

National Coordinator and an applicant for ONC-ATCB status or an ONC-ATCB is the day the e-mail was sent.

(b) In circumstances where it is necessary for an applicant for ONC-ATCB status or an ONC-ATCB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

**§ 170.410 Types of testing and certification.**

Applicants may seek authorization from the National Coordinator to perform the following types of testing and certification:

- (a) Complete EHR testing and certification; and/or
- (b) EHR Module testing and certification.

**§ 170.415 Application prerequisite.**

Applicants must request in writing an application for ONC-ATCB status from the National Coordinator. Applicants must indicate:

- (a) The type of authorization sought pursuant to § 170.410; and
- (b) If seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. If qualified, applicants will only be granted authorization to test and certify the types of EHR Modules for which they seek authorization.

**§ 170.420 Application.**

The application for ONC-ATCB status consists of two parts. Applicants must complete both parts of the application in their entirety and submit them to the National Coordinator for the application to be considered complete.

(a) *Part 1.* An applicant must provide all of the following:

- (1) General identifying information including:
  - (i) Name, address, city, state, zip code, and Web site of applicant; and
  - (ii) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.
- (2) Documentation of the completion and results of a self-audit against all

sections of ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499), and the following:

- (i) A description of the applicant's management structure according to section 4.2 of ISO/IEC Guide 65:1996;
- (ii) A copy of the applicant's quality manual that has been developed according to section 4.5.3 of ISO/IEC Guide 65:1996;
- (iii) A copy of the applicant's policies and approach to confidentiality according to section 4.10 of ISO/IEC Guide 65:1996;
- (iv) A copy of the qualifications of each of the applicant's personnel who oversee or perform certification according to section 5.2 of ISO/IEC Guide 65:1996;
- (v) A copy of the applicant's evaluation reporting procedures according to section 11 of ISO/IEC Guide 65:1996; and
- (vi) A copy of the applicant's policies for use and display of certificates according to section 14 of ISO/IEC Guide 65:1996.

(3) Documentation of the completion and results of a self-audit against all sections of ISO/IEC 17025:2005 (incorporated by reference in § 170.499), and the following:

- (i) A copy of the applicant's quality system document according to section 4.2.2 of ISO/IEC 17025:2005;
- (ii) A copy of the applicant's policies and procedures for handling testing nonconformities according to section 4.9.1 of ISO/IEC 17025:2005; and
- (iii) The qualifications of each of the applicant's personnel who oversee or conduct testing according to section 5.2 of ISO/IEC 17025:2005.
- (4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC-ATCBs.

(b) *Part 2.* An applicant must submit a completed proficiency examination.

**§ 170.423 Principles of proper conduct for ONC-ATCBs.**

An ONC-ATCB shall:

- (a) Operate its certification program in accordance with ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499) and testing program in accordance with ISO/IEC 17025:2005 (incorporated by reference in § 170.499);