ExTAG Training Workshop
Application ISO/IEC 80079-34:2018

CERTIF 2018
LA CERTIFICATION, VECTEUR DE CONFIANCE

INERIS
controlling risks
for sustainable development

ISO/IEC 80079-34:2018

- ISO/IEC 80079-34:2018 was published on 2018-08-30
- ISO/IEC 80079-34:2018 is the second edition of ISO/IEC 80079-34
- As previously, it does not preclude the use of other quality management systems that are compatible with the objectives of ISO 9001:2015
- The clause numbering in regard to the previous edition has changed in order to be in line with ISO 9001:2015.
- For the convenient of the reader, the text of ISO 9001:2015 is copied and pasted in the text of ISO/IEC 80079-34:2018

ISO/IEC 80079-34:2018

- ISO/IEC 80079-34:2018 specifies particular requirements and information for establishing and maintaining a quality management system to manufacture Ex Products in accordance with the certificates.

- ISO/IEC 80079-34:2018 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.

- The normal “Table of Significant Changes” has not been included for this reason.

Application of ISO/IEC 80079-34:2018

The application of ISO/IEC 80079-34:2018 is intended to cover:

- electrical equipment (IEC 60079-0, -1, -2, -5, -6, -7, -11, -13, -15, -18, -28, - 33)
- non-electrical equipment (ISO 80079-36 and -37),
- protective systems(ISO 16852),
- safety devices (IEC 60079-29),
- Ex Components (IEC 60079-0, …)
- and their combinations as assembly of Ex equipment (IEC 60079-46).

Definitions

Some definitions have been withdrawn because these words are already defined in IEC 60079-0 and not changed:

- Ex Component
- Ex Equipment
- Type of Protection

New definitions:

- 3.5 Ex Product

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

- 3.10 Technical documentation

  Adding of the “Formal Ignition hazard identification and assessment” for Non-electrical equipment conforms to ISO 80079-36

4 Context of the organization

~~Quality management system~~

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.

5.3 Organizational roles, responsibilities and authorities ~~Old 5.5.1 Responsibility~~

1. The Ex authorized person(s) is/are now clearly defined
2. Due to the fact new ISO/IEC 9001:2015 is more flexible, responsibilities and authority to ensure requirements need to be defined and documented.
3. In the note of c) it written that the change of an Ex authorized person is considered as a “substantial” change

Ex authorized person(s) ~~Responsibilities and authority~~ for 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 ~~equipment intended for use in explosive atmospheres;~~Ex Products;

b) …

c) …

NOTE …The change of an Ex authorized person is considered as a “substantial” change.

5.3 Organizational roles, responsibilities and authorities ~~Old 5.5.1 Responsibility~~

4. Informations given to customers like sales literature and installation instructions shall include applicable Specific Conditions of Use and any Schedule of Limitations;
5. Inclusion of the responsibility regarding whole manufacturing including the parts which are subcontracted
6. When a manufacturer have multiple manufacturing sites an Ex authorized person is required per sites

f) the ~~customers~~accuracy of relevant information ~~of~~ 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);…

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.

5.3 Organizational roles, responsibilities and authorities ~~Old 5.5.1 Responsibility~~

7. Records demonstrating the Responsibilities and authority for all Ex authorized person(s) and who do what, shall be available and be maintained as documented information.

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

7.1.5 Monitoring and measuring resources

~~Old7.8Control of monitoring and measuring equipment~~

8. The first note is now a requirement.

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 ~~preferably~~ covered by a multilateral international agreement) ~~and obtaining a certificate bearing the accreditation logo. Where such a certificate is obtained, the~~ calibration laboratory need not be subjected to further evaluation.

7.2 Competence ~~Old 6.2 Human resources~~

~~Old 6.2.1 General Old 6.2.2 Competence, training and awareness~~

9. Due to the fact new ISO/IEC 9001:2015 is more flexible, the manufacturer has to defined and documented how all persons having an impact on the compliance of Ex Products are trained and competent.

The manufacturer shall have a documented process to identify and ensure that all persons having an impact on ~~Ex~~the compliance ~~receive appropriate training~~of Ex Products are trained and competent.

NOTE 1 ~~Example: people having~~ Parties who might have an impact ~~may include~~on the compliance of Ex Products are the Ex authorized person(s), manufacturing, inspecting, testing, sales, marketing, supply management, calibration and quality control services and other services.

NOTE 2 Competence requirements of 7.2 also address the awareness of 7.3.

7.4 Communication ~~Old 5.5.3 Internal communication~~

10. Due to the fact new ISO/IEC 9001:2015 is more flexible, the manufacturer has to defined and documented how he performs the communication with his personnel but also with his clients .

Internal and external communication relating to Ex Products shall be controlled.

NOTE 1 Communication includes manufacturer documentation, technical documentation, certificates, non-conforming products placed on the market, etc.

NOTE 2 External communication includes communication with clients, certification bodies, providers, economic operators (authorised representatives, importers, distributors, external providers …), authorities etc.

7.5 Documented information

~~Old 4.2 Documentation requirements~~

11. Due to the new ISO/IEC 9001:2015 quality manual, policies, procedure and instructions has to be documented in a systematic and orderly manner.

All requirements and provisions adopted by the manufacturer ~~in order~~ to ensure compliance of ~~the~~ Ex Products with their~~its Ex~~ certificates and technical documentation, and to demonstrate compliance to this document, shall be appropriately documented in a systematic and orderly manner. This may be achieved in the form of ~~written~~manuals, policies, procedures ~~and~~, instructions., flowcharts, spread sheets, forms, or other appropriate means. The quality management system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records.

7.5.3 Control of documented Information

~~Old 4.2 3.Control of documents~~

12. The quality system has to ensure that nothing defined in the Certificate and the technical documentation can be changed without permission of the issuer of the certificate

a) …

b) …

c) the quality management system shall ensure that no factor (type, characteristic, position etc.) defined within the ~~Ex~~ certificate and technical documentation (e.g. schedule drawings) is modified unless otherwise permitted by the issuer of the certificate;

d) …

7.5.3 Control of documented Information

~~Old 4.2.4 Control of records~~

13. The note regarding the minimum period of time retention is now a requirement

j) The manufacturer shall retain adequate quality records to demonstrate conformity of Ex Products ~~the product and satisfy National regulation and legislation. NOTE In the absence of specific National regulation and legislation it is suggested a~~. A minimum of 10 years ~~period is applied.~~ retention after each Ex Product (batch) has been placed on the market is required. As a minimum, the list of ~~documents~~quality records requiring control and retention, as far as applicable, shall be:

- those arising from regulatory requirements;
- quality documented information;
- responsibilities and authorities for Ex relevant roles assignment and communication within the organization;
- …;
- design and development changes;
- …;
- manufacturing traceability;
- …;
- other documented information, if needed.

8 Operation ~~Old 7 Product realization~~

14. The note regarding use of Annexe A and B are now a requirement even if it is said that other method can be used

~~NOTE Examples are given in Annexes A and B.~~

The information in Annexes A and B for control and acceptance of processes for Ex Products are one method to ensure compliance with the requirements of the certificate. If other methods are used, they should be evaluated to ensure full compliance with the requirements of certification.

8.2.3 Review of the requirements for products and services

~~Old 7.2.2 Review of requirements related to the product~~

15. The note regarding use internet sales is now a requirement in order to include the information given to customer

~~NOTE —~~In some situations, such as internet sales, a formal review ~~may~~ might ~~be~~ impractical. In such a case appropriate information shall be made available to the customer ~~and the order acknowledgement should include as a minimum the Ex marking .~~

8.3.6 Design and development changes

~~Old 7.3.7 Control of design and development changes~~

16. The Ex Authorized Person is defined the person who has to be in the approval process of any change which can occur on an Ex product

The Ex authorized person(s) identified in 5.3~~clause 5.5.1 a)~~ shall ~~approve~~ be involved in the approval process of any ~~changes~~ substantial modification or change (e.g. changes to the manufacturer's documentation, quality management system or marketing documents) that could ~~compromise~~affect Ex Product compliance.

8.4 Control of externally provided processes, products and services ~~Old 7.4 Purchasing~~

17. As it is written in ISO 9001:2015, the supplier is called external provider
18. It also specified what kind of processes shall be used to verify the continued conformity of the materials critical to the applied Type of Protection, used in the production of the Ex Products:

1. Review the Declaration(s) of Conformity from the external provider …
2. Review the material manufacturer's confirmation …
3. Review the material manufacturer's process and data for the validation ..
4. Confirmation that equipment testing, necessary to confirm the material is in accordance with the certificate or schedule drawings, is repeated as required.

Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity.

Receipt or acceptance of a declaration of conformity does not absolve the manufacturer from responsibility to ensure continuing conformity.

Note: Annex C provides guidance for the development of an external provider's declaration of conformity.

Annex A: Information relevant to particular Types of Protection and specific Ex Products

19. All markings should be in accordance with schedule drawings.
20. External Provider's Declaration of Conformity, see Annex C
21. Introduction of the batch testing and welded construction for Ex 'd' enclosure
22. Introduction of specification for enclosures for Group III or reduced spacing like some Intrinsic safety
23. Introduction of specification for Ex m, Ex o, Ex op and Ex h

ISO/IEC 80079-34:2018

When to start to use it?

ISO/IEC 80079-34:2018 is now published.

Then in principle we can start to use it.

During its last meeting in June ExMC WG5 is suggesting to use it from now and before next year.

This will be decided at the next ExMC meeting this week.

Thank you for your attention

Do you have any questions ?

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