BS EN ISO/IEC 80079-34:2020

BSI Standards Publication

Explosive atmospheres

Part 34: Application of quality systems for ex product manufacture

bsi.

National foreword

This British Standard is the UK implementation of EN ISO/IEC 80079-34:2020. It is identical to ISO/IEC 80079-34:2018. It supersedes BS EN ISO/IEC 80079-34:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EXL/23, Explosion and fire precautions in industrial and chemical plant.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPÄISCHE NORM

EN ISO/IEC 80079-34

March 2020

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Supersedes EN ISO/IEC 80079-34:2011

English Version

Explosive atmospheres - Part 34: Application of quality systems for ex product manufacture (ISO/IEC 80079-34:2018)

Atmosphères explosives - Partie 34: Application de systèmes de management de la qualité pour la fabrication des produits Ex (ISO/CEI 80079-34:2018)

Explosionsgefährdete Bereiche - Teil 34: Anwendung von Qualitätsmanagementsystemen für die Herstellung von Ex-Produkten (ISO/IEC 80079-34:2018)

This European Standard was approved by CEN on 29 December 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

The text of ISO/IEC 80079-34:2018 has been prepared by Technical Committee ISO/TMB "Technical Management Board - groups" of the International Organization for Standardization (ISO) and has been taken over as EN ISO/IEC 80079-34:2020 by Technical Committee CEN/TC 305 "Potentially explosive atmospheres - Explosion prevention and protection" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by March 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO/IEC 80079-34:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative Annex ZA, ZB, ZC and ZD, which are an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 80079-34:2018 has been approved by CEN as EN ISO/IEC 80079-34:2020 without any modification.

Annex ZA
(normative)

Normative references to international publications and the corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050-426	—	International Electrotechnical Vocabulary — Part 426: Equipment for explosive atmospheres	—	—
IEC 60079-0	—	Explosive atmospheres — Part 0: Equipment — General requirements	EN IEC 60079-0	2018
ISO 9000	2015	Quality management systems — Fundamentals and vocabulary	EN ISO 9000	2015

Annex ZB
(informative)

Information relevant to equipment and protective systems according to standards harmonized under Directive 2014/34/EU

ZB.1 Introduction

The requirements laid down in the Directive and the standards harmonized under the Directive are the basis for the quality assurance of the production process and the assessment of the quality system as well. The quality system must ensure that the products resulting from the regular production process comply with the types tested in the EU-type examination and with the applicable requirements of the Directive.

This annex draws attention to a number of standards harmonized under the Directive which can be used to gain detailed information on specific requirements. These references might be useful for manufacturers to check whether the safety-relevant aspects are considered in the quality system and covered by adequate procedures (see 8). They can also be used for internal or external quality audits (see 9.1 and 9.2).

In quality system assessments according to Annexes IV and VII of Directive 2014/34/EU performed by a Notified Body the auditing team must have knowledge with regard to the product specific requirements according to the Directive.

NOTE The following examples do not cover all protection concepts and product specific requirements but give some advice and will be supplemented to in the next edition.

ZB.2 Non-electrical equipment (EN 13463-1)

Safety aspects are covered by clause A.14 for non-electrical equipment (EN ISO 80079-36).

ZB.3 Protection by flow restricting enclosure "fr" (EN 13463-2)

Safety aspects are covered by the general clause for non-electrical equipment (EN ISO 80079-36).

ZB.4 Protection by flameproof enclosure "d" (EN 13463-3)

The same safety aspects as for electrical equipment apply (see A.3; for aspects of dust ignition protection, see also A.10).

ZB.5 Protection by constructional safety "c" (EN 13463-5)

Safety aspects are covered by clause A.15 for non-electrical equipment (EN ISO 80079-37).

ZB.6 Protection by control of ignition sources "b" (EN 13463-6)

Safety aspects are covered by clause A.16 for non-electrical equipment (EN ISO 80079-37).

ZB.7 Protection by pressurised enclosures "p" (EN 13463-7)

The same safety aspects as for electrical equipment apply (A.6), according to A.14.1.

ZB.8 Protection by liquid immersion "k" (EN 13463-8)

Safety aspects are covered by clause A.17 for non-electrical equipment (EN ISO 80079-37).

ZB.9 Fans (EN 14986)

ZB.9.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

ZB.9.2 Material

— Selection of specified materials; material name complies with the requirement;

— material properties (composition with regard to corrosion, thermal conduction and mechanical sparks, mass fraction of aluminium, titanium, magnesium, zirconium, flammability);

— cracks, inclusions, blow holes and porosity (either by a visual test or another suitable test method depending on exposure);

— heat treatment (e.g. hardening, tempering);

— dimensional accuracy including all parts without machining.

ZB.9.3 Assembled equipment and protective systems

— Adaption of suitable electrical equipment (explosion group, temperature class, equipment category);

— adaption of specified protective systems for fans of category 1G.

ZB.9.4 Routine tests

— Sealing systems (fit, lubrication, initial tension, primary pressure);

— dynamic vibrations (e.g. critical rotation speed, bearing at standstill or at transport);

— functional test of the complete assembly (distance between rotor/stator modules, clamping, clearance, free room of motion);

— excess rotation speed;

— thickness of linings;

— impeller-shaft attachment (avoidance of drift, joint is secured against loosening);

— mounting of autonomous protective systems, if applicable;

— functional test of the temperature monitoring devices in the flame arresters, if applicable;

— pressure test for fans of category 1G, if applicable.

ZB.10 Petrol dispensers (EN 13617-1)

ZB.10.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

ZB.10.2 Electrical installation

— Type of cable;

— installation of cable;

— correct wiring;

— connection technique;

— torque of screwed connections (traceability).

ZB.10.3 Information for safe operation

— Availability of operating instructions;

— marking on the type label (technical data, type of protection, etc.);

— passing on of warning notes;

— maintenance instructions.

ZB.10.4 Assembly groups

— Drives or electrical equipment;

— subassemblies (gears, couplings, belts);

— components;

— safety-relevant verifications for the interconnection of apparatus, subassemblies and components;

— protective systems within the gas recirculation system.

ZB.10.5 Assembling

— Correct components and parts;

— minimum distances of moving parts (rotor/stator);

— measures performed for equipotential bonding (to ground, between subassemblies);

— protective covers.

ZB.10.6 Monitoring equipment

— Installation of sensors and actuators (fail safe characteristics, separate power supply);

— installation of sensors (position, correct interfacing, prevention of lag elements);

— tests during maintenance (according to operating instructions);

— functional tests and precision control;

— insulation of cables.

For additional information, see also ZB.6.

ZB.10.7 Electrostatic discharge capacity

— Materials (electrostatic discharge capacity resp. surface resistance of non-metallic parts, belts, tubes, etc.);

— limitation of the surface area for the corresponding explosion group;

— thickness of the material for the corresponding explosion group.

ZB.10.8 Routine tests

— Pressure test;

— deactivation/activation of the controlling system before release;

— insulation resistance;

— functional test.

ZB.11 Electrostatic spraying equipment

ZB.11.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

Electrostatic spraying equipment according to the following harmonized standards:

— EN 50050-1,

— EN 50050-2,

— EN 50050-3,

— EN 50176,

— EN 50177,

— EN 50223.

NOTE This section ZB.11 may also be used for electrostatic spraying equipment in accordance with EN 50059 and EN 50348 harmonized under directive 2006/42/EC.

ZB.11.2 Electrical assembly

The characteristics of the following parts including control devices and accessories should be tested with respect to the application in electrostatic spraying equipment; this means normally that the marking on the component parts or the packaging is verified where appropriate statistical methods may be applied as necessary:

— selection of the high voltage transformer (type, manufacturer, insulation, voltage);

— equipotential bonding and grounding system for the spraying equipment and control device;

— number of stages of the cascade and turn ratio of the high-voltage transformer and the capacity of the cascade;

— assembling, type and value of each current limiting resistor, diode, Zener diode, capacitor or any other safety-relevant component (e.g. hardware-watch-dog);

— manual or automatic assembly of printed circuit boards;

— fixing and soldering of transformer, diodes, capacitors of the cascades;

— date of expiry and storage of adhesives and casting compounds;

— mixing procedures (e.g. pressure, temperature, time characteristics);

— surface treatment (degreasing or equivalent measures are usually required immediately before the potting process to ensure proper adhesion);

— processing, e.g. filling instructions, void-free potting, temperature conditions;

— curing process including: curing time, all relevant environmental factors, provisions made to ensure that the curing process will proceed (e.g. mains power failure detection);

— selection and installation of the display;

— selection and installation of power supply and line filter of the control device;

— selection of cable (high voltage, low voltage);

— length, type and electric strength of the cable including grounding and screening if applicable;

— connection techniques and fixing method of cables between controlling device and spraying equipment.

NOTE 1 For printed circuit boards, the manufacturer should provide a list of safety-relevant electronic components (e.g. resistors, Zener diodes) used. 100 % of the listed components should be tested. This can be done by visual test or for SMD-components by assuring correct charging of the component insertion automat and by visual test of correct positioning or by automated test equipment (ATE) provided that each individual safety-relevant electronic component is considered and that a visual inspection is performed to check the type code and direction of components.

NOTE 2 If the SMD-insertion automat selects the correct component carrier on the basis of a value measurement of the component, this measuring function should be calibrated.

ZB.11.3 Mechanical assembly

— Materials of spraying equipment and control devices should be inspected for stability, cracks, inclusions, bubbling and porosity;

— dimensional accuracy, evenness, surface roughness, fitting accuracy, depth of bushings, flanges and threads of the nozzles of spraying equipment and accessories (extensions, angles, etc.);

— dimensional accuracy and position accuracy of the electrode(s) with respect to the nozzle;

— uniformity of joints;

— gaps and dimensions between the bell and the stator;

— balancing of rotating parts;

— mounting of spraying equipment and control unit;

— torque of the screwed connections if safety relevant;

— IP protection (see ZB.2.6 for details);

— continuous weld seams;

— mounting of annular and flat gaskets;

— continuity of moulded tongues and grooves;

— application of adhesives.

ZB.11.4 Tests

— I_{max} and $I_{short\text{-}circuit}$ of the spraying equipment with and without associated accessories;

— U_{max} of the spraying equipment with and without associated accessories;

— open-circuit monitoring between spraying equipment and control device, if applicable;

— response of the safety facilities in case of simulated malfunction, if applicable.

Where spraying equipment and associated accessories are intended to be combined user-defined, criteria of acceptance for the tests should consider the worst case.

ZB.12 Protective systems

ZB.12.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

— the properties of dissipative plastics are proven by the manufacturer by dint of a material certificate and examined at least through routine tests (e.g. in accordance with HD 429, neglecting the climate);

— layer thicknesses of non-conductive coatings are examined by routine tests at a sufficient amount of adequate measuring points;

— packing boxes without a temperature control are tightened with a predefined torque;

— every examination is documented.

NOTE Routine tests can be a requirement in certificates or be required by the auditing notified body.

ZB.12.2 Explosion resistant equipment (EN 14460)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

— pressure shock resistant devices are manufactured according to EN 13445-4, if designed according to EN 13445-3;

— pressure test for each cast part is carried out;

— pressure test is carried out according to EN 14460:2018, Table 1, lasting at least 3 min (routine test); if this is impossible due to technical or safety-relevant reasons, there must be material;

— certificates according to EN 10204, or non-destructive tests of the weld seams (at least supersonic) as well as a dimensions comparison must be carried through;

— weld seams are tested considering the weld seam factor;

— material certificates according to EN 13445-2 are available for the pressure-loaded main parts;

— correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);

— correct assembling.

For further aspects regarding pressure resistance, see A.3 of this standard.

ZB.12.3 Explosion venting devices (EN 14797)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

— the static activation overpressure (see EN 14491);

— leak test, if applicable;

— material certificates for the explosion venting devices (e.g. for the plates processed, rubber clamp profiles);

— stability tests are required for explosion venting valves as well as for the baskets for flameless devices;

— dimensional accuracy (e.g. gaps, predetermined breaking points of the bursting discs, wall thicknesses of the processed plates;

— gaskets;

— mass of the insulation, if applicable;

— heating installations on the moveable elements, if applicable;

— weld seams are tested considering the weld seam factor;

— correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);

— correct assembling;

— number of tests according Table 2 (EN 14797) for non-reusable venting devices.

ZB.12.4 Explosion isolation systems (EN 15089)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

— closing time of the system (sum of the activation time of sensor, activation time of isolation device and closing time of the isolation device) are tested in routine tests (see EN 15089);

— operating values of all sensors (e.g. pressure, temperature, light);

— correct implementation of required safety functions (e.g. control and indicating equipment settings);

— dimensional accuracy, particularly of the sealing elements;

— dimensions of enclosure, rotors, blades, discs and gaskets;

— gaps between rotors and enclosures of rotary valves;

— mechanical integrity for the maximum explosion overpressure according to the intended use;

— closing force of passive explosion protection valves;

— installations in the interior necessary for safe operation (e.g. rotors of rotary valves, blades, discs, sleeves);

— proof of material (e.g. type of steel, suppressant);

— welding procedure, if applicable;

— correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);

— correct assembling;

— maintenance when the wear limit is reached (in case of rotary valves);

— use of the correct extinguishing powder and filling quantity (in case of extinguishing barriers);

— information on maintenance.

ZB.12.5 Flameless explosion venting devices (EN 16009)

A flameless venting device is a combination of a venting device with flame extinguishing elements.

The following safety aspects as specified in the technical file should be realized by systematic production techniques and/or verifications and tests on the basis of written procedures:

— all aspects of ZB.12.3 "Explosion venting devices" (EN 14797);

— material certificates of the flame extinguishing elements;

— dimensional accuracy of the flame extinguishing elements (e.g. gaps, layer thickness);

— gaskets;

— pressure resistance of the mechanical mounting / casing of the flame extinguishing elements;

— correct assembling;

— information on maintenance;

— correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary).

ZB.12.6 Explosion diverters (EN 16020)

An explosion diverter is a mechanical explosion resistant device (typically installed in a pipe) which is equipped with an explosion venting device.

The following safety aspects as specified in the technical file should be realized by systematic production techniques and/or verifications and tests on the basis of written procedures:

— All aspects of ZB.12.2 "Explosion resistant equipment" (EN 14460);

— in case

  a) the explosion venting device is purchased from other manufacturers:

  — by control of incoming goods it is safeguarded that the installation of the venting device is permitted on explosion diverters according to the intended use of the venting device

  — Correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary).

b) the venting device is produced by the manufacturer of the explosion diverter itself:

— all aspects of ZB.12.3 "Explosion venting devices" (EN 14797);

— the expected maximum explosion pressure in pipes at the maximum permissible installation distance is taken into account (according to the intended use).

— correct assembling;

— information on maintenance;

— correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary).

ZB.12.7 Explosion isolation flap valves (EN 16447)

The following safety aspects as specified in the technical file should be realized by systematic production techniques and/or verifications and tests on the basis of written procedures:

— material certificates;

— pressure resistance;

— functional safety of the locking mechanism;

— correct assembling;

— mechanical integrity for the maximum explosion overpressure according to the intended use;

— information on maximum and minimum installation distance;

— information on maintenance;

— correct marking and warning labels (e.g. maximum dust load of the process flow, maximum operational pressure, maximum operational temperature, if necessary).

Annex ZC
(informative)

Significant changes between these European Annexes and the European Annexes of EN ISO/IEC 80079-34:2011

This document will supersede EN ISO/IEC 80079-34:2011.

Table ZC.1 — Significant changes between these European Annexes and the European Annexes of EN ISO/IEC 80079-34:2011

		Type		
Significant changes	**Clause**	**Minor and editorial changes**	**Extension**	**Major technical changes**
Normative references were updated according to ISO/IEC 80079-34	ZA	X		
Changed references; shift of technical information to Annex A; editorial improvements	ZB	X		
Added a new subsection related to EN 16009	ZB.12.5		X	
Added a new subsection related to EN 16020	ZB.12.6		X	
Added a new subsection related to EN 16447	ZB.12.7		X	

NOTE 1 The technical changes referred to include the significant technical changes from the revised EN but this is not an exhaustive list of all modifications from the previous version.

Explanations

A) Definitions

Minor and editorial changes clarification
decrease of technical requirements
minor technical change
editorial corrections

Changes in a standard classified as 'Minor and editorial changes' refer to changes regarding the previous standard, which modify requirements in an editorial or a minor technical way. In addition, changes of the wording to clarify technical requirements without any technical change are classified as 'Minor and editorial changes'.

A reduction in level of existing requirement is also classified as 'Minor and editorial changes'.

Extension addition of technical options

Changes in a standard classified as 'extension' refers to changes regarding the previous standard, which add new or modify existing technical requirements, in a way that new options are given, but without

increasing requirements for equipment that was fully compliant with the previous standard. Therefore these 'extensions' will not have to be considered for products in conformity with the preceding edition.

Major technical changes addition of technical requirements
increase of technical requirements

Changes in a standard classified as 'Major technical change' refer to changes regarding the previous standard that add new technical requirements or increase the level of existing technical requirements, in a way that a product in conformity with the preceding standard will not always be able to fulfil the requirements given in the new standard. 'Major technical changes' have to be considered for products in conformity with the preceding edition. For every change classified as 'Major technical change', additional information is provided in clause B) of Annex ZC.

NOTE 2 These changes represent current technological knowledge[1)]. However, these changes should not normally have an influence on equipment already placed on the market.

B) Information about the background of 'Major technical changes'

None

1) See also ATEX Guidelines (2017), § 140 and Annex ZD.

Annex ZD
(informative)

Relationship between this European Standard and the essential requirements of 2014/34/EU [2014 OJ L96] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/BC/CEN/92/46 to provide one voluntary means of conforming to essential requirements of 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZD.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZD.1 — Correspondence between this European Standard and Annex II of Directive 2014/34/EU [2014 OJ L96]

Essential Requirements of 2014/34/EU	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1, 2, 3	All clauses	Construction and quality aspects are mainly addressed through contents of annex IV and VII of Directive 2014/34/EU (rather than annex II)

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Bibliography

Add the following references:

ATEX 2014/34/EU *Guidelines* (2nd Edition – 2017)

EN 1834 (all parts), *Reciprocating internal combustion engines — Safety requirements for design and construction of engines for use in potentially explosive atmospheres*

EN 10204, *Metallic products — Types of inspection documents*

EN 13445-2, *Unfired pressure vessels — Part 2: Materials*

EN 13445-3, *Unfired pressure vessels — Part 3: Design*

EN 13445-4, *Unfired pressure vessels — Part 4: Fabrication*

EN 13463-2[2)], *Non-electrical equipment for use in potentially explosive atmospheres — Part 2: Protection by flow restricting enclosure 'fr'*

EN 13463-3[3)], *Non-electrical equipment for use in potentially explosive atmospheres — Part 3: Protection by flameproof enclosure 'd'*

prEN 13463-7[4)], *Non-electrical equipment for use in potentially explosive atmospheres — Part 7: Protection by pressurisation 'p'*

EN 13617-1, *Petrol filling stations — Part 1: Safety requirements for construction and performance of metering pumps, dispensers and remote pumping units*

EN 14460:2018, *Explosion resistant equipment*

EN 14491, *Dust explosion venting protective systems*

EN 14678-1, *LPG equipment and accessories — Construction and performance of LPG equipment for automotive filling stations — Part 1: Dispensers*

EN 14797, *Explosion venting devices*

EN 14986, *Design of fans working in potentially explosive atmospheres*

EN 15089, *Explosion isolation systems*

EN 16009, *Flameless explosion venting devices*

EN 16020, *Explosion diverters*

EN 16447, *Explosion isolation flap valves*

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2) This standard has been withdrawn, but there can be products on the market in accordance with this standard.

3) This standard has been withdrawn, but there can be products on the market in accordance with this standard.

4) This draft standard is now abandoned.

EN 24003, *Permeable sintered metal materials — Determination of bubble test pore size*

EN 50050 (all parts), *Electrical apparatus for potentially explosive atmospheres — Electrostatic hand-held spraying equipment*

EN 50059, *Electrostatic hand-held spraying equipment - Safety requirements - Hand-held spraying equipment for non-ignitable coating materials*

EN 50176, *Stationary electrostatic application equipment for ignitable liquid coating material - Safety requirements*

EN 50177, *Stationary electrostatic application equipment for ignitable coating powders - Safety requirements*

EN 50223, *Stationary electrostatic application equipment for ignitable flock material - Safety requirements*

EN 50348, *Stationary electrostatic application equipment for non-ignitable liquid coating material - Safety requirements*

EN 50495, *Safety devices required for the safe functioning of equipment with respect to explosion risks*

EN 60079 (all parts), *Explosive atmospheres*

EN ISO 2738, *Sintered metal materials, excluding hardmetals — Permeable sintered metal materials — Determination of density, oil content and open porosity*

EN ISO 16852, *Flame arresters — Performance requirements, test methods and limits for use*

EN ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

EN ISO/IEC 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

EN ISO/IEC 17050-2, *Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation*

EN ISO 19011, *Guidelines for auditing management systems*

EN ISO 80079-36, *Explosive atmospheres — Part 36: Non-electrical equipment for explosive atmospheres — Basic method and requirements*

EN ISO 80079-37, *Explosive atmospheres — Part 37: Non-electrical equipment for explosive atmospheres — Non-electrical type of protection constructional safety "c", control of ignition sources "b", liquid immersion "k"*

EN ISO/IEC 80079-38, *Explosive atmospheres — Part 38: Equipment and components in explosive atmospheres in underground mines*

HD 429, *Methods of test for volume resistivity and surface resistivity of solid electrical insulating materials (IEC 60093)*

ISO/IEC 80079-34

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Explosive atmospheres –
Part 34: Application of quality management systems for Ex Product manufacture

Atmosphères explosives –
Partie 34: Application de systèmes de management de la qualité pour la fabrication des produits Ex

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EXPLOSIVE ATMOSPHERES –

Part 34: Application of quality management systems for Ex Product manufacture

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard ISO/IEC 80079-34 has been prepared by subcommittee 31M: Non-electrical equipment and protective systems for explosive atmospheres of IEC technical committee 31: Equipment for explosive atmospheres.

This second edition cancels and replaces the first edition, published in 2011, and constitutes a full technical revision.

The significant changes with respect to the previous edition should be considered as minor technical revisions. However, the clause numbering in regard to the previous edition has changed in order to be in line with ISO 9001:2015. The normal "Table of Significant Changes" has not been included for this reason.

This publication is published as a double logo standard.

This standard should be read in conjunction with ISO 9001:2015.

In order to help the reader, the text of the applicable sections of ISO 9001:2015 is reproduced in a rectangular box. Where clauses are referenced within a rectangular box these refer to ISO 9001:2015.

The text of this International standard is based on the following documents:

FDIS	Report on voting
31M/130/FDIS	31M/135/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 60079 series, under the general title *Explosive atmospheres*, as well as the ISO/IEC 80079 series, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This part of ISO/IEC 80079 specifies requirements for a quality management system that can be used by an organization for the manufacture of Ex Products.

It can also be used by third parties including certification bodies, to assess the organization's ability to meet conformity assessments system requirements and/or regulatory requirements.

The application of this document is intended to cover both electrical and non-electrical equipment, protective systems, safety devices, Ex Components and their combinations. The detailed content (e.g. annexes) is currently focused on the established documents.

Quality requirements are an integral part of most certification schemes and as such this document has been prepared with the IECEx system requirements in mind, is intended to support ATEX Directive requirements for quality management system and can be applied in other national or regional certification schemes that relate to the manufacture of Ex Products.

In Annex D there is a correlation matrix regarding ISO/IEC 80079-34:2011 to ISO/IEC 80079-34:2018.

EXPLOSIVE ATMOSPHERES –

Part 34: Application of quality management systems for Ex Product manufacture

1 Scope

This document specifies particular requirements and information for establishing and maintaining a quality management system to manufacture Ex Products in accordance with the certificates. While it does not preclude the use of other quality management systems that are compatible with the objectives of ISO 9001:2015 and which provide equivalent results, the minimum requirements are given in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-426, *International Electrotechnical Vocabulary – Part 426: Equipment for explosive atmospheres*

IEC 60079-0, *Explosive atmospheres – Part 0: Equipment – General requirements*

ISO 9000, *Quality management systems – Fundamentals and vocabulary*

ISO 9001:2015, *Quality management systems – Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-426, IEC 60079-0, ISO 9000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
certificate
document that conveys the assurance of the conformity of a product, process, system, person, or organization with specified requirements

Note 1 to entry: This is equivalent to the term “certificate” defined in IEC 60079-0.

Note 2 to entry: The certificate is either the supplier’s declaration of conformity or the purchaser’s recognition of conformity or certification (as a result of action by a third party) as defined in ISO/IEC 17000.

3.2
manufacturer
organization, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

Note 1 to entry: The term "manufacturer" is used instead of "organization" as used in ISO 9001:2015. For the purposes of this document they are interchangeable.

3.3
contract
requirements forming an agreement between different parties and transmitted by any appropriate means

3.4
customer complaint
reported, written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the certificate

3.5
Ex Product
Ex Equipment, protective system, safety device, Ex Component and their combination, as well as software and services

3.6
protective system
device other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion

Note 1 to entry: Protective systems can be integrated into equipment or separately released for use as autonomous systems.

3.7
safety device
device intended for use inside or outside explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion

3.8
schedule drawing
drawing or document listed in the certificate or test report

3.9
related drawing
drawing or document not listed in the certificate but linked to the schedule drawing, and used for example, for detailed manufacture or purchase of component parts

3.10
technical documentation
documentation that enables the conformity of the product with the requirements of the standard(s) to be assessed

Note 1 to entry: This includes schedule drawings

Note 2 to entry: It covers the design, manufacture and operation of the product and can contain:

– a general description;

– design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

– descriptions and explanations necessary for the understanding of drawings and layouts and the operation of the product;

– a list of the standards referred to in the certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the standards;

– results of design calculations made, examinations carried out, risk assessment etc.;

– test reports.

Note 3 to entry: For Non-electrical equipment, this includes the “Formal Ignition hazard identification and assessment” referred to in ISO 80079-36

3.11
manufacturer’s documentation
documents required by a manufacturer but not subject to assessment by body responsible for verification when making an application for a test report or a certificate

Note 1 to entry: For example, manufacturing instructions, related drawings, data sheets and sales literature.

Note 2 to entry: The manufacturer’s documentation can be either in paper form or electronic form.

3.12
body responsible for verification
body which conducts documentation review and periodical audit as appropriate

Note 1 to entry: The body can be a manufacturer (first party), purchaser (second party), or a Certification body (third party).

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

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

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.2 of ISO 9001:2015 applies.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.3 of ISO 9001:2015 applies.

4.4 Quality management system and its processes

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) assign the responsibilities and authorities for these processes;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

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 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c) ensuring the integration of the quality management system requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the quality management system are available;

f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

g) ensuring that the quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.1 of ISO 9001:2015 applies.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

5.1.2 of ISO 9001:2015 applies.

5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

5.2.1 of ISO 9001:2015 applies.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.2.2 of ISO 9001:2015 applies.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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 Products 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 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization’s or its customers’ needs.

6.1 of ISO 9001:2015 applies.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

6.2 of ISO 9001:2015 applies.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

a) the purpose of the changes and their potential consequences;
b) the integrity of the quality management system;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

6.3 of ISO 9001:2015 applies.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1.1 of ISO 9001:2015 applies.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.2 of ISO 9001:2015 applies.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.3 of ISO 9001:2015 applies.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.4 of ISO 9001:2015 applies.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

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 the 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

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.1.6 of ISO 9001:2015 applies.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

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

The organization shall ensure that persons doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d) the implications of not conforming with the quality management system requirements.

7.3 of ISO 9001:2015 applies.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

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, non-conforming products placed on the market, etc.

NOTE 2 External communication includes communication with clients, certification bodies, providers, economic operators (authorised representatives, importers, distributors, external providers …), authorities etc.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

– the size of organization and its type of activities, processes, products and services;

– the complexity of processes and their interactions;

– the competence of persons.

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

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.2 of ISO 9001:2015 applies.

7.5.3 Control of documented Information

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the 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 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

   1) the processes;

   2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned;

   2) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

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 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.1 of ISO 9001:2015 applies.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:
   1) any applicable statutory and regulatory requirements;
   2) those considered necessary by the organization;
b) the organization can meet the claims for the products and services it offers.

8.2.2 of ISO 9001:2015 applies.

8.2.3 Review of the requirements for products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by the organization;
d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;
b) on any new requirements for the 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

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

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 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision 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

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.2 of ISO 9001:2015 is not within the scope of this document.

8.3.3 Design and development Inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;

b) information derived from previous similar design and development activities;

c) statutory and regulatory requirements;

d) standards or codes of practice that the organization has committed to implement;

e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on 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

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.4 of ISO 9001: 2015 is not within the scope of this document.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on 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

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

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 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

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

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

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, non-metallic 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

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

   1) products and services;

   2) methods, processes and equipment;

   3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

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 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:
   1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
   2) the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities.

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

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable 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

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

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

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.4 of ISO 9001:2015 applies.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.5 of ISO 9001:2015 applies.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

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

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

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

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

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 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

9.1.1 of ISO 9001:2015 applies.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.2 of ISO 9001:2015 applies.

9.1.3 Analysis and evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.1.3 of ISO 9001:2015 applies.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:
   1) the organization's own requirements for its quality management system;
   2) the requirements of this International Standard;
b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) take appropriate correction and corrective actions without undue delay;
f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

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 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

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

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

   1) customer satisfaction and feedback from relevant interested parties;

   2) the extent to which quality objectives have been met;

   3) process performance and conformity of products and services;

   4) nonconformities and corrective actions;

   5) monitoring and measurement results;

   6) audit results;

   7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.2 of ISO 9001: 2015 applies.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

9.3.3 of ISO 9001:2015 applies.

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.1 of ISO 9001:2015 applies.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.2 of ISO 9001:2015 applies.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

10.3 of ISO 9001:2015 applies.

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.

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.

The test facility should have the capacity to maintain the required pressure during the test period. Leakage from flamepaths can be reduced by the use of gaskets or 'O' rings.

The pressure gauge should be calibrated, of suitable resolution and range, located such that it does not invalidate the test (e.g. due to pressure drop down pipelines).

The method of test should enable any leakage to be monitored during the test period.

The verification of the routine overpressure test should include verification of the product for visible damage or deformation, e.g. flange flamepaths are still within the dimensions shown in the Schedule Drawings.

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.

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 isolator	type, isolation, voltage”
Semiconductors: – Diodes – Zener diodes – Transistors – Integrated circuits – Thyristors	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, 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.

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.

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.

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.

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).

A.9 Ex q – Powder filling covered by IEC 60079-5

A.9.1 Material control

The material should be of defined size and type.

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.

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.

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.

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).

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);

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.

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 units 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;

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.

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.

Annex B
(informative)

Verification criteria for elements with non-measurable paths used as an integral part of a Type of Protection

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,

i.e. σ_p 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:

$$\rho = \frac{M_1 \times \rho W}{M_2 - M_3}$$

substitute as follows:

$$\rho = \frac{(m_3 - m_1) \times \rho W}{(m_4 - m_1) - (m_5 - m_2)}$$

where

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.

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.

Annex C
(informative)

External Provider's Declaration of Conformity

C.1 External Provider's Declaration of Conformity

The manufacturer should ensure that externally provided processes, products and services do not adversely affect the manufacturer’s ability to consistently deliver conforming products and services to its customers. This may be accomplished by requesting an “External Provider's Declaration of Conformity” which is intended to assure the compliance of the externally provided processes, products and services.

As applicable, the External Provider's Declaration of Conformity should contain the following elements:

a) unique identification of the External Provider's Declaration of Conformity;

b) the name and contact address of the issuer of the External Provider's Declaration of Conformity;

c) the identification of the object of the External Provider's Declaration of Conformity and any linking information:

   1) Product description or description of a process;

   2) Serial numbers, batch or lot identification, or an alternate means of traceability;

   3) Manufacturer’s drawing or document number with revision status;

   4) External provider’s drawing or document number with revision status (if different from manufacturer’s drawing);

   5) Provider's work order number, internal tracking reference, or batch number, if applicable;

   6) Purchase order number;

   7) Quantity of processes, products and services conforming to the declaration;

   8) Reference to documentation from the External Provider outlining in detail all critical process parameters for the manufacturing of the provided part(s). For example, for a casting process, the temperatures, pressures, heating/cooling times etc.);

   9) A recapitulation of all special processes or inspections required in organizations purchase order the list of special requirements. This may include a complete and clear list of standards or other specified requirements, as well as the selected options, if any.

d) a statement confirming that no part of the External Provider's production process has been subcontracted to third parties without the written consent of the Manufacturer;

e) a statement of conformity in the following format; We (issuer name) do declare that the information provided in this “External Provider's Declaration of Conformity” is accurate and confirm that the processes, products and services supplied by (issuer name) comply in all respects with the Purchase order requirements;

f) the date and place of issue of the External Provider's Declaration of Conformity;

g) the signature (or equivalent sign of validation), name and function of the authorized person(s) acting on behalf of the issuer;

h) any limitation on the validity of the External Provider's Declaration of Conformity.

NOTE 1 This annex is based on ISO/IEC 17050-1

NOTE 2 The term “External Provider's Declaration of Conformity” is used in this standard to align with ISO 9001:2015. An “External Provider's Declaration of Conformity” in accordance with this Annex is equivalent to a Suppliers Declaration of Conformity in accordance ISO/IEC 17050-1.

C.2 Additional Supporting information

Additional supporting information may be provided to relate the External Provider's Declaration of Conformity to the conformity assessment results on which it is based, for example:

a) the name and address of any conformity assessment body involved (e.g. testing or calibration laboratory, inspection body, certification body);

b) reference to relevant conformity assessment reports, and the date of the reports;

c) reference to any management systems involved;

d) reference to the accreditation documents of conformity assessment bodies involved where the scope of accreditation is relevant to the External Provider's Declaration of Conformity;

e) reference to the existence of associated supporting documentation;

f) additional information regarding certificates, registrations or marks that have been obtained;

g) other activities or programs of the conformity assessment body (e.g. membership in an agreement group).

References in the documentation to conformity assessment results should not misrepresent their applicability nor mislead the recipient of the External Provider's Declaration of Conformity.

C.3 Responsibility of the Organization

Receipt or acceptance of an External Provider's Declaration of Conformity does not absolve the manufacturer from responsibility to ensure conformity. The organization responsible for compliance should verify that all critical dimensions and requirements are in accordance with the technical documentation. Example of measures that may need to be considered are;

a) Confirmation by either 100 % inspection or by an appropriate statistical basis (if allowed per the relevant Ex-standard) that all critical dimensions and requirements comply with the technical documentation.

b) Review of the Declaration(s) of Conformity from the material external provider within the supply chain that may impact the material characteristics; as applicable; to demonstrate that the material used in the production of the Ex Products is in accordance with schedule drawings.

c) Review of the manufacturer’s confirmation that the material maintains the particular material property of concern; e.g. flammability, CTI, RTI, or UV resistance, chemical composition, physical properties.

d) Review of the manufacturer’s process and data for the validation of material characteristics.

e) Confirmation that equipment testing necessary to confirm that 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.

f) Confirmation that the External Provider's Declaration of Conformity conforms to the specific type and extent of control and is in accordance with 8.4.2.

C.4 Example of an External Provider's Declaration of Conformity

1) Document No. .....

2) Issuer: .....
.....
(Name and full address)

3) Object of the declaration: .....
.....
....., quantity.....serial or batch number.....

4) Manufacturers purchase order: ....., dated .....

5) Issuers work order: ....., dated .....

6) Declaration:

We <issuer name> herewith declare that the information provided in this “External Provider's Declaration of Conformity” is accurate and confirm that the processes, products and services supplied by <issuer name> are in conformity to the requirements stated in the following documents:

Document No.	Title	Edition/Date of issue
.....	.....	.....
.....	.....	.....
.....	.....	.....

7) Subcontracting:

We confirm that no part of the production of the object described above has been subcontracted to third parties without the written consent of the manufacturer.

8) Limits of the validity of this declaration: .....

9) Additional information: .....

.....

10) Signed for and on behalf of:

(Name, function) (Signature or equivalent authorized by the issuer)

.....

.....

11) Place and date of issue

.....

Annex D
(informative)

ISO/IEC 80079-34:2011 to ISO/IEC 80079-34 Edition 2 Correlation Matrix

ISO/IEC 80079-34:2011		ISO/IEC 80079-34 Edition 2	
4	Quality management system	4	Context of the organization
4.1	General requirements	4.4	Quality management system and its processes
4.2	Documentation requirements	7.5	Documented information
4.2.1	General	7.5.1	General
4.2.2	Quality manual	4.3	Determining the scope of the quality management system
		7.5.1	General
		4.4	Quality management system and its Processes
4.2.3	Control of documents	7.5.3	Control of documented Information
4.2.4	Control of records	7.5.3	Control of documented Information
5	Management responsibility	5	Leadership
5.1	Management commitment	5.1	Leadership and commitment
		5.1.1	General
5.2	Customer focus	5.1.2	Customer focus
5.3	Quality policy	5.2	Quality policy
5.4	Planning	6	Planning
5.4.1	Quality objectives	6.2	Quality objectives and planning to achieve them
5.4.2	Quality management system planning	6	Planning for the quality management system
		6.1	Actions to address risks and opportunities
		6.3	Planning of changes
5.5	Responsibility, authority and communication	5	Leadership
5.5.1	Responsibility and authority	5.3	Organizational roles, responsibilities and authorities
5.5.2	Management representative	5.3	Organizational roles, responsibilities and authorities
5.5.3	Internal communication	7.4	Communication
5.6	Management review	9.3	Management review
5.6.1	General	9.3.1	General
5.6.2	Review input	9.3.2	Management review inputs
5.6.3	Review output	9.3.3	Management review outputs
6	Resource management	7.1	Resources
6.1	Provision of resources	7.1.1	General
		7.1.2	People
6.2	Human resources	7.2	Competence
6.2.1	General	7.2	Competence
6.2.2	Competence, training and awareness	7.2	Competence
		7.3	Awareness
6.3	Infrastructure	7.1.3	Infrastructure
6.4	Work environment	7.1.4	Environment for the operation of processes

ISO/IEC 80079-34:2011		ISO/IEC 80079-34 Edition 2	
7	Product realization	8	Operation
7.1	Planning of product realization	8.1	Operational planning and control
7.2	Customer-related processes	8.2	Determination of requirements for products and services
7.2.1	Determination of requirements related to the product	8.2.2	Determining the requirements related to products and services
7.2.2	Review of requirements related to the product	8.2.3	Review of the requirements related to the products and services
7.2.3	Customer communication	8.2.1	Customer communication
7.3	Design and development	8.5	Production and service provision
7.3.1	Design and development planning	8.3	Design and development of products and services
		8.3.1	General
		8.3.2	Design and development planning
7.3.2	Design and development inputs	8.3.3	Design and development Inputs
7.3.3	Design and development outputs	8.3.5	Design and development outputs
7.3.4	Design and development review	8.3.4	Design and development controls
7.3.5	Design and development verification	8.3.4	Design and development controls
7.3.6	Design and development validation	8.3.4	Design and development controls
7.3.7	Control of design and development changes	8.3.6	Design and development changes
7.4	Purchasing	8.4	Control of externally provided processes, products and services
7.4.1	Purchasing process	8.4.1	General
7.4.2	Purchasing information	8.4.3	Information for external providers
7.4.3	Verification of purchased product	8.4.2	Type and extent of control
7.5	Production and service provision	8.5	Production and service provision
7.5.1	Control of production and service provision	8.5.1	Control of production and service provision
		8.5.5	Post-delivery activities
7.5.2	Validation of processes for production and service provision	8.5.1	Control of production and service provision
7.5.3	Identification and traceability	8.5.2	Identification and traceability
7.5.4	Customer property	8.5.3	Property belonging to customers or external providers
7.5.5	Preservation of product	8.6	Release of products and services
7.6	Control of monitoring and measuring equipment	7.1.5	Monitoring and measuring resources
8.0	Measurement, analysis and improvement	9.1	Monitoring, measurement, analysis and evaluation
8.1	General	9.1.1	General
8.2	Monitoring and measurement	9.1	Monitoring, measurement, analysis and evaluation
8.2.1	Customer satisfaction	9.1.2	Customer satisfaction
8.2.2	Internal audit	9.2	Internal audit
8.2.3	Monitoring and measurement of processes	9.1.1	General
8.2.4	Monitoring and measurement of product	8.6	Release of products and services
8.3	Control of nonconforming product	8.7	Control of nonconforming outputs
8.4	Analysis of data	9.1.3	Analysis and evaluation
8.5	Improvement	10	Improvement

ISO/IEC 80079-34:2011		ISO/IEC 80079-34 Edition 2	
8.5.1	Continual improvement	10.1	General
		10.3	Continual Improvement
8.5.2	Corrective action	10.2	Nonconformity and corrective action
8.5.3	Preventive action	6.1	Actions to address risks and opportunities (see 6.1.1, 6.1.2)

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