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COMMISSION IMPLEMENTING DECISION (EU) 2024/581

of 16 February 2024

on the harmonised standard for accreditation of medical laboratories drafted in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council

(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 accordance with Article 11(1) of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([2]), national accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, by having successfully undergone peer evaluation pursuant to Article 10 of that Regulation are to be presumed to fulfil the requirements laid down in its Article 8.

(2) Regulation (EC) No 765/2008 defines 'accreditation' as an attestation by a national accreditation body that, in addition to any additional sector-specific requirements, a conformity assessment body meets the requirements set by harmonised standards.

(3) By Implementing Decision C(2021)9277 ([3]), the Commission made a request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of and the revision of harmonised standards in support of Regulation (EC) No 765/2008 and the Union legislation listed in point 2 of Annex II to that Decision. The Commission requested to base the harmonised standards listed in Table 2 of Annex I to Implementing Decision C(2021)9277 on standards of the International Organization for Standardization (ISO) and of the International Electrotechnical Commission (IEC).

(4) On the basis of the request set out in Implementing Decision C(2021)9277, CEN revised harmonised standard EN ISO 15189:2012, the reference of which is published in Commission communication 2018/C 209/02 ([4]). This resulted in the adoption of harmonised standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023.

(5) The Commission together with the CEN has assessed whether the standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023 complies with the request set out in Implementing Decision C(2021)9277.

([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 repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

([3]) Commission Implementing Decision C(2021)9277 of 17 December 2021 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards accreditation and conformity assessment in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council.

([4]) Commission communication (2018/C 209/02) in the framework of the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision No 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 1221/2009 of the European Parliament and of the Council (*Publication of titles and references of harmonised standards under Union harmonisation legislation*) (OJ C 209, 15.6.2018, p. 12.)

(6) The standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023 satisfies the requirements which it aims to cover and allows for a national accreditation body to fulfil its obligations laid down in Article 8(10) of Regulation (EC) No 765/2008. It is therefore appropriate to publish the reference of that harmonised standard and its amendment in the *Official Journal of the European Union*.

(7) Harmonised standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023 replaces harmonised standard EN ISO 15189:2012. It is therefore necessary to withdraw the reference of harmonised standard EN ISO 15189:2012 from the *Official Journal of the European Union*.

(8) In order to allow for the national accreditation bodies time to adapt their accreditation schemes for medical laboratories for application of harmonised standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023, it is necessary to defer the withdrawal of the reference of harmonised standard EN ISO 15189:2012.

(9) Conformity with the criteria laid down in the relevant harmonised standard confers a presumption of conformity with the corresponding requirements for accreditation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The reference of harmonised standard EN ISO 15189:2022 as amended by EN ISO 15189:2022/A11:2023 Medical laboratories – Requirements for quality and competence (ISO 15189:2022) drafted in support of Regulation (EC) No 765/2008 is hereby published in the *Official Journal of the European Union*.

Article 2

The reference of the harmonised standard EN ISO 15189:2012 Medical laboratories – Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15) is hereby withdrawn from the *Official Journal of the European Union*, as from 20 August 2025.

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, 16 February 2024.

For the Commission
The President
Ursula VON DER LEYEN