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ISO/IEC DIS 80079-34

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

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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 of IEC technical committee 31: Equipment for explosive atmospheres.

This third edition cancels and replaces the second edition, published in 2018, and constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

Users of this document are advised that interpretation sheets clarifying the interpretation of this document can be published. Interpretation sheets are available from the IEC webstore and can be found in the “history” tab of the page for each document.

The significant changes with respect to ISO/IEC 80079-34 are listed below.

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Significant changes	Clause	Type		
		Minor and editorial changes	Extension	Major technical changes
Definition for *Ex Product certificate* added	3.2	X		
Definition for *manufacturer* modified	3.3.1		X	
Definition for *manufacturing location* added	3.3.2		X	
Definition for *production site* added	3.3.3		X	
Definition for *local assembler* added	3.3.4		X	
Definition for *trade agent* added	3.3.5		X	
Modified definition of *schedule drawing* to be consistent within TC31.	3.9	X		
Definition for *External provider's declaration of conformity* added	3.13	X		
Deleted term technical documentation	-			C4
Deleted term manufacturer's documentation	-			C5
Clarified that the organization shall determine the extent of control it applies to the respective locations	4.1		X	
Clarified that one Ex authorized person may be appointed to multiple locations	5.3	X		
Added that the Ex authorized person shall be involved in the approval process of changes to the quality management system	6.3			X
Clarified that the intent of the clause is, that personnel has the necessary competence and not that it necessarily has to be trained.	7.2		X	
Clarified that there are no additional requirements in addition to those of ISO 9001:2015	7.4	X		
Clarified the retention period in the context of the newly introduced organizational sub-structure.	7.5.3j)	X		
Added External provider's declaration of conformity to the list of required records	7.5.3j) 12)	X		
Clarified that a review shall take place, when customers state requirements and clarified that where no requirements are stated appropriate information shall be made available.	8.2.3		X	
Clarified that the Ex authorized person shall ensure that procedures are reviewed and approved, not necessarily always be involved in.	8.2.4			
Relocated and reworded requirements regarding outsourcing and ensuring compliance with the Ex Product certificate and technical documentation.	8.4.1			
Relocated the complete section of external provider selection to Annex E.	8.4.18.4.2			C1
Clarified the requirements regarding nonconforming Ex Products that have been deemed unsafe and which have been released for use.	8.7c)			C2
Clarified that each applicable element of the quality management system shall be internally audited in intervals not exceeding 14 months.			X	

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Significant changes	Clause	Type		
		Minor and editorial changes	Extension	Major technical changes
Clarified the effects of temperature during measurement	A.2	X		
Clarified that there should be documented procedures with defined acceptance criteria for all routine and batch verifications	A.2			
Removed information deemed redundant with respect to the responsibility of the organization. Information is now contained in 8.4.1 and Annex E.	C.2			
Drafted Guidance for the application of ISO/IEC 80079-34 in the context of different types of organizations	Annex D			C3

NOTE The technical changes referred include the significant technical changes in the revised standard but 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 the level of an existing requirement is also classified as a ‘minor and editorial change’.

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. These ‘extensions’ will therefore 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, which add new or increase the level of existing technical requirements, in a way that a product in conformity with the previous standard will not always be able to fulfil the requirements given in the standard. ‘Major technical changes’ have to be considered for products in conformity with the previous edition.

B) Information about the background of Changes

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C1 The requirements surrounding the type and control of externally provided products, processes and services have been reworded to better suit the needs of different organizations. In particular the concept of three different types of raw materials (custom, non-custom and general parts) have been introduced including minimum external provider evaluation levels. The evaluation levels are based on whether the verification is performed by the organization itself or whether it is performed by the external provider regardless if done via sub-contracting or because it is no longer possible at a later time.

C2 The concept of how to handle nonconforming Ex Products that have been deemed unsafe and have been released for use has been introduced. In particular the information flow to certificate issuers, customers and so forth has been clarified.

C3 Edition 3.0 of ISO/IEC 80079-34 splits the organization into five sub-organizations commonly encountered in the industry. The document has been updated to reflect and address the needs of the different organizations and Annex D has been drafted to facilitate the extent of auditing at each organizational level. It is however paramount that Annex D serves as guidance and the context of the organization is determined for each individual organization.

C4 The definition of the term technical documentation had significant overlap with the definition of the term schedule drawing. The terms and definitions were aligned with IEC 60079-0, which resulted in the deletion of the term. The document has been updated to reflect the new term.

C5 The definition of the term manufacturer's documentation had significant overlap with the definition of the term related drawing. The terms and definitions were aligned with IEC 60079-0, which resulted in the deletion of the term. The document has been updated to reflect the new term.

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/XX/FDIS	31M/XX/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. In ISO, the standard has been approved by XXX P members out of YYY having cast a vote.

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 web site under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,

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- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

The National Committees are requested to note that for this document the stability date is XXXX.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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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 (for example 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 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.

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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 (IEV) - 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: The certificate is either the supplier's declaration of conformity (1st party declaration) or the purchaser's recognition of conformity (2nd party acceptance) or certification (3rd party attestation). Declaration, acceptance and certification are defined in ISO/IEC 17000.

[SOURCE: IEC 60050-426:2020, 426-04-23]

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3.2
Ex Product certificate
certificate for an Ex Product

3.3
organization

3.3.1
manufacturer
organization, situated at a stated location, that controls such stages in the manufacturing process, assessment, handling and storage of an Ex Product that enables it to accept responsibility for continued compliance of the Ex Product with the relevant requirements and undertakes all obligations in that connection

3.3.2
manufacturing location
facility, under control of or under contract with a manufacturer, that may be a site of the manufacturer or an external provider that carries out manufacturing, handling, storage, or other activities, up to and including releasing the Ex Product for use, bearing the Ex Product certificate number

3.3.3
production site
facility that may be either a facility of the manufacturer or an external provider that is subject to the application of this document, that does not release the Ex Product for use, but carries out manufacturing, handling, storage, or other activities related to the Ex Product, or parts of the Ex Product, under the control of, or under contract with, a manufacturing location

3.3.4
local assembler
site of the manufacturer or agent of the manufacturer where final assembly of the Ex Product is performed in accordance with the definition authorized by the manufacturer

3.3.5
trade agent
organization that is presenting themselves to the market as the manufacturer, has a contract with the original Ex Product certificate holder and assumes full responsibility as manufacturer for each product that is sold under their name.

Note 1 to entry: A trade agent is usually distributor of the certified product who would like that the product be under their name and without information of the original equipment manufacturer OEM on the product.

3.4
contract
requirements forming an agreement between different parties and transmitted by any appropriate means

3.5
customer complaint
reported, written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any Ex Product as defined in the Ex Product certificate

3.6
Ex Product
Ex Equipment, protective system, safety device, Ex Component and their combination, as well as software and services

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3.7
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.

3.8
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

3.9
schedule drawing
DEPRECATED: technical documentation
drawing or document listed in the certificate or test report that enables the conformity of the product with the requirements of the standard(s) to be assessed

[SOURCE: IEC 60050-426:2020, 426-04-43]

3.10
related drawing
drawing or document not listed in the certificate or test report but linked to the schedule drawing, and used for example, for detailed manufacture or purchase of component parts

3.11
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).

[SOURCE: IEC 60050-426:2020, 426-04-44]

3.12
risk
effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats. The concept of “Risk-based thinking” is explained in A.4 of ISO 9001:2015

Note 2 to entry: Objectives can have different aspects and categories, and can be applied at different levels.

Note 3 to entry: Risk is usually expressed in terms of risk sources, potential events, their consequences and their likelihood.

Note 4 to entry: This definition differs from that specified in IEC 60050 and hence the rest of the IEC 60079 and ISO/IEC 80079 series of standards.

[SOURCE: ISO 31000:2018, 3.1, modified — Note 1 to entry and Note 3 to entry have been modified, Note 4 to entry has been added]

3.13
external provider’s declaration of conformity
document issued by an external provider confirming that the products, processes or services are as requested

NOTE 1 to entry: The external provider’s declaration of conformity can take the form of a declaration, certificate or compliance statement.

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