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, CH·1211, Geneve 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—Permanent Certification Program for HIT

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

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, subpart E was amended by removing the phrases ''permanent certification program for HIT'' and ''permanent certification program'' and add in their place ''ONC HIT Certification Program'' wherever they may occur, effective Oct. 4, 2012.

§ 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 permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

§ 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 permanent certification program as well as certain ongoing responsibilities for an ONC–AA.

§ 170.502 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ACB by submitting an application for ONC–ACB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

Development site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

Gap certification means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

ONC–Approved Accreditor or ONC–AA means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

ONC–Authorized Certification Body or ONC–ACB means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB