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**ExMC/1960/DV**

**June 2023**

**INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USEIN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

## Title: Amendment to IECEx F-001, 4.0

To: Members of the IECEx Management Committee, ExMC

**Introduction**

This document contains a proposal for amendments to Edition 4.0 of form IECEx F-001, IECEx Quality Assessment Report as recommended by ExMC Working Group 5 following their April 2023 meeting.

This is now submitted for approval during the 2023 ExMC meeting for publication as Edition 5.0.

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

**IECEx Secretary**

|  |  |
| --- | --- |
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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Project No.** |  | | | | |
| **Ex QMS Certificates** |  | | | | |
| ManufacturerInclude Address with post code |  | | | | |
| **Locations audited**  Include Address with post code |  | | | | |
| **Product Description** |  | | | | |
| **Employee count** | Total onsite: | | Total involved in Ex products: | | |
| **Scope of Audit** | Initial Assessment Re-Assessment | | | Surveillance Assessment Special Assessment | |
| **Scheme** | IECEx | Spare | | | Spare |
| **Ex equipment with type(s) of protection** | d  e  h  i  m  n  p  t  op  Other *(specify)*  *(Delete where not applicable)* | | | | |
| **Audit Team Leader** |  | | | | |
| **Audit Date** |  | | | | |

|  |  |  |
| --- | --- | --- |
|  | **Contents:** |  |
| 1 | Summary Report |  |
| 2 | Audit information |  |
| 3 | Documentation Review and Assessment of Implementation |  |
| 4 | Certificate List |  |
| 5 | Audit Non-Conformities and Observations |  |

**NOTE: whilst some parts of this form / template are optional there is an expectation that all ExCBs will**

* **use the form as published**
* **only add content, and**
* **not ignore the non-optional aspects**

**IECEx ExCB**

|  |  |  |
| --- | --- | --- |
| *ExCB Logo* | *ExCB Address* | *Accreditation Logo (optional)* |

**1. Summary Report**

**Assessment Summary and Conclusions:**

*(State the most important* ***results*** *and* ***conclusions*** *of the quality assessment)*

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| **Next Quality Audit due** | **:** |  |

**Non-Conformities**

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

|  |  |
| --- | --- |
| **NCR No.(s):** |  |
|  |  |

**Audit Team Leader Recommendations**

*(Delete where not applicable)*

**Notification / Certification to be issued/maintained**once satisfactory technical assessment of the product is completed and a test report is issued

**Notification / Certification to be issued/maintained\*** following receipt of satisfactory documentary evidence supporting effective corrective action, and a test report is issued. Corrective action to be verified at next surveillance visit

**Notification / Certification to be issued/maintained\* following a satisfactory follow-up visit** and verification that corrective actions have been effectively documented and implemented, and test report issued.

**Notification / Certification to be refused/suspended\*** A further complete assessment to be conducted

**Notification / Certification to be refused/suspended\*** Close the application/withdraw the notification and inform the Scheme Administrator or other Notified Bodies.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Audit Team Leader Signature** |  | **Technical Reviewer** |

**2. Audit Information**

**2.1 Scope of Audit:**

|  |  |
| --- | --- |
| **Type A** initial assessment/reassessment of manufacturer **with** a certified QMS\* |  |
| **Type B** initial assessment/reassessment of manufacturer **without** a certified QMS |  |
| **Type C** surveillance of manufacturer **with** a certified QMS\* |  |
| **Type D** surveillance of manufacturer **without** a certified QMS |  |
| *\* where manufacturer has a certified quality system, include certification/registration body, date of registration, certificate No. and scope or append a copy of the certificate (including scope)* | |

|  |  |  |  |
| --- | --- | --- | --- |
| **2.2 Audit Criteria**  *List any other reference documents*, *against which Audit was conducted* | **:** | ISO/IEC 80079-34, Ed. 2.0:2018 |  |
| *Other applicable reference Standards* |  |
| *Other applicable reference Standards* |  |
| *Other applicable reference Standards* |  |
| **2.3 Date(s) and Duration of Audit**  *Include total number of auditor days on site* | **:** |  |  |

**2.4 Certified Quality System**

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO 9001 Certificate No** | **Certified by** | **Expiry date** | **Scope** |
|  |  |  |  |

If ISO 9001 certified, were non-conformities from the last ISO 9001 audit reviewed?

Yes  No  N/A (no NCs)

**Comments to ISO 9001 non-conformities.**

|  |
| --- |
|  |

**2.5 Composition of Audit Team:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Position** | **Role in Audit** *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)* |
|  |  |  |
|  |  |  |
|  |  |  |

**2.6 Interviewed Representatives of Manufacturer (Auditee):**

| **Name** | **Position** |
| --- | --- |
|  |  |
|  |  |
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|  |  |

**2.7 External Providers:** (*Use this table to list External Providers reviewed during audit of supplier evaluation)*

| **Name of Supplier** | **Critical item or service provided** |
| --- | --- |
|  |  |
|  |  |
|  |  |

**2.8 Manufacturers Documentation:**

(*Use this table to list details of the manufacturers quality management system documentation cited in Section 3 by document identity and reviewed during the audit covered by this Quality Audit Report)*

| **Document No.** | **Document Name** | **Rev.** | **Date** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |



**3. Documentation Review and Assessment of Implementation**

Note 1: Regarding the entry of Manufacturer’s Document References in the following table - you only need to reference the document number (and if desired the title) if the details of document number, title and revision status are listed in Clause 2.8. Commentsare to be 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 9001:2015 the auditor shall provide a verdict in accordance with the Note 3 below. *The IECEx System expectation is that where the form specifies that “ISO 9001:2015 applies” for the manufacturing of Ex product, these requirements are reviewed and assessed as necessary by the ExCB irrespective of whether the manufacturer has ISO 9001:2015 certification (guidance on ExMC decisions in this area is available in 17021-1, Clause 9.1.3.4)*

Note 3: Possible audit verdicts: P = Pass, NA = Not applicable, F = Fail, add the Non-conformity number against a clause where a Non-conformity has been issued.

| **Clause** | **Requirement** | **Documents 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. | |  |  |
| **4.2** | **Understanding the needs and expectations of interested parties** |  |  |
| 4.2 of ISO 9001:2015 applies. |
| **4.3** | **Determining the scope of the quality management system** |  |  |
| 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. | |  |  |
| **5.1.1** | **General** |  |  |
| 5.1.1 of ISO 9001:2015 applies. |
| **5.1.2** | **Customer focus** |  |  |
| 5.1.2 of ISO 9001:2015 applies. |
| **5.2.1** | **Establishing the quality policy** |  |  |
| 5.2.1 of ISO 9001:2015 applies. |
| **5.2.2** | **Communicating the quality policy** |  |  |
| 5.2.2 of ISO 9001:2015 applies. |
| **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; | |  |  |
| 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; | |  |  |
| 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. | |  |  |
| d) the authorization of initial approval and changes to related drawings, where appropriate; | |  |  |
| e) the authorization of concessions (see 8.7 f)); | |  |  |
| 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 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. | |  |  |
| Records demonstrating this shall be available and be maintained as documented information. | |  |  |
| **6.1** | **Actions to address risks and opportunities** |  |  |
| 6.1 of ISO 9001:2015 applies. |
| **6.2** | **Quality objectives and planning to achieve them** |  |  |
| 6.2 of ISO 9001:2015 applies. |
| **6.3** | **Planning of changes** |  |  |
| 6.3 of ISO 9001:2015 applies. |
| **7.1.1** | **General (Support and Resources)** |  |  |
| 7.1.1 of ISO 9001:2015 applies. |
| **7.1.2** | **People** |  |  |
| 7.1.2 of ISO 9001:2015 applies. |
| **7.1.3** | **Infrastructure** |  |  |
| 7.1.3 of ISO 9001:2015 applies. |
| **7.1.4** | **Environment for the operation of processes** |  |  |
| 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: | |  |  |
| 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. | |  |  |
| 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;  • 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). | |  |  |
| **7.1.6** | **Organizational knowledge** |  |  |
| 7.1.6 of ISO 9001:2015 applies. |
| **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. | |  |  |
| **7.3** | **Awareness** |  |  |
| 7.3 of ISO 9001:2015 applies. |
| **7.4** | **Communication** 7.4 of ISO 9001:2015 applies with the following addition: | | |
| Internal and external communication relating to Ex Products **shall be controlled.**  NOTE 1: Communication includes manufacturer documentation, technical documentation, certificates, nonconforming products placed on the market, etc.  NOTE 2: External communication includes communication with clients, certification bodies, providers, economic operators (authorized representatives, importers, distributors, external providers...), authorities etc. | |  |  |
| **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 | |  |  |
| **7.5.2** | **Creating and updating** |  |  |
| 7.5.2 of ISO 9001:2015 applies. |
| **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; | |  |  |
| 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; | |  |  |
| 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; | |  |  |
| d) there shall be a documented system that refers all related drawings to the relevant schedule drawings; | |  |  |
| 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  that the change to the component for the one product is not implemented without approval from the responsible persons for all end-products that use that component. | |  |  |
| 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. | |  |  |
| 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. | |  |  |
| 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; | |  |  |
| i) the manufacturer shall have a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications; | |  |  |
| 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. | |  |  |
| **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 methods are used, they should be evaluated to ensure full compliance with the requirements of certification. | |  |  |
| **8.2.1** | **Customer Communications** |  |  |
| 8.2.1 of ISO 9001:2015 applies. |
| **8.2.2** | **Determining the requirements for products and services** |  |  |
| 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. | |  |  |
| **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. | |  |  |
| **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. | |  |  |
| **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; | |  |  |
| 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. | |  |  |
| 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. | |  |  |
| c) external providers providing calibration services (including verification on measuring devices by 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; | |  |  |
| 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; | |  |  |
| 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. | |  |  |
| 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. | |  |  |
| **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; | |  |  |
| 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 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; | |  |  |
| 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; | |  |  |
| 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; | |  |  |
| f) where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch; | |  |  |
| 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; | |  |  |
| 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; | |  |  |
| i) where an external provider provides product with evidence of conformity applicable to use in an explosive atmosphere, (e.g. certificate), then 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; | |  |  |
| 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. | |  |  |
| **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 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; | |  |  |
| 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; | |  |  |
| 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. | |  |  |
| **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. | |  |  |
| 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). | |  |  |
| **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; | |  |  |
| 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. | |  |  |
| **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. | |  |  |
| **8.5.4** | **Preservation** |  |  |
| 8.5.4 of ISO 9001:2015 applies. |
| **8.5.5** | **Post-delivery activities** |  |  |
| 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. | |  |  |
| **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. | |  |  |
| 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. | |  |  |
| **8.7** | **Control of nonconforming outputs** 8.7 of ISO 9001:2015 applies and the following shall be defined: | | |
| a) the manufacturer shall maintain a documented system, such that in the event of an Ex Product not conforming to the certificate and having been supplied, then the manufacturer’s customer can be identified; | |  |  |
| b) the manufacturer shall take action appropriate to the degree of risk, where nonconforming Ex Product has been supplied to a customer. It is recommended that the manufacturer liaise with the body responsible for the issue of the certificate; | |  |  |
| c) where unsafe nonconforming Ex Products have been supplied to a customer, the manufacturer shall, in writing, inform its customer and the body responsible for the verification of the quality management system and the issuer of the certificate; | |  |  |
| d) where it is not possible to trace unsafe nonconforming Ex Products (e.g. Ex Products supplied via a distributor, or for high volume Ex Products such as Cable Glands) then a  notice shall be placed in appropriate publications providing recommended action to be taken; | |  |  |
| e) for all nonconforming Ex Products that have been supplied to a customer, the manufacturer shall maintain, for a minimum period of 10 years, records of:   1. serial numbers or identification of Ex Products supplied; 2. the customer who received the Ex Products; 3. the action taken to inform customers and the body responsible for the verification of the quality management system in the case of unsafe nonconforming Ex Products; 4. the action taken to implement corrective and preventative action; | |  |  |
| f) concessions for Ex Products that take the Ex Products outside the design as defined in the certificate and technical documentation are not permitted. | |  |  |
| **9.1.1** | **General (Monitoring, measurement, analysis and evaluation)** |  |  |
| 9.1.1 of ISO 9001:2015 applies. |
| **9.1.2** | **Customer satisfaction** |  |  |
| 9.1.2 of ISO 9001:2015 applies. |
| **9.1.3** | **Analysis and evaluation** |  |  |
| 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. | |  |  |
| 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 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. | |  |  |
| 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. | |  |  |
| **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. | |  |  |
| **9.3.2** | **Management review inputs** |  |  |
| 9.3.2 of ISO 9001: 2015 applies. |
| **9.3.3** | **Management review outputs** |  |  |
| 9.3.3 of ISO 9001:2015 applies. |
| **10.1** | **General (Improvement)** |  |  |
| 10.1 of ISO 9001:2015 applies. |  |  |
| **10.2** | **Nonconformity and corrective action** |  |  |
| 10.2 of ISO 9001:2015 applies. |
| **10.3** | **Continual improvement** |  |  |
| 10.3 of ISO 9001:2015 applies. |

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| **Annex A** (informative) | |
| **Information relevant to particular Types of Protection and specific Ex Products** | |
| **A.1** | **Overview** |
| 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. | |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
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| **A.3** | **Ex d – Flameproof enclosures covered by IEC 60079-1** | |  |
| **A.3.1** | **Verification** | |  |
| Verification consists of a visual inspection and/or measurement.  The measurement should be done with suitable measuring equipment. The persons doing this measurement should have the competence and knowledge of using this measuring equipment. | |  |  |
| **A.3.2** | **Castings** | | |
| Castings should be subject to verification that demonstrates conformity, e.g.:  a) 100 % visual inspection should be done on each part;  b) wall thickness (including those parts not subject to machining);  c) flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality).  NOTE: Verification can be accomplished by 100 % visual inspection, or by another means deemed appropriate based on the ability of the manufacturer to effectively control production.  Recovery of porous castings by impregnation methods, e.g. silicone is not permitted.  In the event that a casting is recovered by welding it will become subject to the requirements applicable to welded enclosures, e.g. routine pressure testing. | |  |  |
| **A.3.3** | **Machining** | | |
| Machining should be subject to verification by either 100 % inspection or statistical techniques as appropriate that demonstrates conformity, e.g. the following should be verified:  a) flatness of flanged flamepaths;  b) surface roughness of non-threaded flamepaths;  c) fit of all threaded flamepaths (e.g. threaded entries and threaded access covers);  d) depth of drilling and tapping of blind holes to ensure adequate residual wall thickness;  e) dimensional requirements of all flamepaths.  NOTE: Suitable statistical techniques are used in ISO 2859-1, ISO 3951-1 or equivalent standard. | |  |  |
| **A.3.4** | **Cemented joints and potted assemblies** | | |
| Documented procedures should address the following, as applicable:  a) shelf life and storage of cement, potting compounds;  b) mixing;  c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);  d) application e.g. filling instructions, freedom from voids and temperature conditions;  e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;  f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques. | |  |  |
| **A.3.5** | **Routine overpressure testing** | | |
| **A.3.5.1** | **General** | | |
| The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation.  Leakage through cemented joints or potted assemblies would constitute a failure unless otherwise permitted by the issuer of the certificate.  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 the static routine overpressure test, it is sufficient to test the enclosure empty. The individual parts of a flameproof enclosure (for example, cover and base) can be tested separately. For enclosures that contain more than one discrete compartment, each compartment should be tested individually. The method used should ensure that the assembly, sub-assembly or component parts are subjected to representative stress patterns e.g. actual fastening facilities are used. Clamping that affects the mechanical properties of the Type of Protection would invalidate the test results.  Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended. | |  |  |
| **A.3.5.2** | **Batch testing** | | |
| Where permitted by the certificate, the routine overpressure testing may be replaced by a batch test according to the following criteria, based on ISO 2859-1;  a) For a production batch up to 100, a sampling of 8 should be tested at 1,5 times the reference pressure with no failures.  b) For a production batch from 101 to 1 000, a sampling of 32 should be tested at 1,5 times the reference pressure with no failures.  c) For a production batch from 1 001 up to 10 000, a sampling of 80 should be tested at 1,5 times the reference pressure with no failures.  d) Batches above 10 000 should be subdivided into smaller batches.  If there are any non-compliant test results,100 % of all remaining samples in the batch should be tested at 1,5 times the reference pressure. Future batches should be routine tested at 1,5 times the reference pressure until confidence is established to reconsider batch testing.  NOTE: Upon non-compliant test results, reconsideration of this batch testing approach is at the discretion of the party issuing the certificate. | |  |  |
| **A.3.5.3** | **Welded construction** | | |
| Where permitted by the certificate, the routine overpressure testing may be replaced by one of the following inspection methods:  a) radiographic weld inspection; or  b) ultrasonic weld inspection; or  c) magnetic particle weld inspection; or  d) liquid penetrant weld inspection.  NOTE: ISO standards exist for each of the above weld inspection methods. | |  |  |
| **A.3.6** | **Flanged joints** | | |
| Flanged joints should be verified after final assembly to ensure the gap specified in the Schedule Drawings is not exceeded. If not practical, special measure should be taken during the production. | |  |  |
| **A.3.7** | **Elements, with non-measurable paths, of breathing and draining devices** | | |
| For products containing elements like sintered metal, pressed metal wire or metal foam, see Annex B. | |  |  |

| **Clause** | **Requirement** | | | **Documents or Comments** | **Verdict** |
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| **A.4** | **Ex i – intrinsic safety covered by IEC 60079-11** | | | | |
| **A.4.1** | **Components for intrinsically safe products** | | |  |  |
|  | The following features should be verified with respect to the following components for use in intrinsically safe apparatus and associated apparatus. This normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate, as shown in Table A.1: | | |  |  |
|  | **Table A.1 Component features requiring compatibility** | | | |  |
| **Resistors:** value, power, type, tolerance, case size | | | |  |  |
| **Capacitors:** value, tolerance, type, rated voltage, case size | | | |  |  |
| **Piezo-electric devices:** manufacturer, type, capacitance | | | |  |  |
|  | **Inductive components:** type, inductance, DC. resistance, number of turns, wire gauge and material, material specification of core and bobbin where appropriate | | |  |  |
| **Transformers:** type, manufacturer, isolation, voltage | | | |  |  |
| **Optical isolators:** Optical isolator type, isolation, voltage | | | |  |  |
| **Semiconductors:** | | – Transistors  – Integrated circuits  – Thyristors  – Diodes  – Zener diodes | type number, power value and where appropriate, the manufacturer |  |  |
| **Cells and batteries:** manufacturer and type number, or IEC designation | | | |  |  |
| **Fuses:** manufacturer, type, value | | | |  |  |
| **Insulating materials:** specification, dimensions and where appropriate type number | | | |  |  |
| **Connectors** (e.g. plugs/sockets and terminals): type number and where appropriate, the manufacturer | | | |  |  |
| **A.4.2** | **Printed circuit boards (PCB)** | | | | |
| **A.4.2.1** | **Non-populated PCBs** | | | | |
| PCBs may be accepted with a declaration of conformity (see Annex C). 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. For simple single- or double- sided PCBs, the copper artwork may be visually verified using photographic negative (transparency), certified drawing or controlled inspection samples. Purchase documents should specify copper thickness with tolerances, PCB thickness with tolerances and CTI values. | | | |  |  |
| **A.4.2.2** | **Populated PCBs** | | | | |
| * Varnish and coatings should be controlled with respect to the specification of material and effectiveness of the application. * Documented procedures should ensure that the application of varnish and coatings are in conformity with the certificate and/or schedule drawings. * For PCBs the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and Zener diodes) determined during Ex Equipment assessment. The safety critical components placed on the PCB should be verified on a 100 % basis. * Specified distances and clearances on manually assembled PCBs should be verified on a 100 % basis. * This may be conducted by one of the following methods:   a) a visual verification;  b) for surface mount components, by ensuring correct loading of the "pick and place" machines and a visual verification of correct placement;  c) by automatic test equipment (ATE) if the ATE addresses each individual safety critical component and by a visual verification conducted to verify type number of components in shunt Zener diode/diode assemblies.   * 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. * Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering. * Documented procedures should ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area and insulation thickness are in conformity with the schedule drawings. | | | |  |  |
| **A.4.3** | **Sub-assemblies and assemblies** | | | | |
| Documented procedures should ensure that production documentation includes all relevant variations to the product design.  Production documentation should address all safety critical components, and in the case of encapsulated parts, the compound manufacturer, type, mix and minimum depth. Documented procedures should address the following:  a) shelf life and storage of cement and potting compounds;  b) mixing;  c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);  d) application e.g. filling instructions, freedom from voids and temperature conditions;  e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;  f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques.  Documented procedures should also ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area, insulation thickness and labels (where appropriate) are fitted.  Sealing arrangements should be verified for compatibility with the product’s ingress protection rating. | | | |  |  |
| **A.4.4** | **Enclosures for Group III or reduced spacing** | | | | |
| For intrinsically safe apparatus for Group III, or for apparatus that relies on the enclosure for reduced spacing, demonstration of the conformity of the enclosure with the schedule drawings should include the following:  a) depths of bore holes and tap holes;  b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability;  c) insulating coatings and surface conditioning; material, layer thickness.  Documented procedures should address the following:  a) the gaskets correspond to the quoted specification;  b) the sealing elements' effectiveness, e.g. by checking the sealing elements' correct fit.  If a gasket's correct fit becomes apparent only after assembly, the imprint could be visually examined, e.g. by use of adequate methods such as use of chalk. | | | |  |  |
| **A.4.5** | **Routine verifications and tests** | | | | |
| Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests, e.g. high voltage tests on complete assemblies or individual components such as transformers, should be controlled by documented procedures and conducted on a 100 % basis unless otherwise permitted. | | | |  |  |
| **A.4.6** | **Intrinsically safe circuits and assemblies incorporated in Ex equipment of other types of protection** | | | |  |
| Where Ex equipment contains intrinsically safe circuits then precautions should be taken as stated in the certificate to ensure that other items listed in the certificate are selected, mounted and installed in accordance with schedule drawings. | | | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.5** | **Ex e – Increased safety covered by IEC 60079-7** | | |
| **A.5.1** | **Ingress protection (IP)** | | |
| Documented procedures should ensure that the following is verified:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) application of cements including a visual inspection after curing. | |  |  |
| **A.5.2** | **Internal wiring and contact integrity** | | |
| Documented procedures should ensure that the following are verified:  a) wiring is clamped as specified in the schedule drawings;  b) wiring is terminated as specified in the schedule drawings;  c) wires are as specified in the schedule drawings;  d) connections are tightened as specified in the schedule drawings;  e) creepage distances and clearances are as specified in the schedule drawings and have not been compromised. | |  |  |
| **A.5.3** | **Rotating machines** | | |
| Documented procedures should ensure that the following are verified:  a) rotor end connections and fixing bars are as specified in the schedule drawings;  b) the fabrication process for die-cast rotors is as specified in the schedule drawings;  c) production controls are in place for:  – the air gap (rotor to stator) as specified in the schedule drawings;  – the fan clearance as specified in the schedule drawings;  – the bearing seal clearances as specified in the schedule drawings.  NOTE: The schedule drawings might not specify a bearing seal clearance as not all Levels of Protection require a bearing seal clearance for all bearing seal designs. | |  |  |
| **A.5.4** | **Windings** | | |
| Documented procedures should ensure that the following are verified:  a) wire and insulation system are as specified in the schedule drawings;  b) the impregnations process is as specified in the schedule drawings;  c) insulation materials are as specified in the schedule drawings;  d) mechanical securing of conductors are as specified in the schedule drawings;  e) type and mounting of protective devices (e.g. thermal cut-outs) are as specified in the schedule drawings. | |  |  |
| **A.5.5** | **Terminal boxes** | | |
| Documented procedures should ensure that the following are verified:  a) terminals are as specified in the schedule drawings;  b) creepage distances and clearances as specified in the schedule drawings have not been compromised. | |  |  |
| **A.5.6** | **Cable Glands, terminals and other accessories** | | |
| The dimensions specified in the schedule drawings should be confirmed on a statistical basis. Where entry openings are secured by non-Ex temporary plugs (e.g. for transport only), additional information should be provided. | |  |  |
| **A.5.7** | **Routine verifications and tests** | | |
| Procedures for all routine verifications and tests specified in the schedule drawings should be reviewed, along with the results of those verifications and tests. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.6** | **Ex p – Pressurized equipment covered by IEC 60079-2** | | |
| **A.6.1** | **Ingress protection (IP)** | | |
| Documented procedures should ensure that the following is verified:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) application of cements including a visual inspection after curing. | |  |  |
| **A.6.2** | **Components and manufacturing process** | | |
| The documented procedure should at least ensure the verification of assemblies with typical components as specified in the schedule drawings:  a) Monitoring devices (and their location), for pressure, differential pressure, purging time, rate of volume, flow, temperature;  b) Ex Components and Ex Equipment;  c) Enclosure, enclosure parts, materials of enclosure and enclosure parts and gaskets. | |  |  |
| **A.6.3** | **Components, constructional characteristics** | | |
| The documented procedure should include the verification, the manufacturing processes and quality assurance technology for components and constructional characteristics relevant for  safety as specified in the schedule drawings:  a) Purging openings inside the pressurized enclosure or in the enclosure wall;  b) Internal installations (components, partitions, enclosures);  c) Installations into the enclosure wall (components, entries);  d) Purging pipes, purge controller components (internal, external) should be verified with respect to their constructional specifications and the constructional characteristics. | |  |  |
| **A.6.4** | **Routine verifications and tests** | | |
| All tests should be documented. Typical tests include:  a) a functional test of the pressurized equipment;  b) a leakage test;  c) an infallible containment system test;  d) a containment system for a limited release system test. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.7** | **Ex m – Encapsulation covered by IEC 60079-18** | | |
| **A.7.1** | **Production documentation** | | |
| Thermal protection (e.g. thermal fuses) should be positioned according to and be of the type specified in the schedule drawings.  Documented procedures should address the following:  a) shelf life and storage of cement, potting compounds;  b) mixing;  c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);  d) application e.g. filling instructions, freedom from voids and temperature conditions;  e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;  f) after curing, an inspection should be done on each potted assembly. Depending on the nature and repeatability of the process and the potted assembly, this could be for example using statistical techniques. | |  |  |
| **A.7.2** | **Routine verifications and tests** | | |
| All tests should be documented. Typical tests include:  a) visual examination;  b) dielectric strength test. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.8** | **Ex o – Liquid immersion covered by IEC 60079-6** | | |
| **A.8.1** | **Material control** | | |
| All materials including filling liquid used should be of defined type. | |  |  |
| **A.8.2** | **Filling** | | |
| Filling method and liquid level should be as stated in the schedule drawings. The process of filling and amount of liquid should be documented. | |  |  |
| **A.8.3** | **Ingress protection** | | |
| Documented procedures should ensure that the following aspects are verified:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) application of cements including a visual inspection after curing. | |  |  |
| **A.8.4** | **Routine verifications and tests** | | |
| All tests should be documented. Typical tests include:  a) reduced pressure test (sealed enclosures only);  b) overpressure test (sealed and unsealed enclosures).  Note: IEC 60079-6 Edition 4, Amendment 1 shows in the scope a significant increase in voltage allowed for Ex o Level of Protection “oc” from 15 kV AC RMS or DC and up to 245 kV AC RMS or DC. This will impact on the assessment of the manufacturer where certified equipment with these higher voltages is made because of the routine tests required. See also Decision Sheet DS xxxx/-xx | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.9** | **Ex q – Powder filling covered by IEC 60079-5** | | |
| **A.9.1** | **Material control** | | |
| Evidence should exist as to the flammability verification of enclosure materials and these materials should align with those specified in the schedule drawings. | |  |  |
| **A.9.2** | **Filling** | | |
| Filling should be made without voids. Care is needed to ensure that voids are not created after filling by shaking down. The process for filling should be documented and the documentation should include verification criteria. | |  |  |
| **A.9.3** | **Ingress protection (IP)** | | |
| Documented procedures should ensure that the following aspects are verified:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) application of cements including a visual inspection after curing. | |  |  |
| **A.9.4** | **Routine verifications and tests** | | |
| All tests should be documented. Typical tests include:  a) pressure test;  b) dielectric strength test of filling material. | |  |  |
| **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 | |  |  |
| **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 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. | |  |  |
| **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. | |  |  |
| **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 ). | |  |  |
| **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. | |  |  |
| **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. | |  |  |
| **A.10.4.4** | **Test equipment** | | |
| Documented methods should ensure the correct assembling and function of test equipment. | |  |  |
| **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. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.11** | **Ex t – Dust ignition protection by enclosure covered by IEC 60079-31** | | |
| **A.11.1** | **Casting** | | |
| Castings should be subject to verification that demonstrates conformity with the schedule drawing, e.g.:  a) wall thickness (including the non-machinable parts);  b) cracks, inclusions, bubbles and porosity. | |  |  |
| **A.11.2** | **Enclosure parts** | | |
| Enclosure parts should be subject to verification that demonstrates conformity with the schedule drawing, e.g.:  a) depths of bore holes and tap holes;  b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability;  c) insulating coatings and surface conditioning; material, layer thickness. | |  |  |
| **A.11.3** | **Gaskets** | | |
| Documented procedures should address the following:  a) the gaskets correspond to the quoted specification;  b) the sealing elements' effectiveness, e.g. by checking the sealing elements' correct fit.  If a gasket's correct fit becomes apparent only after assembly, the imprint could be visually examined, e.g. by use of adequate tools such as chalk. | |  |  |
| **A.11.4** | **Protection devices** | | |
| Protection devices should be subject to verification that demonstrates conformity with the schedule drawings. Wherever protection devices (e.g. thermal safety devices) are specified in the certificate, they should be verified according to type and placement. | |  |  |
| **A.11.5** | **Cemented and cast enclosure parts** | | |
| Documented procedures should address the following:  a) shelf life and storage of cement, potting compounds;  b) mixing;  c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);  d) application e.g. filling instructions, freedom from voids and temperature conditions;  e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period;  f) after curing, 100% visual inspection should be done on each assembly. | |  |  |
| **A.11.6** | **Ingress protection (IP)** | | |
| Documented procedures should ensure that the following is verified:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) application of cements including a visual inspection after curing. | |  |  |
| **A.11.7** | **Routine verifications and tests** | | |
| All tests should be documented. Typical tests include:  a) the visual inspection;  b) further verification and test requirements can result from the concepts of the dusts explosion protection standards. However, these can essentially be derived from the requirements for the types of protection listed so far. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.12** | **Ex op – Optical radiation covered by IEC 60079-28** | | |
| The following features should be verified for equipment containing source(s) of optical radiation. For components, this normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate:  a) optical source;  b) driver circuit;  c) Fibre optic connectors;  d) Fibre optic cable;  e) enclosure construction;  f) optical components, which have an impact on the safety relevant properties of the optical beam (e.g. lenses, filters, mirrors). | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.13** | **Gas detectors covered by IEC 60079-29** | | |
| The manufacturer should confirm the regular operation of the measuring function by performing the following checks on each gas detector manufactured:  a) input and output functions, e.g. operation of displays, LEDs, alarms and push buttons;  b) sensitivity of the sensor;  c) software version.  In addition, the following checks should be performed on a sample basis:  1) response time;  2) calibration curve;  3) response to other gases, if applicable;  4) long-term stability;  5) any other check that is considered necessary to confirm the measuring function is in compliance with the relevant standards (for example, effects of temperature or humidity on sensors); | |  |  |

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| **A.14** | **Ex h – Non-electrical equipment covered by ISO 80079-36** | | |
| **A.14.1** | **General** | | |
| The following safety aspects as specified in the technical documentation should be realized by systematic production techniques and/or verifications and tests based on written procedures.  For protection concepts based on types of protection "d", "p" and "t", the safety aspects laid down in A.3, A.6 and A.11 may also apply. | |  |  |
| **A.14.2** | **Non-metallic parts** | | |
| Non-metallic parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) material characteristics;  b) finish;  c) surface resistance;  d) surface area of non-conductive parts;  e) limitation of thickness;  f) measures for charge bonding (earthed frames). | |  |  |
| **A.14.3** | **Casing and external parts** | | |
| Casing and external parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) material of the casing and content of light metals;  b) protection of removable parts against unintentional or inadvertent removal;  c) materials used for cementing including a visual inspection after curing. | |  |  |
| **A.14.4** | **Earthing and equipotential bonding of conductive parts** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings:  a) earthing terminal;  b) effective connection of conductive parts;  c) bonding cables. | |  |  |
| **A.14.5** | **Light transmitting parts** | | |
| The following light transmitting parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) material;  b) integrity;  c) guards and protective covers. | |  |  |
| **A.14.6** | **Ingress protection (IP)** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) weld continuity;  b) fitting of gaskets and seals;  c) continuity of moulded grooves and tongues;  d) after curing, an inspection should be done on each cemented part. Depending on the nature and repeatability of the cementing process and the cemented part, this could be for example use statistical techniques | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.15** | **Non-electrical equipment protected by constructional safety “c”**  **covered by ISO 80079-37** | | |
| **A.15.1** | **General** | | |
| Additional to the safety aspects for non-electrical equipment defined in A.14 the following safety aspects are relevant. | |  |  |
| **A.15.2** | **Metal-based material** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) material name complies with the requirement;  b) material properties (composition with regard to corrosion, thermal conduction and mechanical sparks, mass fraction of aluminium, titanium, magnesium, zirconium, flammability);  c) cracks, inclusions, blow holes and porosity (either by a visual test or another suitable test method depending on exposure);  d) heat treatment (e.g. hardening, tempering);  e) dimensional accuracy including all parts without machining. | |  |  |
| **A.15.3** | **Machining** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) compliance with tolerances for shape, position, concentricity, quality of finish;  b) dimensional accuracy of functional surfaces (e.g. tolerances for diameters; especially for indicator unit pre-adjustment and correct polarity);  c) depth and configuration of cut-in to ensure the constructional intended stress concentration. | |  |  |
| **A.15.4** | **Cemented joints and potted assemblies** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) shelf-life and storage of adhesives and casting compounds;  b) mixing procedure;  c) surface treatment (degreasing or equivalent measures are usually required immediately before the potting-process to ensure proper adhesion);  d) curing process, which should include: curing time, any relevant environmental factors and all provisions made to ensure that the curing process will proceed without disturbance;  e) after curing, 100 % visual inspection should be done on each potted assembly. | |  |  |
| **A.15.5** | **Assembling** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) correct components and parts;  b) distances between moving parts or between fixed and moving parts;  c) equipotential bonding between subassemblies;  d) mechanical seals;  e) protective covers. | |  |  |
| **A.15.6** | **Routine tests** |  |  |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) sealing systems (fit, lubrication, initial tension, primary pressure);  b) dynamic vibrations (e.g. critical rotation speed, bearing at standstill or at transport);  c) functional test of the complete assembly (distance between rotor/stator modules, clamping, clearance, free room of motion). | |  |  |
| **A.15.7** | **Power transmission systems** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) conditions of the lubrication;  b) belt tension;  c) equipotential bonding (especially couplings, belt drives, chain drives, gears, shafts). | |  |  |
| **A.16** | **Non-electrical equipment protected by control of ignition sources “b”**  **covered by ISO 80079-37** | | |
| **A.16.1** | **General** | | |
| Additional to the safety aspects for non-electrical equipment defined in A.14 the following safety aspects are relevant. | |  |  |
| **A.16.2** | **Ignition protection system** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) selection of appropriate sensors, actuators and other relevant parts (e.g. temperature range);  b) indicating devices marked to indicate the maximum and minimum operating levels; | |  |  |
| **A.16.3** | **Assembling** | | |
| The following parts should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) installation of sensors and actuators (fail safe characteristics, separate power supply);  b) connection installation of sensors;  c) position of sensors;  d) correct interfacing. | |  |  |
| **A.16.4** | **Routine verifications and tests** | | |
| Typically, the following routine verifications and tests should be done at the manufacturers’ site. If the ignition protection system is intended to be assembled during installation at the users’ site, the instructions should give specific guidance how to carry out these tests.  The following tests should be performed in order to demonstrate conformity with the schedule drawings, e.g.:  a) tests before initial operation or specification of these tests in the instructions;  b) functioning;  c) accuracy;  d) response behavior;  e) fail-safe;  f) interlocking of settings. | |  |  |

| **Clause** | **Requirement** | **Documents or Comments** | **Verdict** |
| --- | --- | --- | --- |
| **A.17** | **Non-electrical equipment protected by liquid immersion “k” covered by**  **ISO 80079-37** | | |
| **A.17.1** | **General** | | |
| Additional to the safety aspects for non-electrical equipment defined in A.14 the following safety aspects are relevant. | |  |  |
| **A.17.2** | **Protective liquid** | | |
| The following features should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) type of liquid;  b) liquid level or flow rate or pressure (depending on the system). | |  |  |
| **A.17.3** | **Casing** | | |
| The following items should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) leak tightness of the protective liquid closed loop;  b) protections against unintentional or inadvertent of fastenings;  c) measures against protective liquid impurity. | |  |  |
| **A.17.4** | **Measuring or indicating devices** | | |
| The following features should be subject to verification that demonstrates conformity with the schedule drawings, e.g.:  a) dipstick;  b) marking of maximum/minimum criteria for the protective liquid level;  c) marking of maximum permissible angle of inclination. | |  |  |

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| **A.18** | **Flame arresters covered by ISO 16852** | | |
| Documented procedures should ensure that the following aspects are verified, if relevant:  a) gap width measurement on the enclosure, between cage and enclosure, on thread openings into the enclosure and between flame arrester and enclosure;  b) flow measurement;  c) leak test of housing;  d) pressure test of housing;  e) assurance of material properties;  f) tests of welded joints;  g) determination of limits of use;  h) measurement of the triangle´s height, dimension or of the porosity of the flame arrester element;  i) marking of the pipe connection facilities to be protected. | |  |  |

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| **Annex B** (informative) *May be deleted if not applicable* |
| **Verification criteria for elements with non-measurable paths used as an integral part of a Type of Protection** |

| **Clause** | **Requirement** | | **Verdict** |
| --- | --- | --- | --- |
| **B.1** | **Overview** | |  |
| Sintered material is used in many products, such as gas detectors and loudspeakers. When the certificate involves such components, then the design parameters for the component normally covers three factors:  a) maximum bubble test pore size;  b) minimum density; c) component construction: – for sintered metal and metal foam: material, diameter and thickness, – for pressed metal wire: material, wire diameter and mesh size, element thickness.  Therefore, the purpose of this annex is not to add any technical requirements but to provide manufacturers with guidance as to how they can demonstrate that the actual components comply with the design requirements as detailed in the certificate. | | |  |
| **B.2** | **Verification Guidance** | | |
| Three options are available:  a) the manufacturer conducts the verification examination and tests;  b) the manufacturer conducts a pre-contract and follow-up periodic documented assessment of the component external provider and accepts sinters with an External Provider's Declaration of Conformity;  c) the manufacturer accepts sinters with an External Provider's Declaration of Conformity from a component manufacturer, who has an acceptable quality management system with an appropriate scope.  NOTE: See 8.4 for control of external providers | | |  |
| **B.3** | **Tests** | |  |
| The tests for all verification options should be performed in accordance with the requirements of the certificate. Typical test requirements are given in ISO 4003 and ISO 2738.  The test may be conducted on a statistical basis if the sample size is not less than 5 % of the batch size. A single failure in the 5 % sample should result in another 5 % being tested; if a failure is detected in the second sample all sinters in the batch should be 100 % tested. Where tests to determine the maximum bubble test pore size and density are conducted on a  sample basis, then the results should be calculated to establish the standard deviation (*σ*) for the sample batch, where  σp is the maximum bubble test pore size standard deviation;  *σ*D is the density standard deviation.  The maximum bubble test pore size should not be exceeded, and the minimum density should remain equal to or greater than the value as stated in the certificate when 3 *σ* is considered.  Therefore, the mean value of the sample batch, plus 3 *σ*p (for pore size) and minus 3 *σ*D (for density) should not invalidate the requirements of the certificate. | | |  |
| **B.4** | **Test examples** | | |
| **B.4.1** | **General** | | |
|  | The following examples for sintered metal are provided for guidance: | | |
| **B.4.2** | **Example 1 (pore size)** | | |
| Maximum permitted bubble test pore size as detailed in the  • certificate = 150 μm  • mean value = 140 μm  • standard deviation (*σ*p) = 2 μm  Therefore, maximum value = 140 μm + (2 x 3) μm = 146 μm (PASS).  If standard deviation (*σ*p) = 5 μm, then maximum value = 140 μm + (5 x 3) μm = 155 μm (FAIL). | | | |
| **B.4.3** | **Example 2 (density)** | | |
|  | Minimum permitted density as detailed in the  • certificate = 5 gcm-3  • mean value = 5,3 gcm-3  • standard deviation (*σ*D) = 0,05 gcm-3  Therefore, minimum value = 5,3 gcm-3 – (0,05 x 3) gcm-3 = 5,15 gcm-3 (PASS).  If standard deviation (*σ*D) = 0,12, then minimum value = 5,3 gcm-3 – (0,12 x 3) gcm-3 = 4,94  gcm-3 (FAIL).  NOTE: In some cases, the sinter is formed directly in a solid housing.  To establish the density value, the following formula is used:    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. | | |
|  |  | **Documents reference and/or comments** | **Verdict** |
| **B.5** | **Purchase information** | | |
| The manufacturer should ensure that the purchase documents include the following:  • the component material specification detailed in the schedule drawings;  • the dimensional requirements;  • the maximum bubble test pore size and the standard called up in the schedule drawings e.g. ISO 4003;  • the minimum density and the standard called up in schedule drawings e.g. ISO 2738. | |  |  |
| **B.6** | **Pre-tested components** |  |  |
| Where the manufacturer does not conduct their own tests, the External Provider's Declaration of Conformity, and should also include the following:  • the manufactured batch size;  • the sample size taken to establish the maximum bubble test pore size and the minimum density;  • the number of components supplied;  • the calculated maximum bubble test pore size and  • minimum density, e.g. the mean values and standard deviation should be stated. | |  |  |
| **B.7** | **Measurement and monitoring** |  |  |
| Upon receipt of the components, the manufacturer should:  • check the External Provider's Declaration of Conformity against the requirements of Clause B.5;  • check the compatibility of the purchase order requirements with the External Provider's Declaration of Conformity (if not testing on site and giving special attention to the stated bubble test pore size and density data to ensure that when taking the stated tolerance into account the specification is not exceeded;  • conduct the tests (if testing on site);  • conduct a statistical check on the overall size of the component e.g. diameter and thickness. | |  |  |

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*NOTE: The following pages contain the Certificate list and the Audit non-conformities and observations. These pages are normally created as two separate documents and are attached to the end of the audit report to minimize cut and paste errors.*

*Depending on the format of the documents added page orientation may need to be changed from portrait to Landscape. In Word 365 and other recent Word versions this may be done in the following manner:*

*Select* ***layout*** *from the top menu and in the* ***page setup*** *pane select the* ***arrow on the bottom right hand side.*** *In the new pane select* ***Orientation, and*** *either* ***portrait*** *or* ***landscape*** *and then under* ***preview*** *select* ***this page forward.***

**4. List of certificates relating to IECEx QAR** *No mandated format required*

|  |  |
| --- | --- |
| Notification No.: |  |
| IECEx QAR No.: |  |
| Manufacturer.: |  |
| Project No.: |  |

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| --- | --- |
| Date: | Sign: |











**5.**