calendar year that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant for each complaint.

(o) *Scope reduction.* Be prohibited from reducing the scope of a Health IT Module's certification when it is under surveillance or under a corrective action plan.

(p) *Real world testing.* (1) Review and confirm that applicable health IT developers submit real world testing plans in accordance with §170.405(b)(1).

(2) Review and confirm that applicable health IT developers submit real world testing results in accordance with §170.405(b)(2).

(3) Submit real world testing plans by December 15 of each calendar year and results by March 15 of each calendar year to ONC for public availability.

(q) *Attestations.* Review and submit health IT developer Conditions and Maintenance of Certification requirements attestations made in accordance with §170.406 to ONC for public availability.

(r) *Test results from ONC–ATLs.* Accept test results from any ONC–ATL that is:

(1) In good standing under the ONC Health IT Certification Program, and

(2) Compliant with its ISO/IEC 17025 accreditation requirements as required by 170.524(a).

(s) *Information for direct review.* Report to ONC, no later than a week after becoming aware of, any information that could inform whether ONC should exercise direct review under §170.580(a).

(t) *Health IT Module voluntary standards and implementation specifications updates notices.* Ensure health IT developers opting to take advantage of the flexibility for voluntary updates of standards and implementation specifications in certified Health IT Modules per §170.405(b)(8) provide timely advance written notice to the ONC–ACB and all affected customers.

(1) Maintain a record of the date of issuance and the content of developers' §170.405(b)(8) notices; and

(2) Timely post content or make publicly accessible via the CHPL each §170.405(b)(8) notice received, publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011; 77 FR 54291, Sept. 4, 2012; 79 FR 54479, Sept. 11, 2014; 80 FR 62755, Oct. 16, 2015; 80 FR 76872, Dec. 11, 2015; 81 FR 72465, Oct. 19, 2016; 85 FR 25950, May 1, 2020; 85 FR 70084, Nov. 4, 2020]

§170.524 Principles of proper conduct for ONC–ATLs.

An ONC–ATL shall:

(a) *Accreditation.* Maintain its NVLAP accreditation for the ONC Health IT Certification Program, including accreditation to ISO/IEC 17025 (incorporated by reference, *see* §170.599);

(b) *Mandatory training.* Attend all mandatory ONC training and program update sessions;

(c) *Training program.* Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test health IT;

(d) *Reporting.* Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key testing personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to test health IT.

(e) *Onsite observation.* Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing performed pursuant to the ONC Health IT Certification Program;

(f) *Records retention.* (1) Retain all records related to the testing of Complete EHRs and/or Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of three years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (f)(1) of this section;

(g) *Approved testing methods.* Only test health IT using test tools and test procedures approved by the National Coordinator; and

(h) *Refunds.* Promptly refund any and all fees received for:

(1) Requests for testing that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing that will not be completed as a result of its conduct; and

(3) Previous testing that it performed if its conduct necessitates the retesting of Health IT Modules.

[81 FR 72465, Oct. 19, 2016, as amended at 85 FR 25951, May 1, 2020]

§ 170.525 Application submission.

(a) An applicant for ONC–ACB or ONC–ATL status must submit its application either electronically via email (or Web site submission if available), or by regular or express mail.

(b) An application for ONC–ACB or ONC–ATL status may be submitted to the National Coordinator at any time.

[81 FR 72465, Oct. 19, 2016]

§ 170.530 Review of application.

(a) *Method of review and review timeframe.* (1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.* (1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.* (1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC–ACB or ONC–ATL status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot reapply for ONC–ACB or ONC–ATL status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

(d) *Satisfactory application.* (1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ACB or ONC–ATL status.

(3) Once notified by the National Coordinator of its successful achievement of ONC–ACB or ONC–ATL status, the applicant may represent itself as an ONC–ACB or ONC–ATL (as applicable)