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SLI Compliance ONC-ATL Testing Program Guide

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Purpose of this Guide

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

Who is SLI Compliance

SLI Compliance (SLI) is an Office of the National Coordinator Accredited Test Laboratory (ONC-ATL) under the 45 CFR Part 170 Establishment of the Permanent Certification Program for Health Information Technology; Final Rule Effective September 4th 2012. SLI is an ideal ONC-ATL candidate to test your product set. Since its founding in 1996 as SysTest Labs, SLI's focus has been to help customers manage technology risk. SLI maintains an ISO 9001:2008 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). Our test laboratory has been audited by NVLAP and our Quality System is accredited to ISO 17025.

SLI is fully accredited to test all approved criteria within the ONC-HealthIT Certification Program. The services we provide as an ONC-ATL ensure a product meets the baseline requirements of the ONC-HealthIT Certification Program, and those results are submitted to an ONC-ACB for certification. Once a product has achieved certification, all eligible providers (EPs), 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 under the Meaningful Use Program governed by The Centers for Medicare and Medicaid Services (CMS), an organization within the US Health and Human Services (HHS) Department.

About the ONC-HealthIT Certification Program

Per the [HITECH Act](#), the Office of the National Coordinator was charged with creating the EHR Certification Program. Centers for Medicare and Medicaid Services (CMS) oversees Meaningful Use and provides incentive payments to EPs and EHs who meaningfully use Certified EHR Technology (CEHRT).

The ONC Health Information Technology (HealthIT) 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](#) beginning in 2011.

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

In the ONC-HealthIT 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 Accredited Testing Laboratories (ATLs). Developers and Vendors first test their product with an ATL, and if their product meets the requirements, they work with an 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 Programs and Policy](#)

SLI as Your Testing Partner

To obtain information about the SLI ONC-ATL Testing Program, first begin by completing a short registration process located on the SLI website. Once your registration is received by SLI, your request will be processed and you will receive a follow up phone call or email from an SLI Account Executive who will be the primary resource to help guide you and complete the process.

Registration & Scheduling

To register with SLI you can go to the SLI website www.SLICompliance.com and navigate to the “Testing for Certification of Health IT” selection. You will see a link “Register for ONC-ATL Testing” and once selected, it will step you through a series of questions regarding what scope of testing you are looking for. Upon completion and submission this will begin the process for testing and our staff will reach out to you using the contact information provided in the registration.

Or

To schedule your product for testing you may contact our ONC-HealthIT Test Manager:

Dustin George
dgeorge@slicompliance.com

During the registration process, you will be asked what date you would like to begin your test. Please note, this is a tentative testing date and to secure a test date, you must submit a completed Services Agreement and provide a non-refundable 50 percent deposit for the services selected. Final payment is required prior to issuance and submission of the report to an ONC-ACB.

Agreements and Contracts

After a vendor completes the online registration process with SLI, the SLI Services Agreement will be sent to the vendor by the Account Executive for the vendor to review. The SLI Services Agreement needs to be mutually executed and a 50% deposit of the testing services fees must be received by SLI in order for the vendor to be considered “under contract” with SLI. At this point in the process, the vendor will have access to the Vendor Packet as well as the ONC Testing Team for interpretation guidance. Payment options for the 50% deposit are located within the SLI Services Agreement, and any questions pertaining to the SLI Services Agreement and/or deposit should be directed toward your assigned SLI Representative.

Pricing

Pricing for the 2014 & 2015 criteria begins with a base charge for any vendor testing with SLI and then each criteria is rated according to complexity, resulting in a per criteria fee built in addition to the base charge. Pricing includes all of the pre-testing activities, issuance of a vendor packet, 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 selected Approved Certification Body. For specific pricing as it applies to each vendor, please contact an SLI Representative for a quote based on the applicable modules for each vendor.

Identifying Your Scope of Testing

Your product may be certified to 2014 or 2015 Certification Criteria for Ambulatory, Inpatient or both settings of care. Identifying the scope can be accomplished by reviewing [Testing and Test Methods](#) and determining for which criteria your product meets the requirements.

The possible designations and configurations you may test to are as follows:

Complete - Testing to <u>ALL Criteria</u> for the designated setting below	
2014 Test Methods (Ambulatory)	Practice setting which is grouped by all applicable 170.314
2014 Test Methods (Inpatient)	Practice setting which is grouped by all applicable 170.314

Modular - Testing to <u>specific selected</u> criteria for the designated setting below and meeting the <u>minimum requirements</u>	
2014 Test Methods (Ambulatory)	*Includes the minimum required criteria. The minimum for 2014 is determined by what criteria is selected
2014 Test Methods (Inpatient)	*Includes the minimum required criteria. The minimum for 2014 is determined by what criteria is selected
2015 Test Methods (Ambulatory)	*Includes the minimum required criteria. The minimum for 2015 is determined by what criteria is selected
2015 Test Methods (Inpatient)	*Includes the minimum required criteria. The minimum for 2015 is determined by what criteria is selected

** SLI will assist in identifying what the required minimum for 2014 & 2015 criteria based on what criteria the vendor selects.*

For specific details on the the program requirements please visit the HealthIT.gov website and Policy and Researchers/Implementors page:

<https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>

Conducting Testing with SLI

This section provides an overview of the ONC-HealthIT testing process conducted by SLI Compliance. Successful execution of testing is highly dependent on both the vendor/client and SLI having the necessary information prior to testing in order to be fully prepared. The below sections provide an overview of the testing process.

Pre-Test Activities

Once the registration and contractual agreements have been executed, SLI will schedule a Kick-off call to introduce you to the team you'll be working with and answer initial questions you may have. The testing team will provide the client a Vendor Start-up Package containing pretest materials. These materials will provide information regarding what the vendor must complete and return to SLI for review prior to testing.

Required Forms and Information

There is specific information that must be provided to SLI. The following documents and information must be completed and submitted to SLI for review at a minimum 2 business days prior to the testing date. The forms will be provided to you as part of the vendor package.

- Vendor Certification Information form (provided in the Vendor Packet)
- Documentation of All 'Required Vendor Information' specified in Test Procedures section of each ONC Test Criteria that will be tested.
- 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

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 supports remote testing as our method for the ONC-HealthIT testing. SLI will provide the means for remote video access to your system.

Client Test Environment

SLI requires testing to be conducted in an environment that meets a minimum specification to ensure the integrity of testing. SLI'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 schedules a test window with a client for interactive testing based on the scope of testing the vendor has selected. This can vary from system to system and is highly dependant of what criteria the vendor is testing to. SLI requires 2 days in addition to the interactive testing for SLI personnel to complete offline testing and reporting. If there are additional days needed to complete testing in addition to the initial test window the vendor is required to arrange and pay for these additional days per the executed SLI Services Agreement.

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 will send the client a remote session invitation (SLI utilizes GoTo Meeting) for connecting. SLI will act as a 'proctor' for any functions that must be manually executed on the system. The SLI 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 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 tester/proctor will record the testing session and take screen images as needed. The SLI testers are required to visually inspect and verify specific functionality being demonstrated for compliance to the criteria requirements.

Offline Verification

All validation that does not require remote session interaction between the client and SLI will be conducted by SLI test staff offline. This includes documentation review and any test artifact manual validation. Upon completion of offline testing, SLI 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 & criteria required but also all the associated conformance tools.

Testing Results

SLI 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. Incomplete or partially completed criterion is considered failed until fully demonstrated and successful. SLI maintains all test artifacts and official test results for each engagement.

Exceptions and Interpretations

A system may have specific circumstances that require SLI 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 re-schedule a future test session to retest the particular problem. It is at the discretion of SLI 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 will work with you to expedite the scheduling process.

Support

As part of the contract with SLI each client is given 8 hours of support time to communicate with SLI. SLI staff can answer questions, provide feedback, clarifications, and interpretations of the certification criteria to a client. Per the rules of the certification program in NO WAY can SLI perform consulting to assist a client in obtaining successful testing and certification.

Certification

Upon successful testing, SLI will complete and submit an official test report to an Approved Certification Body (ONC-ACB), for evaluation and if accepted final certification. As a separate entity, the ONC-ACB executes all matters pertaining to certification criteria associated with ISO 17065 that are required for the ONC-HEALTH IT Certification program.

SLI will assist in the coordination and communication with the Certification Body to make the whole process as seamless as possible.