


ExNB	Co-ordination of Notified Bodies Directive 2014/34/EU of the European Parliament and of the Council (ATEX) <i>Equipment and protective systems intended</i> <i>for use in potentially explosive atmosphere</i>	Clarification Sheet ExNB/CS/009
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Status:	Initial proposal by	WG 04/13 Quality questions (Convener: R. Schmidt)	Date:	2018-10-22
	Final draft			2019-04-17

Auditing practice of the Notified bodies within the directive 2014/34/EU (Annexes IV and VII) during the transition time until the mandatory availability of the standard EN ISO/IEC 80079-34: in the current states: EN ISO/IEC 80079-34:2011, ISO/IEC 80079-34:2018 and prEN ISO/IEC 80079-34 based upon ISO/IEC 80079-34:2018) for products covered by the ATEX Directive

Authorised by Chairman:	Dr. Thedens	Date:	2019-05-24
Date of application:		Signature:	

Description of situation:

Unfortunately it is dissatisfying that the implementation of the standard ISO 9001:2015 is officially ahead and closed for the manufacturers of the mandatory application of ISO/IEC 80079-34:2018 and EN ISO/IEC 80079-34:2019 respectively.

Thus for customers and for the Notified bodies' auditors arise the difficulty, which standard to apply for the foreseen QAN audit before EN ISO/IEC 80079-34:2019 is finally confirmed.

Officially in fact and law the valid standard is EN ISO/IEC 80079-34:2011 – based on the previous version ISO 9001:2008. Actually, most of the manufacturer apply the new ISO 9001:2015.

Otherwise ISO/IEC 80079-34:2018 is confirmed, but currently not as finalized EN standard.

Thus, it is practicable and reasonable to use applicable parts of prEN ISO/IEC 80079-34:2017. It is under the responsible position of the Notified body and its auditor(s) to adduct appropriate and relevant parts respectively of this new standard.

Answer:

Recommendations (of the QM-WG 04/13 for the months until publishing the new European Standard based upon ISO/IEC 80079-34:2018):

Considering most of the manufacturer apply the new ISO 9001:2015

It is proposed to use ISO/IEC 80079-34:2018 with the following schedule :

- from now, ISO/IEC 80079-34:2018 + Annex ZB of EN ISO/IEC 80079-34:2011,
- when prEN ISO/IEC 80079-34 based upon ISO/IEC 80079-34:2018 will be published, ISO/IEC 80079-34:2018 + Annex ZB of prEN ISO/IEC 80079-34 based upon ISO/IEC 80079-34:2018,
- when EN ISO/IEC 80079-34 based upon ISO/IEC 80079-34:2018 will be published, the complete new European version.

The audit report should contain the relevant references to the applied standards.

The QAN (QA certificate) may refer to the valid standard EN ISO/IEC 80079-34:2011 as current version or to prEN ISO/IEC 80079-34 based upon ISO/IEC 80079-34:2018 and/or ISO/IEC 80079-34:2018. It should be laid down in a recorded agreement between the auditor (on behalf of the NB) and the customer what should be done during the audit. E.g., the audit can be carried out based on EN ISO/IEC 80079-34:2011 with amendments following prEN ISO/IEC 80079-34:2018 based upon ISO/IEC 80079-34:2018. The QAN (QA notification as QA certificate according to the modules D or E, Annexes IV or VII) does not contain

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any references to the ISO/IEC standard. The QAN only confirms that the manufacturer is establishing and maintaining a quality assurance system for the production/final inspection according to the relevant annexes of the directive 2014/34/EU. The reference to the applied standards is exclusively provided by the underlying audit report.

Normative references

ISO 9001:2015 Quality management systems – Requirements

ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary.

ISO 19011:2018 Guidelines on quality and/or environmental management systems auditing.

EN ISO/IEC 80079-34: 2011 Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture

ISO/IEC 80079-34: 2018- Part 34: Application of quality systems for equipment manufacture

EN ISO/IEC 17065: 2012 Conformity assessment — Requirements for bodies certifying products, processes and services