to assess a specific event (Section 63(1) (9) of the Nuclear Energy Act). The specific duty of such a team is to determine the root causes of the event and define the objectives for corrective measures.

431. If STUK detects a safety deviation in the operation of a nuclear facility, it will require remedial action through the use of the procedures specified for this purpose in Chapter 10 of the Nuclear Energy Act.

432. In addition to the regulatory control of the operation of nuclear facilities, STUK maintains the ability to respond to emergency situations at the facilities and makes appropriate preparations in view of threats. STUK assists the organisations responsible for rescue services as an expert by issuing recommendations for protective measures in case of emergency situations, and assists the police in case of threats.

4.8 Renewal of the operating licence and periodic safety review

433. When an application is filed for the renewal of the operating licence, STUK issues a statement on the application to the Ministry of Employment and the Economy, attaching to the statement its safety assessment and evaluation of the documents required under Section 36 of the Nuclear Energy Decree, as well as the statement from the Advisory Committee on Nuclear Safety. When preparing the safety assessment, STUK requests from the Ministry of the Interior a statement on the documents referred to in Section 36(7) of the Nuclear Energy Decree concerning the physical protection and emergency arrangements.

434. In its safety assessment, STUK gives an opinion on the fulfilment of the requirements laid down in the relevant legislation and YVL Guides with regard to the issues falling under its regulatory responsibilities.

435. STUK will not give its statement on the application for a renewal of the operating licence until it has approved the licensee's periodic safety review and action plan for improving plant safety in their essential parts by issuing a specific decision to that effect.

436. In the event that a separate periodic safety review is required of the licensee, STUK will make a decision on its potential approval and at-

tach to it its own safety assessment following the same procedure as applied to the renewal of the operating licence.

4.9 Assessment of operating experience and communications

437. STUK monitors operational events at nuclear facilities in Finland and abroad. STUK receives operational event reports of foreign nuclear facilities through international organisations and directly from the regulatory authorities of various countries. STUK forwards the reports received to the licensees for information, to which end the licensees shall have procedures in place for their assessment and utilisation. STUK also carries out an in-house assessment of the reports to evaluate specifically to each individual Finnish facility whether any safety-enhancing measures are called for based on the lessons learnt from the accumulated operating experience. Additionally, STUK follows the measures taken by the licensees for the purpose of monitoring and assessing the operating experience gained by foreign facilities. More specific requirements pertaining to the assessment of operating experience data are set out in Guide YVL A.10.

438. Annually, STUK prepares the report purported by Section 121 of the Nuclear Energy Decree which it publishes and submits to the Ministry of Employment and the Economy. The report provides a description of the efforts made during the year; key events and observations important to safety; and an assessment of the safety of nuclear facilities, whether operational, under construction or being decommissioned.

439. STUK participates in international cooperation to enhance nuclear and radiation safety, and in the preparation and development of standards by international organisations, including the exchange of information and cooperation between national regulatory authorities.

440. STUK disseminates information on national and international safety issues related to the use of nuclear energy significant to the Finns, including general information on nuclear standards.

4.10 Other regulatory control of the use of nuclear energy

441. STUK issues – in response to an application – the licences purported by Section 3.11 of this Guide for nuclear materials, nuclear wastes and the materials, devices, equipment and technology referred to in Appendix A to the Nuclear Energy Decree.

442. According to the Act on Environmental Impact Assessment Procedure, the Centre for Economic Development, Transport and the Environment concerned acts as the coordinating authority insofar as mining and milling operations are concerned. In the case of mining and milling operations related to the production of uranium or thorium, STUK contributes to the EIA procedure by issuing its statement on the assessment plan and report to the Centre for Economic Development, Transport and the Environment concerned.

443. STUK reviews the documents related to the licence applications for mining and milling operations purported by Section 62 of the Nuclear Energy Decree and issues statements to the Ministry of Employment and the Economy on licence applications addressed to the Government.

444. Provisions on the regulatory oversight exercised by STUK related to the use of nuclear energy at locations other than nuclear facilities are set out in Sections 112 a, 115, 115 a, 116, 118, 118 a, 119, and 120 of the Nuclear Energy Decree.

445. STUK oversees the operation of authorised inspection bodies and the licensee's in-house inspection organisation.

4.11 Regulatory control of decommissioning and nuclear waste management

446. Supplementary descriptions of the regulatory control exercised by STUK related to the decommissioning of nuclear facilities and nuclear waste management are provided in Guides YVL D.3, D.4 and D.5.

4.12 Nuclear safeguards

447. In accordance with the obligations assumed by Finland under international treaties and conventions, licensees of nuclear facilities and other operators purported by the Nuclear Energy Act shall have in place nuclear safeguards necessary for the prevention of the proliferation of nuclear weapons. Guide YVL D.1 specifies the obligations of both licensees and other users regarding, among other things, the nuclear accountancy of events and inventory changes related to nuclear safeguards and their reporting to STUK and the European Commission in accordance with regulation 302/2005.

STUK, the IAEA and the European Commission carry out on-site inspections relating to nuclear use items at facilities and other locations within the sphere of nuclear safeguards.

4.13 Nuclear liability arrangements

448. STUK is required, for its part, to verify that the licensees meet the obligations regarding liability for damages stipulated in view of accidents involving nuclear facilities and the transport of nuclear material and nuclear wastes. STUK checks the compliance of the insurance policies within the limits of its regulatory responsibilities. A description of the control of nuclear liability arrangements is provided in Annex C.

Definitions

Particular safeguards obligation

Particular safeguards obligation shall refer to an obligation arising from a bilateral nuclear agreement concluded by Finland or the European Union with some other state or a group of states outside the EU which covers the possession, manufacture, production, transfer, handling, use, storage, transport, export or import of nuclear material, nuclear waste, ore or some other material, component, equipment or technology as referred to in Section 8(1) (Nuclear Energy Decree, 161/1988).

Auditing

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

Authorised inspection body

Authorised inspection body shall refer to an independent inspection organisation approved by the Radiation and Nuclear Safety Authority under Section 60 a of the Nuclear Energy Act to carry out inspections of the pressure equipment, steel and concrete structures and mechanical components of nuclear facilities in the capacity of an agency performing public administrative duties.

Ageing management programme

Ageing management programme shall refer to the functions and duties defined by the licensee, pursuant to which the licensee implements the ageing management of a nuclear facility.

Management system

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

Licensee under a waste management obligation

Licensee under a waste management obligation shall refer to a licensee whose operations generate or have generated nuclear waste. (Nuclear Energy Act 990/1987)

Encapsulation plant

Encapsulation plant shall refer to a nuclear facility that is used to encapsulate spent nuclear fuel for final disposal.

Operational event

Operational event shall refer to a failure, flaw or non-conformity in safety functions, systems, components, structures or an organisation's activities that has a bearing on radiation safety or nuclear safety. Operational events also include emergencies and disturbances as well as events compromising radiation safety. Operational events also include events taking place during the construction phase.

Plant modification

Plant modification (plant modification project) shall refer to a modification to the safety-classified systems of an operating nuclear facility that calls for the reassessment of the design bases and safety requirements of systems, the renewal of the design basis analyses, and considerable equipment acquisitions. Examples of plant modifications include a power increase of the reactor or a modernisation of the protection I&C systems.

Disposal facility

Disposal facility shall refer to an entirety comprising the rooms for the disposal of the waste packages (emplacement rooms) and the adjoining underground and above-ground auxiliary facilities.

Licensee

Licensee shall refer to the holder of a licence entitling to the use of nuclear energy. The use of nuclear energy refers to the operations laid down in Sections 2(1) and 2(2) of the Nuclear Energy Act.

Licensee's in-house inspection organisation

Licensee's in-house inspection organisation shall refer to the licensee's separate inspection unit, the position of which is arranged in compliance with the type B requirements of ISO/IEC EN 17020, the operations of which meet the specific requirements laid down by STUK, and which STUK has approved to carry out inspection tasks pertaining to the pressure equipment, steel and concrete structures and mechanical components of a nuclear facility in the form of in-house control by the licensee.

Long-term safety

Long-term safety shall refer to the safety of disposal after the operational period of a disposal facility, taking account of radiological impacts on man and the environment. (Government Decree 736/2008)

Qualification body

Qualification body shall refer to an independent expert body that plans, conducts, assesses and witnesses qualifications of inspection systems.

Non-destructive testing

Non-destructive testing shall refer to inspections that do not essentially alter the geometry and size of the item inspected.

Division of inspection responsibilities

Division of inspection responsibilities shall refer to the division of inspections of mechanical components between STUK, an inspection organisation and a third party.

Inspection organisation

Inspection organisation shall refer to an organisation that performs inspections to examine a product, process, service or installation, or the design thereof, and to verify their conformity to requirements. (EN 17020)

Testing organisation

Testing organisation shall refer to an organisation performing testing activities requiring special competence. (Nuclear Energy Act 990/1987)

Nuclear Information

Nuclear Information shall refer to

- software that has been specially designed or modified for the development, production or use of the goods mentioned in Category 0 of Annex 1 of the Council Regulation 428/2009;
- technology which means special information, in written or other form, necessary for the development, production or use of the goods mentioned in Category 0 of Annex 1 of the Council Regulation 428/2009, and that is not generally available or not related to basic scientific research. This information takes the form of technical data or technical assistance. Technical data may take forms such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories. Technical assistance may take forms such as instructions, skills, training, working knowledge and consulting services and may involve the transfer of technical data. (Council Regulation (EC) no. 428/2009)

Probabilistic risk assessment

Probabilistic risk assessment (PRA) shall refer to a quantitative assessment of hazards, probabilities of event sequences and adverse effects influencing the safety of a nuclear power plant. (Government Decree 717/2013)

Product

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

Security arrangements

Security arrangements shall refer to the measures needed to protect the use of nuclear energy against illegal activities in the nuclear facility, its precincts other places or vehicles where nuclear energy is used.

Operational Limits and Conditions (OLC)

The Operational Limits and Conditions (OLC) set out the technical and administrative requirements for ensuring the plant's operation in compliance with the design bases and safety analyses; the requirements for ensuring the operability of systems, structures and components important to safety; and the limitations that must be observed in the event of component failure.

Emergency arrangements

Emergency arrangements shall refer to advance preparation for accidents or events impairing safety at the nuclear facility or in its site area or other places or vehicles where nuclear energy is used. (Nuclear Energy Act 990/1987)

Nuclear material

Nuclear material shall refer to special fissionable materials or source materials, such as uranium, thorium and plutonium, suited for obtaining nuclear energy. (990/1987, Section 3)

Nuclear waste

Nuclear waste shall refer to radioactive waste in the form of spent nuclear fuel or in some other form generated during or as a result of the use of nuclear energy. Nuclear waste also refers to materials, objects and structures which, having become radioactive during or as a result of the use of nuclear energy and having been removed from use, require special measures owing to the danger posed by their radioactivity. (Nuclear Energy Act 990/1987)

Nuclear waste facility

Nuclear waste facility shall refer to a nuclear facility utilised for the encapsulation of spent nuclear fuel or the conditioning of other nuclear waste for disposal, and to a disposal facility for spent nuclear fuel or other nuclear waste. (Government Decree 736/2008)

Nuclear facility

Nuclear facility shall refer to facilities used for the generation of nuclear energy, includ-

ing research reactors, facilities implementing the large-scale final disposal of nuclear waste, and facilities used for the large-scale production, generation, use, processing or storage of nuclear material or nuclear waste. However, nuclear facility shall not refer to:

- a. mines or milling facilities intended for the production of uranium or thorium, or premises and locations with their areas where nuclear waste from such facilities is stored or located for final disposal; or
- b. premises finally closed and where nuclear waste has been placed in a manner approved as permanent by the Radiation and Nuclear Safety Authority. (Nuclear Energy Act 990/1987)

Nuclear use item

Nuclear use item shall refer to nuclear material and the substances, devices, equipment, nuclear information and agreements referred to in Sections 2(1)(5) and 2(2)(1) of the Nuclear Energy Act (990/1987) (732/2008). (Nuclear Energy Decree 161/1988)

Nuclear safeguards

Nuclear safeguards shall refer to regulatory control preventing the proliferation of nuclear weapons to ensure that the nuclear materials and nuclear energy are used peacefully as defined in international treaties, and to ensure that they or any technology related to them is not used to promote the proliferation of nuclear weapons.

Nuclear liability

Nuclear liability shall refer to the liability of an operator of a nuclear facility for damage incurred to a third party.

Nuclear power plant

Nuclear power plant shall refer to a nuclear facility for the purpose of electricity or heat production, equipped with a nuclear reactor, or a complex consisting of nuclear power plant units and other related nuclear facilities located at the same plant site. (Nuclear Energy Act 990/1987)

EIA procedure

EIA procedure shall refer to an environmental impact assessment procedure whereby the environmental impact of certain projects is investigated and assessed, and the views of authorities and those whose circumstances or interests may be affected by the project, as well as the communities and foundations whose field of activity may be affected by the project, are heard.

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. Act on the control of exports of dual-use items (562/1996).
5. Act on Environmental Impact Assessment Procedure (468/1994).
6. Act on Electronic Services and Communication in the Public Sector (13/2004).
7. Nuclear Liability Act (484/1972).
8. Radiation Act (592/1991).
9. Decree on the Radiation and Nuclear Safety Authority (618/1997).
10. Decree on the Advisory Committee on Nuclear Safety (164/1988).
11. Government Decree on the Safety of Nuclear Power Plants (717/2013).
12. Government Decree on the Security in the Use of Nuclear Energy (734/2008).
13. Government Decree on Emergency Arrangements at Nuclear Power Plants (716/2013).
14. Government Decree on the Safety of Disposal of Nuclear Waste (736/2008).
15. Treaty establishing the European Atomic Energy Community (Euratom Treaty).
16. Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel.
17. Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.
18. Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.
19. IAEA Safety Guide GS-G-4.1, Format and Content of the Safety Analysis Report for Nuclear Power Plants, 2004.
20. Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.
21. Commission Recommendation (Euratom) No. 635/2010 of 11 October 2010 on the application of Article 37 of the Euratom Treaty.
22. Commission Regulation (Euratom) No. 302/2005 of 8 February 2005 on the application of Euratom safeguards.
23. Convention on Nuclear Safety 74/1996.
24. Governmental, Legal and Regulatory Framework for Safety General Safety Requirements Part 1 Series No. GSR Part 1, published Monday, October 04.
25. Safety of Nuclear Power Plants: Design Specific Safety Requirements
26. Series No. SSR-2/1, published Monday, February 20, 2012.
27. Safety of Nuclear Power Plants: Commissioning and Operation Specific Safety Requirements
28. Series No. SSR-2/2, published Thursday, July 14, 2011.
29. IAEA Specific Safety Guide No. SSG-25, Periodic Safety Review of Nuclear Power Plants, 2013.
30. IAEA Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide GS-G-1.3.
31. IAEA Review and Assessment of Nuclear Facility by the Regulatory Body, Safety Guide GS-G-1.2.

ANNEX A Documents to be submitted to STUK in connection with an application for a decision-in-principle and the licensing process

A.1 Application for a decision-in-principle

A01. The following clarifications for each facility project shall be separately submitted to STUK for information when an application for a decision-in-principle is filed for a nuclear facility:

- the design principles and description of operation of the nuclear facility and its safety systems, and where a nuclear power plant is concerned, also those of its reactor, primary circuit and containment (see YVL B.1);
- preliminary principles for the siting and layout of the facility, buildings and structures of the facility, and preliminary plans for provisions for internal and external threats (see YVL B.7);
- preliminary principles for the provisions for aircraft crash (see YVL A.11);
- summary of the safety analyses pertaining to the facility option concerned, including an environmental impact analysis of the worst-case accident scenario and principles according to which offsite radiation doses and releases are limited and monitored (see YVL B.3 and YVL C.3);
- general plans pertaining to the organisation implementing the plant, the suppliers of the plant and its major components, and quality management of the implementation (see YVL A.3, YVL A.5);
- preliminary personnel plan (see Guide YVL A.4)
- references to the nuclear facilities that have served as models, and a summary of the most significant modifications made compared to them;
- the licence applicant's own assessment of the feasibility of the implementation of the nuclear facility project concerned in compliance with the Finnish safety regulations.

A.2 Application for a construction licence

A02. Preliminary Safety Analysis Report

The Preliminary Safety Analysis Report (PSAR) is to demonstrate that all the relevant factors affecting safety and the regulations pertaining to safety have been duly taken into account. The PSAR can be supplemented by the so-called topical reports.

The PSAR shall include a description of the safety objectives and principles of the nuclear facility concerned, its design basis and other criteria used in the design and the fulfilment thereof; a detailed description of the facility and the site where it is located (see YVL A.2); a description of structural radiation safety (see YVL C.1); a description of the operation of the facility; a description of the facility's behaviour in transient and accident conditions; a summary of the results of the probabilistic risk assessment (PRA); and a report on the environmental impact of the operation of the facility. The PSAR pertaining to nuclear waste and final disposal facilities shall also discuss the matters required under the relevant guides YVL D.3, D.4 and D.5. Detailed requirements pertaining to the description of safety-classified systems are specified in Guides YVL B.1 and YVL B.7. With regard to nuclear power plants, requirements pertaining to the analysis methods and results of deterministic accident analyses are specified in Guide YVL B.3.

Topical reports, such as those describing, for example, the fuel, the reactor, the reactor pressure vessel, safety systems and the containment, shall be used for substantiating, in detail, what kinds of experimental research and theoretical analyses the design of the facility is based on. The reports

may relate to the facility concerned, or to another facility of a similar type. In the PSAR, reference shall be made to the topical reports that are of relevance for the assessment of the report.

Reports shall state the research results that are of relevance with regard to design; describe in detail the calculation models used in the design and the programs used in computer analyses; and state the main results and conclusions.

The safety analysis report shall be primarily drawn up in Finnish or Swedish. However, STUK may, in response to an application, agree that specific parts of the safety analysis report may be submitted to STUK in some other language approved by the same. An example of the content of the safety analysis report is provided in reference [19]. The requirements pertaining to the safety analysis report and design of the facility limits are specified in Guide YVL B.1.

The topical reports shall be submitted to STUK in such a way that they can be processed concurrently with the corresponding section of the PSAR.

A03. Probabilistic risk assessment in the design stage

The design-stage PRA of a nuclear power plant refers to a preliminary analysis comprising Levels 1 and 2 of the probabilistic risk assessment (PRA). The PRA of Level 1 analyses the probability of reactor core damage. Level 2 analysis assesses the quantity of radioactive substances leaking out of the containment, the probability of releases and their distribution over time.

The licence applicant shall demonstrate by means of a nuclear power plant's design stage probabilistic risk assessment that the facility in conformance with the PSAR meets the quantitative safety objectives specified in Guide YVL A.7. The preliminary PRA shall be based on the facility specifications provided in the PSAR. Requirements pertaining to the probabilistic risk assessment and its input data are also provided in Guide YVL B.1.

Guide YVL A.7 sets out detailed requirements pertaining to documents concerning the probabilistic risk assessment and its applications that are to be submitted to STUK for information or approval in connection with the application for a construction licence or during construction.

A04. Proposal for a safety classification document

The proposal for a safety classification document shall specify the classification of structures, systems and components important to the safety of the nuclear facility on the basis of their significance with respect to safety. The functions with which the systems, structures and components are linked shall also be considered when preparing the classification.

The safety class is of relevance with regard to the requirements set for the design, manufacture, installation, testing and inspections. STUK determines the regulatory control measures to be taken in respect of each item based on the safety class the item is assigned to.

Detailed requirements pertaining to the safety classification of nuclear facilities are specified in Guide YVL B.2.

A05. Report on quality management during construction and quality manuals

Under Section 35 of the Nuclear Energy Decree, the licence applicant shall submit a description of quality management during the construction of the nuclear facility, showing the systematic procedures adhered to by the organisations involved in the design and construction of the nuclear facility concerned in their operations affecting quality.

In addition to the description, the licence applicant's quality manual for the construction stage describing the licence applicant's management system procedures related to the control of safety and quality management shall be submitted to STUK for approval.

A project plan for the construction stage, complete with resource and quality plans as well

as risk management plans related to safety and quality, shall also be submitted to STUK for information.

Additionally, the quality manuals of the nuclear facility supplier, nuclear fuel supplier, suppliers of principal components and equipment, and design organisations shall be submitted to STUK for information. STUK may, at its discretion, request that the quality manuals of other organisations involved in the facility project be submitted to STUK for information as well.

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

A06. Preliminary plans for security and emergency arrangements

The purpose of security arrangements is to prevent unlawful action against the nuclear facility and nuclear materials. The preliminary plans for security arrangements comprise a preliminary security plan and a preliminary security standing order, a plan for principles for security as provided in Section 19 of Government Decree 734/2008, as well as the other documents specified in Guides YVL A.11 and A.12. The preliminary security 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. The preliminary security standing order shall provide the preliminary information required under Section 7 n of the Nuclear Energy Act. The general requirements concerning security arrangements at nuclear facilities are specified in Government Decree 734/2008 on the Security in the Use of Nuclear Energy. Detailed requirements are specified in Guide YVL A.11. The requirements pertaining to information security are specified in Guide YVL A.12.

Emergency arrangements are aimed at limiting nuclear damage in the nuclear facility and its vicinity in the event of an accident. The preliminary emergency plan shall include a plan for the nuclear facility's own emergency arrangements

and their relation to the emergency plans the authorities are responsible for. The plan shall incorporate consideration of the emergency arrangements in the facility design, and the relevant administrative procedures. The general requirements concerning emergency arrangements at nuclear power plants are presented in Government Decree 716/2013. Detailed requirements concerning emergency arrangements are specified in Guide YVL C.5.

A07. Plan for arranging the necessary safeguards to prevent the proliferation of nuclear weapons

The purpose of nuclear safeguards is to assure that the facility site, nuclear materials or other nuclear use items are not used for the preparation of nuclear weapons or other nuclear explosives, and that no undeclared activities take place in the facility site. The plan for implementing the safeguards shall include, among other things, the design data concerning the facility structure and the basic data concerning its operation, as well as a description of how the nuclear safeguards are intended to be managed at the facility.

Detailed requirements pertaining to nuclear safeguards and the regulatory control measures taken by STUK are specified in Guide YVL D.1.

A08. Preliminary description of the transport arrangement for nuclear material and nuclear waste, and a preliminary plan for transport security arrangements

The preliminary description shall make it possible to assess the feasibility of the planned transport and security arrangements pursuant to the requirements of Guide YVL D.2.

A09. Verification of the opportunities for regulatory control referred to in Section 19(7) of the Nuclear Energy Act.

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.

A10. Description of compliance with safety requirements

The licence applicant shall submit to STUK for information a description demonstrating compliance with the requirements specified in Government Decrees (734/2008, 736/2008, 716/2013, 717/2013), and applicable YVL Guides.

A11. Conceptual plan for ageing management

The licence applicant shall describe the principles according to which the ageing management of the components of the foreseen nuclear facility is planned to be implemented.

Detailed requirements pertaining to ageing management and the content of the conceptual plan are specified in Guide YVL A.8.

A12. Conceptual plan for in-service inspections

The licence applicant shall submit to STUK a conceptual plan for in-service inspections specifying the in-service inspections performed on pressure equipment by means of non-destructive examination methods as well as other in-service inspections performed on pressure equipment and other mechanical components. The conceptual plan shall include preliminary descriptions of the risk-informed processes used for selecting the objects of examination, the examination methods and intervals, and of the procedure used for reporting and assessing the inspection results and flaw indications.

Detailed requirements pertaining to the non-destructive in-service inspection of nuclear facility pressure equipment and the conceptual plan are specified in Guide YVL E.5. Guides YVL E.3, E.4 and E.8 set out the requirements for other in-service inspections of pressure equipment, and Guides E.9, E.10 and E.11 the requirements for the in-service inspections of other mechanical components.

A13. Licensing plan

The licence applicant shall submit to STUK for information a licensing plan for the construction

project of the nuclear facility concerned, describing how compliance with nuclear and radiation safety requirements will be demonstrated at different stages of the project.

Detailed requirements pertaining to the licensing plan are specified in Guide YVL A.5.

A14. Description of safety management and culture during construction

The description shall specify how the licence applicant will ensure the supplier's competence and the appropriateness of project management systems for pursuing the construction project in compliance with the safety culture requirements specified in the YVL Guides. The description shall also present how the licence applicant will assess the fulfilment of safety culture requirements during the construction stage in respect of its in-house organisation, the facility supplier's organisation, and other organisations involved in the project.

Detailed requirements pertaining to safety management and culture, project management, the management of the facility supplier and subcontractors, and the management of requirements and non-conformances are specified in Guides YVL A.3, A.4 and A.5.

A15. Safety case demonstrating long-term safety of the nuclear waste final disposal facility

Compliance with the requirements concerning long-term radiation safety, and the suitability of the disposal method and disposal site, shall be proven through a safety case. The safety case shall be submitted to STUK for approval.

Detailed requirements for demonstrating long-term safety and for presenting the safety case are specified in Guide YVL D.5.

A16. Programme for determining the baseline environmental conditions of the nuclear facility

The licence applicant shall submit the programme for determining the baseline environmental conditions to STUK for approval at the construction li-

cence application stage. The plan shall specify how the licence applicant intends to survey the off-site radiation impact of the nuclear facility prior to the commissioning of the facility. The determination of baseline conditions makes it possible to accurately and reliably separate radioactive releases from other ambient radiation.

Detailed requirements pertaining to the determination of baseline environmental radiological conditions are specified in Guide YVL C.4.

A17. Programme for decommissioning the nuclear facility

In the construction licence application stage, the licence applicant shall submit to STUK for approval a plan based on the decommissioning strategy established for the nuclear facility concerned that provides an outline of the implementation stages involved in decommissioning complete with timetables, the dismantling and waste management solutions adopted, and the end state of the facility site.

Guide YVL D.4 sets out detailed requirements for the decommissioning of a nuclear facility.

A.3 Application for an operating licence

A18. Final Safety Analysis Report

The general requirements for the Preliminary Safety Analysis Report also apply to the Final Safety Analysis Report (FSAR). The safety analysis report and its plant descriptions, accident analyses and topical reports shall be based on the actual systems, structures and components implemented at the nuclear facility concerned, with due consideration given to the construction status of the facility where possible. Detailed requirements pertaining to the description of safety-classified systems are specified in Guides YVL B.1 and YVL B.7.

In addition to the information concerning the nuclear facility and its site, the FSAR shall also include descriptions of the commissioning and operation of the facility. The requirements pertaining to the commissioning of nuclear power plants are specified in Guide YVL A.5.

Detailed requirements pertaining to the safety analysis report for a nuclear waste final disposal facility are also specified in the relevant Guide YVL D.5.

A19. Probabilistic risk assessment

The probabilistic risk assessment (PRA) shall include analyses in accordance with Levels 1 and 2, which are based on the systems, structures and components specified in the FSAR of the nuclear facility.

The licence applicant shall demonstrate by means of a probabilistic risk assessment that the nuclear power plant meets the quantitative safety objectives specified in Guide YVL A.7. Requirements pertaining to the probabilistic risk assessment of a nuclear power plant are also provided in Guide YVL B.1.

Guide YVL A.7 sets out detailed requirements pertaining to documents concerning the probabilistic risk assessment and its applications that are to be submitted to STUK for information or approval in connection with the application for an operating licence.

A20. Safety classification document

The document specifies the classification of structures, systems and components important to the safety of the nuclear facility on the basis of their significance with respect to safety. Detailed requirements pertaining to the safety classification of nuclear facilities are specified in Guide YVL B.2.

A21. Quality management programme and quality manuals for the operation of the nuclear facility

When an application for an operating licence is filed, the licence applicant shall submit to STUK for approval the quality management programme for the operation of the nuclear facility concerned, specifying the structured procedures to be complied with during the commissioning and operation of the nuclear facility in respect of any functions with quality and safety implications.

In addition to the quality management programme, the licence applicant's quality manuals concerning the management system used during the operation of the nuclear facility and the facility's safety management, as well as the licence applicant's quality manual concerning nuclear fuel shall be submitted to STUK for approval.

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

A22. Operational Limits and Conditions

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

Guide YVL A.6 sets out detailed requirements pertaining to the OLC of a nuclear power plant. The comprehensiveness and sufficient balance of the OLC shall be verified in accordance with Guide YVL A.7.

A23. Summary programme for in-service inspections

The summary programme for in-service inspections shall specify the periodic inspections of components and structures important to safety that are to be carried out at regular intervals after commissioning. The programme that, as such, supplements the conceptual plan for in-service inspections shall comprise the items scheduled for inspection, including the scopes, methods and periods of inspection, the principles governing their selection, and the procedure used for re-

porting and assessing the inspection results and flaw indications.

Detailed requirements pertaining to the non-destructive in-service inspection of nuclear facility pressure equipment and the summary programme are specified in Guide YVL E.5. Guides YVL E.3, E.4 and E.8 set out the requirements for other in-service inspections of pressure equipment, and Guides E.9, E.10 and E.11 the requirements for the in-service inspections of other mechanical components.

A24. Plans for security and emergency arrangements

The security and emergency plans shall take account of the rooms, systems and components constructed at the facility, as well as the structure and areas of responsibility of the facility's operating organisation.

The plans for security arrangements include a security plan, a security standing order, and the other documents specified in Guide YVL A.11. The requirements pertaining to the content of the security plan, security standing order and other security arrangement documents that are to be submitted to STUK for approval are specified in Guide YVL A.11.

Detailed requirements pertaining to emergency arrangements and the emergency plan are specified in Guide YVL C.5.

A25. Clarification of the arrangement of the necessary safeguards to prevent the proliferation of nuclear weapons

The clarification shall comprise a manual concerning the nuclear accountancy and safeguards system that provides a description and instructions as to how the licence applicant fulfils the safeguards, accounting, reporting and other obligations under its responsibility that are necessary for implementing the control of its material balance area or other corresponding accounting item, or the control defined in the Additional Protocol to the Safeguards Agreement.

Detailed requirements pertaining to the nuclear accountancy and safeguards system are specified in Guide YVL D.1.

A26. Description of the transport arrangement for nuclear material and nuclear waste and a plan for transport security arrangements

At the operating licence application stage, the licence applicant shall submit to STUK for approval a description of the transport arrangement for nuclear materials and a plan for transport security arrangements. Guide YVL D.2 sets out detailed requirements pertaining to the transport arrangements for nuclear material and nuclear waste, and for transport security arrangements.

A27. Administrative rules

As provided under Section 122 of the Nuclear Energy Decree, the duties, competencies and responsibilities of the responsible manager of a nuclear facility, his or her deputy and the rest of the personnel necessary for the operation of the facility shall be determined in the administrative rules.

The duties, competencies and responsibilities of the licensee's organisational units, as well as qualification requirements for the personnel, shall be specified in a separate organisation manual or similar document, which shall be submitted to STUK for information.

A28. Environmental radiation monitoring programme

The environmental radiation monitoring programme shall describe the structured procedures under the licensee's responsibility that are used for monitoring the occurrence of radioactive substances originating from a nuclear facility in the vicinity of the facility concerned.

In addition to the radiation monitoring programme, the results of the determination of the baseline radiological conditions of the new nuclear facility shall be submitted to STUK for approval in connection with the application for an operating licence, if not earlier.

Detailed requirements pertaining to the radiological control of the environment are specified in Guide YVL C.4.

A29. Description of compliance with safety requirements

The licence applicant shall provide a description demonstrating compliance with the requirements specified in Government Decrees (734/2008, 736/2008, 716/2013, 717/2013) and applicable YVL Guides.

As regards compliance with the requirements specified in the YVL Guides, any implementation decisions for the guides issued in respect of the nuclear facility concerned shall be reviewed and the implementation status of the measures defined in connection with the decisions specified. As regards any departures from the due fulfilment of the requirements set out in the guides observed in the implementation decision stage, any changes made or foreseen in the design or operational organisation of the facility shall be specified.

A30. Ageing management programme

To make provision for the ageing of the facility, a plan shall be presented as to how the design and qualification of components and structures, their operation and operational experience feedback, in-service inspections and tests and maintenance are integrated so as to form a comprehensive ageing management programme. The plan shall take account of all relevant ageing and wear mechanisms and ageing-induced degradation. Due consideration shall also be given to the provisions made with regard to changes in technology.

Detailed requirements pertaining to the ageing management programme are specified in Guide YVL A.8.

A31. Nuclear fuel use supervision programme

A plan for the supervision of nuclear fuel use shall be submitted to STUK for approval together with the application for an operating licence for a nuclear power plant. The programme shall

be used to monitor and supervise the operating conditions and actual condition of the nuclear fuel during use. An approved nuclear fuel use supervision programme is a prerequisite for starting the loading of nuclear fuel.

Detailed requirements pertaining to the nuclear fuel use supervision programme are specified in Guide YVL E.2.

A32 Control rod use supervision programme

An operation supervision plan that ensures the reliable performance of control rods shall be submitted to STUK for approval together with the application for an operating licence for a nuclear power plant. An approved nuclear fuel use supervision programme is a prerequisite for starting the loading of nuclear fuel.

Detailed requirements pertaining to the control rod use supervision programme are specified in Guide YVL E.2.

A33. Spent nuclear fuel storage supervision programme

A supervision programme for the spent nuclear fuel storage that is used to monitor any changes that may occur in the properties of the nuclear fuel assemblies and their storage conditions shall be submitted to STUK for approval together with the application for an operating licence for a nuclear facility. An approved supervision programme is a prerequisite for starting the use of a spent nuclear fuel storage facility.

Detailed requirements pertaining to the supervision programme for the spent nuclear fuel storage are specified in Guide YVL D.3.

A34. Plan for the plant's safety indicators

The licensee shall submit to STUK for information a summary of the safety indicators monitored during operation of the nuclear power plant.

A35. Plan for decommissioning the nuclear facility

A detailed decommissioning plan consistent with the type of the facility concerned, specifying the implementation stages complete with timetables, the dismantling and waste management solutions adopted, and the end state of the facility site shall be submitted to STUK for approval in connection with the application for an operating licence. The plan shall also include preliminary reports on the radiation safety of the foreseen actions.

Guide YVL D.4 sets out detailed requirements for the decommissioning of a nuclear facility.

A36. Safety case demonstrating long-term safety of the nuclear waste final disposal facility

Compliance with the requirements concerning long-term radiation safety, and the suitability of the disposal method and disposal site, shall be proven through a safety case. The safety case shall be submitted to STUK for approval.

Detailed requirements for demonstrating long-term safety and for presenting the safety case are specified in Guide YVL D.5.

A.4 Renewal of the operating licence and periodic safety review

A37. The documents referred to in Section 36 of the Nuclear Energy Decree.

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. The documents shall be kept up-to-date at all times, and the updated versions shall be submitted to STUK on a regular basis. Upon renewal of the operating licence or in connection with a periodic safety review, the documents may be submitted to STUK only insofar as they have been amended since the previous updates. Furthermore, the licensee shall provide a summary of the most significant changes to the documents since the previous operating licence was granted and a description of the up-to-date-ness of the documents.

A38. Description demonstrating compliance with the requirements of Government Decrees and YVL Guides

The licensee shall provide a description demonstrating compliance with the requirements specified in Government Decrees (734/2008, 736/2008, 716/2013, 717/2013) and applicable YVL Guides.

For the points of the Government Decrees in respect of which a detailed report will be separately provided, a simple reference to such a report is sufficient in this connection.

As regards compliance with the requirements specified in the YVL Guides, any implementation decisions for the guides issued in respect of the nuclear facility concerned shall be reviewed and the implementation status of the measures defined in connection with the decisions specified. As regards any departures from the due fulfilment of the requirements set out in the guides observed in the implementation decision stage, any changes made or foreseen in the design or operational organisation of the facility to satisfy the requirement concerned shall be specified.

A39. Description of the reassessment of the design bases of the facility site

The licensee shall assess the site-specific design bases concerning external threats and the potential need for updating them in connection with the periodic safety review. The description shall take due account of the advancement of the methods used to determine external threats. If the design bases need to be updated, this shall be taken into account in the update of the safety analyses. Guide YVL B.7 addresses external threats and provides detailed requirements for making provision against them.

A40. Summary of the previous periodic safety review

The description shall summarise the action plan prepared in connection with the previous periodic safety review and the implementation status of the actions.

A41. Description of the facility's ageing and ageing management

In the description, the licensee shall provide a summary of the ageing management programme concerning the operating licence period applied or remaining for the facility. The description may draw upon the annually submitted ageing management follow-up report by extending the description of ageing management to also cover the next safety review or renewal of the operating licence.

Detailed requirements pertaining to ageing management and the content of the follow-up report are specified in Guide YVL A.8.

A42. Description of the environmental qualification of equipment

In the description, the licensee shall provide a summary of the equipment qualification procedures concerning the operating licence period applied or remaining for the facility, specifying how the qualifications are maintained and what the current status of the qualification is.

A43. Summary of renewed safety analyses

The transient and accident analyses, strength analyses, failure mode and effect analyses, probabilistic risk assessments as well as any other essential analyses concerning the facility shall be reviewed in connection with a periodic safety assessment. The analyses shall be updated where necessary and submitted to STUK. The summary shall provide a description of the up-to-dateness of the analyses, the conclusions drawn from the results of the renewed analysis, and the steps taken based on them, if any.

If the object of the operating licence renewal or periodic safety review is the disposal of nuclear waste, the long-term safety cases shall be reviewed, updated where necessary, and submitted to STUK. Detailed requirements for demonstrating long-term safety and for presenting the safety case are specified in Guide YVL D.5.

A44. Summary of the plant's safety indicators

The description shall provide a summary of the safety indicators monitored at the nuclear power plant and their development trends since the operating licence was granted or the previous periodic safety review was carried out.

A45. Description of the licensee's safety culture and safety management

The description shall specify the assessment methods, the conclusions drawn in respect of the current state and their implications for the subsequent or remaining operating licence period, and the steps taken to improve safety culture. The assessment and improvement of safety culture shall draw upon the expertise in organisational studies and nuclear safety practices.

A46. Summary of plant procedures

The summary shall specify the structure of the plant procedures, describing their up-to-dateness and any development projects currently underway or foreseen.

A47. Summary of the plant's radiation protection arrangements

The description shall provide a summary of the radiation protection of plant workers, the monitoring of radioactive releases, and the results of the environmental radiation monitoring programme. The description shall also provide a summary of the procedures by which the occupational radiation exposure of plant workers and radioactive releases are kept as low as reasonably achievable. Furthermore, an assessment shall be provided as to how the limitation of radioactive releases to and radiation levels in the environment is implemented employing the best available techniques.

A48. Summary of the waste management procedures and decommissioning of the facility

The description shall provide a summary of the storage, handling and disposal of operating waste and spent fuel, accompanied by a summary of the decommissioning plan of the facility.

A49. Summary of the plant's operating experience feedback and research activities and plant improvements

The description shall provide a summary of the plant's internal and external operating experience feedback activities and the uses made of research results to improve safety. The description shall also provide a summary of the plant improvements implemented since the previous operating licence was granted.

A50. Summary of fulfilment of the requirements laid down in Section 20 of the Nuclear Energy Act, and compliance with the conditions of the operating licence

The description shall address the requirements of Section 20 of the Nuclear Energy Act and the conditions of the operating licence, and demonstrate that they have been complied with.

A51. Summary of the periodic safety review and action plan for improving plant safety

The description shall provide a summary of the periodic safety assessment results; an overall assessment of the safe operation of the plant following the previous periodic safety review; an assessment of the current state of the plant; and the preconditions for continuing its safe operation until the next periodic safety review.

An action plan for plant improvements carried out pursuant to Section 7 a of the Nuclear Energy Act, complete with timetables, shall be provided as a summary of the periodic safety review.

ANNEX B Submission of documents to STUK

B.1 Document structure

B01. A document may be composed of a covering letter, a front sheet describing the processing of the matter complete with the necessary annexes where applicable, or some other presentation referred to in Section 6 of the Archives Act (831/1994), the sending of which shall be separately agreed upon between STUK and the sender. According to Section 5(1) of the Act on the Openness of Government Activities (621/1999), a document is defined as *a written or visual presentation, and also as a message relating to a given topic or subject-matter and consisting of signs which, by virtue of the use to which they are put, are meant to be taken as a whole, but are decipherable only by means of a computer, an audio or video recorder or some other technical device.*

B02. A document shall comprise a covering letter, a front sheet and the necessary annexes when:

- a licence or approval is applied for;
- the submission of the document to STUK for information is required under a YVL Guide, a decision issued by STUK, a request for further clarification, or an inspection protocol.

A separate front sheet is not necessary if the information to be marked on the front sheet, such as processing, inspection and approval, is given in the annexes to the covering letter. This applies to the submission of operating instructions, for example. The front sheet is also not necessary if STUK has requested the submission of general documentation that will not be directly used as an approval criterion for anything.

B03. A covering letter shall include the following:

- date, author and the sender's reference;
- the plant unit, function or other object discussed in the document, and the information necessary for identifying and delimiting the matter concerned, such as system and component designations;
- a description of the matter being presented, the STUK control measure to which the matter pertains, and what the document submits

for approval or information (purpose of the document);

- references to other correspondence between STUK and the sender in the matter concerned;
- references to other relevant documents and negotiations;
- a statement on the acceptability of the document and the measures proposed therein;
- where necessary, a proposal for handling the document as confidential, complete with reasoning;
- the sender's signature, name in print and position within the organisation; and
- a list of annexes.

If the same covering letter is used for submitting matters or documents both for approval and for information, the covering letter shall clearly indicate the items submitted for approval and those submitted for information.

The covering letter or annexed summary of justifications (requirement 374) shall indicate the extent and independence of the document review carried out by the licensee, complete with a rationale for the conformance and acceptability of the document and the measures proposed therein.

B04. The conclusions and statements presented in the covering letter shall be based on the factual content of the annexes, and they may not contradict with the annexes.

B05. The front sheet of the document shall include the following information:

- the sender;
- the plant unit, or the name of the other nuclear facility concerned;
- the matter discussed in the document;
- the safety class in the event that the document concerns systems, structures or components;
- the author or handler of the document, the inspectors and their inspection responsibilities.

ties, the approver, as well as the drafting or processing, review and approval dates; and

- signatures with names in print.

In the event that the front page of a hardcopy document is not signed manually but furnished with an electronic signature, STUK may, in response to an application, confirm such compensatory procedure that is based on the records management procedures contained in the licensee's quality management system that can be deemed to be up to the required standard.

B06. The duties and responsibilities of those who draw up, process, review and approve documents to be submitted to STUK shall be defined in the licensee's management system.

B07. The documents submitted to STUK shall be in Finnish or Swedish. Annexes may also be provided in English. STUK may, in response to an application, also accept annexes in other languages.

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 further clarification will be made.

B.2 Document content and the mode of presentation

B09. Requirements pertaining to the content of the documents submitted to STUK are specified in Finnish legislation and in the YVL Guides. Requirements pertaining to the content of licence applications are set out in Sections 35 and 36 of the Nuclear Energy Act. These requirements are specified in greater detail in the YVL Guides.

B10. The application document shall state the factual justification of the operations presented in the application including, among other things, the radiation and nuclear safety regulations specifically applicable to the matter concerned as well as potential deviations from them, complete with reasoning. The individuals involved in the preparation of the document shall be identified. When the matter is prepared, due consideration shall be given to any information available that can be used for assuring safety. Compliance with official regulations and guides does not entitle anyone to ignore information that could yield better results with regards to safety.

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. If the document makes reference to literature or research results, their bibliographic information shall be given. If the referenced material is not part of the public domain, it shall be made available to STUK.

B12. If a document contains colour pictures the information content or legibility of which is based on the use of colours, all copies of the document shall be in colour, or the pictures in the copies shall be provided with clarifying markings to facilitate the interpretation of the pictures. When the colours are selected, due consideration shall be given to the potential limitations related to their perception.

B13. The facts presented, conclusions drawn and statements made in a document shall represent the best of the licensee's knowledge in the matter concerned. Any information that is of relevance for resolving the matter concerned, insofar as it is known to the licensee, shall be presented in its entirety. If, for example, the sender of the document is aware of research results that contradict with what is proposed, such results shall also be discussed in the application.

B.3 Submission of documents

B15. A document submitted for official review shall be addressed to STUK. Documents addressed to individual persons are not, as a rule, registered or archived by STUK. An exception to the above are confidential documents defined with the licensee which, when addressed to STUK, can be delivered to the agreed person if separately so agreed.

B16. If a deadline for the submission of a document has been established in the YVL Guides or in a decision issued by STUK, the document shall be submitted in such a manner that it reaches STUK no later than the deadline. If necessary, a document or its part can be sent to STUK in advance in the form of an electronic communication (e.g. by fax or e-mail). If, for some reason, the licensee is unable to abide by the set deadline, the licensee shall, prior to the expiry of the original deadline, present for STUK's approval a proposal for a new deadline and the reason for the delay, complete with its potential implications in terms of safety, quality or oversight.

B17. The hardcopy document and any pictures, data disks, radiographic pictures, etc. enclosed with it shall be appropriately protected for delivery.

B18. The annexes to a hardcopy document shall be submitted to STUK in two copies. However, STUK may specifically require additional copies of the document or its annexes to be submitted. If the applicant wishes that an annex to the document concerned be returned furnished with the approval markings of STUK, this shall be mentioned in the covering letter and STUK shall be provided with an additional return copy. In this case, space shall be reserved on the front sheet for STUK's inspection markings.

B.4 Documents submitted in electronic format

B19. When an electronic document is used, STUK may, at its discretion, also require that a hardcopy document be submitted. The guiding principle is that at least one copy in hardcopy format shall be submitted to STUK for any document that, pursuant to the central government archiv-

ing regulations, is required to be stored permanently or for a long period of time (more than 10 years).

B20. In addition to the hardcopy document, the related extensive documentation relating to the licensing of a nuclear facility referred to in Sections 35 and 36 of the Nuclear Energy Decree shall be made available to STUK in electronic format, or by providing electronic access to the documents concerned. At the same time, a reliable procedure for ensuring the up-to-dateness of the electronic documents shall be presented.

B21. STUK may, at its discretion, require that in addition to the hardcopy, other extensive bodies of documentation pertaining to the nuclear facility concerned be also submitted in electronic format. These may include, for example, manuals and operating procedures describing the management system.

B.5 Amendments to documents

B22. Any amendments to a document submitted to STUK shall be processed in the manner specified in the licensee's management system and submitted to STUK in the same way as the original document.

B23. If there are material changes to the information contained in a document already submitted to STUK for approval, STUK shall be promptly notified thereof and a revised application, which has been changed as necessary, shall be re-submitted to STUK. In case of minor amendments, the submission of supplementary information or amendments to the document concerned can be separately agreed upon with STUK.

B.6 Document materials

B24. When documents other than instructions submitted for information are prepared, materials that endure long-term storage (more than 10 years) shall be used for at least one series of documents. The covering letter accompanying any instructions submitted for information shall, in any event, meet the aforementioned storage requirements.

B.7 Publicity of documents

B25. As a rule, a document submitted to STUK becomes part of the public domain as soon as it has been registered at STUK. STUK decides on the confidentiality of a given document based on the Act on the Openness of Government Activities and, insofar as its confidentiality policy is con-

cerned, complies with the Decree on the Openness of Government Activities and on Good Practice in Information Management (1030/1999); the Government Decree on Information Security in Central Government (681/2010); and the instructions issued by the Government Information Security Management Board VAHTI.

ANNEX C **Nuclear liability arrangements**

C.1 General

c01. Nuclear liability means a liability provided by means of special regulations for damage caused by nuclear incidents. The basis of the nuclear liability regulation is international. Nuclear liability is regulated in Finland by the Nuclear Liability Act (484/1972). According to internationally agreed principles, the liability for damage lies with the operator of a nuclear facility, who in Finland is the licensee referred to in the Nuclear Energy Act (990/1987). Outside the territory of Finland, the operator of a nuclear facility is the party recognised under the law of the facility state as the operator of that facility.

c02. The liability of a licensee of a nuclear facility situated in Finland in respect of nuclear damage occurring in Finland is unlimited. Additionally, it has been stipulated that part of the liability shall be covered by insurance. To this end, the operators of a nuclear facility are required to take out insurance to cover their liability for nuclear damage (Section 23 of the Nuclear Liability Act). The security for compensation is further stipulated by the provisions of the Nuclear Liability Act concerning liability covered by the State (Sections 29 to 36).

c03. The provisions of the Nuclear Energy Act concerning nuclear waste management limit the licensee's liability in terms of duration. When nuclear waste has been disposed of in an approved manner, the ownership to and responsibility for the waste is transferred to the State (Section 34 of the Nuclear Energy Act), at which time the licensee's obligation to take out insurance in respect of the disposed nuclear waste ceases.

c04. The arrangements required from licensees involve specific administrative procedures and the approval of insurances. The applicable provisions are contained in the Nuclear Liability Act. The regulatory authorities are the Ministry of Employment and the Economy, and the Financial Supervisory Authority.

c05. Provisions on the regulatory control carried out by STUK are contained in the Nuclear Energy Act and Decree (Sections 55(3), 20(2)(1) and 21(2) of the Nuclear Energy Act and Section 58 of the Nuclear Energy Decree). This annex presents the regulatory control procedures of STUK as regards liability insurance for nuclear damage occurring at a nuclear facility and nuclear damage occurring in the course of the carriage of nuclear material.

C.2 Licensee's obligations

Liability insurance for nuclear facilities

c06. The licensee shall submit to STUK for information a copy of a valid insurance policy and its annexes prior to the beginning of each insurance period.

c07. The insurance documents shall be accompanied by documents proving that the Financial Supervisory Authority has approved the insurance as provided under Section 23 of the Nuclear Liability Act. The approval shall cover both the insurance policy and its annexes, in other words the insurance in its entirety.

The Nuclear Liability Act contains provisions (Sections 23 to 28) concerning the content of nuclear liability insurances as regards insurance law and substance (the content of the insurance obligation, the form of the insurance policy, the amount of insurance liability, etc.). Responsibility for evaluating and inspecting the acceptability of the aforementioned matters along with the terms and conditions and other technicalities of the insurance rests with the Financial Supervisory Authority.

c08. In the event that the validity of a duly approved insurance is extended (without any changes to the form, content or conditions of the insurance), no separate approval is needed for the insurance thus renewed. A copy of the renewed insurance policy submitted to STUK and

proof of the previous approval by the Financial Supervisory Authority are sufficient.

C09. Documents proving the approval of the Financial Supervisory Authority shall be submitted to STUK whenever changes are made to the insurance, either due to changes in the requirements stipulated by the Nuclear Liability Act or issued thereunder, or due to other reasons.

FiR1 research reactor

C10. The State is exempted from the obligation under the Nuclear Liability Act to take out insurance (Section 28(1) of the Nuclear Liability Act). Hence, the foregoing requirements pertaining to liability insurances for nuclear facilities do not apply to the FiR1 research reactor operated by the Technical Research Centre of Finland (VTT).

Shipment into Finland from a Contracting State (see Section 1(13) of the Nuclear Liability Act)

C11. Under Section 58 of the Nuclear Energy Decree, an application for a transport licence shall contain a description of the arrangement of liability for nuclear damage. The licensee shall submit a certificate issued by the insurer of the state of origin referred to in Section 40 of the Nuclear Liability Act in connection with the transport plan, if not earlier. The licensee shall, for their part, ensure that the certificate is of reliable origin and appropriate with regard to its content. Requirements pertaining to the carriage of nuclear materials and the transport plan are specified in Guide YVL D.2.

If the certificate is submitted separately from the other transport licence documents, it can be submitted to STUK for information. STUK verifies that the form of the certificate is consistent with the regulations; that the certificate contains the information required under the regulations; and that it contains a statement of the competent authority of the state of origin on the status of the operator liable for transport damage.

Shipment into Finland from a non-Contracting State

C12. A licensee shall take out insurance for transport damage occurring in the territory of Finland.

The insurance shall be approved by the Financial Supervisory Authority. The insurance may be a separate insurance as provided in Section 23(3) of the Nuclear Liability Act. In these cases, the insurance documents and approval documents shall be submitted to STUK in connection with the transport plan, if not earlier.

C13. If the licensee arranges indemnification for nuclear damage during the transport of nuclear material in such a way that the transport insurance:

- is a part of a wider nuclear liability insurance package covering other operations as well; or
- covers, for the period defined in the insurance policy, all shipments of nuclear materials for which the licensee is obligated to take out insurance,

the insurance documents and documents showing the approval of Financial Supervisory Authority shall be promptly submitted to STUK upon signing the insurance contract and whenever changes are made to the insurance.

C14. If the validity of a duly approved insurance is extended without alterations (a new insurance period without any changes to the form, content or conditions of the insurance), no separate approval is needed for the insurance thus renewed. It is sufficient that the new insurance policy is submitted to STUK, accompanied by a copy of its previous approval.

C15. A certificate issued by the insurer consistent with the regulated form shall be submitted to STUK for each individual shipment regardless of the form and duration of the transport insurance. The certificate shall include the statement of the Ministry of Employment and the Economy referred to in Section 40 of the Nuclear Liability Act.

Shipment from a Finnish licensee

C16. The procedures specified in paragraphs C12 through C15 shall apply when a Finnish licensee (the operator of the facility concerned) consigns nuclear materials for carriage to a consignee located abroad or in Finland.

Transit through Finland

C17. As regards the provisions of Sections 7 to 11 of the Nuclear Liability Act, typical examples of the carriage of nuclear materials through the territory of Finland are cases where:

1. either the consignor of the nuclear material or its consignee, or both, are operators in a Contracting State within the meaning of Section 1 of the Nuclear Liability Act; or
2. neither is an operator in a Contracting State.

In both cases, transit through Finland is subject to a transport licence pursuant to the provisions of the Nuclear Energy Act and Decree. More specific provisions as to the application and processing of the licence are laid down in Chapter 8 of the Nuclear Energy Decree. The licence application shall be submitted to STUK.

C18. In cases referred to in Section C17 1), the licence application documents shall include a certificate issued by the insurer referred to in Section 40 of the Nuclear Liability Act. The cer-

tificate shall include a statement on the licensee's status given by the competent authority of the home state of the licensee liable for transport damage. If the certificate is submitted separately from the actual licence application, the covering letter shall be signed by the person in charge who is duly authorised to sign for and on behalf of the licence applicant.

C19. In cases referred to in Section C17 2), the holder of the transport licence shall be assimilated to a licensee pursuant to Section 8(3) of the Nuclear Liability Act. Under said provision, the provisions of the Nuclear Liability Act that are applicable to an operator of a nuclear facility situated in Finland are also applicable in respect of such licence holder. Anyone applying for a transit licence shall submit to STUK documents proving that they are holding a valid insurance for transport damage approved by the Financial Supervisory Authority under Section 23 of the Nuclear Liability Act.