



TESTING AND CERTIFICATION OF HEALTH IT

ONC ATL-ACB Services



SLI Compliance has been authorized to perform Conformance Testing and Certification of Health IT by the US Department of Health and Human Services' Office of the National Coordinator as an Authorized Test Lab (**ONC-ATL**) and an Authorized Certification Body (**ONC-ACB**). The following sections detail SLI Compliance ONC ATL-ACB processes for testing and certification.

(ONC-ATL) Testing Services

SLI Compliance conducts testing as an ONC Authorized Testing Laboratory (ONC-ATL) against the approved 2015 & 2015 Cures Update Edition ONC criteria.

SLI Compliance's ONC-ATL Testing steps include:

1. ONC-ATL Preparation Activities
2. ONC-ATL Testing Process
3. ONC-ATL Testing Completion



1. ONC-ATL Preparation Activities

Once the contractual agreement has been executed, the SLI Compliance ATL Team will create an ONC-ATL Vendor Start-up Package based on the Client's scope; and will be assigned a dedicated ATL Test Specialist / Proctor for their ATL engagement.

ONC-ATL Vendor Start-up Package

ONC-ATL Vendor Start-up Package materials include:

- ▶ Vendor Certification Information form.
- ▶ Documentation of All 'Required Vendor Information' specified in the Test Procedures section of each ONC Test Criterion that will be tested.
- ▶ Attestation forms / documentation for completion and signature(s).
- ▶ Any additional supporting vendor documentation that may be needed to satisfy the criteria (e.g., system manuals, security implementation, vendor policies).
- ▶ Any 3rd party software or tools you will require to demonstrate compliance to the criteria.

ONC-ATL Preparation Support

A dedicated ATL Test Specialist / Proctor is assigned to you for the duration of the ATL engagement. Your ATL Test Specialist / Proctor is available for support on interpretation of testing criteria and requirements, answering vendor questions and feedback on attestation documents. This dedicated ATL team member will also be the official Test Proctor for your ATL test engagement.

Per the rules of the ONC Health IT Program, in NO WAY can SLI Compliance perform consulting to assist a client in obtaining successful testing and certification.



2. ONC-ATL Testing Process

Please note, the Client must complete and return the ATL Vendor Package materials to the SLI Compliance ATL Team for review a minimum of 2 business days prior to their ATL test start date. The scheduled test window with a Client for ATL testing is based on the scope of testing the client has selected. This can vary from system to system and is highly dependent on what criteria the vendor is testing to.

- Throughout the test effort, the client is expected to provide personnel competent in the functions and navigation of the system under test. At the beginning of testing each day, SLI Compliance will send the client a remote session invitation (SLI Compliance utilizes Zoom) for connecting.
- SLI Compliance will act as a 'proctor' for any functions that must be manually executed on the system. The SLI Compliance Test Proctor will instruct your staff to follow a prescribed set of steps that demonstrate compliance with the certification criteria requirements.
 - Some example patient information and test data are required to be entered on the day of testing with SLI Compliance selecting the data and/or witnessing the data input.
 - Other test data may be pre-loaded prior to the day of testing (Please refer to the approved Test Methods for all data requirements).

Types of Testing

Remote Interactive Testing - Visual Verification: Throughout the testing process, the SLI Compliance ATL Test Specialist /Proctor will record the testing session and take screen images as needed. The SLI Compliance test proctors are required to visually inspect and verify specific functionality being demonstrated for compliance to the criteria requirements.

Remote Interactive Testing - Tool Verification: Many of the requirements utilize conformance testing tools. The approved Test Methods provide the tool detail. The tools in many cases contain test scenarios, test cases, and test data that will be used in the testing process. In addition, the testing tools will provide automated validation and reports where called out in the Test Methods. It is highly encouraged that the client be familiar with not only the Test Methods & criteria required but also all the associated conformance tools.

Offline Verification Testing: All validation testing that does not require remote session interaction between the Client and SLI Compliance will be conducted by SLI Compliance ATL Team offline. This includes documentation review and any test artifact manual validation, such as Self-attest/attestation criteria testing. Upon completion of offline testing, SLI Compliance will communicate the results to the client in a timely manner.

Additional Testing Time

If a Client is unable to complete all of the required testing within the initial test schedule given, any additional testing day(s) will need to be scheduled to complete the remaining test procedures. The client will be allowed to schedule additional testing days dependent on resource availability and open testing days in SLI's testing schedule. A testing fee of \$1000 per day will be assessed and no partial days are allowed.



Retesting

The requirement for a retest is that if a Client conducts testing with the SLI Compliance ATL Team and during their initial test schedule has failures that cannot be corrected within those designated testing days a retest needs to be scheduled. After the initial testing SLI Compliance will generate a status report to the Client communicating what failures must be retested. A retest consists of additional interactive testing days that will be scheduled on a mutually agreed upon date. The first retest is free (1 day). If failures occur or remain after the free retest day, any additional retest days required to complete testing are subject to the retesting fee. Each retest day is \$1000 per day.

3. ONC-ATL Testing Completion

Upon successful testing, SLI Compliance requires a minimum of 2 days in addition to the complete testing for the ATL Team to complete the final ATL Test Report process.

SLI Compliance ATL Team will submit an official test report to the SLI Compliance Authorized-Certification Body (ONC-ACB), for evaluation and if accepted final certification. As a separate entity, SLI Compliance's ONC-ACB executes all matters pertaining to certification criteria associated with ISO 17065 that are required for the ONC-Health IT Certification program.

We recommend all Clients read the SLI Compliance: ONC-ATL Test Program Guide prior to their ATL test engagement, the document is located on the SLI Compliance website:

https://slicompliance.com/wp-content/uploads/2020/07/SLI-Compliance-Testing-Program-Guide_2020v4.0.pdf

Estimated ONC-ATL Testing Timeframe and Fees

ONC-ATL engagement takes 2-5 business days dependent on size and complexity of the product scope.

Base Fee: A one-time fee is charged for each engagement.

ONC-ATL Criteria Testing and Attestation Fees: ATL Testing and attestation fees are in addition to the base testing fee; and determined size and complexity of the criteria selected in the 2015 Criteria tables as the system scope.



(ONC-ACB) Certification Services

SLI Compliance conducts a review of the ATL submitted test results and upon successful completion issue official ONC Health IT Certification for the client system under test (SUT). SLI Compliance shall conduct certification as an ONC Authorized Certification Body (ACB) against the approved 2015 Edition ONC criteria.

1. ONC-ACB Certification Process
2. Certified Health IT Product List (CHPL)
3. ONC-ACB Certificate of Compliance



1. ONC-ACB Certification Process

The SLI Compliance ONC-ACB Team is responsible for implementing certification procedures by evaluating the testing results and supporting documentation and ensuring that all certification requirements have been met. If deficiencies are identified, the customer and the Testing Lab, as appropriate, will have the opportunity to provide clarification or additional information. Certification is granted based on the requirements of ISO/IEC 17065:2012 and the rules and regulations of the ONC Health IT Certification Program. At the conclusion of the certification process:

- SLI Compliance will issue the certification and the certification information is published to the ONC's Certified Health IT Product List (CHPL), provided there are no deficiencies or other issues.
- SLI Compliance issues a Certificate of Compliance that documents the criteria under which the product is certified. The Client will receive an ACB Certificate Package with the ACB certificate and other documentation for 2015 Edition certification compliance.

We recommend all Clients review the SLI ACB certification process. Please refer to the SLI Compliance ONC-ACB Certification Program manual on our website:

<https://slicompliance.com/wp-content/uploads/2019/11/SLI-Compliance-ONC-ACB-Certification-Program-Manual.pdf>

2. Certified Health IT Product List (CHPL)

The product information transmitted to ONC for listing on the CHPL website is taken from the certification information document. The ACB vendor form must be completed by the customer to state the customer name and product name as they are to be listed on the CHPL and SLI Compliance website. A signature from the customer's senior management is required, and the signed form must be received from the customer prior to commencement of the product certification.

If the customer also engaged SLI Compliance for testing, this information is already supplied during the testing application.

The CHPL ID is created with certification date, this is posted to the CHPL and communicated to the Client.



3. **ONC-ACB Certificate of Compliance**

SLI Compliance issues a Certificate of Compliance that documents the criteria under which the product is certified. The Client will receive their ONC-ACB certification package which will include:

- Certificate;
- SLI Certified Mark Terms of Use;
- Link to SLI Certification Program Manual;
- Quarterly Attestation Form;
- Customer List requirements;
- Link to SLI ONC-ACB Surveillance Plan;
- Mandatory Disclosures Information; and
- Costs & Limitations requirements for communications about the certified product.

Estimated ONC-ACB Certification Timeframe and Fees

ONC-ACB Certification typically takes 1-3 weeks based on size and complexity of scope.

ONC-ACB Certification Fee: ACB certification fee is based on project size/number of criteria for the 2015 Edition certification review.

4. **ONC-ACB Maintenance and Surveillance**

Once the product is certified, the ONC-ACB will provide ongoing maintenance and surveillance of the certified product – as required by the Office of the National Coordinator (ONC). To support ONC program, ACB maintenance activities include but not limited to, inquiries relevant to the certified criteria and requirements; reactive and randomized surveillance; quarterly reporting on the certified products; and handling any complaints or concerns by users on a certified product. SLI Compliance's approach is to treat developers fairly, conduct activities in a transparent manner and respond to developers inquiries.

An annual maintenance fee for year one is charged to the Client once the product is certified and posted to the CPHL. Client shall pay the amount of the invoice upon receipt. Annual maintenance schedule starts on 2015 Edition certification date and is renewed annually on the certification anniversary date.

We recommend all Clients review, please refer to the SLI Compliance ONC-ACB Surveillance Plan on our website:

<https://www.slicompliance.com/wp-content/uploads/2020/01/SLI-Compliance-ONC-ACB-2020-Surveillance-Plan.pdf>



Additional Health IT Services

Not ready for 2015 Edition ONC ATL-ACB? SLI Compliance offers the following preparation services for the ONC Health IT Certification Program.

1. Pre-Certification Testing

SLI Compliance offers pre-certification testing services for the 2015 Edition ONC criteria. Our ATL test team follows the same process as the official testing for ONC ATL-ACB engagement, with exception of requiring the official documentation and final reporting to the certification body. Benefits of pre-certification testing:

- ▶ Establish criteria for qualifying technologies.
- ▶ Efficiently identify your system scope and define process starting point.
- ▶ One-on-one subject matter expert resource consultations.
- ▶ Vendor has the opportunity to ask questions during testing and receives real-time feedback on issues and risks.
- ▶ An opportunity for the vendor to decide which criteria need review and testing for their system/product.
- ▶ Provides the assurance of third-party verification of the product/system to ensure it meets the ONC Health IT Program requirements.

This is separate service offering, not part of the official ONC-ATL testing.

Pre-certification testing session is a fixed rate of \$1500 per (8 hour) day. SLI Compliance offers a 10% discount towards ATL testing services for those that sign up for pre-certification testing.

2. Independent 3rd Party Testing and Assessment Services

As program rules and requirements change, vendors may need assistance in testing to ensure their product meets the necessary criteria for certification. SLI Compliance can help vendors gain a high level of confidence in their product(s) and assist with verifying conformance to the ONC Health IT Program criteria by performing an Independent 3rd Party Verification. The benefits of 3rd party independent testing and assessment services:

- ▶ 3rd Party verification/QA is independent of testing for ONC Health IT Certification but will provide you with the necessary information about the client's product and assurance the product is ready for meets the certification criteria.
- ▶ SLI Compliance test team provides a report stating those criteria have been verified by an accredited 3rd party lab.

This is separate service offering, not part of the official ONC-ATL testing.

Independent 3rd Party testing and assessment fee is determined on the specific criteria selected by the client.



3. **ONC-ACB Certified Product Update**

SLI Compliance offers certified product update services for those products for which SLI Compliance has provided the 2015 Edition ONC-ACB Certification. This allows the client to add criteria to their current 2015 Edition certified product. The fees for a certified product update include testing and certification review of the additional criteria; fees are determined by the size and complexity of the criteria selected in the updated product scope.

ONC Health IT Program 2015 Edition Resources

We highly recommend clients review these ONC resources when starting the 2015 Edition test and certification process.

ONC 2015 Edition Test Methods:

The ONC website provides vendors/developers with the information with both the testing procedure and certification companion guides for each criterion:

<https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method>

<https://www.healthit.gov/topic/certification-ehrs/2015-edition-cures-update-test-method>

<https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method/2015-edition-cures-update-base-electronic-health-record-definition>

ONC Master Table of Related and Required Criteria:

<https://www.healthit.gov/sites/default/files/MasterTable.pdf>

ONC's Cures Act Final Rule website and resources:

<https://www.healthit.gov/curesrule/>

<https://www.healthit.gov/curesrule/what-it-means-for-me/health-it-developers>

<https://www.healthit.gov/curesrule/resources/fact-sheets>

<https://www.healthit.gov/curesrule/resources/webinars>

ONC Health IT Certification Program Guidance:

<https://www.healthit.gov/topic/certification-ehrs/onc-health-it-certification-program-guidance>

ONC Conditions & Maintenance of Certification:

<https://www.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification>



ONC ATL-ACB FAQs

Q: What do I need to do to be a complete certified product?

A: For 2015 Edition Certification, ONC has dropped the 'complete' certification designation, so all products certified will be called certified modules. ONC has also dropped the 'ambulatory' and 'inpatient' domain designations. You will need to identify what scope (i.e. criteria) you want your product certified to. You can select from the ONC Test Methods at:

<https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method>

Q: How do I know what the minimum is to get certified?

A: The overall testing scope will highly depend on what your customers need in order to attest. Per the ONC Final Rule, 170.315(g)(4) Quality Management System and 170.315(g)(5) Accessibility centered design are required with every certification. There are many other "conditional requirements". We recommend first reaching out to your customers to see what their need are and what CMS incentive programs they are required to do reporting.

Q: Can I submit documentation prior to testing?

A: Yes. Submitting required documentation prior to beginning the test procedure will give your proctor time to review and return any documents requiring additional information back to you.

Q: What Test Data requirements do I need to have in place for testing 2015 Criteria?

A: On the ONC website, Test Methods page (refer to the ONC links above) each public test procedure has the following logo. It will either have the "ONC Supplied Test Data" 'x'd out if no test data is requiring or no 'x' present stating there is ONC supplied data you will be required to enter for testing. In addition, there are Companion Guides on the Test Methods page associated with each test procedure. The companion guides also reference if Test data is required for the test procedure with a link to the test data.

Q: How can I most effectively manage my testing time?

A: Careful preparation for each test procedure will help with time management; i.e.

1. Enter as much test data as allowed for each test procedure in advance.
2. Prepare patients and/or login accounts as required for each test procedure
3. Plan & prepare patients and test data for use for test procedures that allow vendor supplied test data
4. Self-pretest with ONC testing tools prior to your official test date.
5. During testing; if a step in a procedure fails, make appropriate fixes offline then plan to retest after completing all untested test procedures first, then go back and retest any/all failures.

Q: Can I contact an SLI Compliance testing expert with questions?

A: Yes, support time is part of your contract; you will be assigned a test specialist to assist you with pre-test questions pertaining to the test procedures you are requesting to test. If you wish to purchase additional support time, contact the Test Manager for details.

Q: Can I pretest certification test procedures with SLI Compliance proctor?

A: We offers a pre-certification test service for a fee.



For Additional ONC FAQs - please visit the official ONC pages:

<https://www.healthit.gov/policy-researchers-implementers/onc-regulations-faqs>

<https://www.healthit.gov/policy-researchers-implementers/permanent-certification-program-faqs>

For Additional information on the CMS Incentive Programs:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification>

<https://www.cms.gov/files/document/2015-edition-cehrt-fact-sheet.pdf>

<https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it>

Why SLI Compliance?

Experience. We've been working as an authorized ONC lab with the Health IT Certification Program since 2010.

Customer Service. We understand the Health IT Certification Program can be confusing, which is why our team of experts is here to walk you through the process, from pre-testing to certification.

Integrity. Our culture is built on transparency, ownership, and accountability. We are committed to maintaining independence, impartiality and holding ourselves to the highest of standards.

Contact us today to achieve your ONC Health IT Program goals!



MEMBER 2019

ANSI Accredited
Standards Developer



NVLAP Lab Code 200733-0



ISO/IEC 17065

PRODUCT CERTIFICATION
BODY



ISO 9001:2015
CERTIFIED