



IECEX OD 208

Edition 1.0 2017-11

IECEX OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for
use in Explosive Atmospheres (IECEX System)

IECEX Certified Equipment Scheme –

IECEX Quality System Requirements for Manufacturers –
Audit Checklist

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INTERNATIONAL
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Readline Version

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document 208005-2 –
IECEX Certified Equipment Scheme –
IECEX Quality System Requirements for Manufacturers –
Part 2: Audit Checklist

INTRODUCTION

This Operational Document, OD 208005-2 provides an Audit Checklist when assessing a manufacturer's quality system for compliance with ISO/IEC 80079-34:2011 Part 1 of this Operational Document (OD) Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture.

~~OD 005, IECEx Quality System Requirements for Manufacturers, has now been published in two parts:~~

- ~~— Part 1: Guidance on the establishment and maintenance of a quality system~~
- ~~— Part 2: Audit Checklist~~

This Document needs to be read in conjunction with both ISO/IEC 80079-34:2011 and ISO 9001:2008.

Document History

Date	Summary
Nov 2011	This document is based on a proposed amendment to IECEx OD 005-2 Edition 1.0 as considered (as circulated as ExMC/1253/DV) and approved (refer Decision 2017/44) during the 2017 Washington ExMC meeting for publication as Edition 1.0 of IECEx OD 208 that replaces all Editions of OD 005-1 and OD 005-2 immediately upon publication.

Proposed changes are shown using the tracking tools to indicate proposed **additions**, **changes** and **deletions**.

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AUDIT CHECKLIST

NOTE: If the Manufacturer does not have a certified ISO 9001 Quality System, covering manufacturing of the product, all questions need to be answered. If the Manufacturer does have a certified ISO 9001 Quality System, covering manufacturing of the product, skip questions stated as ISO 9001 applies, providing it is demonstrated by way of last ISO 9001 audit report that these questions have been successfully assessed.

NOTE: The requirements covering non-electrical equipment are covered in IECEx OD 005-3

Question:	Document Reference	Auditor Notes:	Result
<p>General</p> <ul style="list-style-type: none"> • Check use of mark(s) and Certificate for advertising etc. (attach samples) • Ensure copy of ISO 9001:2008 Certificate is current. Attached to report including scope page if applicable (must be accredited Certification Body, that is a member of International Accreditation Forum, (IAF)) • Ensure report references product checks made (Quality Plan/Test Schedule) • Are Certificates current (Attach copies to report) 			
<p>4 Quality management system requirements</p>			
<p>4.1 General requirements</p> <p>Does the Quality System ensure compliance of the product with the IECEx Test Report, ExTR?</p>			
<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>ISO 9001:2008 applies.</p> <p>4.2.2 Quality manual</p> <p>ISO 9001:2008 applies.</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>4.2.3 Control of documents</p> <p>a) Are equipment documents and manufacturer's documents controlled?</p> <p>b) Is there a documented procedure which ensures that the manufacturer's documents/drawings are compatible with the equipment documents? (ensure that related drawings are in compliance with schedule drawings)</p> <p>c) Is there a procedure/system in place to ensure that no factor (type, characteristic, position etc.) defined in the ExTR and technical documentation (e.g. schedule drawings) are modified without notification to the certification body?</p> <p>d) Is there a documented system that refers all related drawings to the schedule drawings?</p> <p>e) Is there a documented system in place that ensures that where there are common schedule drawings associated with more than one ExTR, all drawings and ExTRs are revised?</p> <p>f) Is there a system in place that clearly identifies schedule and related drawings?</p> <p>g) Is there a system in place to ensure all documents remain legible and readily identifiable?</p> <p>h) Does the manufacturer document which ExCB is responsible for each IECEx Certificate of Conformance?</p> <p>i) Are equipment/manufacturer's documents which are supplied to third parties supplied in a way that is not misleading?</p> <p>4.2.4 Control of records</p> <p>Is there evidence that quality records such as:</p> <ul style="list-style-type: none"> • those arising from regulatory requirements; • customer order; • contract review; 			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> • training records; • inspection and test data (per batch); • calibration data; • sub-contractor evaluation; • delivery data (serial numbers, date, customer etc.) <p>have a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of these records?</p>			
5 Management responsibility			
5.1 Management commitment ISO 9001:2008 applies.			
5.2 Customer focus ISO 9001:2008 applies.			
5.3 Quality policy ISO 9001:2008 applies.			
5.4 Planning 5.4.1 Quality objectives Is there management commitment to ensure that the quality system ensures that products covered under ExTRs are in compliance with the applicable IEC and IECEx Scheme Rules (IECEx 02)?			

Question:	Document Reference	Auditor Notes:	Result
<p>5.4.2 Quality management system planning</p> <p>Does the quality system ensure that product conforms to the type described in the ExTR and the technical documentation</p> <ul style="list-style-type: none"> • is the quality system documented in a systematic and orderly manner in the form of written policies, procedures, instructions, etc.; • will the manufacturer if asked facilitate an arrangement whereby the ExCB may audit aspects of suppliers how are critical to the type of protection called out in the ExTRs. 			
<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Is the responsibility and authority defined for the following responsibilities?</p> <ol style="list-style-type: none"> a) The effective co-ordination of activities with respect to products intended for use in potentially explosive atmospheres b) The need to liaise with the ExCB responsible for the issue to the ExTR with respect to changes that affect the design, schedule/related drawings and technical documentation c) The need to liaise with ExCB responsible for the issuing of the IECEx CoC with respect to intended updating of the quality system d) The authorizing of initial approval and changes to related drawings, where appropriate e) The authorizing of concessions (concessions cannot be made that takes product outside the scope of the ExTRs) f) Informing its customers of any applicable special conditions for safe use and schedule of limitations 			

Requiring Version

Question:	Document Reference	Auditor Notes:	Result
<p>5.5.2 Management representative</p> <p>Has top management appointed a member of the organization's management who shall have responsibility and authority that includes:</p> <ul style="list-style-type: none"> – ensuring processes for the quality management system are established, implemented and maintained? – communicate on the performance of the quality management system? – promotion of customer requirements throughout the organisation? <p>5.5.3 Internal communication</p> <p>Has top management established systems within the organization to communicate the effectiveness of the quality management system?</p>			
<p>5.6 Management review</p> <p>5.6.1 General</p> <p>a) How often are management reviews held? <i>(reviews should be held every 12 months and should not exceed 14 months)</i></p> <p>b) Does top management chair the review?</p> <p>c) Does the person responsible for the activities detailed in 5.5.1(authorized person) participate in the review?</p> <p>5.6.2 Review input</p> <p>ISO 9001:2008 applies.</p> <p>Does the review include a statement on the overall effectiveness of the quality management system with respect to product intended for use in potentially explosive atmospheres? <i>(this review can include the results of both internal and external audits)</i></p>			

Question:	Document Reference	Auditor Notes:	Result
5.6.3 Review output ISO 9001:2008 applies.			
6 Resource management			
6.1 Provision of resources ISO 9001:2008 applies.			
6.2 Human resources 6.2.1 General ISO 9001:2008 applies. Is appropriate education and training provided to personnel ensuring competent performance? 6.2.2 Competence, training and awareness ISO 9001:2008 applies.			
6.3 Infrastructure ISO 9001:2008 applies.			
6.4 Work environment ISO 9001:2008 applies.			
7 Product realization 7.1 Planning of product realization ISO 9001:2008 applies.			

Question:	Document Reference	Auditor Notes:	Result
<p>7.2 Customer-related processes</p> <p>7.2.1 Determination of requirements related to the product Is there as system in place to determine the product category and marking required by their customer?</p> <p>7.2.2 Review of requirements related to the product ISO 9001:2008 applies. The system shall ensure that any stated customer requirement is compatible with ExTR, e.g. ambient temperature range.</p> <p>7.2.3 Customer communication ISO 9001:2008 applies.</p>			
<p>7.3 Design and Development (not within scope of this Operational Document)</p>			
<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process ISO 9001:2008 applies.</p> <p>a) Is manufacture, test and final inspection sub-contracted? If yes, does the facility holding the ExTR maintain responsibility for the conformance of the product covered by the ExTR(s)?</p> <p>b) Are the suppliers providing a product, process, or service that can effect the product's compliance with the ExTR selected after an acceptable evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements?</p> <p>c) The evaluation shall be made by one or more of the following methods: <i>(review any audits to insure that an adequate job has been done)</i></p>			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> • the supplier has third party quality system certification to the appropriate standard and scope issued by an accredited body which demonstrate that it operates in compliance with ISO/IEC 17021-1, <i>Conformity assessment – Requirements for bodies providing audit and certification of management systems. (this can be achieved by an accredited certification);</i> • a documented evaluation which provides objective evidence that the supplier can provide product, process or service that is fit for purpose; • a documented site assessment to ensure that all relevant controls are available, documented understood and effective. <p>NOTE the evaluation should take into account the criticality of the product, process or service, degree of difficulty, or variability in the manufacturing process, location of the supplier and hence the effectiveness of communications, does the supplier, in turn sub-contract the product, process or service.</p> <p>d) Are the suppliers supplying calibration service evaluated on their ability to meet stated requirements?</p> <p>e) Are audits and periodic site assessments performed on suppliers which supply product with features that cannot be verified at a later stage e.g. encapsulated intrinsically safe circuits? <i>(The assessment shall be done on the suppliers premises to ensure relevant controls are available, documented, understood and effective)</i></p> <p>f) Are suppliers not used for a period exceeding one year re-evaluated prior to the placing of the contract/purchase order?</p> <p>g) Does the client fully verify each item for conformance? <i>(if each pieces is fully evaluated for compliance then b and f above is not required)</i></p> <p>h) Is the ongoing ability of the supplier(s) to provide conforming product, process or service reviewed at least once a year?</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>7.4.2 Purchasing information</p> <p>ISO 9001:2008 applies.</p> <ul style="list-style-type: none"> a) Do the purchasing documents clearly describe the specific requirements pertaining to subcontracted product set out in the ExTR and in the technical documentation? b) Do the purchasing documents set out specific quality requirements and procedures that cannot be verified after manufacture e.g. encapsulated intrinsically safe circuits? c) Are technical specifications and documents stated in the purchase order traceable to the order? d) Is there a system in place to ensure that documents such a drawings/specifications/procedures etc. used by suppliers are current and in good order? <p>7.4.3 Verification of purchased product</p> <p>ISO 9001:2008 applies.</p> <ul style="list-style-type: none"> a) Is there a system in place to insure purchased products that can compromise the type of protection standards and testing requirements listed in the ExTR are verified to demonstrate compliance? b) Does the manufacturer take into account the nature of the purchased product and how critical it is to the type of protection listed in the ExTR when determining the product verification level? c) Where a supplier has been evaluated and documented evidence has been obtained, are Declarations of Conformity to ISO/IEC 17050 supplied with each batch of product? d) Where the IECEx CoC specifies routine tests or inspections is there documentation available which demonstrates compliance by: 			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> • showing the manufacture has the capability to perform the test and is these results recorded? <p style="text-align: center;">– OR –</p> <ul style="list-style-type: none"> • If done by the supplier, is there documented evidence that the supplier has in place the necessary quality plan and is a Declaration of Conformity to ISO/IEC 17050 supplied with each batch? e) Where verification of a product cannot be carried out after manufacture, e.g. the internal parts of an encapsulated intrinsically safe, is a Declaration of Conformity to ISO/IEC 17050 supplied with each batch? f) Where permitted, are sample inspections or tests conducted in a manner which demonstrates conformity to the entire batch? g) Are training records for tests or verification requiring special knowledge or training available for review? h) If inspections and tests are carried out at the supplier's premises is there documented evidence that the tests remain under the manufacturer's responsibility? i) Not applicable unless the manufacture considers it necessary. 			
<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>ISO 9001:2008 applies.</p> <p>Does the manufacturer provide procedures, production equipment, working environment, inspection and testing facilities that ensures that all the requirements of the described in the ExTR are in compliance?</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>7.5.2 Validation of processes for production and service provision</p> <p>ISO 9001:2008 applies.</p> <p>7.5.3 Identification and traceability</p> <p>ISO 9001:2008 applies</p> <p>a) Is there evidence that the manufacturer has an established system that maintains product identification during all stages of production, testing, and final inspection?</p> <p>b) Is there a system in place that ensures the traceability of the final product and its significant parts?</p> <p>7.5.4 Customer property</p> <p>ISO 9001:2008 applies.</p> <p>In the case where customer product is supplied, does the manufacturer verify compatibility with the requirements of the ExTR?</p> <p>7.5.5 Preservation of product</p> <p>ISO 9001:2008 applies.</p> <p>a) Does the manufacturer supply the customer with instructions for safe use?</p> <p>b) Are special conditions of use listed in the ExTR supplied to customers?</p>			
<p>7.6 Control of monitoring and measuring equipment</p> <p>ISO 9001:2008 applies.</p> <p>a) Is equipment used for manufacturing and final testing calibrated?</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>b) Is there evidence that the calibration is traceable to National or International measurement standards?</p> <p>c) If the calibration certificate does not bear the accreditation logo of a national accreditation authority, does the calibration certificates contain the following?</p> <ul style="list-style-type: none"> • Calibration stickers • Method of calibration • Statement of Compliance • Calibration results • Date of calibration • Signature of the responsible person • Name and address of issuing organization 			
<p>8 Measurement, analysis and improvement</p>			
<p>8.1 General</p> <p>ISO 9001:2008 applies.</p>			
<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer Satisfaction</p> <p>Is customer satisfaction with respect to the IEC Standard and ExTR tracked?</p> <p>8.2.2 Internal audit</p> <p>ISO 9001:2008 applies.</p> <p>Are the requirements of the Quality System outlined in ISO/IEC 80079-34 OD-005-4 audited every 12-14 months?</p>			

Question:	Document Reference	Auditor Notes:	Result
Does the audit address the effectiveness of the Quality system?			
<p>8.2.3 Monitoring and measurement of processes</p> <p>ISO 9001:2008 applies.</p> <p>Are process that can effect the integrity of a type of protection that cannot be verified after manufacture (e.g. environmental conditions required of curing an encapsulate) documented and controlled?</p> <p>8.2.4 Monitoring and measurement of product</p> <p>ISO 9001:2008 applies.</p> <p>Are routine test called for in the IECEx CoC performed in accordance with the report?</p> <p>When is the label placed on the equipment? (<i>where practicable the label should not be affixed until after final inspection and test</i>)</p>			
<p>8.3 Control of non-conforming product</p> <p>ISO 9001:2008 applies.</p> <p>d) Does the manufacturer maintain a system which in the case of nonconforming product having been supplied, then the customer can be notified?</p> <p>e) Does the system require the manufacture to take action where non-conforming product has been supplied?</p> <p>f) Does the system require the manufacturer to notify the ExCB for the IECEx Certificate to be notified in writing?</p> <p>g) Does they system require the appropriate notices be placed in appropriate publications detailing recommended action to be taken for product that is not traceable?</p> <p>h) Does the system require the manufacturer to retain for 10</p>			

Question:	Document Reference	Auditor Notes:	Result
years non-conforming product records of: <ul style="list-style-type: none"> • serial numbers or identification of products supplied? • the customers who received the product? • action taken? • corrective action? 			
8.4 Analysis of data ISO 9001:2008 applies.			
8.5 Improvement ISO 9001:2008 applies. 8.5.1 Continual improvement Does the organization utilize the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review to continually improve the quality management system? 8.5.2 Corrective action ISO 9001:2008 applies. 8.5.3 Prevention action ISO 9001:2008 applies.			
Annex A – Information relevant to particular types of protection			
A.1 Introduction			
A.2 General Are Declarations of Conformity per ISO/IEC 17050, <i>Conformity assessment – Supplier's declaration of conformity</i> for material			

Question:	Document Reference	Auditor Notes:	Result
composition being supplied with each batch?			
<p>A.3 Ex d- Flameproof enclosures</p> <p>A.3.1 Castings</p> <p>Castings shall be subject to 100 % inspection in relation to the following:</p> <ul style="list-style-type: none"> • wall thickness (including those parts not subject to machining); • freedom from flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality). <p>Recovery of porous castings by impregnation methods, e.g. silicon is not permitted. Recovery by welding is permitted, subject to the casting satisfying the pressure test specified in the ExTR and the maintenance of dimensional requirements of the certification documents.</p>			
<p>A.3.2 Machining</p> <p>The following shall be verified:</p> <ul style="list-style-type: none"> • flatness of flanged flamepaths; • surface finish of all flamepaths; • fit of all threaded flamepaths (e.g. cable entries and threaded access covers); • depth of drilling and tappings to ensure adequate residual wall; • thickness; • dimensional requirements of all flamepaths. 			
<p>A.3.3 Cemented joints and potted assemblies</p> <p>Written procedures shall address the following:</p>			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> • shelf life and storage of cement and potting compounds; • mixing; • surface preparation (degreasing or equivalent is usually required immediately before the potting operation to ensure good adhesion); • application e.g. filling instructions, freedom from voids and temperature conditions; • curing, which shall include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period. 			
<p>A.3.4 Routine pressure testing</p> <p>All equipment not exempt shall be subject to routine pressure test as specified in the ExTR.</p> <p>The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation and that there is no leakage from the enclosure during the test other than through constructional gaps, e.g. flamepaths.</p> <p>Leakage through cemented joints or potted assemblies is not permitted.</p> <p>The test can be a single test conducted on a complete assembly, or a series of tests on each sub assembly or component part. For enclosures that contain more than one discrete compartment, each compartment shall be tested individually. The method used shall ensure that the assembly, sub assembly or component parts are subjected to representative stress patterns e.g. actual fastening facilities are used. Clamping is not permitted.</p> <p>Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended.</p> <p>The test facility shall be adequate to readily provide the required pressure during the test period. Leakage from flamepaths can be</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>reduced by the use of gaskets or 'O' rings.</p> <p>The pressure gauge shall be calibrated, of suitable size, range and located such that it does not invalidate the test (e.g. due to pressure drop down pipe lines).</p> <p>The method of test shall enable any leakage to be monitored during the test period.</p>			
<p>A.3.5 Flanged joints</p> <p>Flanged joints shall be inspected after final assembly to ensure the specified gap is not exceeded.</p>			
<p>A.3.6 Sintered components</p> <p>see Annex B.</p>			
<p>A.4 Ex i – Intrinsic safety</p> <p>A.4.1 The following features shall be verified with respect to the following components. This may be achieved using statistical techniques where appropriate:</p> <ul style="list-style-type: none"> • Resistors: value, power, type • Capacitors: value, tolerance, construction, segregation across terminals • Encapsulated assembly: depth of encapsulant • Inductive components: inductance, d.c. resistance, number of turns, wire gauge and material, plus material specification of core and bobbin where appropriate • Diodes • Zener diodes • Transistors • Integrated circuits <p style="margin-left: 150px;">} Type number and where appropriate, the manufacturer</p>			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> • Cells and batteries: manufacturer and type number • Insulating materials: specification, dimensions and where appropriate type number • Connectors (e.g. plus/sockets and terminals): type number and where appropriate, the manufacturer. 			
<p>A.4.2 Printed Circuit Boards (PCB)</p> <p>A.4.2.1 Non-populated PCBs</p> <p>A.4.2.1.1 For high volume or complex PCBs e.g. multilayer PCBs, the batch can be accepted with a declaration of conformity in accordance with ISO/IEC 17050. The declaration should state compliance to the purchase documents e.g. a quality plan that lists the factors that together demonstrate conformity of the product.</p> <p>A.4.2.1.2 For simple single or double sided PCBs, the copper artwork should be visually verified using photographic negative (transparency), certified drawing or controlled inspection sample.</p> <p>Purchase documents should specify copper thickness, PCB thickness and CTI values.</p> <p>A.4.2.2 Populated PCBs</p> <p>A.4.2.2.1 Varnish and coatings should be controlled with respect to the specification of material, effectiveness of cover and where required application of two independent coverings, i.e. the first covering is allowed to cure or to dry for a time suitable for overcoating before the second.</p> <p>A.4.2.2.2 For PCBs the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and Zener diodes) which have been agreed with the Accepted Certification Body that has issued the Assessment and Test Report. The components on this list should be verified on a</p>			

Reading Version

Question:	Document Reference	Auditor Notes:	Result
<p>100 % basis.</p> <p>This may be conducted by:</p> <ul style="list-style-type: none"> – a visual verification; or – for surface mount components, by ensuring correct loading of the “pick and place” machines and a visual verification of correct placement; – by automatic test equipment (ATE) provided that the ATE addresses each individual safety critical component and by a visual verification is conducted to verify type number of components in shunt Zener diode/diode assemblies. <p>NOTE Where the surface mount component “pick and place” machine selects the component reel based on measuring the component value, the measuring function should be calibrated.</p> <p>A.4.2.2.3 Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering.</p> <p>A.4.2.2.4 Specified segregation for hand built PCBs should be verified on a 100 % basis.</p>			
<p>A.4.3 Sub-assemblies and assemblies</p> <p>A.4.3.1 The documented procedures shall ensure that the production documentation includes all relevant variations to the product design.</p> <p>A.4.3.2 The production documentation shall address all safety critical components including covers for exposed parts, e.g. battery charging sockets.</p> <p>A.4.3.3 Documented procedures shall ensure that segregation is maintained and that specified labels are correct and fitted.</p> <p>A.4.3.4 Sealing arrangements shall be verified for compatibility</p>			

Question:	Document Reference	Auditor Notes:	Result
with the products ingress protection requirements.			
<p>A.4.4 Tests</p> <p>Any tests required by the ExTR, e.g. high voltage tests on complete assemblies or individual components such as transformers, shall be controlled by documented procedures and conducted on a 100 % basis unless otherwise permitted (see General Requirements).</p>			
<p>A.4.5 Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures</p> <p>Where Ex d, Ex p or Ex q enclosures contain intrinsically safe circuits then precautions shall be taken as stated in the ExTR to ensure that other items mounted within the enclosure are selected and mounted so that they do not invalidate an intrinsic safety feature e.g. segregation shall be maintained, specified voltages and specified ambient temperatures are not exceeded.</p>			
<p>A.5 Ex e – Increased safety</p> <p>A.5.1 Ingress protection</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> • weld continuity; • fitting of gaskets and seals; • continuity of moulded grooves and tongues; • application of cements. 			
<p>A.5.2 Internal wiring and contact integrity</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> • wiring is effectively clamped; • wiring is correctly terminated; 			

Question:	Document Reference	Auditor Notes:	Result
<ul style="list-style-type: none"> wiring insulation has the appropriate temperature rating. 			
<p>A.5.3 Rotating machines</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> rotor end connections and fixing bars are correctly tightened; air gap is verified; fan clearance is verified, bearing clearance is verified. 			
<p>A.5.4 Windings</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> impregnations are free of voids, insulation materials meet stated specifications; security of conductors are verified; protective devices are the type specified 			
<p>A.5.5 Tests</p> <p>All test should be documented e.g. dielectric, and bearing insulation for rotating machines.</p>			
<p>A.6 Ex p – Pressurized apparatus</p> <p>A.6.1 Ingress protection</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> weld continuity; fitting of gaskets and seals, continuity of moulded grooves and tongues, application of cements. 			

Question:	Document Reference	Auditor Notes:	Result
<p>A.6.2 Tests</p> <p>Overpressure tests at stated in the ExTR of Certificate of Conformity followed by a leakage test shall be documented.</p>			
<p>A.7 Ex m – Encapsulation</p> <p>A.7.1 Production documentation</p> <p>A.3.3 applies for encapsulation and thermal protection should be positioned according to schedule drawings.</p>			
<p>A.8 Ex o – Oil immersion</p> <p>All tests e.g. reduced pressure and overpressure tests should be documented.</p>			
<p>A.9 Ex q – Powder filling</p> <p>A.9.1 Material control</p> <p>The size and type should be defined.</p>			
<p>A.9.2 Filling</p> <p>Filling should be made without voids. The procedure should be documented.</p>			
<p>A.9.3 Ingress protection</p> <p>Documented procedures should ensure the following are verified:</p> <ul style="list-style-type: none"> • weld continuity; • fitting of gaskets and seals, • continuity of moulded grooves and tongues, • application of cements. 			

Question:	Document Reference	Auditor Notes:	Result
<p>A.9.4 Tests</p> <p>Tests should be documented e.g. pressure and dialectical strength test of filling material.</p>			
<p>Annex B – Verification criteria for sintered components used as an integral part of a type of protection</p>			
<p>B.1 Introduction</p>			
<p>B.2 Verification guidance</p> <p>There are three options available:</p> <ul style="list-style-type: none"> the supplier conducts the verification tests; the supplier conducts a pre-contract and follow up periodic documented assessment of the sinter manufacturer and accepts sinters with a Declaration of Conformity, that is in accordance with ISO/IEC 17050, <i>Conformity assessment – Supplier's declaration of conformity</i>; the supplier accepts sinters with a Declaration of Conformity that is in accordance with ISO/IEC 17050, <i>Conformity assessment – Supplier's declaration of conformity</i> from a sinter manufacturer who has a certified Quality Management System with an appropriate scope. 			
<p>B.3 Tests</p> <p>The tests, for all verification options shall be performed in accordance with the requirements of the product certification and International Standards (ISO 4003 and ISO 2738).</p> <p>The test may be conducted on a sample basis provided that the sample size is not less than 1 % of the batch size or 10 units whichever is the greater.</p> <p>Where tests to determine pore size and density are conducted on a sample basis, then the results shall be calculated to establish the Standard Deviation (σ) for the sample batch, i.e.</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>Φ_p = the pore size standard deviation; Φ_D = the density standard deviation.</p> <p>The maximum pore size shall not be exceeded and the minimum density shall remain equal or greater than the value as stated in the ExTR when 3Φ is taken into account. Therefore the mean value of the sample batch, plus $3 \Phi_p$ (for pore size) and minus $3 \Phi_D$ (for density) shall not invalidate the requirements of the ExTR.</p>			
<p>B.4 Test examples</p> <p>The following examples are provided for guidance.</p> <p>Example 1 (pore size)</p> <p>Maximum permitted pore size as detailed in the Assessment and Test Report = 150 :m Mean value = 140 :m Standard deviation (σ_p) = 2 :m Therefore maximum value = $140 + (2 \times 3) = 146$:m (PASS) If standard deviation (σ_p) = 5 :m Then maximum value = $140 + (5 \times 3) = 155$:m (FAIL)</p> <p>Example 2 (density)</p> <p>Minimum permitted density as detailed in the Assessment and Test Report = 5 gcm^{-3} Mean value = $5,3 \text{ gcm}^{-3}$ Standard deviation (σ_D) = $0,05 \text{ gcm}^{-3}$ Therefore minimum value = $5,3 - (0,05 \times 3) = 5,15 \text{ gcm}^{-3}$ (PASS)</p>			

Question:	Document Reference	Auditor Notes:	Result
<p>If standard deviation (σ_D) = 0,12</p> <p>Then minimum value = $5,3 - (0,12 \times 3) = 4,94 \text{ gcm}^{-3}$ (FAIL)</p> <p>NOTE In some cases the sinter is formed directly in a solid housing. To establish the density value, the following formula should be used:</p> $\rho = \frac{M_1 \times \rho W}{M_2 - M_3}$ <p>substitute as follows:</p> $\rho = \frac{(m_3 - m_1) \times \rho W}{(m_4 - m_1) - (m_5 - m_2)}$ <p>where</p> <p>ρW is the density of water; m_1 is the housing only, weight in air; m_2 is the housing only, weight in water; m_3 is the housing and sinter (assembly), weight in air; m_4 is the coated assembly, weight in air; m_5 is the coated assembly, weight in water.</p>			
<p>B.5 Purchase information</p> <p>The supplier shall ensure that the purchase documents include the following:</p> <ul style="list-style-type: none"> - the sinter material specification; - the dimensional requirements; - the maximum pore size (ISO 4003); - the minimum density (ISO 2738 as stated in the ExTR). 			

Question:	Document Reference	Auditor Notes:	Result
<p>B.6 Pre-tested components</p> <p>Where the supplier does not conduct their own tests, then the Declaration of Conformity shall be in accordance with ISO/IEC 17050, <i>Conformity assessment – Supplier's declaration of conformity</i> and shall also include the following:</p> <ul style="list-style-type: none"> – the manufactured batch size; – the sample size taken to establish the maximum pore size and the minimum density, – the number of components supplied, – the maximum pore size and minimum density. 			
<p>B.7 Measurement and monitoring</p> <p>Upon receipt of the components, the supplier is responsible for</p> <ul style="list-style-type: none"> – checking the “Declaration of Conformity” against the requirements of Clause 3 of this Annex; – checking the compatibility of the purchase order requirements with the Declaration of Conformity (if not tested on site) and giving special attention to the stated pore size and density data to ensure that when taking the stated tolerance into account the specification is not exceeded; – conducting the tests (if testing on site); – conducting a statistical check on the overall size of the sintered component. 			

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