

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Explosive atmospheres –
Part 34: Application of quality management systems for Ex Product manufacture
(standards.iteh.ai)

Atmosphères explosives –
Partie 34: Application de systèmes de management de la qualité pour la
fabrication des produits Ex

<https://standards.iteh.ai/catalog/standards/sist/ccaec5b-afb9-4b27-969e-291133fcbd9f/iso-iec-80079-34-2018>



THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2018 ISO/IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about ISO/IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'ISO/IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing 21 000 terms and definitions in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR-34-2018

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue

Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org

Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient 21 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	9
2 Normative references	9
3 Terms and definitions	9
4 Context of the organization.....	11
4.1 Understanding the organization and its context.....	11
4.2 Understanding the needs and expectations of interested parties	12
4.3 Determining the scope of the quality management system	12
4.4 Quality management system and its processes.....	13
5 Leadership	14
5.1 Leadership and commitment	14
5.1.1 General	14
5.1.2 Customer focus	14
5.2 Policy.....	15
5.2.1 Establishing the quality policy.....	15
5.2.2 Communicating the quality policy.....	15
5.3 Organizational roles, responsibilities and authorities.....	15
6 Planning.....	16
6.1 Actions to address risks and opportunities.....	16
6.2 Quality objectives and planning to achieve them.....	17
6.3 Planning of changes.....	17
7 Support	18
7.1 Resources	18
7.1.1 General	18
7.1.2 People.....	18
7.1.3 Infrastructure	18
7.1.4 Environment for the operation of processes	18
7.1.5 Monitoring and measuring resources	19
7.1.6 Organizational knowledge.....	20
7.2 Competence	20
7.3 Awareness	21
7.4 Communication	21
7.5 Documented information	22
7.5.1 General	22
7.5.2 Creating and updating	22
7.5.3 Control of documented Information	23
8 Operation	25
8.1 Operational planning and control	25
8.2 Requirements for products and services	25
8.2.1 Customer communication	25
8.2.2 Determining the requirements for products and services.....	26
8.2.3 Review of the requirements for products and services	26
8.2.4 Changes to requirements for products and services.....	27
8.3 Design and development of products and services.....	27
8.3.1 General	27

ITeH STANDARD PREVIEW

(standards.iteh.ai)

ISO/IEC 80079-34:2018

[https://standards.iteh.ai/catalog/standards/sist/ccaace5b-afb9-4b27-969e-](https://standards.iteh.ai/catalog/standards/sist/ccaace5b-afb9-4b27-969e-291133fcb99f/iso-iec-80079-34-2018)

[291133fcb99f/iso-iec-80079-34-2018](https://standards.iteh.ai/catalog/standards/sist/ccaace5b-afb9-4b27-969e-291133fcb99f/iso-iec-80079-34-2018)

8.3.2	Design and development planning	27
8.3.3	Design and development Inputs	28
8.3.4	Design and development controls	28
8.3.5	Design and development outputs	29
8.3.6	Design and development changes	29
8.4	Control of externally provided processes, products and services	30
8.4.1	General	30
8.4.2	Type and extent of control	31
8.4.3	Information for external providers	33
8.5	Production and service provision	34
8.5.1	Control of production and service provision	34
8.5.2	Identification and traceability	34
8.5.3	Property belonging to customers or external providers	35
8.5.4	Preservation	35
8.5.5	Post-delivery activities	35
8.5.6	Control of changes	36
8.6	Release of products and services	36
8.7	Control of nonconforming outputs	37
9	Performance evaluation	38
9.1	Monitoring, measurement, analysis and evaluation	38
9.1.1	General	38
9.1.2	Customer satisfaction	38
9.1.3	Analysis and evaluation	38
9.2	Internal audit	39
9.3	Management review	39
9.3.1	General	39
9.3.2	Management review inputs	40
9.3.3	Management review outputs	40
10	Improvement	41
10.1	General	41
10.2	Nonconformity and corrective action	41
10.3	Continual improvement	42
Annex A (informative)	Information relevant to particular Types of Protection and specific Ex Products	43
A.1	Overview	43
A.2	General	43
A.3	Ex d – Flameproof enclosures covered by IEC 60079-1	43
A.3.1	Verification	43
A.3.2	Castings	43
A.3.3	Machining	44
A.3.4	Cemented joints and potted assemblies	44
A.3.5	Routine overpressure testing	44
A.3.6	Flanged joints	45
A.3.7	Elements, with non-measurable paths, of breathing and draining devices	45
A.4	Ex i – intrinsic safety covered by IEC 60079-11	46
A.4.1	Components for intrinsically safe products	46
A.4.2	Printed circuit boards (PCB)	46
A.4.3	Sub-assemblies and assemblies	47

A.4.4	Enclosures for Group III or reduced spacing	47
A.4.5	Routine verifications and tests	48
A.4.6	Intrinsically safe circuits and assemblies incorporated in Ex equipment of other types of protection	48
A.5	Ex e – Increased safety covered by IEC 60079-7	48
A.5.1	Ingress protection (IP)	48
A.5.2	Internal wiring and contact integrity	48
A.5.3	Rotating machines	48
A.5.4	Windings	49
A.5.5	Terminal boxes	49
A.5.6	Cable Glands, terminals and other accessories	49
A.5.7	Routine verifications and tests	49
A.6	Ex p – Pressurized equipment covered by IEC 60079-2	49
A.6.1	Ingress protection (IP)	49
A.6.2	Components and manufacturing process	49
A.6.3	Components, constructional characteristics	50
A.6.4	Routine verifications and tests	50
A.7	Ex m – Encapsulation covered by IEC 60079-18	50
A.7.1	Production documentation	50
A.7.2	Routine verifications and tests	50
A.8	Ex o – Liquid immersion covered by IEC 60079-6	50
A.8.1	Material control	50
A.8.2	Filling	51
A.8.3	Ingress protection	51
A.8.4	Routine verifications and tests	51
A.9	Ex q – Powder filling covered by IEC 60079-5	51
A.9.1	Material control	51
A.9.2	Filling	51
A.9.3	Ingress protection (IP)	51
A.9.4	Routine verifications and tests	51
A.10	Equipment covered by IEC 60079-15	52
A.10.1	General requirements	52
A.10.2	Ex nA – Non sparking equipment	52
A.10.3	Ex nC – Sealed devices	52
A.10.4	Ex nR – Restricted Breathing	52
A.11	Ex t – Dust ignition protection by enclosure covered by IEC 60079-31	53
A.11.1	Casting	53
A.11.2	Enclosure parts	53
A.11.3	Gaskets	53
A.11.4	Protection devices	53
A.11.5	Cemented and cast enclosure parts	53
A.11.6	Ingress protection (IP)	54
A.11.7	Routine verifications and tests	54
A.12	Ex op – Optical radiation covered by IEC 60079-28	54
A.13	Gas detectors covered by IEC 60079-29	54
A.14	Ex h – Non-electrical Equipment covered by ISO 80079-36	55
A.14.1	General	55
A.14.2	Non-metallic parts	55
A.14.3	Casing and external parts	55

A.14.4	Earthing and equipotential bonding of conductive parts	55
A.14.5	Light transmitting parts	55
A.14.6	Ingress protection (IP)	56
A.15	Non Electrical Equipment protected by constructional safety “c” covered by ISO 80079-37	56
A.15.1	General	56
A.15.2	Metal-based material	56
A.15.3	Machining	56
A.15.4	Cemented joints and potted assemblies	56
A.15.5	Assembling	57
A.15.6	Routine tests	57
A.15.7	Power transmission systems	57
A.16	Non-electrical equipment protected by control of ignition sources “b” covered by ISO 80079-37	57
A.16.1	General	57
A.16.2	Ignition protection system	57
A.16.3	Assembling	57
A.16.4	Routine verifications and tests	58
A.17	Non-electrical equipment protected by liquid immersion “k” covered by ISO 80079-37	58
A.17.1	General	58
A.17.2	Protective liquid	58
A.17.3	Casing	58
A.17.4	Measuring or indicating devices	58
A.18	Flame arresters covered by ISO 16852-34:2018	58
Annex B (informative)	Verification criteria for elements with non-measurable paths used as an integral part of a Type of Protection	60
B.1	Overview	60
B.2	Verification guidance	60
B.3	Tests	60
B.4	Test examples	61
B.4.1	General	61
B.4.2	Example 1 (pore size)	61
B.4.3	Example 2 (density)	61
B.5	Purchase information	62
B.6	Pre-tested components	62
B.7	Measurement and monitoring	62
Annex C (informative)	External Provider's Declaration of Conformity	63
C.1	External Provider's Declaration of Conformity	63
C.2	Additional Supporting information	64
C.3	Responsibility of the Organization	64
C.4	Example of an External Provider's Declaration of Conformity	65
Annex D (informative)	ISO/IEC 80079-34:2011 to ISO/IEC 80079-34 Edition 2 Correlation Matrix	66
Bibliography	69
Table A.1 – Component features requiring compatibility	46

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO/IEC 80079-34:2018](#)

<https://standards.iteh.ai/catalog/standards/sist/ccaace5b-afb9-4b27-969e-291133fcbd9f/iso-iec-80079-34-2018>

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.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

[ISO/IEC 80079-34:2018](https://standards.iteh.ai/catalog/standards/sist/ccaec5b-afb9-4b27-969e-291133fcbd9f/iso-iec-80079-34-2018)

<https://standards.iteh.ai/catalog/standards/sist/ccaec5b-afb9-4b27-969e-291133fcbd9f/iso-iec-80079-34-2018>

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.

ISO/IEC 80079-34:2018

<https://standards.iteh.ai/catalog/standards/sist/ccae5b-afb9-4b27-969e-291133fcbd9f/iso-iec-80079-34-2018>

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.