STUK

GUIDE **YVL 3.4** / 14 JANUARY 2004

APPROVAL OF THE MANUFACTURER OF NUCLEAR PRESSURE EQUIPMENT

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Authorisation

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

- Section 55, paragraph 2, point 3 of the Nuclear Energy Act (990/1987)
- Section 29 of the Government Resolution (395/1991) on the Safety of Nuclear Power Plants
- Section 13 of the Government Resolution (396/1991) on the Physical Protection of Nuclear Power Plants
- Section 11 of the Government Resolution (397/1991) on the Emergency Preparedness of Nuclear Power Plants
- Section 8 of the Government Resolution (398/1991) on the Safety of a Disposal Facility for Reactor Waste
- Section 30 of the Government Resolution (478/1999) on the Safety of Disposal of Spent Nuclear Fuel.

Rules for application

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

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

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

Translation. Original text in Finnish.

1 General

In accordance with Section 60a of the Nuclear Energy Act (990/1987), *the Radiation and Nuclear Safety Authority (STUK) approves manufacturers of nuclear pressure equipment for their duties and inspection organisations or testing organisations for duties pertaining to the control of pressure equipment at nuclear facilities.*

A prerequisite for the approval of an inspection and testing organisation is that the inspection or testing organisation is operationally and economically independent and that it carries liability insurance. In addition, the inspection organisation and testing organisation shall have an advanced quality system, a competent and experienced personnel as well as appropriately qualified methods, facilities and equipment for manufacturing and operation.

If the operation of the manufacturer, inspection organisation or testing organisation of pressure equipment falls short of stipulated requirements and conditions, or of those stated in a decision of approval, the Radiation and Nuclear Safety Authority (STUK) may withdraw its approval. If justified by reasons pertaining to the assurance of safety, the Radiation and Nuclear Safety Authority (STUK) may, after having granted the corporation or establishment concerned a hearing, change the requirements and conditions established in its decision of approval.

Nuclear pressure equipment consists of the pressure equipment included in safety classes 1, 2, 3 and 4.

In accordance with Section 60 of the Nuclear Energy Act (990/1987), *where technical requirements for conventional pressure equipment at nuclear facilities, demonstration of safety and other preconditions for their placing on the market are concerned, the provisions of the Pressure Equipment Act (869/1999) are in force.* Conventional pressure equipment at nuclear facilities consists of the pressure equipment included in class EYT.

In accordance with Section 117 of the Nuclear Energy Decree, *the duty of Radiation and Nuclear Safety Authority (STUK) is to control the pressure vessels and specially to set more detailed requirements for fabrication of pressure vessels and their quality control.*

In accordance with Section 117a of the Nuclear Energy Decree, *the manufacturer of nuclear pressure vessels has to be able to demonstrate on demand that the planning and fabrication of the pressure vessel meets the safety requirements of use of nuclear energy.*

Section 21 of the Government Resolution (395/1991) requires that *the systems, structures and components important to safety shall be designed, manufactured, installed and operated so that their quality level and the inspections and tests required to verify their quality level are adequate considering any item's safety significance*.

This Guide is applied in manufacturing nuclear pressure equipment and its parts as well as in installing, repairing and modifying nuclear pressure equipment. The Guide deals with the procedure to be followed in assessing the competence of the manufacturer of nuclear pressure equipment, the acceptance procedure, and the obligations imposed on the manufacturer and supervision of the operations.

The approval of foreign manufacturers that comply with Pressure Equipment Directive 97/23/EY and the supervision of their operations take place in accordance with this Guide, and the obligations defined in this Guide apply to them. If the equipment is manufactured in accordance with a standard approved by the ASME or some other standard approved by a nuclear energy authority, Radiation and Nuclear Safety Authority (STUK) will evaluate fulfilment of the requirement level of this Guide separately.

In this Guide, the manufacture refers to the making of permanent joints of pressure equipment or its part, their heat treatment, and cold and hot working.

In this Guide, the licensee means the licensee referred to in the Nuclear Energy Act (990/1987).

2 Approval of the manufacturer

2.1 Scope

STUK approves the manufacturer of nuclear pressure equipment in the following equipment groups:

- pressure vessels

- pipes
- pumps
- safety devices
- pressurized auxiliary equipment.

If the manufacturer has several independent business sectors, the competence of each sector is assessed separately. Also the licensee may apply for an approval as a manufacturer of pressure equipment.

An approval of the manufacturer in accordance with this Guide is not required, if it is a question of the manufacture of material or the manufacture of standardized parts of pressure equipment (e.g. elbows and reducers).

Manufacturers that carry out the installation, repairs and modifications of conventional pressure equipment do not need an approval in accordance with this Guide, but they shall be qualified for their jobs. In its instruction manual, the licensee shall define the detailed requirements for the manufacturers of conventional pressure equipment and for the manufacturers that carry out the installation, repairs and modifications.

Before beginning the installation, repairs and modifications of conventional pressure equipment, the licensee shall verify that the manufacturing organization has technical and administrative preconditions for high-quality operations. Furthermore, the licensee shall make sure that the manufacturer is sufficiently familiar with the nuclear energy legislation and YVL Guides as well as the licensee's quality management system and related instructions. The manufacturing methods to be employed and the persons that carry out the manufacture shall be qualified in accordance with Section 4.2 below.

2.2 Requirements for the manufacturer's quality management system

Section 60a of the Nuclear Energy Act (990/1987) defines the general requirements for the manufacturer. In accordance with that Section, the manufacturer shall have, for instance, an advanced quality management system.

Section 5 of the Government Resolution (395/1991) also requires that *advanced quality assurance programmes shall be employed in all activities which affect safety and relate to the design, construction and operation of a nuclear power plant*. On the basis of the above-mentioned requirements, such pressure equipment manufacturers and sub-suppliers whose operations affect the safety of a nuclear power plant shall have an advanced quality management system in use. In accordance with the requirements set by the nature and scope of the operations, the quality management system shall define the measures with the aid of which the requirements relating to safety are fulfilled. All principles applied by the manufacturer and all requirements it has set for its operations shall be systematically gathered in documents to form the measures, procedures and instructions.

Advanced quality management requires that, when drawing up and maintaining the quality management system, the principle laid down in Section 27 of the Government Resolution (395/1991) is complied with concerning systematic monitoring and assessment of the operating experience and the results of safety research, and implementation of the necessary measures that enhance the safety. The features of an advanced quality management system include regular self-assessment of the operations, the use of independent assessments, and continuous development of the operations on their basis.

The quality management documents shall define the following in detail:

- quality targets and structure of the organization
- areas of responsibility and authority of the management pertaining to the quality of pressure equipment
- technologies and methods employed in the manufacture, particularly the methods used in making permanent joints and the qualifications required for them
- methods employed in the inspection and management of quality
- inspections and tests that are carried out before, during or after the manufacture
- documents, such as inspection reports and testing, calibration and tuning data, reports on the competence or approval of the personnel concerned, particularly reports on the competence and approval of the personnel that make permanent joints and non-destructive testing

- methods to control the fulfilment of the quality requirements set for the manufacturing operations and the efficiency of operation of the quality management system.

In building the quality management system and in assessing its scope, the standards commonly applied by industry shall be taken into account. The quality management system is usually described in the quality manual. If the system consists of several documents, the set of documents and their interrelationships must be specified. Guide YVL 1.4 defines the requirements for the quality management system of an organization that applies for a licence to construct and operate a nuclear facility. STUK takes a decision on the acceptability of the quality management system on the basis of the licensee's proposal.

In evaluating the manufacturer of nuclear pressure equipment, the modules used by the manufacturer to prove the compliance of the equipment with the requirements laid down in pressure equipment legislation can be exploited. When such modules are used, the licensee and the manufacturer shall assess the fulfilment of the requirement level in accordance with the YVL Guides. With respect to non-conformances, such supplementary measures shall be implemented with the aid of which the requirement level set by the YVL Guides is reached. A report on these measures shall be attached to the document submitted to STUK for approval.

2.3 Manufacturer in safety classes 1 and 2

The licensee shall apply for STUK's approval for the manufacturers of pressure equipment belonging to safety classes 1 and 2.

The licensee's application shall contain the data required to evaluate the manufacturer. In drawing up the application, the equipment groups, manufacturing processes and technical requirement level of the manufacture must be taken into account. In terms of evaluation of the manufacturer, the following issues, for instance, are important. Data on

- the place of manufacture
- the organization
- technical expertise in the manufacture of pressure equipment
- the quality management system, its independent assessment and results of the assessment
- quality management of the manufacturing process
- procedure tests of the different manufacturing methods performed and their supervision, and the licensee's opinion on their acceptability and suitability for the manufacture concerned
- qualification of the persons that make permanent joints
- the person/persons responsible for the manufacture in accordance with Section 3 below, his/her/their training, work experience and position in the organization
- the knowledge gained by the person/persons responsible for the manufacture of nuclear power plants: familiarity with the plant, if the manufacture takes place at a nuclear facility, knowledge of the official permits and YVL Guides
- the equipment group the manufacture of which is concerned
- the qualified manufacturing and welding instructions
- the rooms and equipment used in the manufacture
- previous operations of the manufacturer at nuclear facilities
- training of the personnel
- any external services, labour or equipment used by the manufacturer;
- the procedures to verify the traceability of materials.

The applications and other documents shall be submitted to STUK in accordance with Guide YVL 1.2 through the licensee.

For a good reason, the application can also be made as part of the construction plan of the pressure equipment to be submitted to STUK. In such a case, the approval of the manufacturer is of a one-time nature.

2.4 Manufacturer in safety classes 3 and 4

The licensee shall apply for STUK's approval for the manufacturers of pressure equipment

belonging to safety classes 3 and 4 as well. The application shall include a report on

- the quality management system for the manufacture of pressure equipment approved by a notified body or another third party
- the person responsible for the manufacture
- procedure tests of the different manufacturing methods performed and their supervision, and the licensee's opinion on their acceptability and suitability for the manufacture concerned
- qualification of the persons that make permanent joints.

The report shall define the equipment group the manufacture of which is concerned, and the compliance with the general preconditions required of the manufacturer in Section 60a of the Nuclear Energy Act.

The applications, including the reports, shall be submitted to STUK in accordance with Guide YVL 1.2 through the licensee.

For a good reason, an application can also be submitted to STUK for a single delivery of pressure equipment. The report attached to the application shall prove that the manufacturer has an advanced quality management system assessed by a third party and that other requirements set for the manufacturer mentioned in this section are fulfilled.

2.5 Approval and period of validity of the approval

STUK assesses the manufacturer's competence and operations on the basis of the submitted reports and the inspection visits to the manufacturer's premises.

The approval is licensee-specific, and it is valid for a maximum of five years at a time. An application for an extension of the period of validity of the approval shall be submitted to STUK no later than three months before the period of validity of the approval expires.

3 The person responsible for the manufacture

The manufacture shall take place under supervision of a person whom STUK has found to be qualified. That person's task is to ensure that the pressure equipment is manufactured in accordance with the accepted contruction plan in a technically appropriate manner and in accordance with the regulations issued.

The tasks of the person responsible for the manufacture also include ensuring that

- the conditions stated in the decision of approval rendered by STUK are complied with and that the obligations imposed on the manufacturer in the YVL Guides are fulfilled
- the persons making permanents joints have proper, valid certificates of qualification
- the manufacturing methods have been appropriately qualified and proper instructions have been drawn up
- the equipment used in the manufacture is maintained and its working condition is checked at regular intervals
- the instructions given on the marking of materials are followed
- if heat treatment or hot working is included in the manufacturing process, the accuracy of the temperature-monitoring equipment is sufficient and the control and measuring equipment has been regularly checked.

In addition, the person responsible for the manufacture shall participate, if necessary, in contractual and planning reviews or the manufacturer's quality management system shall otherwise verify the correctness of the matters related to the manufacture to be dealt with in the reviews.

The person responsible for the manufacture shall draw up a written pressure equipment-specific report stating the manufacture has taken place in accordance with the accepted construction plan and that the requirements established in this Guide and in other YVL Guides concerning the manufacture of pressure equipment have been fulfilled. Non-conformances that have occurred in the manufacture must be stated in the report.

If the manufacturer has several persons responsible for the manufacture, the area of responsibility of each person shall be clearly defined.

The person responsible for the manufacture shall have basic technical training, further training in the manufacturing technology concerned, and practical work experience in the design, man-

ufacture or inspection of pressure equipment. The person shall be familiar with the legislation and YVL Guides related to the pressure equipment to be manufactured. If the manufacture takes place at the plant site, he/she shall have knowledge of nuclear facilities. The person responsible for the manufacture shall be employed by the manufacturer, and he/she shall mostly stay in the place of manufacture.

The person responsible for the manufacture shall not act as an inspector or a tester in accordance with Guide YVL 1.3 of the items for the manufacture of which he/she has been responsible.

4 Obligations imposed on the manufacturer of nuclear pressure equipment

4.1 General obligations

Guide YVL 3.0 defines the general obligations concerning the activities of the manufacturer of nuclear pressure equipment. The same regulations and obligations apply to both the manufacturer proper and the sub-suppliers involved in the manufacture.

The manufacturer is obliged to ensure that

- as a manufacturer of nuclear pressure equipment, it complies with the Nuclear Energy Act and Decree and the Government Resolution on the general requirements for the safety of nuclear power plants, as well as with the decisions and guides issued by STUK
- the manufacture is carried out in accordance with the accepted construction plans
- the instructions and standards linked with the manufacture are available in the place of manufacture.

Furthermore, the approved manufacturer is responsible for keeping the information contained in the application submitted to STUK up to date. If essential changes occur in the preconditions for the manufacture defined in the application, the manufacturer shall inform STUK of them without delay through the licensee.

4.2 Qualification of the manufacturing methods and the persons involved in the manufacture

The manufacturer of pressure equipment shall verify that after the measures linked with the manufacture the accepted material properties on which the design is based remain unchanged. The effect of manufacture on the properties of the pressure equipment material shall be established whenever the manufacture involves manufacturing stages and methods that may alter them. These include, for instance, welding, working and heat treatment. Material properties that cannot be examined after the manufacture shall be proved in these cases by means of a procedure test to be conducted before the manufacture. In the procedure test, the manufacturer of pressure equipment must manufacture a test sample, whose essential properties correspond with the intended manufacture. The test sample shall be subjected to destructive and non-destructive tests to establish the properties of the final structure. The measured properties of the test sample shall be compared with the properties required from the material. The purpose of the procedure test is to prove the properties of the finished structure and the manufacturer's competence for the use of the manufacturing method concerned.

The manufacturing method shall be qualified with the aid of a procedure test conducted under control of the supervisor of a third party. Procedures and requirements linked with the qualification of welding methods of nuclear pressure equipment have been presented, for instance, in standard ASME Boiler and Pressure Vessel Code Section III and IX [9]. Requirements for the qualification of welding methods of conventional pressure equipment have been defined in standards in accordance with the Pressure Equipment Directive and in standard ASME Boiler and Pressure Vessel Code Section VIII [11]. The licensee shall describe the detailed requirements and procedures concerning the qualification of manufacturing methods in its quality management system and related instruction manuals. In addition to the licensee's own manufacturing operations, these requirements shall also take account of the requirements set for the pressure equipment suppliers and welding contractors. STUK assesses the acceptability

of the requirements and procedures as part of the evaluation of the licensee's quality management system. Guide YVL 1.14 deals with STUK's control and inspections linked with the qualification tests of manufacturing methods.

The persons that make permanent joints shall have an appropriate qualification. The qualification test shall be carried out under control of the supervisor of a third party. The qualification shall verify the person's knowledge about the joining technique and his/her mastery of the joining technique. Furthermore, the qualification shall take account of the requirements set for the joints to be made. The qualification is valid for a fixed period and after that the qualification can be extended on the basis of the documents related to the manufacture or by carrying out a new qualification test. The procedures to be followed in the qualification of persons shall be based on the standard commonly applied to the joining method concerned. The licensee shall describe the detailed requirements and procedures concerning the qualification of persons in its quality management system and related instruction manuals. These requirements shall take account of the manufacture of pressure equipment and installation at the plant site. STUK assesses the acceptability of the requirements and procedures as part of the evaluation of the licensee's quality management system.

5 Supervision of the operations

5.1 Supervision performed by the licensee

The licensee shall specify the procedures by means of which it supervises the manufacturers of pressure equipment. The licensee is obliged to ensure that the manufacturer's quality management system is subjected to periodic audits. The purpose of the audits is to verify that the manufacturer maintains and complies with the quality management system. These periodic audits must be conducted at such time intervals that a complete re-evaluation is carried out over the course of three years.

A report shall be submitted to STUK for information every calendar year on the implemented evaluations of the quality management systems of the manufacturers approved by STUK and on the evaluation results. The report must include the results of the licensee's own inspection visits and a statement about the fulfilment of the requirements and conditions established in the YVL Guides and decisions of approval, and of those set by the licensee itself.

5.2 Supervision performed by STUK

STUK supervises operations of the manufacturers it has approved by means of control visits within the scope it considers necessary and during its own inspection activities. The purpose of the supervision is to verify that the manufacturer complies with and maintains the quality management system in such a manner that it fulfils the requirements and operates efficiently. The supervision pays attention to, for instance, the following issues:

- efficiency of the quality management system
- fulfilment of the obligations imposed on the manufacturer in the YVL Guides
- compliance with the conditions stated in STUK's decision of approval
- the quality documents that have been required in the quality management system concerning the manufacture, e.g., inspection reports; testing, calibration and tuning data; reports on the qualification of personnel concerned, etc.
- implementation of the accepted construction plans
- the validity of the provisions and standards applied to the manufacture
- appropriateness of the manufacturing facilities
- qualification of the manufacturing methods and the personnel involved in the manufacture.

6 References

1. Nuclear Energy Act (990/1987)
2. Nuclear Energy Decree (161/1988)
3. Government Resolution on the general regulations for the safety of nuclear power plants (395/1991)
4. Pressure Equipment Act (869/1999)
5. Decision of the Ministry of Trade and Industry on the safety of pressure equipment (953/1999).
6. Decision of the Ministry of Trade and Industry on pressure equipment (938/1999).
7. SFS-EN 729-2: Quality requirements for welding. Fusion welding of metallic materials. Part 2: Comprehensive quality requirements.
8. SFS-EN 719: Welding coordination. Tasks and responsibilities.
9. ASME Boiler and Pressure Vessel Code Sections III and IX.
10. SFS-EN 288-3: Specification and qualification of welding procedures for metallic materials. Part 3: Procedure tests of arc welding of steels.
11. ASME Boiler and Pressure Vessel Code Section VIII.