

Expert commentary

BS EN ISO/IEC 80079-34:2020 — *Explosive atmospheres – Part 34: Application of quality systems for Ex product manufacture (ISO/IEC 80079-34:2018)*

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Full document details: BS EN ISO/IEC 80079-34:2020 ExComm

1 Overview

This revision of BS EN ISO/IEC 80079-34 brings this important document up to date to supplement the basic requirements of BS EN ISO 9001:2015 in order to allow an organization to establish and maintain a quality management system to manufacture Ex products.

1.1 Reasons for change

The main reason for the change is to take account of the revision of BS EN ISO 9001:2015, which has been restructured in line with other QMS standards.

Changes have been made to BS EN ISO 9001:2015 to introduce a risk-based approach. The changes to BS EN ISO/IEC 80079-34 are all relatively minor and should not pose any problems for compliance as long as the basic requirements of BS EN ISO 9001:2015 have been satisfied.

1.2 Summary:

- Basic reference to BS EN ISO 9001:2015
- Addition of Annex ZB which covers the requirements for Ex products covered by standards harmonized under the ATEX Directive 2014/34/EU
- Relocation of some of the requirements from the earlier version of the standard from Annex ZB to Annex A.

2 Main commentary

The next sections explain more about those changes.

2.1 BS EN ISO 9001: 2015

The revision and restructuring of BS EN ISO 9001 created a need for an update to this standard. To aid the user of BS EN ISO/IEC 80079-34:2020, the text of the relevant requirement from BS EN ISO 9001:2015 has been included in a rectangular box within the standard.

2.2 Annex ZB

This annex provides requirements for Ex products which are covered by harmonized standards according to the ATEX Directive 2014/34/EU. Harmonized standards are basically those which have been accepted as meeting the relevant essential health and safety requirements of the ATEX Directive. These standards are in general EN standards that have not been adopted as IEC or ISO standards. They do not appear in the IEC/ISO version of this standard. Several of these standards are being used as a basis for creating IEC or ISO standards.

2.3 Changes in the main body of the Standard

As this standard supplements BS EN ISO 9001:2015, only the supplementary requirements are considered below.

- Section 4.1 – minor rewording but no significant technical change
- Section 4.2 – new 9001 section but no additional requirements
- Section 4.3 – new 9001 section but no additional requirements
- Section 4.4 – was section 4.1 – no change
- Section 5.3 – was section 5.5 – introduction of an 'Ex authorized person' with defined responsibility and authority. This role was included in the previous version but was not given a title, except referred to in a note. The responsibility has been clarified in respect of information given to customers and where there are multiple manufacturing sites there needs to be an authorized person appointed for each site. This is to take into account the increasing use of distributed manufacturing facilities in larger organizations.
- Section 6 – was Section 6.4 – no changes
- Sections 7.1.1 – 7.1.4 – were sections 6.1 – 6.4. No changes
- Section 7.1.5 – was section 7.6 – addition of clarification to indicate that if an accredited certificate is available for monitoring or measuring equipment, no further evaluation is necessary.
- Section 7.1.6 – was section 6.2.1 – no change
- Sections 7.2 and 7.3 – was section 6.2.2 – addition of the requirement for relevant persons to be competent as well as trained. Addition of the term 'competent'

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