

Proposals by KAN for informative Annexes Z in standards governing the accreditation of conformity assessment bodies

Results of a follow-up study to KAN Report 47,
"Accreditation of conformity assessment bodies"

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1 Initial situation

The standards relevant to conformity assessment bodies are developed not at European level, but at international level with the involvement of the European stakeholders. They therefore reflect the broad spectrum of interests worldwide in the accreditation of conformity assessment bodies. They are generally adopted unchanged as harmonized European standards and their titles published in the Official Journal of the EU. The users of these harmonized standards may then assume that by applying them, they are also satisfying the binding legal requirements in the EU that are covered by the standards concerned (presumption of conformity).

The extent to which the harmonized standards the references of which are published in the Official Journal of the European Union correspond to the essential requirements for conformity assessment bodies formulated in Decision 768/2008/EC was examined on behalf of KAN in a study entitled "Accreditation of conformity assessment bodies" and published in January 2011 in the form of KAN Report 47¹. This study showed that the content of these standards does not fully cover the relevant requirements of Decision 768/2008/EC. In addition, the harmonized standards do not precisely reflect the structure of the conformity assessment procedures (i.e. the module-specific requirements) contained in Annex II of the decision.

In other words, the standards do not make it explicitly clear in respect of which of the statutory provisions they actually give rise to a presumption of conformity. Descriptions in the various standards of the same subject-matter deviating both between the standards and from Decision 768/2008/EC also hinder comparison between the standards and with the underlying legal conditions.

2 Conclusions reached by KAN

The KAN stakeholders are of the view that standards which give rise to the presumption of conformity must indicate unambiguously what legal provisions they support, i.e. to what their presumption of conformity actually applies. KAN has therefore asked its secretariat to formulate proposals for informative Annexes Z for the standards that in the view of the occupational safety and health lobby are essential for the accreditation of conformity assessment bodies, and that it submit these proposals to the standardization process. KAN has also asked the German

¹ KAN Report 47, 1/2011, see <http://www.kan.de/en/publikationen/kan-berichte.html>

government to lobby the European Commission for the references of harmonized standards to be published in the Official Journal of the EU only if they include an Annex Z.

Besides the harmonized standards, international (for example of the International Laboratory Accreditation Cooperation ILAC or of the International Accreditation Forum IAF), European (of the European Co-operation for Accreditation EA) and in some cases national provisions and guidelines are used for the accreditation of conformity assessment bodies. Opinions therefore differ on whether European harmonized standards must *address* or even *support all* relevant statutory provisions. Irrespective of this however, informative Annexes Z are always necessary and useful in order to illustrate to the users of harmonized standards what the standards actually achieve and what use may have to be made of other resources.

3 Formulation of the proposals for Annexes Z

In order to provide a basis for proposals concerning Annexes Z, KAN commissioned a follow-up study to KAN Report 47 to examine the following standards and draft standards in depth:

- ISO/IEC DIS 17020:2011-01, Conformity assessment – General criteria for the operation of various types of bodies performing inspection
- EN ISO 17021:2011-07, Conformity assessment – Requirements for bodies providing audit and certification of management systems
- EN ISO 17025:2005, General requirements for the competence of testing and calibration laboratories
- ISO/IEC DIS 17065:2011-05, Conformity assessment – Requirements for bodies certifying products, processes and services

The versions of the standards examined were those available at the launch of the project on 1 August 2011.

3.1 Comparison with the essential requirements of Articles R17 and R20

The study first examined whether and to what extent these standards support or at least address in a general sense the essential requirements for conformity assessment bodies set out by Articles R17 and R20 in Annex I of Decision 768/2008/EC. The following template developed by the project partners was used for the purpose of systematic review:

Column A	Column B	Column C	Column D	Column E	Column F	Column G	Column H	Column I
R17 and R20	Comparison	<i>Within the scope?</i>	Standard sections	Supported?	Text of the standard	Evaluation	Proposal for Annex Z – Section No	Proposal for Annex Z – Comments
Paragraphs/ clauses	Text of the requirements set out in Articles R17 and R20 "paragraph by paragraph"; a separate line is assigned for each paragraph, sentence or indent	<i>This column is hidden for comparison of the standards with Articles R17 and R20, since these requirements are always applicable to the standards</i>	Standard sections addressing the requirement set out in R17/R20	In the <u>normative</u> part of the standard (notes are not normative), the requirement is: <i>Supported</i> → + <i>Included only in abstract form or paraphrased</i> → 0 <i>Not addressed</i> → -	Text of the standard for which the evaluation in Column E was relevant	Reasoning for the evaluation: A brief text explaining and commenting the evaluation in Column E	Number of the supporting section for informative Annex Z	Comment for informative Annex Z

Table 1: Template for comparison of the standards with the requirements of Articles R17 and R20 in Annex I of Decision 768/2008/EC

The results of the review were compiled in an Excel file. Each standard was assigned a worksheet of its own ([download the file](#)). The file shows where the essential requirements of Articles R17 and R20 formulated in Annex I of Decision 768/2008/EC are:

- *Supported* (see Column I: "Supported in: ..."),
- *Addressed*, i.e. included at least in abstract form or paraphrased from the decision (see Column I: " ... is addressed"), or
- *Not dealt with* (see Column I: " ... is however not dealt with")

3.2 Comparison with the requirements of the modules

In the second step, the individual standards were examined by means of the method described in Section 3.1 for the extent to which they satisfy the requirements set out in the modules in Annex II of Decision 768/2008/EC. All modules were included with the exception of A, A1, A2 and C, since conformity assessment bodies are of no relevance in these modules.

As already noted in KAN Reports 30 and 47, the standards are not cross-referenced structurally to the discrete tasks of the notified bodies set out in the modules. For this reason, the comparison presented a particular challenge and first necessitated an analysis of which standards are applicable in the first instance to which modules. This has long been controversial and is not viewed consistently within Europe. In the course of the present study, the scope and definitions stated in the standards were analysed in conjunction with the *functional approach* described in Annex A of EN ISO/IEC 17000 and compared with the requirements in the modules. Table 2 summarizes the assessed scope of application of the four standards to the various modules for the purpose of comparing their content.

The template shown in Table 3 was used for the comparison proper. The essential difference between Tables 1 and 3 concerns Column C, which is irrelevant in the former. In Table 3, comparison between the standards and the requirements of the modules always includes an indication of whether the module text concerned falls in the first instance within the scope of the standard under examination. Only where "Yes" is stated in Column C was the corresponding meaningfulness of the standard studied. The results of these studies can be found in four Excel files ([download the zipped-files](#)) containing a separate data sheet for each module studied.

Standards/ modules	B	C1/C2	D/D1	E/E1	F/F1	G	H	H1
ISO/IEC DIS 17020:2011-01 (inspection)	Partly applicable	Partly applicable	Not applicable	Not applicable	Partly applicable	Partly applicable	Not applicable	Partly applicable
DIN EN ISO 17021:2011-07 (QM certification)	Not applicable	Not applicable	Applicable ²	Applicable ²	Not applicable	Not applicable	Applicable ²	Partly applicable
DIN EN ISO/IEC 17025:2005 (testing)	Partly applicable	Partly applicable	Only for Paras. 4.4 (D)/6.4 (D1), Sentences 2 and 3	Only for Paras. 4.4 (E)/6.4 (E1), Sentences 2 and 3	Partly applicable	Partly applicable	Only for Para. 4.4, Sentences 2 and 3	Partly applicable
ISO/IEC DIS 17065:2011-05 (product certification)	Partly applicable	Not applicable	Not applicable	Not applicable	Partly applicable	Partly applicable	Not applicable	Partly applicable

Table 2: Applicability of the standards studied to Modules B, C1/C2, D/D1, E/E1, F/F1, G, H and H1 in Decision 768/2008/EC

- "Not applicable" = the scope of the standard does not correspond to the module
- "Partly applicable" = the standard is applicable to (specific) parts of the module
- "Applicable" = the scope of the standard corresponds to the module

² The aspect of product testing is not covered; cf. the row for DIN EN ISO/IEC 17025:2005 (testing).

Column A	Column B	Column C	Column D	Column E	Column F	Column G	Column H	Column I
Module No	Comparison	Within the scope?	Standards sections	Supported?	Text of the standard	Evaluation	Proposal for Annex Z – Section No	Proposal for Annex Z – Comments
Paragraphs/ clauses of the module in Decision 768/2008/EC	Text of the decision with requirements from the relevant module, "paragraph by paragraph"; a separate row is assigned for each paragraph, sentence or indent	Does the text of the module fall within the scope of the standard? "Yes" or "No"	Sections addressing the requirement set out in the relevant module	In the <u>normative</u> part of the standard (notes are not normative), is the requirement (with respect to the task/module): <i>Supported</i> → ++ <i>Included only in abstract form or paraphrased</i> → 0 <i>Not addressed</i> → –	Text of the standard for which the evaluation in Column E was relevant	Reasoning for the evaluation: A brief text explaining and commenting the evaluation in Column E	Supporting section number for informative Annex Z	Comment for informative Annex Z

Table 3: Template for comparison of the standards with the requirements of the modules from Annex II of Decision 768/2008/EC

The obligations upon manufacturers defined in the modules, for example to present their products for testing in homogeneous lots (Module F1), and the duty of manufacturers to retain documentation were deemed to lie outside the scope of the standards.

Certain aspects such as the "application" and the "conformity marking" are dealt with differently between the standards. As a result, "conformity marking" was for example classified as being "within the scope" of ISO/IEC DIS 17065:2011-05 but "not within the scope" of ISO/IEC DIS 17020:2011-01.

4 Proposals for Annexes Z

Based upon the content of Columns A (section number of the requirement in the decision/module), D (relevant standard sections) and I (comments) of the Excel tables produced, proposals were formulated for informative Annexes Z. For this purpose, not only were all columns other than A, D and I hidden, but also all rows concerning the legal requirements which the standard under analysis neither supports, nor addresses in abstract or paraphrased form.

Consequently, an Annex ZA is always produced for each standard for the requirements deriving from Articles R17 and R20 of Decision 768/2008/EC, and further Annexes Z (ZB, ZC, etc.) for each applicable module.

These annexes indicate clearly to the users what contribution the standards can actually make to the satisfaction of the statutory requirements. If they were parts of the standards or at least publicly accessible, it would for example be easier to determine where reference need be made to further specifications in the course of accreditation. In addition, this approach facilitates discussion, including at international level, of the areas in which the standards would benefit from amendment.

4.1 Annexes Z for EN ISO/IEC 17020

Drafted with reference to version ISO/IEC DIS 17020:2011-01

Annex ZA concerning Art. R17/R20

Article	Standard section	Comments
R17		
Para. 2	5.1.1 5.1.2	Supported in 5.1.1, 5.1.2
Para. 3, Sentence 1	4.1.6 in conjunction with Annex A 4.1.6.1	Supported in 4.1.6, 4.1.6.1 in conjunction with normative Annex A
Sentence 2	4.1.6 in conjunction with Annex A 1 d) ii	Is addressed
Para. 4, Sentence 1	4.1.6 4.1.6.1 to 4.1.6.4 in conjunction with Annex A 1b	Is addressed
Sentence 3	4.1.6 in conjunction with Annex A 1 a), b)	Is addressed
Sentences 4 and 5	4.1.6	Is addressed
Para. 5, Sentence 1	6.1.1 6.1.2 6.1.3 6.1.4 6.1.5	Supported in 6.1.3 (relevant knowledge), 6.1.4 (obligation to state duties, responsibilities and authorities), 6.1.5 (obligation to possess procedures), but partly not dealt with (professional integrity and technical competence)
Sentence 2	6.1.11 6.1.12	Is addressed
Para. 6	5.2.2 in conjunction with 6 7	Is addressed
a)	6.1.3	Supported in 6.1.3
b), Sentence 1	7.1.1 7.1.3	Is addressed

Article	Standard section	Comments
c) Sentence 2	6.2 6.2.1 6.2.11	Partly supported in 6.2 (with reference to equipment/facilities/procedures), but partly not dealt with (with reference to access to facilities)
Para. 7		
a)	6.1.1 6.1.2 6.1.3	Is addressed
b)	6.1.3	Is addressed
Para. 8, Sentence 1	4.1.5 5.2.1 6.1.12	Is addressed
Sentence 2	6.1.11	Is addressed
Para. 9	5.1.4	Is addressed
Para. 10	6.1.13	Partly addressed (assurance of confidentiality), but partly not dealt with (proprietary rights)
R20		
Para. 1	6.3.1	Is addressed
Para. 2	6.3.3	Is addressed
Para. 4	6.3.4	Is addressed

Annex ZB concerning Module B

Module B	Standard section	Comments
4	7.	Partly addressed (requirements concerning methods and procedures), but partly not dealt with
4.1	7.1.6	Is addressed
4.4	6.2.1	Partly addressed (6.2.1, facilities, equipment), but partly not dealt with
4.5	6.3.2	Partly addressed (6.3.2, duty to inform of intent to subcontract), but partly not dealt with
5	7.3.1 7.4.1 7.4.2 7.4.4 4.2.2	Supported in 7.4.1, 7.4.4 (retrievability), 7.4.2 (content of reports)
6., Sentences 1 + 2	7.4.2	Partly addressed, but partly not dealt with (content of the certificate, inadequate)
Sentence 3	7.4.2	Partly addressed, but partly not dealt with (content of the

Module B	Standard section	Comments
		certificate, inadequate)
7., Sentences 1 + 2	6.1.2 6.1.3 6.1.5 6.1.6 d)	Partly supported in 6.1.6 c) (keep itself apprised of changes in the generally acknowledged state of the art), but partly not dealt with (effects of changes in the generally acknowledged state of the art upon approved types, duty to inform manufacturers)
8.; Sentences 3, 4 + 5		Partly addressed (duty of retention), but partly not dealt with (duties of information)

Annex ZC concerning Module C2

Module C2	Standard section	Comments
3., Sentences 1, 2 and 3	6.1 6.2 7.1 7.2 7.3 7.4	Partly supported in: 6.1, personnel 6.2, facilities and equipment 6.3, subcontracting 7.1.5 supports document control 7.1.6 supports control of the work 7.1.7 supports duties for the recording of data (regarding performance of the "examinations and tests") However, partly not dealt with

Annex ZD concerning Module F1

Module F1	Standard section	Comments
4., Sentence 1	6.1 6.2 7.1 7.2 7.3 7.4	Partly supported in: 6.1, personnel 6.2, facilities and equipment 7.1.5 supports document control 7.1.6 supports control of the work 7.1.7 supports duties for the recording of data 7.2, handling of inspection items and samples 7.3, inspection records 7.4.2 supports the content of certificates 7.4.5, for correction of certificates/reports Also partly dealt with, but inadmissibly supported in 6.3 (subcontracting)
Sentence 2	As above 6.1 6.2 7.1	Partly supported in: 6.1, personnel 6.2, facilities and equipment 7.1.5 supports document control

Module F1	Standard section	Comments
	7.2 7.3 7.4 and 7.1.3	7.1.6 supports control of the work 7.1.7 supports duties for the recording of data 7.4.2 supports the content of certificates 7.4.5, for correction of certificates/reports Also partly dealt with, but inadmissibly supported in 6.3 (subcontracting)
5.1	7.1.1	Partly supported in 7.1.1 (methods and procedures), but partly not dealt with (inadmissibly weakened: in relation to development of requirements)
5.2, Sentence 1	7.4.1 7.4.2	Falls only partly within the scope; supported in 7.4.1, 7.4.2 (generation of an inspection report)
6.2	7.1.1 7.1.3 7.2	Partly supported in: 7.1.1 (development of requirements) 7.1.3 (instructions) 7.2 (handling of inspection items and samples) Partly not dealt with (specific requirements concerning the procedure)
6.3, Sentence 2	7.4.1 7.4.2	Falls only partly within the scope; supported in 7.4.1, 7.4.2 (generation of an inspection report)

Annex ZE concerning Module H1

Module H1	Standard section	Comments
4.1.	5.1.5 7.1.6	Partly addressed, but partly not dealt with (requirements concerning an application)
4.2.	5.1.5 7.1.6	Partly addressed, but partly not dealt with (requirements concerning an application)
4.3, Sentences 1, 2 + 3	7.1.1 7.1.2 7.1.3 7.1.5 7.1.6 7.1.7 7.4.1 7.4.2 7.4.5	Partly supported in: 7.1.5 supports document control 7.1.6 supports control of the work 7.1.7 supports duties for the recording of data 7.4.2 supports the content of certificates 7.4.5, concerning corrections to certificates/reports But partly not dealt with (provisions for design examination)
Sentence 4	7.4.2	Supported in 7.4.2 (information in certificates, at least in part)
4.4, Sentence 1	6.1.2 6.1.3 6.1.5 6.1.6 d)	Partly supported in 6.1.6 c) (keeping pace with developing technology) But partly not dealt with (effects of changes in the state of the

Module H1	Standard section	Comments
		art upon approved designs, duty to inform manufacturers)
4.5, Sentences 3 + 4	8.4.1 8.4.2	Partly addressed, but partly not dealt with
Sentence 5	8.4.1 8.4.2	Partly addressed, but partly not dealt with

4.2 Annexes Z for EN ISO/IEC 17021

Drafted with reference to version: DIN EN ISO 17021:2011-07

Annex ZA concerning Art. R17/R20

Article	Standard section	Comments
R17		
Para. 2	5.1.1	Supported in 5.1.1
Para. 3, Sentence 1	4.2 5.2 6.2	Supported in 4.2 (impartiality), 5.2 (management of impartiality), 6.2 (committee for safeguarding impartiality)
Para. 4, Sentence 4	4.2.3 4.2.4	Supported in 4.2.4 (threats to impartiality)
Para. 4, Sentence 5	7.3 7.5.3 b) 7.5.3 c)	Is addressed
Para. 5	4.3 7.1 7.2.1 Annex A	Partly supported in 7.1 (competence of management and personnel) and Annex A (required knowledge and skills), but partly not dealt with (professional integrity)
	5.2.12 5.3.2	Is addressed
Para. 6	7.1.1 7.2.1 (certification) 9.1 7.2.2 (auditing)	Is addressed
a)	4.3 7.1 7.2.1 to 7.2.12 9.1.3.2 to 9.1.3.5	Supported in 7.2.1 to 7.2.12 (certification), 9.1.3.2 to 9.1.3.5 (auditing)
b), Sentence 1	8.6.1 9.1.2.2	Partly supported in 9.1.2.2 (determining audit objectives, scope and criteria), partly addressed (certification methods)
c), Sentence 1	9.1.4.1	Partly addressed (auditing activity), but partly not dealt with (certification activity)
Sentence 2	6.1.2 i) 7.1.4.2	Is addressed
Para. 7		
a)	4.3 7.1.2 in conjunction with Annex A 7.2.1	Supported in 7.1.2, 7.2.1 in conjunction with Annex A

Article	Standard section	Comments
	9.1.3	
b)	7.1.2 in conjunction with Annex A 7.2.1 9.1.3	Supported in 7.1.2, 7.2.1 in conjunction with Annex A
Para. 8, Sentence 1	5.2.1	Is addressed
Para. 9	5.3.1	Supported in 5.3.1 (geographic reference)
Para. 10	7.3 7.5.1 7.5.3 b) 8.5	Partly supported in 8.5 (assurance of confidentiality), but partly not dealt with (proprietary rights)
R20		
Para. 1	7.5.3	Is addressed
Para. 2	7.5.3	Is addressed

Annex ZB concerning Module D

Module D	Standard section	Comments
3.1, Sentence 1	1 9.2.1 9.9.2	Supported in 9.2.1, 9.9.2 (records and handling of records)
Sentence 2 (enumeration)	9.2.1.	Is addressed
3.3, Sentence 1	1. 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
Sentence 2	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
Sentence 3	7.1.3 7.2 9.1	Supported in 7.1.3, 7.2, 9.1
Sentence 4	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10.1	Supported in 8.2.3, 8.6.1, 9.1.10.1
3.5, Sentence 1	8.6.3	Is addressed
Sentence 2	8.6.3 9.3.1.1	Is addressed
Sentence 3	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10.1	Supported in 8.1.3, 8.2.1, 8.2.3, 8.6.1, 9.1.10.1
4.1.	9.3	Supported in 9.3
4.3.	9.1 9.1.1.1 9.1.2.1 9.1.10 9.5	Supported in 9.1.1.1, 9.1.2.1, 9.1.10
4.4.	9.1.10.1 9.5.2	Partly addressed (short-notice audits/reports), but partly not dealt with (unannounced audits)
7., Sentence 2	8.1.1 8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1

Annex ZC concerning Module D1

Module D1	Standard section	Comments
5.1, Sentence 1	1 9.2.1 9.9.2	Supported in 9.2.1, 9.9.2
Sentence 2 (enumeration)	9.2.1.	Is addressed
5.3.	1 7.1.1 7.2.1	Supported in 7.1.1., 7.2.1
	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
	7.1.3 7.2 9.1	Supported in 7.2, 9.1
	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10	Supported in 8.1.3, 8.2.1, 8.2.3, 8.6.1, 9.1.10.1
5.5.	8.6.3	Is addressed
	8.6.3 9.3.1.1	Is addressed
	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10	Supported in 8.1.3, 8.2.1, 8.2.3, 8.6.1, 9.1.10.1
6.1.	9.3	Supported in 9.3
6.3.	9.1.1.1 9.1.2.1 9.1.10 9.5	Supported in 9.1.1.1, 9.1.2.1, 9.1.10
6.4.	9.1.10.1 9.5.2	Partly addressed (short-notice audits/reports), but partly not dealt with (unannounced audits)
9., Sentence 2	8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1

Annex ZD concerning Module E

Module E	Standard section	Comments
3.1, Sentence 1	9.2.1 9.9.2	Supported in 9.2.1, 9.9.2
Sentence 2 (enumeration)	9.2.1.	Is addressed
3.3, Sentence 1	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
Sentence 2	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
3., Sentences 4 + 5	7.1.3 7.2.1 9.1.1.1 9.1.3.1	Supported in 7.2.1, 9.1.1.1, 9.1.1.3
Sentence 6	8.1 8.2 8.6 9.1.9.8 9.1.10	Supported in 8.6, 9.1.10
3.5, Sentence 1	8.6.3	Is addressed
Sentence 2	8.6.3 9.3.1.1	Is addressed
Sentences 3 + 4	8.1 8.2 8.6 9.1.9.8 9.1.10	Supported in 8.2, 8.6, 9.1.10
4.1.	9.3	Supported in 9.3
4.3.	9.1 to 9.5	Supported in 9.1, 9.2, 9.3, 9.4, 9.5
4.4.	9.1.10.1 9.5.2	Partly addressed (short-notice audits/reports), but partly not dealt with (unannounced audits)
7., Sentence 1	8.1.1 8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1
Sentence 2	8.1.1 8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1

Annex ZE concerning Module E1

Module E1	Standard section	Comments
5.1, Sentence 1	1 9.2.1 9.9.2	Supported in 9.2.1, 9.9.2
Sentence 2 (enumeration)	9.2.1.	Is addressed
5.3, Sentence 1	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
Sentence 2	1 7.1.1 7.2.1	Supported in 7.1.1, 7.2.1
3., Sentences 4 + 5	7.1.3 7.2 9.1	Supported in 7.2, 9.1
	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10.1	Supported in 8.2.1, 8.6.1, 9.1.10.1
5.5, Sentence 1	8.6.3	Is addressed
Sentence 2	8.6.3 9.3.1.1	Is addressed
Sentence 3	8.1.3 8.2.1 8.2.3 8.6.1 9.1.10.1	Supported in 8.2.1, 8.2.3, 8.6.1, 9.1.10.1
6.1.	9.3	Supported in 9.3
6.3.	9.1 to 9.5	Supported in 9.1, 9.2, 9.3, 9.4, 9.5
6.4.	9.1.10.1 9.5.2	Partly addressed (short-notice audits/reports), but partly not dealt with (unannounced audits)
9., Sentence 1	8.1.1 8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1
Sentence 2	8.1.1 8.1.3 8.1.4 9.9.1	Supported in 8.1.3, 8.1.4, 9.9.1

Annex ZF concerning Module H1

Module H1	Standard section	Comments
3.3, Sentences 1 + 2	7.1. 7.2. 9	Supported in 9 (audit process)
Sentences 3 + 4	7.1.3 7.2.1 to 7.2.12 9.1.3	Supported in 7.1.3 (evaluation processes), 7.2.1 to 7.2.12 (personnel involved in certification activity), 9.1.3 (audit team selection)
Sentence 5	8.1 8.2 8.3 8.6 9.1.9.8	Supported in 8.1, 8.2, 8.3, 8.6, 9.1.9.8
Sentence 6	8.1.1 8.3 8.6 9.1.10	Supported in 8.1.1, 8.3, 8.6, 9.1.10
3.5, Sentence 1	8.6.3	Is addressed
Sentence 2	8.6.3 9.3 9.3.1.1 9.5.2	Is addressed
Sentence 3	8.1.1 8.3 8.6 9.1.10	Supported in 8.1.1, 8.3.2, 8.6 (information exchange between a certification body and its clients), 9.1.10 (audit report)
3.6, Sentence 1	8.3	Is addressed
Sentence 2	8.3	Is addressed
5.	9.3	Supported in 9.3 (surveillance activities)
5.1, Sentence 1	9.3	Supported in 9.3 (surveillance activities)
5.2, Sentence 2	9.3	Supported in 9.3 (surveillance activities)
Bullet point 1	9.3. 9.3.2.1	Supported in 9.3 (surveillance activities), 9.3.2.1 (surveillance audit)
Bullet point 2	9.3. 9.3.1.2	Supported in 9.3 (surveillance activities), 9.3.2.1 (surveillance audit)
Bullet point 3	9.3. 9.3.1.2	Supported in 9.3 (surveillance activities), 9.3.2.1 (surveillance audit)
5.3.	9.3. 9.3.2.2	Supported in 9.3 (surveillance activities), 9.3.2.2 (surveillance audit)

4.3 Annexes Z for EN ISO/IEC 17025

Drafted with reference to version: DIN EN ISO 17025:2005

Annex ZA concerning Art. R17/R20

Article	Standard section	Comments
R17		
Para. 2	4.1.1	Partly addressed (legal personality/responsibility), but partly not dealt with (establishment under national law)
Para. 3	4.1.4 4.1.5 a)	Partly addressed (independence), but partly not dealt with (conflict of interest)
Para. 5, Sentence 1	5.2.1 5.2.3	Partly addressed (technical competence), but partly not dealt with (professional integrity)
Sentence 2	4.1.5 b)	Is addressed
Para. 6	4.1.2	Is addressed
a)	4.1.5 a) 5.2.1 Note 2	Is addressed
b) Para. 1	4.6.1 5.4.1 5.4.2 5.4.4 Note 2	Partly addressed in 4.6.1; 5.4.1; 5.4.2 (essential rules and methods for testing and calibration), 5.4.1 (instructions for testing and calibration) The content of the procedural instructions is supported in 5.4.4, but not normatively, since only by means of an (informative) note
c) Sentence 2	5.3.1 5.5.1 5.5.4 5.5.5	Supported in 5.5.5 (mandatory marking of facilities)
Para. 7 a)	5.2.1 5.2.3	Is addressed
b)	5.2.1 5.2.3 in conjunction with 4.1.5	Is addressed
Para. 8, Sentence 1	4.1.5 b) 4.1.5 d)	Is addressed
Para. 10	4.1.5 c)	Is addressed
R20		
Para. 1	4.4.3 4.5.1 4.5.4	Is addressed

Article	Standard section	Comments
Para. 2	4.5	Is addressed
Para. 3	4.5.2	Is addressed
Para. 4	4.5.4	Is addressed

Annex ZB concerning Module B

Module B	Standard section	Comments
4.5	4.7.1.	Is addressed
5.	5.10.1.	Partly addressed (test reports), but partly not dealt with (release of reports and agreement to do so)
7., Sentence 1	5.4.1 5.4.2	Supported in 5.4.1, 5.4.2

Annex ZC concerning Module C

Module C		<i>With the exception of Section 1, which is not addressed, Module C does not fall within the scope of the standard.</i>
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Annex ZD concerning Module C1

Module C1	Standard section	Comments
3., Sentences 1 and 2	1.2 5.4.1 5.4.2	Is addressed

Annex ZE concerning Module C2

Module C2	Standard section	Comments
3., Sentence 1	5.4.1 5.4.2	Supported in 5.4.1, 5.4.2
3., Sentences 2 and 3	5.4.1 5.4.2	Is addressed

Annex ZF concerning Module D

Module D	Standard section	Comments
4.4	5.4.1 5.4.2 5.10.1	Partly supported in 5.4.1, 5.4.2, 5.10.1 (tests/reports), but partly not dealt with (visits)

Annex ZG concerning Module D1

Module D1	Standard section	Comments
6.4	5.4.1 5.4.2 5.10.1	Partly supported in 5.4.1, 5.4.2, 5.10.1 (tests/reports), but partly not dealt with (visits)

Annex ZH concerning Module E

Module E	Standard section	Comments
4.4	5.4.1 5.4.2 5.10.1	Partly supported in 5.4.1, 5.4.2, 5.10.1 (tests/reports), but partly not dealt with (visits)

Annex ZI concerning Module E1

Module E1	Standard section	Comments
6.4	5.4.1 5.4.2 5.10.1	Partly supported in 5.4.1, 5.4.2, 5.10.1 (tests/reports), but partly not dealt with (visits)

Annex ZJ concerning Module F

Module F	Standard section	Comments
3., Sentence 1	5.4.1 5.4.2	Is addressed
3. Sentence 2	5.4.2 5.7.1	Supported in 5.4.2, 5.7.1

Module F	Standard section	Comments
4.1	5.4.2	Is addressed
5.2	5.4.1 5.4.2 5.7.1	Supported in 5.4.1, 5.4.2, 5.7.1

Annex ZK concerning Module F1

Module F	Standard section	Comments
3., Sentence 1	5.4.1 5.4.2	Is addressed
3. Sentence 2	5.4.2 5.7.1	Supported in 5.4.2, 5.7.1
4.1	5.4.2	Is addressed
5.2	5.4.1 5.4.2 5.7.1	Supported in 5.4.1, 5.4.2, 5.7.1

Annex ZL concerning Module G

Module G	Standard section	Comments
4., Sentences 1 + 2	5.4.1 5.4.2	Is addressed

Annex ZM concerning Module H

Module H	Standard section	Comments
4.4	5.4.1 5.4.2 5.10.1	Partly supported in 5.4.1, 5.4.2, 5.10.1 (tests/reports), but partly not dealt with (visits)

Annex ZN concerning Module H1

Module H1	Standard section	Comments
4.1.	4.7.1	Is addressed

Module H1	Standard section	Comments
4.2.	4.4.1 4.7.1	Is addressed
4.5, Sentence 5	4.13.2.1	Is addressed

4.4 Annexes Z for EN ISO/IEC 17065

Drafted with reference to version ISO/IEC DIS 17065:2011-05

Annex ZA concerning Art. R17/R20

Article	Standard section	Comments
R17		
Para. 2	4.1.1	Supported in 4.1.1
Para. 3	4.2 5.1.1 Annex A.2	Supported in 4.2 in conjunction with Annex A.2
Para. 4, Sentence 1	4.2.6 a) 4.2.6 b) 4.2.6 c) 7.6.4	Is addressed
Sentence 2	4.2.6 a) to 4.6.2 e) 4.2.9 6.1.3 b)	Is addressed
Sentence 3	4.2.1 4.2.6 d)	Is addressed
Sentence 4	4.2.7 6.2.2.2	Is addressed
Para. 5, Sentence 1	6.1 6.1.1.2	Partly supported in 6.1 (technical competence), but partly not dealt with (professional integrity)
Sentence 2	4.2.2 5.1.4 5.2.1 b) 6.1.3 a) to c)	Is addressed
Para. 6, Sentence 1	4.1.2.2 i)	Is addressed
Sentence 2		
a)	6.1.1.1 6.1.1.2 6.1.2 Annex A.3	Supported in 6.1.2 (management of competence), Annex A.3
b), Sentence 1	4.6 Annex A.4.3	Is addressed
Sentence 2	6.1.1.1 7.4.3	Partly addressed (personnel, information, documentation), but partly not dealt with (equipment and facilities)

Article	Standard section	Comments
Para. 7		
a)	6.1.1.2 6.1.2.1 c) Annex A.3	Is addressed
b)	6.1.1.2 6.1.2.1 6.1.2.2 g)	Is addressed
Para. 8	4.2.1 to 4.2.5 4.2.7 4.2.11 4.2.12 5.1.1	Supported in 4.2 (management of impartiality)
Para. 9	4.3.1	Is addressed
Para. 10	4.5 6.1.3 a) A.4.1 4.1.3.1	Partly supported in 4.5 (confidentiality), partly addressed (proprietary rights)
R20		
Para. 1	6.2.2.1	Is addressed
Para. 2	6.2.2.2 6.2.2.4 a)	Is addressed
Para. 4	6.2.2.4	Is addressed

Annex ZB concerning Module B

Module B	Standard section	Comments
3., Sentence 2 (enumeration)	4.1.2.1 4.1.2.2 7.2 7.4.3	Partly addressed, but partly dealt with either not at all, or only in informative notes
4.1	7.3 7.4 7.4.1 7.4.2 7.4.3 7.4.4 7.4.5	Falls only partly within the scope (evaluation, not testing), supported in 7.4.1 (plan for evaluation), 7.4.2 (assignment of personnel for evaluation task)
5.	4.5.1 4.5.2	Partly addressed (7.4.9 governing duty to document and sequence of activities), but partly not dealt with
6., Sentences 1, 2 + 3	7.7.1 7.7.2 7.4.6 7.4.9	Partly addressed (7.7.1, certification documentation), but partly not dealt with
Sentence 4	7.7.1	Partly addressed (7.7.1, certification documentation), but partly not dealt with
Sentence 5	7.6.5	Partly addressed (7.6.5, duty to inform), but partly not dealt with
7., Sentences 1 + 2	7.10.2 7.10.3	Partly addressed, but partly not dealt with
Sentences 3 + 4	4.1.2.2	Partly addressed, but partly not dealt with (explicit duty to inform)
8., Sentence 3	7.12.1 7.12.3	Partly addressed (duty to inform customers of disclosures), but partly not dealt with (duty of retention)

Annex ZC concerning Module F1

Module F1	Standard section	Comments
4.		Supported in: 4.1.2, certification agreement 6.1, certification body personnel 6.2, resources for evaluation 7.4, evaluation 7.5, review 7.6, certification decision 7.7, certification documentation Partly dealt with, but inadmissibly supported in 6.2.2, external resources (outsourcing)
5.2, Sentence 1	7.4.3 7.4.6 7.7.1	Falls only partly within the scope; supported in 7.4.6, 7.7.1 (report and certification documentation)
6.3, Sentence 2	7.4.3 7.4.6 7.7.1	Falls only partly within the scope; supported in 7.4.6, 7.7.1 (report and certification documentation)

Annex ZD concerning Module H1

Module H1	Standard section	Comments
4.1	4.1.2 4.6 c) 7.2	Partly addressed (certification agreement), but partly not dealt with
4.2	4.1.2 4.6 c) 7.2	Partly addressed (certification agreement), but partly not dealt with
4.3	7.3 7.4 7.5 7.6 7.7	Partly supported in 7.4 (evaluation), but partly not dealt with (e.g. concerning selection/arrangements of tests to be performed and responsibility for the evaluation plan)
4.4, Sentences 1 + 2	7.10.2 7.10.3 7.11.1	Partly addressed, but partly not dealt with
Sentences 3 + 4	4.1.2.2	Partly addressed, but partly not dealt with
4.5, Sentences 3 + 4	7.12.1 7.12.3	Partly addressed (duty to inform customers of disclosures), but partly not dealt with
4.5, Sentence 5	7.12	Partly addressed (general duty of retention), but partly not dealt with (duration)

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