

APPENDIX 4. Comparison of the current practice and the proposed new procedure in safety class 3.

The control measures during different phases are presented based on the currently valid versions of the E series of YVL Guides (E.3, E.8 and E.9). The requirements of E.1 and E.12 regarding inspection and testing organisations are also touched on.

Requirements set for the manufacture and modification of the system and equipment		Party performing control activities		Change	Description/justification of the new procedure and change
		Current procedure	New procedure		
Before the manufacture is started	CONTROL MEASURES/APPROVALS BEFORE THE MANUFACTURE IS				
	System design approved to be used for basic design (E.3)	STUK	STUK/LH	Remains & transfers Change in control	STUK has approved the version of the safety analysis report (SAR) valid before the modification. The licence holder assesses the impact of the change to be made on the system and the related SAR. If the essential parts of the system still conform with the safety requirements and design bases set for the original system, processing by the licence holder before the modification work is started is sufficient. If the system modification causes significant changes in the safety analysis report, the modifications shall be approved by STUK already before the start of the preparations for the modification work. The description of the change, the safety assessment for the change and the justifications shall be submitted to the regulatory body (and to STUK for information) immediately upon completion. The documentation as a whole shall be processed by the regulatory body before the actual modification work can be started. The licence holder may, however, start the procurement of any related (serially-manufactured) equipment, in accordance with the design bases it has determined itself, already before submitting the system-related documentation to the regulatory body.
	The basic design of the system has been approved and made available (E.8 and E.9)	STUK	STUK/LH	Remains & transfers Change in control	STUK has approved the version of the safety analysis report (SAR) valid before the modification. The licence holder assesses the impact of the change to be made on the system and the related SAR. If the essential parts of the system still conform with the safety requirements and design bases set for the original system, processing by the licence holder before the modification work is started is sufficient. If the system modification causes significant changes in the safety analysis report, the modifications shall be approved by STUK already before the start of the preparations for the modification work. The description of the change, the safety assessment for the change and the justifications shall be submitted to the regulatory body (and to STUK for information) immediately upon completion. The documentation as a whole shall be processed by the regulatory body before the actual modification work can be started. The licence holder may, however, start the procurement of any related (serially-manufactured) equipment, in accordance with the design bases it has determined itself, already before submitting the system-related documentation to the regulatory body.
	The authority has evaluated the acceptability of the equipment requirement specification (E.8 and E.9)	STUK	STUK	Remains	The licence holder shall have the equipment and material requirement specifications approved by STUK already before equipment procurement.
	The material requirement specifications have been approved (E.8 and E.9)	STUK	STUK	Remains	The licence holder shall have the equipment and material requirement specifications approved by STUK already before equipment procurement.
	The authority has approved that the licence holder has correctly determined the targets and control of the material manufacture in its plant or equipment-specific plans (requirement specifications for materials and equipment, including the general inspection plan) (E.3)	STUK	STUK	Remains	The licence holder shall have the equipment and material requirement specifications approved by STUK already before equipment procurement.
	The manufacturer's/material manufacturer's quality management system has been audited (E.3)	STUK/AIO	LH third party	Changes	The licence holder ensures that the manufacturer has a certified quality system. The licence holder reserves the possibility to perform an audit.
	The manufacturer's quality management system is certified (E.8 and E.9)	STUK/AIO	LH	Remains, change in control	Before concluding an agreement, the licence holder ensures that the manufacturer has a certified quality system and also assesses, in general, the manufacturer's competence to carry out the delivery based on operating experience and historical information as well as any existing experience.
	Manufacturers using special processes have been audited and approved	STUK	LH third party	Changes	Before concluding an agreement, the licence holder ensures that the manufacturer has a certified quality system and also assesses, in general, the manufacturer's competence to carry out the delivery based on operating experience and historical information as well as any existing experience. With respect to the special processes, standards are used as a rule, and it shall be verified that the manufacturer operates according to the standards and procedures laid down in the equipment and material requirement specifications. The conformity of the product and manufacture shall be verified in the acceptance inspection.
	The NDT and DT testing organisations used by the manufacturer's subcontractors have been approved (E.3, E.8 and E.9)	STUK	third party	Changes	Competencies according to the certified quality system. Inspections and tests by accredited organisations based on relevant standards.
	Special processes used in material manufacture and during manufacture have been qualified (E.3)	STUK/AIO	LH third party	Changes	Before concluding an agreement, the LH verifies that the manufacturer has a certified quality system and also assesses, in general, the manufacturer's competence to carry out the delivery based on operating experience and historical information as well as any existing experience.
	The construction plan has been approved (E.3, E.8 and E.9)	STUK/AIO	LH notified body	Changes	Qualifications related to special processes according to a certified quality system, using standards. The licence holder requires the supplier to fulfil the requirements laid down in the requirement specification during manufacture and to prepare manufacturing design and control documentation as well as the delivery's final documentation and documentation as required in the specifications in question. A notified body inspects the design and manufacture (when the equipment is governed by the PED). The licence holder inspects the delivery and documentation in question in connection with the acceptance of the product and submits the manufacturing result documentation to the regulatory body for inspection, at the latest before the installation is started.
	The necessary preliminary suitability analyses for the E/I&C equipment have been processed (E.3, E.8 and E.9)	STUK	LH	Changes	E/I&C procurement suitability assessment before ordering.
	The third party used in manufacture that includes special processes has been selected (E.3, E.8 and E.9)	Manufacturer	Manufacturer, LH verifies	Remains	Before concluding an agreement, the licence holder ensures that manufacturers using special processes are using an independent third party, the use of which has been agreed on in accordance with the specifications.
Manufacture without special processes has been certified	Manufacturer	Manufacturer, LH verifies	Remains	Before concluding an agreement, the LH verifies that the manufacturer has a certified quality system and also assesses, in general, the manufacturer's competence to carry out the delivery based on operating experience and historical information as well as any existing experience.	
Control during manufacture (E.3, E.8, and E.9)	CONTROL DURING MANUFACTURE (E.3, E.8, and E.9)				
	Construction plan has been made available for use	Manufacturer	Manufacturer	Changes	The requirements are specified in the equipment and material requirement specifications and other specifications pertaining to the order (design values).
	Valid personal and method competencies	LH third party	LH verifies third party/notified body	Changes	Before concluding an agreement, the licence holder ensures that the manufacturer has a certified quality system and also assesses, in general, the manufacturer's competence to carry out the delivery based on operating experience and historical information as well as any existing experience. With respect to the special processes, standards are used as a rule, and it shall be ensured that the manufacturer operates according to a certain standard. The conformity of the product and manufacture shall be verified in connection with the acceptance inspection.
	Material testing and sampling is monitored	LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Testing of the welding filler materials is monitored	TP	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Performance of the NDT inspections is monitored	LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Performance of the special processes is monitored	LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Performance of the production tests is monitored	LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	The necessary final suitability analyses for the E/I&C equipment have been processed	STUK	LH	Changes	An installation suitability assessment before the installation to ensure that the location requirements are met.
	Performance of the construction inspection before pressure test at the manufacturer's facility	STUK*/AIO + LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Pressure test at the manufacturer's facility is performed	STUK*/AIO + LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
	Construction inspection at the manufacturer's facility is performed	STUK*/AIO + LH	Notified body/LH verifies	Changes	Manufacture, inspections and tests based on applicable standards/type tests. Notified body inspects the manufacture (when the equipment is governed by the PED). The licence holder verifies product conformity in connection with the acceptance based on the result documentation.
Control during and after installation	CONTROL DURING AND AFTER INSTALLATION				
	Flexibility and support analyses have been conducted and approved (E.3)	STUK/AIO	STUK/LH	Remains & transfers Change in control	The licence holder conducts the analyses immediately when the relevant information becomes available, or during the installation at the latest, and submits the analyses to the regulatory body. Approval is required before moving on to the functional tests of the system (KOT II).
	The installation construction plan is approved	STUK*/AIO	LH STUK*/AIO	Remains, change in control	The licence holder processes the installation construction plan if the change in question is small. STUK/AIO in case of a significant change or pressure equipment subject to registration.
	All components required in the installation have been accepted by construction inspection	STUK*/AIO	LH STUK*/AIO verifies	Remains change in control	The licence holder performs, at its discretion, the construction inspection either at the manufacturer's facility or in connection with the acceptance inspection at the plant site before storage. Before installation, the licence holder verifies that all prefabricated components and equipment have been acceptance tested and approved for use in the installation. The licence holder also checks that the result documentation of the equipment's manufacture and other prefabrication, installation data and operating manuals have been submitted and correct and that the related certificates of conformity have been signed and submitted with design values that correspond with the requirements of the location in question.
	Installation inspection before pressure test is performed	STUK*/AIO + LH	LH, STUK*/AIO verifies	Remains, change in control	Licence holder monitors/inspects, STUK/AIO verifies. STUK in case of pressure equipment subject to registration.
	Structural pressure test of the installation is performed	STUK*/AIO + LH	LH, STUK*/AIO verifies	Remains, change in control	Licence holder monitors/inspects, STUK/AIO verifies. STUK in case of pressure equipment subject to registration.
	Installation construction inspection is performed	STUK*/AIO + LH	LH, STUK*/AIO verifies	Remains, change in control	Licence holder monitors/inspects, STUK/AIO verifies. STUK in case of pressure equipment subject to registration.
	Commissioning and testing plan sent to the authority	LH	LH	Remains	Remains unchanged (sent to the party performing control activities).
KOT I	KOT I – VERIFICATION OF THE READINESS FOR TEST OPERATION				
	Unchanged, not discussed in detail here	STUK/AIO	STUK/AIO	Remains	No essential changes.
KOT II	KOT II – VERIFICATION OF THE READINESS FOR OPERATION				
	Unchanged, not discussed in detail here	STUK	STUK	Remains	No essential changes.

*) STUK when the pressure equipment in question is subject to registration.