

**SLOVENSKI STANDARD**  
**oSIST prEN ISO/IEC 80079-34:2017**  
**01-september-2017**

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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)

**Ta slovenski standard je istoveten z: prEN ISO/IEC 80079-34**

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### Explosive atmospheres —

#### Part 34:

### Application of quality systems for ex product manufacture

*Atmosphères explosives —*

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

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

## 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 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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- 249

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## INTRODUCTION

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

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

255 The application of this standard is intended to cover both electrical and non-electrical  
256 equipment, protective systems, safety devices, Ex components and their combinations. The  
257 detailed content (e.g. annexes) is currently focused on the established standards.

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

263 In order to help the reader, the text of the applicable sections of ISO 9001:2015 is reproduced  
264 in a rectangular box. Where clauses are referenced within a box these refer to ISO  
265 9001:2015.

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## 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;