

AS/NZS ISO/IEC 80079.34:2022
ISO/IEC 80079-34:2018



Australian/New Zealand Standard™

Explosive atmospheres

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



AS/NZS ISO/IEC 80079.34:2022

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- Auckland Regional Chamber of Commerce
- Australian Chamber of Commerce and Industry
- Australian Industry Group
- Australian Petroleum Production and Exploration Association
- Australian Pipelines and Gas Association
- Aviation and Marine Engineers Association
- Better Regulation Division (Fair Trading, Safework NSW, TestSafe)
- Bureau of Steel Manufacturers of Australia
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- Engineers Australia
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Explosive atmospheres

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

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee EL-014, Equipment for Explosive Atmospheres to supersede, AS/NZS 80079.34:2012, *Explosive atmospheres, Part 34: Application of quality systems for equipment manufacture*.

The objective of this document is to specify 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 AS/NZS ISO 9001 and which provide equivalent results, the minimum requirements are given in this document.

This document should be read in conjunction with AS/NZS ISO 9001:2016.

This document is identical with, and has been reproduced from, ISO/IEC 80079-34:2018, *Explosive atmospheres — Part 34: Application of quality management systems for Ex Product manufacture*.

As this document has been reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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 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.

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.

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.

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;
- 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 certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the certificate and the technical documentation;
- c) the liaison with the body responsible for the verification of the quality management system with respect to intended updating of the quality management system;

NOTE 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" updating of the quality management system relevant to the Type of Protection. Similarly, it is not practicable to specify in general terms what types of updating 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 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 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 externally provided products, services and processes detailed in 8.4; In the case of a manufacturer with multiple manufacturing sites an Ex authorized person with relevant responsibilities shall be appointed for each site.

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

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.

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.
- 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;