

§ 170.490

notice. The certification status of the Complete EHR and/or EHR Module can only be maintained thereafter by being re-certified by an ONC-ATCB in good standing.

§ 170.490 Sunset of the temporary certification program.

(a) The temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. On and after the temporary certification program sunset date, ONC-ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules.

(b) ONC-ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

§ 170.499 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 notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is 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. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56,

45 CFR Subtitle A (10-1-14 Edition)

CH-1211, Geneva 20, Switzerland, telephone +41-22-749-01-11, <http://www.iso.org>.

(1) ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for § 170.420 and § 170.423.

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.420 and § 170.423.

(3) [Reserved]

Subpart E—ONC HIT Certification Program

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the ONC HIT Certification Program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

§ 170.501 Applicability.

This subpart establishes the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ACB status; the requirements that ONC-ACBs must follow to maintain ONC-ACB status; and the requirements of ONC-ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the ONC HIT Certification Program as well