

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish a document in the Federal Register and the material must be available to the public. All approved material is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) International Organization for Standardization, Case postale 56, CH-1211, Geneve 20, Switzerland, telephone +41-22-749-01-11, <http://www.iso.org>.

(1) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, “ISO/IEC Guide 65,” IBR approved for § 170.503.

(2) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, “ISO/IEC 17011,” IBR approved for § 170.503.

(3) ISO/IEC 17025:2005(E)—General requirements for the competence of testing and calibration laboratories (Second Edition), 2005-05-15, “ISO/IEC 17025,” IBR approved for §§ 170.520(b) and 170.524(a).

(4) ISO/IEC 17025:2017(E)—General requirements for the competence of testing and calibration laboratories (Third Edition), 2017-11, “ISO/IEC 17025,” IBR approved for §§ 170.520(b), and 170.524(a).

(5) ISO/IEC 17065:2012(E)—Conformity assessment—Requirements for bodies certifying products, processes and services (First Edition), 2012, “ISO/IEC 17065,” IBR approved for §§ 170.503 and 170.523(a).

[81 FR 72471, Oct. 19, 2016, as amended at 85 FR 25955, May 1, 2020]