

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Explosive atmospheres –
Part 34: Application of quality systems for equipment manufacture**

**Atmosphères explosives –
Partie 34: Application des systèmes de qualité pour la fabrication d'équipements**

ISO/IEC 80079-34:2011

<https://standards.iteh.ai/catalog/standards/iec/80079-34-2011>

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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00



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EXPLOSIVE ATMOSPHERES –

Part 34: Application of quality systems for equipment manufacture

FOREWORD

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International Standard ISO/IEC 80079-34 has been prepared by IEC subcommittee 31M: Non-electrical equipment and protective systems for explosive atmospheres, of IEC 31: Equipment for explosive atmospheres.

This publication is published as a double logo standard.

This standard should be read in conjunction with ISO 9001:2008.

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

FDIS	Report on voting
31M/45/FDIS	31M/48/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved because there were no negative votes out of the eleven votes cast.

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

A list of all parts in 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 publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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WITHDRAWN

INTRODUCTION

This International Standard specifies requirements for a quality system that can be used by an organization for the production of equipment and protective systems for explosive atmosphere.

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 standard is intended to cover both electrical and non-electrical equipment and protective systems. The detailed content (e.g. annexes) is currently more focused on the established equipment standards for electrical equipment. However, IEC sub-committee 31M has recently been formed with the responsibility for the development of standards for non-electrical equipment. It is anticipated that, where appropriate, these standards, or requirements related to them, will be referenced within this standard in the future.

Manufacturer's quality requirements are an integral part of most certification schemes and as such this Standard has been prepared with the IECEx equipment certification scheme requirements in mind, is intended to support the ATEX scheme requirements for a manufacturer's quality system and can be applied in other national or regional certifications schemes that relate to the manufacture of explosion-protected equipment.

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WITHOLD

EXPLOSIVE ATMOSPHERES –

Part 34: Application of quality systems for equipment manufacture

1 Scope

This part of ISO/IEC 80079 specifies particular requirements and information for establishing and maintaining a quality system to manufacture Ex equipment including protective systems in accordance with the Ex certificate.

It does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001:2008 and which provide equivalent results.

2 Normative references

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.

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

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

ISO/IEC 17050-1, *Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements*

ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary*

ISO 9001:2008, *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 and ISO 9000:2005, as well as the following definitions, apply.

3.1

Ex Component

part of Ex equipment or a module (other than an Ex cable gland), marked with the symbol “U”, which is not intended to be used alone and requires additional consideration when incorporated into Ex equipment or systems for use in explosive atmospheres

NOTE This definition is identical to that of IEC 60079-0, except that the term “electrical” has been replaced by “Ex” to allow a broader application of the definition.

3.2

Ex Equipment

machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition

NOTE This definition includes "equipment" as defined by IEC 60079-0.

3.3

Ex certificate

document that assures the conformity of a product with specified requirements for explosive atmospheres

NOTE 1 The certificate may be 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 the ISO/IEC 17000 series.

NOTE 2 This is equivalent to the term "certificate" as defined by IEC 60079-0.

3.4

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 The term "manufacturer" is used instead of "organization" as used in ISO 9001:2008. For the purposes of this standard they are interchangeable.

3.5

contract

requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means

3.6

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 Ex certificate

3.7

product

Ex equipment, protective systems, safety devices, Ex Components and their combinations, as well as software and service as defined in 3.4.2 of ISO 9000:2005

3.8

protective systems

design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures

NOTE Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems.

3.9

safety devices

devices 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

3.10

schedule drawing

drawing or document listed in the Ex certificate and/or test report

3.11

related drawing

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

3.12

technical documentation

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

NOTE 1 This may include schedule drawings when a certification body is involved.

NOTE 2 It covers the design, manufacture and operation of the product and 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 Ex 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, etc.;
- test reports.

3.13

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 an Ex certificate

EXAMPLE Manufacturing instructions, related drawings, data sheets and sales literature.

3.14

Type of Protection

specific measures applied to Ex equipment to avoid ignition of a surrounding explosive atmosphere

NOTE This definition is identical to that of IEC 60079-0, except that the term "electrical" has been replaced by "Ex" to allow a broader application of the definition.

3.15

body responsible for verification

body which conducts documentation review and periodical audit as appropriate

NOTE The body may be either a manufacturer, purchaser, third party or a certification body.

4 Quality management system

4.1 General requirements

Subclause 4.1 of ISO 9001:2008 applies, with the following addition:

The quality system shall ensure that the product conforms to the type described in the Ex certificate and the technical documentation.

4.2 Documentation requirements

4.2.1 General

Subclause 4.2.1 of ISO 9001:2008 applies.

4.2.2 Quality manual

Subclause 4.2.2 of ISO 9001:2008 applies.

4.2.3 Control of documents

Subclause 4.2.3 of ISO 9001:2008 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 documentations 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 system shall ensure that no factor (type, characteristic, position etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified,
- 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 Ex certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings,

NOTE 1 Some manufacturers use common components with common drawing numbers on more than one product. Some of these products may have different persons responsible for them. Therefore, if one product with a common component and drawing number is revised to meet a need, and if the necessary supplementary certificate is obtained, there needs to be a system for ensuring that any other certificates that call up such components are also subject to supplementary certification. This is in order to avoid such products not being in compliance with their technical documentation. The system should identify the component drawing version, and this version shouldn't be modified by anybody other than the person(s) responsible for the equipment.

- f) where a manufacturer also has drawings for equipment not intended for use in explosive atmospheres, the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified,

NOTE 2 The following examples indicate some methods of achieving this:

- the use of visual markers;
 - the use of a unique series of drawing numbers, e.g. all drawings concerning a certified equipment have an Ex prefix to the drawing number.
- g) the manufacturer shall document who is responsible for the quality system of each Ex certificate.

NOTE 3 In some certification schemes, the body responsible for the quality system associated with each Ex certificate may be different from the body that issued the Ex certificate and therefore needs to be clearly identified.

- 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.

4.2.4 Control of records

Subclause 4.2.4 of ISO 9001:2008 applies, with the following addition:

The manufacturer shall retain adequate quality records to demonstrate conformity of the product and satisfy national regulation and legislation.

NOTE In the absence of specific national regulations and legislation, it is suggested that a minimum of 10 years period be applied.

As a minimum, the list of documents requiring control and retention, as far as applicable, shall be:

- those arising from regulatory requirements;
- customer order;
- contract review;
- training records;
- inspection and test data (per batch);
- calibration data;
- sub-contractor evaluation;

- delivery data (customer, delivery date and quantity, including serial numbers where available).

5 Management responsibility

5.1 Management commitment

Subclause 5.1 of ISO 9001:2008 applies.

5.2 Customer focus

Subclause 5.2 of ISO 9001:2008 applies.

5.3 Quality policy

Subclause 5.3 of ISO 9001:2008 applies.

5.4 Planning

5.4.1 Quality objectives

Subclause 5.4.1 of ISO 9001:2008 applies.

5.4.2 Quality management system planning

Subclause 5.4.2 of ISO 9001:2008 applies, with the following addition:

All the elements, requirements and provisions adopted by the manufacturer in order to ensure compliance of the product with its Ex certificate and technical documentation shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Subclause 5.5.1 of ISO 9001:2008 applies, with the following addition:

Responsibilities and authority for the following shall be defined:

- a) the effective coordination of activities with respect to equipment intended for use in explosive atmospheres;
- b) the liaison with the issuer of the Ex certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the Ex certificate and the technical documentation;
- c) the liaison with the body responsible for the verification of the quality system with respect to intended updating of the quality system;

NOTE 1 It is not practicable for the manufacturer to inform the body responsible for the verification of the quality system each time the quality system is updated. It is only practicable to inform them of "substantial" updating of the quality 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 recommended that the manufacturer should inform the body responsible for the verification of the quality system on any update of the quality system having consequences on product compliance.

- d) the authorization of initial approval and changes to related drawings, where appropriate;
- e) the authorization of concessions (see 8.3 j));
- f) the customers' information of any applicable specific conditions of use and any schedules of limitations;

NOTE 2 Certificate numbers with a suffix X contain specific conditions of use. Component certificates numbers, (with a suffix U) may contain schedules of limitations.

NOTE 3 For each Ex certificate, it is recommended that an authorized person(s) is (are) appointed who should have responsibility and authority for the above activities so providing an unambiguous focal point within the manufacturer.

- g) the reviewing of Ex certificate and technical documentation and identifying any changes that effect product compliance with the certificate.

5.5.2 Management representative

Subclause 5.5.2 of ISO 9001:2008 applies.

5.5.3 Internal communication

Subclause 5.5.3 of ISO 9001:2008 applies.

5.6 Management review

5.6.1 General

Subclause 5.6.1 of ISO 9001:2008 applies, with the following addition:

- a) the maximum intervals between reviews should normally be 12 months and shall not exceed 14 months;
- b) top management shall chair the review;
- c) the person(s) responsible for the activities as detailed in 5.5.1 shall participate in the review.

5.6.2 Review input

Subclause 5.6.2 of ISO 9001:2008 applies with the following addition:

The review shall include the overall effectiveness of the quality management system with respect to equipment intended for use in explosive atmospheres.

NOTE Results of audits should include both internal audits and those conducted by other parties (e.g. a body responsible for the verification of the quality system, if one is involved).

5.6.3 Review output

Subclause 5.6.3 of ISO 9001:2008 applies.

6 Resource management

6.1 Provision of resources

Subclause 6.1 of ISO 9001:2008 applies.

6.2 Human resources

6.2.1 General

Subclause 6.2.1 of ISO 9001:2008 applies.

6.2.2 Competence, training and awareness

Subclause 6.2.2 of ISO 9001:2008 applies, with the following addition: