



# **ONC-Authorized Testing Laboratory Application**

Pursuant to §170.511, organizations interested in participating in the ONC Health IT Certification Program as an ONC-Authorized Testing Laboratory (ONC-ATL) must complete and submit an application for approval to the National Coordinator for Health Information Technology (National Coordinator). ONC-ATL status will expire three years from the date it is granted by the National Coordinator unless it is renewed in accordance with §170.540(c). Pursuant to §170.535, an applicant who is issued a denial notice may request that the National Coordinator reconsider the application only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ATL status.

Please indicate the type of application by selecting the appropriate box below (only select one):

Application	Revised Application	Renewal		Request for reconsideration
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Applications for ONC – ATL status should be submitted electronically via email to <u>ONC.Certification@hhs.gov</u> with each of the following components completed as instructed:

Application Components per § 170.520(b)	Action Required
Authorization Scope pursuant to §170.511	Provide Information
General Identifying Information	Provide Information
NVLAP Accreditation to the ONC Health IT Certification Program including to International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025	Attach Documentation
Agreement to Adhere to the Principles of Proper Conduct for ONC- ATLs	Sign Agreement

#### **Authorization Scope**

In the space below, indicate the authorization scope sought pursuant to § 170.511, including certification edition(s). Applicants may seek authorization from the National Coordinator to perform testing of Complete EHRs or Health IT Modules to a portion of a certification criterion, one certification criteria adopted by the Secretary under subpart C of Part 170 of the Code of Federal Regulations.

**General IdentifyingInformation** 

Organization Name(s):

Address:

City, State:

Zip Code:

Website URL:

Authorized Representative Name (Last, First):

Title:

Phone:

Mobile:

E-mail:

## **NVLAP Accreditation**

Attach documentation to the application submission confirming NVLAP Accreditation to the ONC Health IT Certification Program, including to ISO/IEC 17025.

## **Principles of Proper Conduct for ONC-ATLs**

Please confirm that you have read, understand, and agree that your organization will adhere to the Principles of Proper Conduct for ONC-ATLs, in accordance with § 170.524, by checking the box next to each Principle of Proper Conduct and signing and dating the attestation below.

An ONC-ATL shall:

- □ (a) Accreditation. Maintain its NVLAP accreditation to 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;
- $\Box$  (f) Records retention.
  - 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 beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of three years

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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) above;
- □ (g) Approved testing methods. Only test health IT using test tools and test procedures approved by the National Coordinator;
- (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 Complete EHRs and/or Health IT Modules.

Once all checkboxes have been checked, print out and sign or insert your digital signature below.

As the Authorized Representative, I agree and am bound to the above conditions for participation. Further, I attest that all statements made in this document are correct to the best of my knowledge and are made in good faith.

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