

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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fabrication des produits Ex**

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EXPLOSIVE ATMOSPHERES –**Part 34: Application of quality management systems
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FOREWORD

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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

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- withdrawn,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

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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.

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4.4 of ISO 9001:2015 applies with the following addition: -34-2018

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