

§ 170.470

and must cease its current testing and certification operations under the temporary certification program.

(3) A testing and certification body that has had its ONC-ATCB status revoked for a Type-1 violation is prohibited from reapplying for ONC-ATCB status under the temporary certification program for one year. If the temporary certification program sunsets during this time, the testing and certification body is prohibited from applying for ONC-ACB status under the permanent certification program for the time that remains within the one year prohibition.

(4) The failure of a testing and certification body that has had its ONC-ATCB status revoked, to promptly refund any and all fees for tests and/or certifications of Complete EHRs and EHR Modules not completed will be considered a violation of the Principles of Proper Conduct for ONC-ATCBs and will be taken into account by the National Coordinator if the testing and certification body reapplies for ONC-ATCB status under the temporary certification program or applies for ONC-ACB status under the permanent certification program.

§ 170.470 Effect of revocation on the certifications issued to complete EHRs and EHR Modules.

(a) The certified status of Complete EHRs and/or EHR Modules certified by an ONC-ATCB that had its status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC-ATCB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC-ATCB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC-ATCB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Modules were improperly certified by the former ONC-ATCB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR

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Modules were improperly certified, the certification status of affected Complete EHRs and/or EHR Modules would only remain intact for 120 days after the National Coordinator publishes the 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, 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 as certain ongoing responsibilities for an ONC-AA.

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

§ 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 ONC HIT 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 ONC HIT 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 has verified that the certification criterion or criteria to which the EHR