ExCB Project No.:	**ExCB Report No. & revision EUFI29-19004277-T1**
Manufacturer Include Address with post code	Vaisala Oyj Vanha Nurmijärventie 21 FI-01670 Vantaa Finland
Production Site(s) audited Include Address with post code	Vanha Nurmijärventie 21 FI-01670 Vantaa Finland
Product Description	Measurement devices
Employee count	Total onsite: 1030 Total involved in Ex products: 30
Scope of Audit	Initial Assessment ☐ Re-Assessment ☐ Surveillance Assessment ☐ **Special audit: Expanding Scope** **X**
Electrical equipment with type(s) of protection of	d ☐ e ☒ h ☐ i ☒ m ☒ n ☒ p ☐ Other *(specify)* ☒ t
Audit Team Leader	Matti Katajisto
Audit Date	22.8.2019

Contents:

1. Summary Report

Assessment Summary and Conclusions:

Vaisala Oyj has acquired K-Patents Group and as a result of the transaction, the Ex production of K-Patents will be transferred to production facilities of Vaisala. Production of Ex equipment will start after 1.9.2019 in Vaisala's premises.

Due to the merging the scope of Vaisala Ex-quality system shall be expanded to cover protection concept Ex n. K-Patents have had own QAR NL/DEK/QAR12.0032/04 which covers Ex n also.

During the audit production lines were checked and approved to be suitable for intended purposes. Production of old K-Patents products will be done according to existing procedures and instructions of K-Patents. Also production control system is transferred as such and used in the new premises.

Since the merging process is in progress, all management system documents are not yet finalised (for example responsibilities). After the fusion has been completed the Ex-responsible of K-Patents Mr. Arto Hämäläinen is going to continue as Ex-responsible related to products transferred from K-Patents to Vaisala. Mr. Petteri Sappinen and Mr. Olli Lauronen will continue with the old Ex-responsibilities.

Due to the merging, there will not be any changes in the external providers. Production staff of K-Patents will be employed by Vaisala.

As a result of this audit one new type of protection (Ex n) is added to scope of Vaisala Oyj, (ref FI/VTT/QAR09.0001/06).

Next Quality Audit due : Surveillance-assessment audit November 2019

Non-Conformities

(Indicate the Serial No.(s) of non-conformities recorded. Individual non-conformities are recorded on the non-conformity reports)

NCR No.(s): 3

Audit Team Leader Recommendations

Add protection concept nA to QAR of Vaisala.

26.8.2018
Audit Team Leader Signature
Date

26.8.2018
ExCB Technical Reviewer
Date

2. Audit Information

2.1 Scope of Audit:

Scope extension audit **X**

2.2 Audit Criteria : ISO/IEC 80079-34 (2018)
Directive 2014/34/EU
List any other reference documents, against which Audit was conducted in addition to IECEx OD 005

2.3 Date(s) and Duration of Audit : 2
Include total number of auditor days on site

2.4 Details of ISO 9001 Certification:

ISO 9001 certificate No	Certified by	Expiry date	Scope
105673-2011-AQ-FIN-FINAS	DNV GL	10 November 2020	Design, development, production, sales and service of instruments, systems, solutions and information for environmental and industrial measurement applications.

2.5 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
Matti Katajisto	Lead Auditor	Lead Auditor
Ilkka Riihimäki	Expert	Auditor Trainee/Technical Expert

2.6 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Petteri Sappinen	**Quality Manager**
Arto Hämäläinen	**K-Patents Director for Production and Supply Chain**
Ulla Asmala	**Process Engineer**
Olli Lauronen	**Electronics Designer, Ex responsible**
Ari Räsänen	**Process Engineer**
Petteri Sappinen	**Quality Manager, Ex responsible**
Mari Jorva	**Project Manager**
Juha Jääskeläinen	**R&D Manager**
Jari-Pekka Mörsky	**Quality Manager, Standards and Approvals**

2.7 Critical Suppliers:

Name of Supplier	Critical item or service provided
Laukamo Electromec Oy	PCB's for PR-23 and PR-21
Darekon	PCB's for PR-43

2.8 Manufacturers Documentation: (*List manufactures documentation related to this Quality Audit Report)*

Document No.	Document Name	Rev.	Date
DOC235909	Ex responsible document	-	-
DOC242294	K-Patents Type of Protection nA training document	-	-
DOC242296	Vaisala General Ex training document	-	-
AUDIT-2087	2019 ATEX IA plan and report		2019-05-30
K-Patents Work instruction	Työohje Indicating Transmitter DTR	3	2014-07-16

3. Documentation Review and Assessment of Implementation

(For surveillance audits, major document changes only may be reviewed)

NOTE 1: **Manufacturer's Document References** need only to reference the document number (and if desired the title) as the title and revision status is listed in 2.7. **Comments** are entered by the auditor to document compliance or noncompliance of a clause.

NOTE 2: Even when there are no additional IEC/ISO 80079-34:2018 requirements to ISO 9001:2005 the auditor shall provide a verdict in accordance with the Note 3 below.

NOTE 3: Possible audit verdicts: P = Pass, F = Fail, NCN number against a clause means Non-conformity

Clause	Requirement	Documents reference and/or comments	Verdict
4.1	**Understanding the organization and its context** 4.1 of ISO 9001:2015 applies with the following addition:		
	In regard to this document, the context of the organization is to ensure that any Ex Product is in accordance with its certificate and technical documentation.	At the moment certificate lists are not yet merged (both companies have own lists). This shall be corrected after the merging.	**P**
4.2	**Understanding the needs and expectations of interested parties**		NA
	4.2 of ISO 9001:2015 applies.		
4.3	**Determining the scope of the quality management system**		NA
	4.3 of ISO 9001:2015 applies.		
4.4	**Quality management system and its processes** 4.4 of ISO 9001:2015 applies with the following addition:		
	The quality management system shall ensure that the Ex Product conforms to the type described in the certificate and the technical documentation.	See FI/VTT/QAR09.0001/06	**P**
5.1.1	**General**		NA
	5.1.1 of ISO 9001:2015 applies.		
5.1.2	**Customer focus**		NA
	5.1.2 of ISO 9001:2015 applies.		
5.2.1	**Establishing the quality policy**		NA
	5.2.1 of ISO 9001:2015 applies.		
5.2.2	**Communicating the quality policy**		NA
	5.2.2 of ISO 9001:2015 applies.		

Clause	Requirement	Documents reference and/or comments	Verdict
5.3	**Organizational roles, responsibilities and authorities** 5.3 of ISO 9001:2015 applies with the following additions:		
	Ex authorized person(s) shall be appointed with defined and documented responsibilities and authority to ensure the following requirements are met:		
	a) the effective co-ordination of activities with respect to Ex Products;	DOC235909 ver B is valid instruction, but it does not cover products of K-Patens. Draft version (ver C) is in process. Arto Hämäläinen has been Ex-responsible in K-Patents and will be Ex-responsible in issues related K-Patents products.	**NCR3**
	b) the liaison with the issuer of the certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the certificate and the technical documentation;	See FI/VTT/QAR09.0001/06	**P**
	c) the liaison with the body responsible for the verification of the quality management system with respect to intended updating of the quality management system; NOTE It is not practicable for the manufacturer to inform the body responsible for the verification of the quality management system each time the quality management system is updated. It is only practicable to inform them of "substantial" updating of the quality management system relevant to the Type of Protection. Similarly, it is not practicable to specify in general terms what types of updating are or are not "substantial". It is therefore normal that the manufacturer informs the body responsible for the verification of the quality management system on any update of the quality management system having consequences on Ex Product compliance. The change of an Ex authorized person is considered as a “substantial” change.	See above	
	d) the authorization of initial approval and changes to related drawings, where appropriate;	See above	
	e) the authorization of concessions (see 8.7 f));	See above	
	f) the accuracy of relevant information regarding Ex Product given to the customer for any sales literature and installation instructions (which shall include applicable Specific Conditions of Use and any Schedule of Limitations); NOTE Ex Equipment Certificate numbers with a suffix “X” contain Specific Conditions of Use. Ex Component certificates	See above	

Clause	Requirement	Documents reference and/or comments	Verdict
	numbers, with a suffix "U" may contain a Schedule of Limitations.		
	g) the effective coordination of manufacturing processes related to Ex Products including externally provided products, services and processes detailed in 8.4; In the case of a manufacturer with multiple manufacturing sites an Ex authorized person with relevant responsibilities shall be appointed for each site.	See above	
	Records demonstrating this shall be available and be maintained as documented information.	See above	
	7.1.4 of ISO 9001:2015 applies.		
7.1.5	**Monitoring and measuring resources** 7.1.5 of ISO 9001:2015 applies with the following addition:		
	When monitoring or measuring is used to verify the conformity of Ex Products, the measuring equipment shall be calibrated and a valid calibration certificate shall exist. Verification of measuring equipment against calibrated equipment is also permitted as long as it is properly documented. The calibration certificate shall meet one of the following requirements:	Vaisala has a program called Indysoft, which tracks and stores all the calibration data.	**P**
	a) Where a calibration certificate bears an accreditation, logo issued by an accredited calibration laboratory (which can demonstrate that it operates in compliance with an internationally recognized standard and is covered by a multilateral international agreement) the calibration laboratory need not be subjected to further evaluation.	See below	NA
	b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information: • an unambiguous identification of the item calibrated; • evidence that the measurements are traceable to international or national measurement standards; • the method of calibration; • a statement of compliance with any relevant specification; • the calibration results;	Calibration (made by Finero id GHI-100/7701191) of HiPot tester ID: 19328, is otherwise ok, but it has not got evidence that the measurements are traceable to international measurement standards.	**NCR2**

Clause	Requirement	Documents reference and/or comments	Verdict
	• the uncertainty of measurement, where necessary; • the environmental conditions, where relevant; • the date of calibration; • the signature of the person under whose authority the certificate was issued; • the name and address of the issuing organization and the date of issue of the certificate; • a unique identification of the calibration certificate.		
	c) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.1.5 b), the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).	See above	NA
7.1.6	**Organizational knowledge** 7.1.6 of ISO 9001:2015 applies.		NA
7.2	**Competence** 7.2 of ISO 9001:2015 applies with the following addition:		
	The manufacturer shall have a documented process to identify and ensure that all persons having an impact on the compliance of Ex Products are trained and competent. NOTE 1 Parties who might have an impact on the compliance of Ex Products are the Ex authorized person(s), manufacturing, inspecting, testing, sales, marketing, supply management, calibration and quality control services and other services. NOTE 2 Competence requirements of 7.2 also address the awareness of 7.3.	Training of nA products for Vaisala employees was arranged 19.8.2019. Participant list was reviewed, ok. Training material (two documents) was available in Aton system: Doc 242284 related to K-Patents products Doc 242296 General Ex information	**P**
7.5.1	**(Documented information) General** 7.5.1 of ISO 9001:2015 applies with the following addition:		
	All requirements and provisions adopted by the manufacturer to ensure compliance of Ex Products with their certificates and technical documentation, and to demonstrate compliance to this document, shall be appropriately documented in a systematic and orderly manner. This may be achieved in the form of manuals, policies, procedures, instructions, flowcharts, spread sheets, forms, or other appropriate means. The quality management system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records	K-Patents documentation will be in use as such until transferred to Aton.	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
7.5.2	**Creating and updating** 7.5.2 of ISO 9001:2015 applies.		**NA**
7.5.3	**Control of documented Information** 7.5.3 of ISO 9001:2015 applies with the following addition:		
	a) technical documentation and manufacturer's documentation shall be controlled;	See above.	**P**
	b) documented procedures shall ensure that information contained within manufacturer's documentation is compatible with the technical documentation. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings;	See FI/VTT/QAR09.0001/06	**P**
	c) the quality management system shall ensure that no factor (type, characteristic, position etc.) defined within the certificate and technical documentation (e.g. schedule drawings) is modified unless otherwise permitted by the issuer of the certificate;	See FI/VTT/QAR09.0001/06	**P**
	d) there shall be a documented system that refers all related drawings to the relevant schedule drawings;	See FI/VTT/QAR09.0001/06	**P**
	e) where there are common schedule drawings associated with more than one certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings; NOTE Some manufacturers use common components with common drawing numbers on more than one product and then have more than one person responsible for the end products. A compliant QMS would assure	See FI/VTT/QAR09.0001/06	**P**
	f) where a manufacturer also has drawings for products that are not Ex Products, the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified; NOTE The following examples indicate some methods to achieve this: – the use of visual markers; – the use of a unique series of drawing numbers, e.g. all drawings concerning a certified Ex Product have an Ex prefix to the drawing number; – the use of a computerized relational database with indentured "Bills of Materials" that identify all Ex critical documents, components and controls unauthorized changes can also be acceptable.	See FI/VTT/QAR09.0001/06	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	g) the manufacturer shall document the body responsible for the verification of the quality management system of each certificate; NOTE In some Certification Schemes, the body responsible for the verification of the quality management system associated with each certificate can be different from the body that issued the certificate.	See FI/VTT/QAR09.0001/06	**P**
	h) where technical documentation or manufacturer's documentation are passed to a third party, they shall be provided in a way that is not misleading;	See FI/VTT/QAR09.0001/06	**P**
	i) the manufacturer shall have a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications;	See FI/VTT/QAR09.0001/06	**P**
	j) the manufacturer shall retain adequate quality records to demonstrate conformity of the Ex Products. A minimum of 10 years retention after each Ex Product (batch) has been placed on the market is required. As a minimum, the list of quality records requiring control and retention, as far as applicable, shall be: • those arising from regulatory requirements; • quality documented information; • responsibilities and authorities for Ex relevant roles assignment and communication within the organization; • customer order; • contract review; • training records; • design and development changes; • inspection and test data (per batch); • calibration data; • manufacturing traceability; • sub-contractor evaluation; • delivery data (customer, delivery date and quantity, including serial numbers where available); • other documented information, if needed.	See FI/VTT/QAR09.0001/06	**P**
8.1	**Operational planning and control** 8.1 of ISO 9001:2015 applies with the following addition:		
	The information in Annexes A and B for control and acceptance of processes for Ex Products are one method to ensure compliance with the requirements of the certificate. If other	See annex A	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	methods are used, they should be evaluated to ensure full compliance with the requirements of certification.		
8.2.1	**Customer Communications**		**NA**
	8.2.1 of ISO 9001:2015 applies.		
8.2.2	**Determining the requirements for products and services**		**NA**
	8.2.2 of ISO 9001:2015 applies.		
8.2.3	**Review of the requirements for products and services** 8.2.3 of ISO 9001:2015 applies with the following addition:		
	The review shall ensure that any stated customer requirement is compatible with the certificate e.g. equipment group, temperature class, Type of Protection, Equipment Protection Level (EPL) and ambient temperature range. In some situations, such as internet sales, a formal review might be impractical. In such a case the appropriate information shall be made available to the customer.	In offers, plus comprehensive web pages.	**P**
8.2.4	**Changes to requirements for products and services** 8.2.4 of ISO 9001:2015 applies with the following addition:		
	The Ex authorized person(s) identified in 5.3 shall be involved in any changes (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could affect Ex Product compliance.	See FI/VTT/QAR09.0001/06	**P**
8.3.1	**General (Design and development of products and services)**		
	8.3.1 of ISO 9001:2015 is not within the scope of this document.		
8.3.2	**Design and development planning**		
	8.3.2 of ISO 9001:2015 is not within the scope of this document.		
8.3.3	**Design and development Inputs**		
	8.3.3 of ISO 9001:2015 is not within the scope of this document.		
8.3.4	**Design and development controls**		
	8.3.4 of ISO 9001: 2015 is not within the scope of this document.		
8.3.5	**Design and development outputs**		
	8.3.5 of ISO 9001:2015 is not within the scope of this document.		
8.3.6	**Design and development changes** 8.3.6 of ISO 9001:2015 applies with the following addition:		
	The Ex authorized person(s) identified in 5.3 shall be involved in the approval process of any substantial modification or change (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could affect Ex Product compliance.	See FI/VTT/QAR09.0001/06	**P**
8.4.1	**General (Control of externally provided processes, products and services)** 8.4.1 of ISO 9001:2015 applies with the following addition:		
	a) while manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the certificate and the technical documentation shall not be sub-contracted;		NA

Clause	Requirement	Documents reference and/or comments	Verdict
	b) external providers providing a product, process, or service that can affect the Ex Product's compliance with the certificate shall only be selected after an evaluation has provided evidence that they have the capability of ensuring compliance with all specified requirements; 1) documented objective evidence that the external provider can provide product, process or service that is fit for purpose shall be made by one or more of the following methods: – the external provider has an acceptable Ex quality management system according to this document assessed by an accredited body, – the external provider has a quality management system certificate in accordance with the appropriate standard and with an acceptable scope, NOTE A certificate issued by an accredited body which can demonstrate that it operates in compliance with ISO/IEC 17021 is generally acceptable; depending on the nature of the product, process, or service, a quality management system in accordance with ISO 9001:2015 might not be sufficient. – a documented site assessment to ensure that all relevant controls are available, documented, understood and effective. NOTE The evaluation takes the following into account: – criticality of the product, process or service; – degree of difficulty, or variability in the manufacturing process; – location of the external provider and hence the effectiveness of communications; – subcontracting of the product, process or service.	Darekon and Laukamo PCB manufactrurers have been external providers for years. See FI/VTT/QAR09.0001/06	**P**
	2) where the features affecting the Type of Protection cannot be verified at a later stage or are not verified by the manufacturer e.g. encapsulated intrinsically safe circuits, then the product, process, or service shall only be accepted by one of the following methods: – the manufacturer can demonstrate that the control process implemented by the external providers ensures Ex compliance, – the body responsible for the verification of the quality management system performs periodic audits at the external providers.		**NA**
	c) external providers providing calibration services (including verification on measuring devices by	See FI/VTT/QAR09.0001/06	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements as well as the requirements of 7.1.5;		
	d) external providers not used for a period exceeding one year shall be re-evaluated in accordance with 8.4.1 b) prior to the placing of a contract or a purchase order;	See FI/VTT/QAR09.0001/06	**P**
	e) requirements 8.4.1 b) and 8.4.1 d) are not mandatory for products, processes or services where the manufacturer verifies conformance according to 8.4.2;		**P**
	f) the ongoing ability of the external providers to provide conforming product, process or service shall be reviewed at periods not exceeding one year; NOTE 1 "Review" is a process by which the manufacturer demonstrates the ongoing suitability and performance in accordance with 8.4.1 b) and c) of their external providers e.g. receiving inspection report analysis. NOTE 2 The terms "re-evaluation" and "review" have different meanings.	See FI/VTT/QAR09.0001/06	**P**
	g) The manufacturer shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality management system may also verify aspects of any external provider's operation that affects the Type of Protection.	See FI/VTT/QAR09.0001/06	**P**
8.4.2	**Type and extent of control** 8.4.2 of ISO 9001:2015 applies with the following addition:		
	a) for purchased processes, products and services that can compromise the Type of Protection, the manufacturer shall determine and implement verification arrangements which demonstrate the product's compliance with the certificate, considering the nature of the product and the nature of the external provider;	CoC's are got	**P**
	b) when deciding what type of verification is required for a particular purchased process, product or service, the manufacturer shall consider the nature of the purchased product, the external provider, and how critical it is to the Type of Protection. In considering whether the external provider should carry out the verification, the manufacturer should consider the results of their evaluation carried out under 8.4.1. The decision should reflect the competence of the external provider, including whether they have a quality management system that covers the activity, the resources, e.g. equipment, and the people with sufficient skill and experience to do it. This latter point is particularly significant when judgement is required, such as when inspecting a	CoC's are got	

Clause	Requirement	Documents reference and/or comments	Verdict
	flameproof casting. When the manufacturer elects to have the external provider carry out test or inspection that is relevant to the Type of protection, the product may be supplied with a declaration of conformity that confirms it has been done;		
	c) where the external provider has been evaluated and documented objective evidence has been obtained to demonstrate that the external provider is fully capable of producing and verifying the process, product or service, no further verification of the process, product or service is required, if a declaration of conformity is supplied for each batch or product;	CoC's are got	
	d) where the certificate specifies routine tests or inspections, these shall be carried out on each and every product. They may be carried out by either the external provider or the manufacturer. When carried out by the external provider they shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the external provider e.g. by a declaration of conformity including test results, if required;	See FI/VTT/QAR09.0001/06	**P**
	e) where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of an encapsulated intrinsically safe circuit, then the product shall only be accepted if supplied with a declaration of conformity. This shall specifically state compliance to the purchase documents, e.g. a quality plan, that lists the factors that together demonstrate conformity of the product;		**NA**
	f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch;		**NA**
	g) where either the external provider or the manufacturer requires training or specialist skill or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented and training records maintained;		**NA**
	h) where the manufacturer chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed on the external provider's premises under the responsibility of the manufacturer;		**NA**
	i) where an external provider provides product with evidence of conformity applicable to use in an explosive atmosphere, (e.g. certificate), then		**NA**

Clause	Requirement	Documents reference and/or comments	Verdict
	further verification is not required unless the manufacturer considers it necessary;		
	j) Where a verification of purchased product is relative to material (metals, alloys, nonmetallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied;	DoC's are got	**P**
	k) One of the following processes shall be used to verify the continued conformity of the materials critical to the applied Type of Protection, used in the production of the Ex Products: 1) Review the Declaration(s) of Conformity from the external provider of the material within the supply chain that can impact the material characteristics; as applicable; to demonstrate that the material used in the production of the Ex product is in accordance with the schedule drawings. 2) Review the material manufacturer's confirmation that the material maintains the particular material properties of concern; e.g. flammability, CTI, RTI, or UV resistance, chemical composition, physical properties. 3) Review the material manufacturer's process and data for the validation of material characteristics. 4) Confirmation that equipment testing, necessary to confirm the material is in accordance with the certificate or schedule drawings, is repeated as required. Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity. Receipt or acceptance of a declaration of conformity does not absolve the manufacturer from responsibility to ensure continuing conformity. NOTE Annex C provides guidance for the development of an external provider's declaration of conformity.	K-Patents receive a DoC with the PCBs, but said DoC does not contain information on the CTI values of the PCBs. The process of reviewing the DoCs was not defined.	**NCR1**
8.4.3	**Information for external providers** 8.4.3 of ISO 9001:2015 applies with the following addition:		
	a) the purchasing documents shall clearly describe the specific requirements pertaining to externally provided product set out in the certificate and the technical documentations (e.g. for process control, testing or inspection); NOTE For particular types of product e.g. castings, machined items and assemblies, the purchasing documents commonly include specific references to required drawings, test	See FI/VTT/QAR09.0001/06	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	procedures, inspection procedures, material certificates, test reports and Declarations of Conformity.		
	b) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;		**NA**
	c) the manufacturer shall define the method by which documents e.g. technical specifications, stated in a particular purchase order remain traceable to the order;	See FI/VTT/QAR09.0001/06	**P**
	d) where the manufacturer does not provide such documents with subsequent orders, then the manufacturer shall have documented procedures for ensuring that external providers have current copies of documents and that their integrity be maintained.	See FI/VTT/QAR09.0001/06	**P**
8.5.1	**Production and service provision (Control of production and service provision)** 8.5.1 of ISO 9001:2015 applies with the following addition:		
	The manufacturer shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the Ex Product with its technical documentation.	See FI/VTT/QAR09.0001/06	**P**
	Where a process can affect the integrity of a Type of Protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters (Annex A can be used to demonstrate compliance).		**NA**
8.5.2	**Identification and traceability** 8.5.2 of ISO 9001:2015 applies with the following addition:		
	a) the manufacturer shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market;	See FI/VTT/QAR09.0001/06	**P**
	b) traceability is required with respect to the final product and its significant parts. Traceability can be achieved using serial number, batch or other acceptable method. NOTE Significant parts are, for example, a printed circuit board (PCB) and safety component of an intrinsically safe circuit, but not each electronic component on a PCB. The significant part can be defined in the technical documentation during the processes of the product assessment.	See FI/VTT/QAR09.0001/06	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
8.5.3	**Property belonging to customers or external providers** 8.5.3 of ISO 9001:2015 applies with the following addition:		
	It is the responsibility of the manufacturer to verify the compatibility of a product supplied by a customer or an external provider with the requirements of the certificate.	See FI/VTT/QAR09.0001/06	**P**
8.5.4	**Preservation**		NA
	8.5.4 of ISO 9001:2015 applies.		
8.5.5	**Post-delivery activities**		NA
	8.5.5 of ISO 9001:2015 applies.		
8.5.6	**Control of changes** 8.5.6 of ISO 9001:2015 applies with the following addition:		
	The Ex authorized person(s) identified in 5.3 shall be involved in changes (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could affect Ex Product compliance.	See 5.3	**P**
8.6	**Release of products and services** 8.6 of ISO 9001:2015 applies with the following addition:		
	Where routine tests are required by the certificate and technical documentation, these tests shall be performed as specified. Unless specifically permitted by the certificate and the technical documentation, statistical methods shall not be used.	Työohje Indicating Transmitter DTR See FI/VTT/QAR09.0001/06	**P**
	Ex Products shall only be released after final inspection and testing have been satisfactorily completed. The manufacturer shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements, including any Specific Conditions of Use or particulars of possible misuse.	See FI/VTT/QAR09.0001/06	**P**
8.7	**Control of nonconforming outputs** 8.7 of ISO 9001:2015 applies and the following shall be defined:		
		See FI/VTT/QAR09.0001/06	**P**
	9.1.3 of ISO 9001:2015 applies.		
9.2	**Internal audit** 9.2 of ISO 9001:2015 applies with the following addition:		
	a) The audit program shall address the effectiveness of the elements of the quality management system as described in this document to ensure that the Ex products are in conformity with the certificate. The maximum period between audits shall not exceed 14 months.	Yearly, Petteri Sappinen has lead 2019 Internal audit 2087. Standard changes main topic Seven sessions 1.4.-24.4. Good audit. Previous Audit 1616 was held 19.3.2018	**P**
	b) One method of demonstrating effectiveness is the use of vertical auditing whereby an Ex Product awaiting dispatch is used to prove the system. The auditor examines all aspects	NOTE: After K-Patents has fully merged with Vaisala, an internal audit regarding the	**P**

Clause	Requirement	Documents reference and/or comments	Verdict
	of the system associated with the production of that Ex Product from a certification viewpoint. This normally includes appropriate documentation (drawings, inspection checklists, test records, material certificates etc.), Ex Product identification, handling, storage, training of staff and any other elements of the system which can affect the compliance of the Ex Product to the certification parameters.	resulting changes shall be performed.	
	c) For those manufacturers that employ checklists to assist in their internal audit programs, the inclusion of the requirements of this document into the appropriate checklists, and the retention of internal audit records, is an alternative method of addressing this requirement. Manufacturers may employ either method or some other equivalent method.		**NA**
9.3.1	**Management review (General)** 9.3.1 of ISO 9001:2015 applies with the following addition:		
	a) the maximum intervals between reviews shall not exceed 14 months; b) top management shall chair the review; c) the Ex authorized person(s) responsible for the activities as detailed in 5.3 shall participate in the review. The review shall include the overall effectiveness of the quality management system with respect to Ex Products, including results of internal and external audits. NOTE Review of results of internal and external audits would provide evidence of the effectiveness of the quality management system.	See FI/VTT/QAR09.0001/06	**P**

Annex A (informative)

Information relevant to particular Types of Protection and specific Ex Products

Clause	Requirement	Documents reference and/or comments	Verdict
A.1	**Overview**		

Clause	Requirement	Documents reference and/or comments	Verdict
	This annex provides information on those aspects that the quality management system should address with respect to particular types of protection. It does not add to or otherwise change the requirements of this document. This annex provides examples of how to meet the requirements of this document, recognizing that other methods which achieve the same objectives are equally acceptable; and draws attention to aspects of requirements that might not be readily apparent to those unfamiliar with quality management systems for products intended for use in explosive atmospheres. NOTE The following examples do not cover all Types of Protection but give some advice and will be supplemented in the next edition.		
A.2	**General**		
	Schedule Drawings, which support the certificate of the Ex Product, may provide conditions for the particular Type of Protection. All markings should be in accordance with schedule drawings. For enclosures and other components forming part of the enclosure and for fans, fan hoods and ventilation screens, the manufacturer should verify the material composition (e.g. External Provider's Declaration of Conformity, see Annex C). Statistical bases are not appropriate for routine tests required by the certificate, except where the following currently permit such techniques: • the relevant standard; or • appropriate interpretation and clarification sheets; All measurements should consider temperature variations.		
A.10	**Equipment covered by IEC 60079-15**		
A.10.1	**General requirements**		
	A routine dielectric strength routine test needs to be performed for all devices and equipment in accordance with IEC 60079-15		**NA**
A.10.2	**Ex nA – Non-sparking equipment**		
A.10.2.1	**Circuit boards (PCBs)**		
	Documented procedures should ensure that the following are verified: a) the CTI, board and copper thickness of single and multi-layer boards is as specified in the schedule drawings and that declarations are received from the supplier; b) populated PCBs are populated correctly and declarations received from the supplier, if applicable; c) conformal coatings used to reduce spacing requirements are those specified in the schedule drawing by inspection or declaration from supplier. d) These verifications can be performed by inspection when it is possible or PCBs may be	CoC are got, but See Clause 8.4.2 k).	**NCR1**

Clause	Requirement	Documents reference and/or comments	Verdict
	accepted with a declaration of conformity (see Annex C). The declaration should state compliance to the purchase documents		
A.10.2.2	**Terminals and internal wiring**		
	Documented procedures should ensure that the following are verified: a) terminals are those specified in the schedule drawings; b) creepage and clearance distances are as specified in schedule drawings; c) wire is the type specified in the schedule drawings and that segregation (where required) is maintained.	See FI/VTT/QAR09.0001/06	**P**
A.10.3	**Ex nC – Sealed devices**		
	Documented methods should ensure the following examinations: a) That creepage distances and clearances should be confirmed on a statistical basis. b) The sealing requirements specified in the schedule drawings should be confirmed on a statistical basis.		NA
A.10.4	**Ex nR – Restricted Breathing**		
A.10.4.1	**General requirements**		
	Documented procedures should ensure that the following are verified: a) creepage distances and clearances of integrated devices, as specified in the schedule drawings, are not affected; b) the dimensions specified in the schedule drawings are confirmed (statistical method may be used only if permitted – see 8.6).		NA
A.10.4.2	**Cable glands**		
	Documented methods should ensure that it is clearly distinguished in the schedule drawings which types of Cable Glands are associated with the enclosure forming a unit or being particularly matched and hence are subjected to the routine test of the enclosure.		NA
A.10.4.3	Plunger actuators, shafts and axles		
	Documented methods should ensure that no lubricants or similar materials are used prior to the routine test .		NA
A.10.4.4	Test equipment		
	Documented methods should ensure the correct assembling and function of test equipment.		NA

Clause	Requirement	Documents reference and/or comments	Verdict
A.10.4.5	Routine tests		
	All routine tests including procedure and records should be documented. These are basically pressure tests for restricted-breathing enclosures and electronic starter and ignition devices.		NA

Document History:

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