SLOVENSKI STANDARD
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Potencialno eksplozivne atmosfere - 34. del: Uporaba sistemov kakovosti za izdelavo opreme (ISO/IEC/DIS 80079-34:2017)

Explosive atmospheres - Part 34: Application of quality systems for equipment manufacture (ISO/IEC/DIS 80079-34:2017)

Explosionsgefährdete Bereiche - Teil 34: Anwendung von Qualitätsmanagementsystemen für die Herstellung von Ex-Produkten (ISO/IEC/DIS 80079-34:2017)

Atmosphères explosives - Partie 34: Application des systèmes de qualité pour la fabrication d'équipements (ISO/IEC/DIS 80079-34:2017)

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Part 34:
Application of quality systems for ex product manufacture

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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

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

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

This publication is published as a double logo standard.

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

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

239 A list of all parts of the IEC 60079 series, under the general title *Explosive atmospheres*, can
240 be found on the IEC website.

241 The committee has decided that the contents of this publication will remain unchanged until
242 2021 as indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the
243 specific publication. At this date, the publication will be

244 • reconfirmed,
245 • withdrawn,
246 • replaced by a revised edition, or
247 • amended.

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INTRODUCTION

This document specifies requirements for a quality management system that can be used by an organization for the manufacture of Ex products and for the provision of Ex services.

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, protective systems, safety devices, Ex components and their combinations. The detailed content (e.g. annexes) is currently focused on the established standards.

Quality requirements are an integral part of most certification schemes and as such this Standard 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 and to the provision of Ex services.

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 box these refer to ISO 9001:2015.

EXPLOSIVE ATMOSPHERES –

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

1 Scope

This part of ISO/IEC 80079 specifies particular requirements and information for establishing and maintaining a quality management system to manufacture Ex products in accordance with the Ex certificates or to provision of Ex services. 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 shall be in accordance with this standard.

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 (IEV) – Chapter 426: Electrical apparatus for explosive atmospheres*

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

ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-426, IEC 60079-0 and ISO 9000:2015, as well as the following definitions, apply.

3.1
Ex Component
equipment intended to be part of Ex Equipment, marked with the symbol "U", which is not intended to be used alone, and requires additional consideration when incorporated into Ex equipment

3.2
Ex Equipment
equipment with explosion protection

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

Note 2 to entry: Such equipment often includes Ex Components, but additional evaluation is always required as part of their incorporation into equipment.

3.3
certificate
document that conveys the assurance of the conformity of an Ex product with specified requirements for explosive atmospheres

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

Note 2 to entry: This term includes the Ex Equipment Certificate and the Ex Component Certificate as defined in 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 1 to entry: The term "manufacturer" is used instead of "organization" as used in ISO 9001:2015. For the purposes of this standard they are interchangeable.

3.5
contract
requirements forming an agreement between different parties 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
Ex Product
Ex Equipment, protective systems, safety devices, Ex Components and their combinations, as well as software and service as defined in 3.7.6 and 3.7.7 of ISO 9000:2015

3.8
protective systems
devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion

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

3.9
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

3.10
schedule drawing
drawing or document listed in the certificate and/or test report

3.11
related drawing
drawing or document not listed in the 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 to entry: This can include schedule drawings when a Certification Body is involved.

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.

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 certificate

NOTE 1 For example, manufacturing instructions, related drawings, data sheets and sales literature.

NOTE 2 The manufacturer's documentation can be either in paper form or electronic form.

3.14
Type of Protection
specific measures applied to equipment to avoid ignition of a surrounding explosive atmosphere

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

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 regards to this Standard, 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;