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Responsible committee: EXL/23 Explosion and fire precautions in industrial and chemical plant

Interested committees:

Title: BS EN ISO/IEC 80079-34 Explosive atmospheres

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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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Responsible Committee Secretary: **Mr Christopher Brown (BSI)**Direct tel: **02089967441**E-mail: **christopher.brown@bsigroup.com**

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



31M/225/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

ISO/IEC 80079-34 ED3

DATE OF CIRCULATION:

2024-05-31

CLOSING DATE FOR COMMENTS:

2024-09-20

SUPERSEDES DOCUMENTS:

31M/224/RR

IEC SC 31M : NON-ELECTRICAL EQUIPMENT AND PROTECTIVE SYSTEMS FOR EXPLOSIVE ATMOSPHERES

SECRETARIAT:

Germany

SECRETARY:

Mrs Anke Sachtleben

OF INTEREST TO THE FOLLOWING COMMITTEES:

TC 31, SC 31G, SC 31J

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☒ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

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Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

Explosive atmospheres - Part 34: Application of quality management systems for Ex Product manufacture

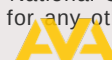
NOTE FROM TC/SC OFFICERS:

With reference to 31/1775/INF, the MT requests comments from the following WGs and MTs:

IEC/TC 31/WG 22, WG 27, WG 37, WG 28, WG 30, WG 42, MT 60079-1, MT 60079-2, MT 60079-7, MT 60079-15, MT 60079-18, MT 60079-26, MT 60079-28, MT 60079-29, MT 60079-30, MT 60079-33, MT 60079-35, MT 60079-46, SC 31G/60079-11, MT 60079-25, MT 60079-47, SC 31M/WG 1, WG 2 and MT 80079-38

Please also note that the comments in the CD refer to the submitted comments on the 31M/194/DC (see also 31M/198AINF)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EXPLOSIVE ATMOSPHERES –

**Part 34: Application of quality management systems
for Ex Product manufacture**

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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 publication is published as a double logo standard.

This standard should be read in conjunction with 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

268 report on voting indicated in the above table. In ISO, the standard has been approved by XXX
269 P members out of YYY having cast a vote.

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

271 A list of all parts of the IEC 60079 series, under the general title *Explosive atmospheres*, as
272 well as the ISO/IEC_80079 series, can be found on the IEC website.

273 The committee has decided that the contents of this document will remain unchanged until the
274 stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to
275 the specific document. At this date, the document will be

- 276 • reconfirmed,
277 • withdrawn,
278 • replaced by a revised edition, or
279 • amended.

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

281

282

283

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

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

288

289

INTRODUCTION

290 This part of ISO/IEC 80079 specifies requirements for a quality management system that can
291 be used by an organization for the manufacture of Ex Products as **M**anufacturer,
292 **m**anufacturing location, **p**roduction site, **L**ocal assembler and **T**rade **a**gent.

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

295 The application of this document is intended to cover both electrical and non-electrical
296 equipment, protective systems, safety devices, Ex Components and their combinations. The
297 detailed content (e.g. for example annexes) is currently focused on the established documents.

298 Quality requirements are an integral part of most certification schemes and as such this
299 document has been prepared with the IECEx system requirements in mind, is intended to
300 support ATEX Directive requirements for quality management system and can be applied in
301 other national or regional certification schemes that relate to the manufacture of Ex Products.

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

305

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 2-1 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.

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

Commented [BN1]: GB01

3.1.1**Ex Product certificate**

certificate of conformity of an Ex Product type to IEC or ISO standards, including Ex Equipment certificates and Ex Component certificates

Commented [BN2]: GB02

3.2**Organization****3.2.1****manufacturer**

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

Commented [BN3]: US

3.2.2**manufacturing location**

facility, under control 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 (for example, assembly, routine tests, procurement, and incoming inspection), up to and including releasing to the market the Ex pProduct bearing the Ex Product certificate number and final packaging.

Commented [BN4]: DE-02

~~Note 1 to entry: Manufacturing location(s) operate under the control of the manufacturer (Applicant) listed on the certificate with respect to the manufacture of Ex equipment.~~

Commented [BN5]: DE-03

Commented [BN6]: DE-02

3.2.3**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 Pproduct to the market but carries out manufacturing, handling or storage of the Ex Pproduct, or parts of the Ex Pproduct, under the control of, or under contract with, a manufacturing location

3.2.4**local assembler**

site of the manufacturer or agent of the manufacturer where final assembly of the Ex pProduct is performed in accordance with the definition authorized by the manufacturer.

~~Note to entry: The determination of the location being qualified as a local assembler or manufacturing location is the responsibility of the issuer of the quality certification~~

Commented [BN7]: GB05

3.2.5**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.~~

3.3**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 of component Ex Product as defined in the Ex Product 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 [Ex Product](#) certificate or test report

3.9**related drawing**

drawing or document not listed in the [Ex Product](#) certificate [or test report](#) but linked to the schedule drawing, and used for example, for detailed manufacture or purchase of component parts

Commented [BN8]: GB07

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 [Ex Product](#) certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the [applicable](#) standards;
- results of design calculations made, examinations carried out, risk assessment etc.;
- test reports.

Commented [BN9]: GB08

Note 3 to entry: For ~~Non~~non-electrical equipment, this includes the ~~Formal~~ [ignition-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 an [Ex Product](#) 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.~~

Commented [BN10]: GB09

3.12**body responsible for verification**

body which conducts documentation review and periodical audit as appropriate

441 Note 1 to entry: The body can be a manufacturer (first party), purchaser (second party), or a Certification body
442 (third party).

443 **3.13**
444 **risk**
445 effect of uncertainty on objectives

446 Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address,
447 create or result in opportunities and threats. [The concept of "Risk-based thinking" is explained in A.4 of](#)
448 [ISO 9001:2015](#)

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

450 Note 3 to entry: Risk is usually expressed in terms of risk sources ([3.14](#)~~3-4~~), potential events ([3.15](#)~~3-5~~), their
451 consequences ([3.16](#)~~3-6~~) and their likelihood ([3.17](#)~~3-7~~).

452 [Note 4 to entry: This definition differs from that specified in IEC- 60050 and hence the rest of the IEC- 60079 and](#)
453 [ISO/IEC- 80079 series of standards.](#)

454 [SOURCE: ISO_31000:2018, 3.1]

455 **3.14**
456 **risk source**
457 element which alone or in combination has the potential to give rise to risk

458 [SOURCE: ISO_31000:2018, 3.4]

459

460 **3.15**
461 **event**
462 occurrence or change of a particular set of circumstances

463 Note 1 to entry: An event can have one or more occurrences, and can have several causes and several
464 consequences.

465 Note 2 to entry: An event can also be something that is expected which does not happen, or something that is not
466 expected which does happen.

467 Note 3 to entry: An event can be a risk source.

468 [SOURCE: ISO_31000:2018, 3.5]

469 **3.16**
470 **consequence**
471 outcome of an event ([3.15](#)~~3-5~~) affecting objectives

472 Note 1 to entry: A consequence can be certain or uncertain and can have positive or negative direct or indirect
473 effects on objectives.

474 Note 2 to entry: Consequences can be expressed qualitatively or quantitatively.

475 Note 3 to entry: Any consequence can escalate through cascading and cumulative effects.

476 [SOURCE: ISO_31000:2018, 3.6]

477 **3.17**
478 **likelihood**
479 chance of something happening

480 Note 1 to entry: In risk management terminology, the word "likelihood" is used to refer to the chance of something
481 happening, whether defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and
482 described using general terms or mathematically (such as a probability or a frequency over a given time period).

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Note_2 to entry: ___The English term "likelihood" does not have a direct equivalent in some languages; instead, the equivalent of the term "probability" is often used. However, in English, "probability" is often narrowly interpreted as a mathematical term. Therefore, in risk management terminology, "likelihood" is used with the intent that it should have the same broad interpretation as the term "probability" has in many languages other than English.

[SOURCE: ISO_31000:2018, 3.7]

3.18
control
measure that maintains and/or modifies risk

Note_1 to entry: ___Controls include, but are not limited to, any process, policy, device, practice, or other conditions and/or actions which maintain and/or modify risk.

Note_2 to entry: ___Controls may not always exert the intended or assumed modifying effect.

[SOURCE: ISO_31000:2018, 3.8]

3.19
External provider's declaration of conformity
document issued by an external provider confirming the products, process or services are as requested

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

NOTE 2 to entry: Annex C provides guidance for external provider's declarations of conformity

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 or part of the Ex Product is in accordance with its Ex Product certificate and technical documentation.

The organization shall determine the extent of control for manufacturing locations, production sites and local assemblers.

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The applicability of the requirements of this standard shall be determined by the type of organization (manufacturer, manufacturing location, production site, local assembler or trade agent) and the role that they play in ensuring that Ex pProduct released to the market is compatible with the technical documentation.

NOTE Annex D: ~~Annex D~~ provides guidance for the applicability of this standard to the different types of organization.

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 or part of the Ex Product conforms to the type described in the [Ex Product](#) 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;
- c) ensuring the integration of the quality management system requirements into the organization's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.1 of ISO 9001:2015 applies.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5.1.2 of ISO 9001:2015 applies.

5.2 Policy**5.2.1 Establishing the quality policy**

Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

5.2.1 of ISO 9001:2015 applies.

5.2.2 Communicating the quality policy

The quality policy shall:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within the organization;
- c) be available to relevant interested parties, as appropriate.

5.2.2 of ISO 9001:2015 applies.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of this International Standard;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3 of ISO 9001:2015 applies with the following additions:

Ex authorized person(s) shall be appointed with defined and documented responsibilities and authority to ensure the following requirements are met:

- a) the effective co-ordination of activities with respect to Ex Products;
- b) the liaison with the issuer of the [Ex Product](#) certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the [Ex Product](#) certificate and ~~the~~ technical documentation;
- c) the liaison with the body responsible for the verification of the quality management system with respect to intended updates~~ing~~ of the quality management system;

NOTE [1](#) It is not practicable for the manufacturer to inform the body responsible for the verification of the quality management system each time the quality management system is updated. It is only practicable to inform them of "substantial" updates~~ing~~ ~~of~~ ~~to~~ the quality management system relevant to the Type of Protection. Similarly, it is not practicable to specify in general terms what types of updates~~ing~~ are or are not "substantial". It is therefore normal that the manufacturer informs the body responsible for the verification of the quality management system on any update of the quality management system having consequences on Ex Products compliance. The change of an Ex authorized person is considered ~~as~~ a "substantial" change.

- d) the authorization of initial approval and changes to related drawings, where appropriate;
- e) the authorization of concessions (see 8.7 ~~e~~ ~~f~~);
- f) the accuracy of relevant information regarding Ex Product given to the customer for any sales literature and installation instructions (which shall include applicable Specific Conditions of Use and any Schedule of Limitations);

NOTE [2](#) Ex Equipment Certificate numbers with a suffix "X" contain Specific Conditions of Use. Ex Component certificates numbers, with a suffix "U" ~~may~~ contain a Schedule of Limitations.

- g) the effective coordination of manufacturing processes related to Ex Products including [those at production sites and](#) externally provided products, services and processes detailed in 8.4;

In the case of a manufacturer with multiple manufacturing locations an Ex authorized person with relevant responsibilities shall be appointed for each location. [One Ex authorized person may be appointed as responsible for multiple locations. It is not required that the individual be continuously present at each location.](#)

NOTE [13](#) The appointed Ex authorized person(s) for the manufacturing location can take responsibility for the production site(s) and the local assembler(s) who perform the final assembly.

~~Records demonstrating this shall be available and be maintained as documented information.~~

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6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

6.1.2 The organization shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
 - 1) integrate and implement the actions into its quality management system processes (see 4.4);
 - 2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.1 of ISO 9001:2015 applies.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.2 of ISO 9001:2015 applies.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

6.3 of ISO 9001:2015 applies [with the following addition](#):

[The Ex authorized person\(s\) identified in 5.3 shall be involved in the approval process of any substantial modification or change to the quality management system that could affect Ex Product compliance.](#)

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7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

7.1.1 of ISO 9001:2015 applies.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.2 of ISO 9001:2015 applies.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.3 of ISO 9001:2015 applies.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
- c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.4 of ISO 9001:2015 applies.

7.1.5 Monitoring and measuring resources**7.1.5.1 General**

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.5 of ISO 9001:2015 applies with the following addition:

When monitoring or measuring is used to verify the conformity of Ex Products, the measuring equipment shall be calibrated and a valid calibration certificate shall exist.

Verification of measuring equipment against calibrated equipment is also permitted as long as it is properly documented.

The calibration certificate shall meet one of the following requirements:

- a) Where a calibration certificate bears the accreditation logo issued by an accredited calibration laboratory (which can demonstrate that it operates in compliance with an internationally recognized standard and is covered by a multilateral international

agreement) the calibration laboratory need not be subjected to further evaluation of the calibration laboratory is not required.

- b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information:

- an unambiguous identification of the item calibrated;
- evidence that the measurements are traceable to international or national measurement standards;
- the method of calibration;
- a statement of compliance with any relevant specification;
- the calibration results;
- the uncertainty of measurement, where necessary;
- the environmental conditions, where relevant;
- the date of calibration;
- the signature of the person under whose authority the certificate was issued;
- the name and address of the issuing organization and the date of issue of the certificate;
- a unique identification of the calibration certificate.

- c) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.1.5b), the organization shall demonstrate a valid relationship to international or national measurement standards by other means, — (e.g. for example a documented site assessment).

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

- a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.1.6 of ISO 9001:2015 applies.

7.2 Competence

The organization shall:

- a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;