Commission Implementing Decision (EU) 2020/1835 of 3 December 2020 on the harmonised standards for accreditation and conformity assessment (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2020/1835

of 3 December 2020

on the harmonised standards for accreditation and conformity assessment

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council[(1)], and in particular Article 10(6) thereof,

Whereas:

(1) In point 10 of Article 2 of Regulation (EC) No 765/2008 of the European Parliament and of the Council[(2)] accreditation is defined as an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

(2) Legal acts of the Union incorporating the reference provisions included in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council[(3)] provide, in certain cases, for the intervention of third-party conformity assessment bodies in the relevant conformity assessment procedures. Furthermore, all such legal acts incorporate Article R17 of Annex I to Decision No 768/2008/EC, setting out the requirements that conformity assessment bodies must meet, and Article R18 of Annex I to Decision No 768/2008/EC providing that where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union,* it is to be presumed to comply with the requirements set out in that Union act, insofar as the applicable harmonised standards cover those requirements.

(3) There are also legal acts of the Union that do not incorporate Articles R17 and R18 of Annex I to Decision No 768/2008/EC. However, they require the intervention of third-party conformity assessment body and provide for accreditation of those bodies in accordance with Regulation (EC) No 765/2008 to demonstrate their competence.

(4) By letter M/417 of 4 December 2007 the Commission made a request to the European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (Cenelec) and European Telecommunications Standards Institute (ETSI) for the completion of the work on harmonised standards in support of the New Legislative Framework, in particular as regards accreditation and conformity assessment or quality assurance, as well as sectoral certification schemes. In that mandate, the Commission asked those organisations to identify all international standards that are relevant to the New Legislative Framework or certain sectoral certification schemes and to adopt them at European level as European standards. European standards in support of Regulation (EC) No 765/2008, legal acts of the Union incorporating the reference provisions of Annex I to Decision No 768/2008/EC setting out the requirements for conformity assessment bodies and legal acts of the Union which, while not incorporating Article R17 and R18 of Annex I to Decision No 768/2008/EC, require the intervention of a third-party conformity assessment body and provide for accreditation of that body in accordance with Regulation (EC) No 765/2008, therefore fall within the scope of the mandate.

(5) On the basis of the request M/417 of 4 December 2007, CEN and Cenelec adopted the standards EN ISO 14064-1:2019 - Greenhouse gases - Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals, EN ISO 14064-2:2019 - Greenhouse gases - Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements, EN ISO 14064-3:2019 - Greenhouse gases - Part 3: Specification with guidance for the verification and validation of greenhouse gas statements, EN ISO 15195:2019 - Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures, and EN ISO/IEC 17029:2019 - Conformity Assessment - General principles and requirements for validation and verification bodies, by transposing the international standards ISO 14064-1:2018, ISO 14064-2:2019, ISO 14064-3:2019, ISO 15195:2018, and ISO/IEC 17029:2019.

(6) The Commission together with CEN and Cenelec has assessed whether standards EN ISO 14064-1:2019, EN ISO 14064-2:2019, EN ISO 14064-3:2019, EN ISO 15195:2019 and EN ISO/IEC 17029:2019 drafted by CEN comply with the request M/417 of 4 December 2007.

(7) Harmonised standards EN ISO 14064-1:2019, EN ISO 14064-2:2019 and EN ISO 14064-3:2019 satisfy the requirements which they aim to cover for conformity assessment bodies for the purposes of performing quantification, monitoring and reporting of activities intended to cause greenhouse gas and of conducting or managing the validation and verification of greenhouse gas assertions as provided for in Regulation (EC) No 1221/2009 of the European Parliament and of the Council[(4)].

(8) Harmonised standard EN ISO 15195:2019 satisfies the requirements which it aims to cover for conformity assessment bodies acting as notified bodies for the purposes of performing calibration using reference measurement procedures, as provided for in Directive 98/79/EC of the European Parliament and of the Council[(5)].

(9) Harmonised standard EN ISO 17029:2019 satisfies the requirements which it aims to cover for conformity assessment bodies acting as verifiers for the purposes of performing validation and verification of conformity assessment activities as provided for in Commission Implementing Regulation (EU) 2018/2067[(6)].

(10) It is therefore appropriate to publish the reference of those standards in the *Official Journal of the European Union.*

(11) Harmonised standards EN ISO 14064-1:2019, EN ISO 14064-2:2019, EN ISO 14064-3:2019 and EN ISO 15195:2019 are revised versions of and thus supersede standards EN ISO 14064-1:2012, EN ISO 14064-2:2012, EN ISO 14064-3:2012 and EN ISO 15195:2003, the references of which are published in the C series of the *Official Journal of the European Union*[(7)]. It is therefore necessary to withdraw the references to harmonised standards EN ISO 14064-1:2012, EN ISO 14064-2:2012, EN ISO 14064-3:2012 and EN ISO 15195:2003 from the *Official Journal of the European Union*. In order to give economic operators and third-party conformity assessment bodies the necessary time to adapt their monitoring, reporting, measuring and verifying methods to the revised harmonised standards, it is necessary to defer the withdrawal of the references to harmonised standards EN ISO 14064-1:2012, EN ISO 14064-2:2012, EN ISO 14064-3:2012 and EN ISO 15195:2003.

(12) Harmonised standard EN ISO/IEC 17025:2017 is a revised version of and thus supersedes standard EN ISO/IEC 17025:2005. The reference of the harmonised standard EN ISO/IEC 17025:2017 is published in the C series of the *Official Journal of the European Union*[(8)] with the 31.12.2020 as the date of cessation of effect of superseded standard EN ISO/IEC 17025:2005. Due to the global impact of the coronavirus outbreak, in order to ensure that all accreditation bodies and the accredited bodies are able to accomplish their tasks in a robust and reliable manner, and in line with the international practice, an extension of the transition period should be warranted,

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for accreditation of conformity assessment bodies listed in Annex II, drafted in support of the legal acts listed in Annex I, are hereby published in the *Official Journal of the European Union*.

Article 2

The references of the harmonised standards listed in Annex III are hereby withdrawn from the *Official Journal of the European Union* as from the dates set out in that Annex.

Article 3

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 3 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

1. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

2. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

3. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

4. Commission Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council (OJ L 334, 31.12.2018, p. 94).

ANNEX II

No	Reference of the standard
1.	EN ISO 14064-1:2019 Greenhouse gases - Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals (ISO 14064-1:2018)
2.	EN ISO 14064-2:2019 Greenhouse gases - Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements (ISO 14064-2:2019)
3.	EN ISO 14064-3:2019 Greenhouse gases - Part 3: Specification with guidance for the verification and validation of greenhouse gas statements (ISO 14064-3:2019)
4.	EN ISO 15195:2019 Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures (ISO 15195:2018)
5.	EN ISO/IEC 17029:2019 Conformity Assessment - General principles and requirements for validation and verification bodies (ISO/IEC 17029:2019)

ANNEX III

No	Reference of the standard	Date of withdrawal
1.	EN ISO 14064-1:2012 Greenhouse gases - Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals (ISO 14064-1:2006)	1.7.2022
2.	EN ISO 14064-2:2012 Greenhouse gases - Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements (ISO 14064-2:2006)	1.7.2022
3.	EN ISO 14064-3:2012 Greenhouse gases - Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions (ISO 14064-3:2006)	1.7.2022
4.	EN ISO 15195:2003 Laboratory medicine - Requirements for reference measurement laboratories (ISO 15195:2003)	1.7.2022
5.	EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005) EN ISO/IEC 17025:2005/AC:2006	1.7.2021

(**1**) OJ L 316, 14.11.2012, p. 12.

(**2**) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(**3**) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(**4**) Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

(**5**) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

(**6**) Commission Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council (OJ L 334, 31.12.2018, p. 94).

(**7**) OJ C 209, 15.6.2018, p. 12.

(**8**) OJ C 209, 15.6.2018, p. 12.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/1835.