SLI Compliance

ONC-ATL Testing

Program Guide

Document Version 4.3
May 5, 2025

Contents

Purpose of this Guide

The purpose of this document is to provide our customers with information and guidance on how SLI Compliance's ONC-ATL Testing process is conducted throughout our partnership. SLI Compliance strives to make the testing process as clear, understandable and efficient as possible. Our goal is to make your experience a success.

About SLI Compliance

SLI Compliance, a division of Gaming Laboratories International, LLC (SLI Compliance) is an Office of the National Coordinator (ONC) Authorized Test Laboratory (ATL) and Authorized Certification Body (ACB) under the *45 CFR Parts 170 Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology and 171 Information Blocking*. SLI Compliance is an ideal ONC-ATL candidate to test your product set. Since its founding in 1996 as SysTest Labs, our focus has been to help customers manage technology risk. We maintain an ISO 9001:2015 certified quality management system. SLI Compliance is a certified lab under the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST) (NVLAP Lab Code 200733-0 – TESTING). Our test laboratory is regularly audited by NVLAP and our Quality System is accredited to ISO/IEC 17025.

SLI Compliance is fully accredited to test all approved criteria within the ONC Health IT Certification Program. The services we provide as an ONC-ATL ensure a product meets the baseline requirements of the ONC Health IT Certification Program, and those results are submitted to the ONC-ACB for certification. Once a product has achieved certification, eligible clinicians (ECs), eligible hospitals (EHs) and critical access hospitals (CAHs) who choose to use certified technology in a meaningful way may be eligible to apply for incentive payments or avoid downward payment adjustments under the Promoting Interoperability Programs governed by The Centers for Medicare and Medicaid Services (CMS), an organization within the US Health and Human Services (HHS) Department. Refer to the specific CMS programs for eligibility requirements.

About the ONC Health IT Certification Program

Per the HITECH Act, the Office of the National Coordinator was charged with creating the EHR Certification Program. The Centers for Medicare and Medicaid Services (CMS) oversees the Promoting Interoperability Programs, which may provide incentive payments to ECs or avoid downward payment adjustments for EH/CAHs who meaningfully use Certified EHR Technology (CEHRT).

The ONC Health Information Technology (Health IT) Certification Program is the second part of ONC's two-part approach to establish a transparent and objective certification process, following the Temporary Certification Program (TCP).

The TCP was established to ensure that Certified EHR Technology (CEHRT) would be available for adoption by health care providers who sought to qualify for the Centers for Medicare and Medicaid Services (CMS) EHR incentive payments (now known as the Promoting Interoperability Programs) beginning in 2011.

The ONC Health IT Certification Program became fully operational on October 4, 2012, and ONC continues to manage the overall program.

In the ONC Health IT Certification Program, certification and testing activities are performed by separate entities. Certification is conducted by ONC-Authorized Certification Bodies (ONC-ACBs) and testing is performed by ONC-Authorized Testing Laboratories (ONC-ATLs). Developers (also called Vendors) first test their product with an ONC-ATL, and if their product meets the requirements, they work with SLI Compliance's ONC-ACB or another ONC-ACB to certify the product. Once the product is certified, it is submitted to ONC, who posts approved products to the Certified Health IT Product List (CHPL).

For additional information about the certification program and rule, please visit:

ONC Certification of Health IT

SLI Compliance as Your Testing Partner

SLI Compliance conducts testing as an ONC-Authorized Testing Laboratory (ONC-ATL) against the approved ONC Certification Criteria for Health IT. The following outlines the registration and testing process.

Registration and Scheduling

To register with SLI Compliance, you can go to the SLI website www.SLICompliance.com and navigate to the "Testing and Certification of Health IT" selection in the "Services" menu. You will see a Register button and once selected, it will step you through a series of questions regarding what scope of testing and/or certification you are looking for. Once your registration is received by SLI Compliance, your request will be processed. You will receive a follow-up phone call or email from our Account Executive, who will be the primary resource to help guide you and complete the process and provide you with a proposal quote on your selected services.

Or you can contact us at HealthIT@slicompliance.com

Note: *During the registration process, you will be asked what date you would like to begin your test. This is a tentative testing date. To secure a test date, the Developer must submit a completed Services Agreement.*

Agreements and Contracts

After a Developer completes the SLI Compliance online registration process and has received the initial quote from our Account Executive, the SLI ONC Services Agreement will be sent by the SLI Account Executive for the Developer to review.

The SLI Compliance ONC Services Agreement needs to be mutually executed, and the Developer may be required to provide a non-refundable 50 percent deposit for the services selected, dependent on credit rating. (If the 50% deposit is required for testing services, fee(s) must be received by SLI Compliance in order for the Developer to be considered "under contract.") At this point in the process, the Developer is now a Client and will have access to the Vendor Package as well as the SLI Compliance ATL Testing Team for interpretation guidance.

Any questions pertaining to the SLI Compliance Services Agreement and/or deposit should be directed toward your assigned SLI Account Executive.

Pricing

Pricing for the ONC Certification Criteria for Health IT begins with a one-time base charge for any testing. Then each criterion is rated according to complexity, resulting in a per criteria fee built in addition to the base charge. Pricing includes all of the test preparation activities, issuance of a vendor package, kick-off call, support services, testing services, one additional re-test (if needed) and the production of a Final Test Report to be sent to the ONC-Authorized Certification Body (ONC-ACB). If SLI Compliance is only providing the ATL Test Services, the final payment is required prior to issuance and submission of the report to another ONC-ACB.

Identifying Your Scope of Testing

The overall 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" outlined on the ONC website in the Certification Dependencies and Privacy & Security Requirements dropdowns for each criterion. Identifying the scope can be accomplished by reviewing Test Procedures and Conformance Methods and determining which criteria to include in your certification scope.

SLI Compliance will assist in identifying the required interdependencies based on what criteria the Developer selects.

For specific details on the program requirements, please visit the HealthIT.gov website Certification of Health IT page:

https://www.healthit.gov/topic/certification-ehrs/certification-health-it

Conducting Testing with SLI Compliance

This section provides an overview of the ONC Health IT testing process conducted by SLI Compliance. Successful execution of testing is highly dependent on both the Developer/Client's level of preparedness and providing the SLI Compliance ATL Team with the necessary information prior to testing in order to be fully prepared. The below sections provide an overview of the testing process.

Test Preparation Activities

Once the registration and contractual agreements have been executed, an SLI Compliance ATL team member will schedule a kick-off call to introduce you to the team you'll be working with and answer initial questions you may have. Our ATL Test Team will provide the Client with a Vendor Start-up Package containing test preparation materials. These materials will provide information regarding what the Client must complete and return to SLI Compliance for review prior to testing.

Required Forms and Information

There is specific information that must be provided to SLI Compliance. The following documents and information must be completed and submitted to SLI Compliance for review <u>at least</u> 5 business days prior to the testing date. The forms will be provided to you as part of the ATL Vendor Package.

- Vendor Testing and Certification Information form, which includes attestations (provided in the Vendor Package)
- Documentation of All 'Required Vendor Information' specified in the Additional Documentation Requirements document (provided in the Vendor Package) and in the Test Procedures section of each ONC Test Criterion that will be tested.
- Any additional supporting vendor documentation that may be needed (e.g., system manuals, configuration management process documents).

Remote Testing

Remote testing allows for the conduct of testing over the internet using a remote video connection and is the most cost-effective approach. SLI Compliance supports remote testing as our method for the ONC Health IT testing. SLI Compliance will provide the means for remote video access to your system.

Client Test Environment

SLI Compliance requires testing to be conducted in an environment that meets a minimum specification to ensure the integrity of testing. SLI Compliance's minimum specifications are as follows:

1. Normal operating conditions and environment for your software.

2. Standard configuration of equipment for testing (i.e., PC or laptop or equivalent).
3. Standard Internet connectivity (wireless or LAN).

Testing

SLI Compliance schedules a test window with a client for interactive testing based on the scope of testing the Developer has selected. This can vary from system to system and is highly dependent on what criteria the Developer is testing. If there are additional days needed to complete testing in addition to the initial test window, the Developer is required to arrange and pay for these additional days per the executed SLI Compliance ONC Services Agreement.

Throughout the test effort, the client is expected to provide personnel competent in the functions and navigation of the system under test. Prior to each testing 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 patient information and test data is 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.)

Visual Verification

Throughout the testing process, the SLI Compliance Test Proctor will record the testing session and take screen images as needed. The SLI Test Proctors are required to visually inspect and verify specific functionality being demonstrated for compliance with the criteria requirements.

Offline Verification

All validation that does not require remote session interaction between the Client and SLI Compliance will be conducted by the SLI Compliance ATL Test Team offline. This includes documentation review and manual validation of any test artifacts. Upon completion of offline testing, SLI Compliance will communicate the results to the client in a timely manner.

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 and criteria requirements, but also all the associated conformance tools.

Testing Results

SLI Compliance will assign each certification criteria requirement a pass or fail status based on the visual, manual or automated verification performed in testing. If a product under test fails any criterion, the test is considered failed. Successful testing is achieved when all designated criteria have been completely tested and deemed accepted by SLI Compliance. An incomplete or partially completed criterion is considered failed until fully demonstrated and successful. SLI Compliance maintains all test artifacts and official test results for each engagement.

Exceptions and Interpretations

A system may have specific circumstances that require SLI Compliance to grant an interpretation or exception to a specific requirement. The ATL has the authority to deem certain requirements not applicable to a specific system depending on the specific circumstances. This is determined on a case-by-case basis.

Retesting

If your product is unsuccessful in any area during the testing process, you may elect to schedule a future test session to retest the particular problem. It is at the discretion of SLI Compliance to determine what level of retesting must be conducted to successfully verify the issues have been resolved and the required criteria are satisfied. The future test effort can be scheduled immediately, and SLI Compliance will work with you to expedite the scheduling process.

Support

As part of the contract with SLI Compliance, the SLI staff can answer questions and provide clarifications of the certification criteria for a client. Per the rules of the certification program, **in NO WAY can SLI Compliance perform consulting to assist a client in obtaining successful testing and certification.**

Certification

Upon completion of successful testing, the SLI Compliance ATL Team will finalize and submit an official test report to the Authorized Certification Body (ACB) for evaluation and, if accepted, final certification. If the Client is using a separate ACB (external to SLI Compliance) for certification services, the Client should provide this information prior to testing.

As a separate entity from the ATL, SLI Compliance's ACB executes all matters pertaining to certification associated with ISO/IEC 17065 that are required for the ONC Health IT Certification program. The ONC-ACB will inform the Client if more information is needed and provide a notification when a certification is complete.