SLI Compliance, a Division of Gaming Laboratories International, LLC

ONC-ACB Certification Program

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Document History

Rev.	Date	Change
2.3	June 8, 2020	ONC Cures Rule updates: removed 2014 Edition and gap certification, removed 7.i, 8. Added 9 re Conditions of Certification and Maintenance; other minor clarifications
2.4	December 1, 2020	Section 2.1: Fixed a hyperlink to SLI's website (link changed when the site was updated)
2.5	March 22, 2021	--Updated wording of company name on title page --Section 1: Changed ANSI to ANAB, updated ISO/IEC 17025:2017 accreditation, which now applies to both of SLI's test labs --Section 9: Updated the year for new ONC Cures Rule required actions --Minor edits and clarifications
2.6	August 24, 2021	--1: Removed reference to ISO 9001 --6.1: Removed fax option, changed Director to Vice President --11: Added newer ONC resource links

Contents

1 About SLI Compliance

This document defines the requirements for the certification of healthcare IT products under the scope of accreditation issued by ANAB to SLI Compliance (SLI) under ISO/IEC 17065:2012 and the Office of the National Coordinator (ONC) certification scheme defined at 45 CFR Part 170. The requirements in this manual apply to SLI (the certification body) and the developer submitting a product(s) for certification. This manual is approved, issued and controlled by SLI management.

SLI is an Authorized Certification Body (ACB) as well as an Authorized Test Laboratory (ATL) under the Office of the National Coordinator's Health IT Certification Program. As an accredited ONC-ATL and ONC-ACB, SLI operates a Quality Management System that is compliant to ISO/IEC 17025:2017 and ISO/IEC 17065:2012. SLI may test and certify health IT products under the certification scheme operated by the U.S Department of Health and Human Services (45 CFR Part 170) through the ONC Health IT Certification Program. This allows the health IT system developer and vendor to engage SLI for testing and certification services.

SLI also holds these accreditations/certifications:
- ISO/IEC 17065:2012 by ANSI National Accreditation Board (ANAB) for the certification of Health Information Technology (ANAB Accreditation ID# 1265)
- ISO/IEC 17025:2017 by National Voluntary Laboratory Accreditation Program (NVLAP) for Healthcare IT Testing and Voting System Testing (NVLAP Lab Code: 200733-0 - TESTING)

For more information about the federal testing and certification program, please visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it.

2 Doing Business with SLI Compliance

2.1 Application

The application process is initiated by contacting SLI (refer to contact information at the end of this document) or visiting https://slicompliance.com/services/testing-certification-health/. An account manager will be assigned who will provide guidance throughout the entire application process including determining product, schedule, scope of services, pricing and other requirements, as well as submission of the test results.

Since SLI also has an ONC-ATL, the customer is encouraged to engage SLI for testing and certification; however, SLI will certify test results from any ONC-ATL in good standing. Information on SLI's testing services may be found in the "Testing Program Guide" available

at https://slicompliance.com/services/testing-certification-health/sli-compliance-health-it-guides-and-manuals/.

Following the initial contact, the account manager initiates the application by providing to the customer the pertinent documents to complete the application. The application documents include the Application Form and the Services Agreement, which includes pricing, the certification agreement and the terms and conditions.

SLI will only accept ONC Program certification projects for health IT products within SLI's ISO/IEC scopes of accreditation. The application process will identify requests that are outside the scope.

2.2 Submission of Materials

After SLI receives the application documents, the customer must facilitate submission of all required test materials. If the customer has used SLI for testing, the certification process will be handled seamlessly. If a test lab other than SLI is used, the test results must be received directly from the test lab. SLI's ONC-ACB management will work with the test lab to ensure the test results and appropriate supporting documentation are submitted. SLI has an approved test results summary template that ATLs can use for test result submission, and will be provided upon request. SLI reserves the right to request additional corroborating documentation such as screen captures or other test records to substantiate the results of the test.

3 Previously Certified Product from another Accredited Certification Body

SLI accepts test results from any NVLAP Accredited Health IT Test Lab and performs product updates for products certified by other ONC-ACBs. All test results from other test labs are subject to review by SLI before SLI makes an independent decision on certification. (Certifications are not transferrable from one ONC-ACB to another.) A service agreement is executed that outlines all obligations of the customer and SLI and the work that SLI will perform including the associated pricing (also see *Company Name Changes, Product Private-Labeling, and/or Product Name Changes* section). If the product update is approved, SLI will issue a certificate to the developer and submit the certification information to the ONC. In order to certify new products, the standard application procedure will be followed (see *Doing Business with SLI Compliance* section).

4 Certification Process

4.1 Certification Body Review

SLI ONC-ACB staff 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 Test Lab, as appropriate, will have the opportunity to provide clarification or additional information. The certification body review may take up to ten (10) business days (or longer if SLI is waiting for information from an outside party). If the certification is approved, SLI will issue the certificate and the certification information will be published to the ONC's Certified Health IT Product List (CHPL).

4.2 Gap Certification

If a product was tested and certified under earlier certification criteria, the customer's selected criteria may be eligible for Gap Certification. The SLI registration form denotes all gap eligible criteria. (Note that starting June 30, 2020, gap certification will not be offered but may be reinstated in the future if there's a new ONC certification edition.)

4.3 Certification to Newer Versions of Certain Standards

ONC-ACBs may certify health IT products to a newer version of certain identified standards as specified in approved final test procedures if the ONC has accepted a newer version of an adopted standard.

4.4 Certification Body Decision

Certification is granted based on the requirements of ISO/IEC 17065:2012 and the rules and regulations of the ONC Health IT Certification Program. If an adverse certification decision is reached by SLI, the customer is provided with a detailed report of findings, including the justification for the adverse certification decision. The customer may have one or more of the below options:

- A NVLAP-accredited Testing Lab may be engaged to perform any required retesting. Customers that engage SLI as the lab for retesting should contact their SLI Account Manager.
- If SLI found required criteria to be satisfactory, but a non-conformity was found in non-required criteria, the customer may request that SLI certify only the compliant criteria.
- The customer may appeal SLI's certification decision (see Appeals and Disputes).

If the SLI certification body grants certification, all ONC certifications will be transmitted to the ONC for listing on the Certified Health IT Product List (CHPL).

4.5   Certified Health IT Product List (CHPL)

The information transmitted to ONC for listing on the CHPL website is taken from the certification information document. The form must be completed by the customer to state the customer name and product name as they are to be listed on the SLI website and the CHPL. 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 for testing, this information is already supplied during the testing application.

Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it for the latest information with regard to any updates and additional guidance on generating certification IDs for CMS attestation purposes.

4.6   Certificate of Compliance

SLI issues a Certificate of Compliance that identifies the developer, product and version along with a list of the criteria to which the product is certified.

4.7   Marketing

Upon issuance of the certification, SLI notifies the customer and provides an electronic Certificate of Compliance, the SLI Certified mark, the ONC Health IT Certified mark and marketing and usage guidelines. Products certified under the ONC certification program must adhere to ONC certification guidelines (see Certification Guidelines).

SLI maintains a listing of certified products on the slicompliance.com website.

5   Maintaining and Extending Certification

5.1   Modifying Certified Products

The ACB must be contacted when a certified product is updated to include new features, or a new software version is released. When a developer wishes to update a product's version listed on the CHPL, SLI requires that a Product Update Form be submitted, along with any additional documentation to facilitate the review. Minor product patches, cosmetic changes or fixes may be reported in the developer's quarterly report to SLI. SLI will review all modifications and determine whether the new version can inherit the original certification (no retesting required) or whether retesting and recertification must occur.

Certification is issued for the *specific product and version* tested. It is normal for healthcare IT products to be updated during the software product's life cycle, and it is possible for a product to be changed and still retain its certification provided the necessary steps are followed. Please see also the ONC's guidance and FAQs on versioning:

- https://www.healthit.gov/sites/default/files/policy/productidandversioningguidance.pdf

- https://www.healthit.gov/sites/default/files/policy/chplproductversioningfaq_12012017.pdf

If a product is no longer supported or needs to be withdrawn as a certified product on the CHPL, the system developer must contact SLI with the request.

5.2 Company Name Changes, Product Name and Other Changes

The customer must report all product name changes to SLI using the Product Update Form, and follow the designated process.

Company headquarters address, billing address, or company contact types of changes may be submitted to SLI in writing and signed by a company signatory; in this case a Product Update Form is not required.

All rebranding or private-label product certification requests must be submitted to SLI using the Product Rebranding Form – see the following section.

5.3 Rebranding, Resellers and Private-Labelers

Health IT developers that have certified a product with SLI may develop business partnerships with third parties to resell a certified product, either under the developer's label or a private label or brand. Under either scenario, the certified product may not be modified, and the third party business partner agrees to adhere to the terms and conditions of the certification issued, including SLI Certified mark and usage guidelines and the ONC Health IT Certified mark and usage guidelines. The reseller/private-labeler must also understand and adhere to the information specified at 45 CFR 170.523 (see ONC Guidelines - Transparency and Disclosure Requirements section).

When reselling under the developer's label or brand, it is the product developer's responsibility to ensure that the reseller adheres to all requirements related to the certification of the product. A letter jointly signed by the original manufacturer and the reseller attesting to the above should be submitted to SLI.

Under a private-labeling agreement, additional requirements must be met. The original manufacturer or company and the company rebranding the product must both sign the Product Rebranding form as evidence that each is aware of the requested changes.

Certifications are *product and version specific*. To extend certification to a private-labeled product, the customer and their business partner/distributor must:

- Complete and sign the Product Rebranding Form;
- Provide documentation of any changes made to the product. For example, a screen capture of 'before' and 'after' displays, written summary of the changes, release notes, etc.;
- Submit a completed Service Agreement form (business partner/distributor only); and
- Remit product rebranding fees.

SLI will evaluate the submitted documentation and determine if the private-labeled product may inherit the original product's certification. The decision is communicated to all affected parties. If the certification is issued, SLI will provide all required information to the private-label organization including requirements regarding the SLI and ONC marks and marketing of the certified product. If certification is suspended, terminated or expired for the originally certified product, certification will also be suspended, terminated or expired for the corresponding private-labeled product.

6 Certification Guidelines

6.1 Appeals and Disputes

When SLI determines a product does not meet the criteria required to issue a certification, the customer can contest the findings by making a written appeal to the SLI Compliance Vice President. All appeals/disputes must be submitted in writing (mail or email). When submitting an appeal/dispute to SLI for review, the following information should be included:

a) The reason(s) that the denial or revocation of certification should be reversed, including objections, corrections, and factual information that may be relevant to the appeal/dispute;

b) The specific elements of the certification program to be addressed in the appeal/dispute;

c) The preference of the customer regarding whether to be present during the review meeting with SLI personnel;

d) The contact information of any person the customer plans to include in the meeting in order to present factual information, and a clear description of the factual information available from this person(s); and

e) A list and copies of all relevant documents, exhibits, or other information the customer intends to submit in support of the appeal/dispute.

SLI acknowledges receipt of each appeal/dispute. Following a thorough assessment of the appeal and any related facts, SLI's Management Team will make a determination of compliance or conformity, in accordance with internal appeals processing procedures. SLI will inform the customer of any further action required to remedy the situation. Once the decision has been confirmed by SLI, no further appeals are accepted unless new evidence is presented or discovered that may result in a reversal of the appeal.

6.2 Surveillance Activities

In order to remain an ONC-ACB in good standing and in compliance with ISO/IEC 17065 requirements, SLI is required to prepare an annual Surveillance Plan. The plan includes reactive and proactive surveillance of certified Health IT products. The current year's plan is available on the SLI website. The types of surveillance activities conducted by SLI will include:

- Reactive surveillance – based on complaints, repeated certification inheritance requests, information provided in transparency disclosures and attestations, nonconformities, etc.
- Proactive surveillance of product related websites and communications, including ONC required public hyperlinks (e.g., Mandatory Disclosures, API documentation, Multi-Factor Authentication use cases).
- Correct usage of the SLI and ONC Health IT Certified marks as appropriate.
- Statements about SLI and the certification achieved must not be misleading or contain inaccuracies.
- The name and version number of the product described as certified by the customer must match the certified product name and version on file at SLI (see Modifying Certified Products).
- The certification body mark, if used, must be from SLI and not from another certification body.
- The required language in the Final Rule concerning marketing of the certified product must be used (see ONC Guidelines – Transparency and Disclosure Requirements).
- The required transparency and disclosure requirements must be adhered to (see ONC Guidelines - Transparency and Disclosure Requirements).

6.3 Complaints

SLI requires that the customer keep a record of all complaints made known to it that relate to compliance with the criteria set forth by the HHS Secretary and the resulting certification issued by SLI. The customer is required to provide these complaints and all required supporting information via email upon request by SLI. The request from SLI shall describe all required information. These processes may be reviewed and verified by SLI as part of ongoing post-certification surveillance procedures.

Users or purchasers of health IT certified by SLI that have complaints or concerns about the certified product functionality may submit them to SLI via email at info@slicompliance.com, or here: https://slicompliance.com/services/testing-certification-health/sli-acb-certified-products-feedback-and-complaints/. All complaints will be reviewed for validity and relevance to a certified health IT product. In the case of a valid and relevant complaint, the product developer, the Test Lab that performed the testing and the ONC will be notified – the complainant may elect to remain anonymous. SLI will keep in contact with the developer using the corrective action process to ensure they are addressing the complaint, making any required product changes and pushing product updates out to users. The product certification may be suspended or terminated if the complaint is valid and compromises the integrity of the product certification. Complaints about the Conditions of Certification and Maintenance (which are reviewed by ONC directly – e.g., information blocking), will be forwarded to the ONC.

6.4 Suspension, Withdrawal, or Revocation of Certification

The status of certified products listed on the CHPL web site is set to one of the following:

- Active – Certification is current
- Retired – Edition is no longer supported by ONC/CMS
- Suspended – Due to non-conformity; corrective action in process
- Terminated – Escalated action following a suspension; corrective action was not applied satisfactorily
- Withdrawn – Per developer's discretion; no longer sold or supported

SLI decides on the appropriate action that is to be taken when a nonconformity with certification requirements is substantiated, whether as a result of surveillance or otherwise. The appropriate action taken can include:

- Continuation of certification under conditions specified by SLI;
- Reduction in the scope of certification to remove the non-conforming product variants;
- Suspension of certification pending remedial action by the client;

- Termination of certification;
- Evaluation, review or a revised certification decision.

There are several causes that may lead to suspension of a product certification, including but not limited to the product is no longer supported by the developer; recall of test results by the ATL; failure to respond to surveillance inquiries or to successfully complete surveillance re-testing; non-adherence to ONC requirements; or a breach in the contractual obligations and agreed upon terms and conditions of certification. Applicants are given ten (10) business days after notice by SLI of the breach to either provide a plan to resolve it or provide a reasonable explanation of why the breach cannot be corrected.

The SLI Certification Manager (or delegate) will inform the customer of the reasons for a suspension and of actions needed to end suspension and restore certification. If a certified product is under suspension for more than thirty (30) calendar days, the conditions of the suspension will be reviewed and SLI will determine if continued suspension is warranted, or if the certification should be terminated.

SLI reports all suspended, withdrawn, and terminated certifications to the ONC. The customer will be required to cease use of the SLI mark and certificate, ONC marks, and making reference to the certification. Also, the product listing will be removed from the SLI website and the status updated on the CHPL.

7 ONC Guidelines – Transparency and Disclosure Requirements

The Department of Health and Human Services and the ONC maintain that companies must adhere to the following guidelines with regards to the certified product per the information specified at 45 CFR 170.523(k)(1).

All certifications must require that a health IT product developer conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the health IT product certification:

(i) "This [Health IT Product] is [specify Edition of EHR certification criteria] compliant and has been certified by SLI in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."

AND

a. The vendor name
b. The date certified

c. The product name and version
d. The unique certification number or other specific product identification
e. Where applicable, the certification criterion or criteria to which each EHR module has been tested and certified
f. The clinical quality measures to which a health IT product has been tested and certified
g. *And* where applicable, any additional software a health IT product relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary
h. *And* where applicable, any additional types of costs that a user may be required to pay to implement or use the health IT product's capabilities, whether to meet [Promoting Interoperability] objectives and measures or to achieve any other use within the scope of the health IT's certification. *(Examples given include: fixed, recurring, transaction-based, or otherwise that are imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.)*

A developer may satisfy the requirement to disclose the information required by § 170.523(k)(1) in its marketing materials, communications statements, and other assertions related to a health IT product's certification by providing an abbreviated disclaimer, appropriate to the material and medium, provided the disclaimer is accompanied by a hyperlink to the complete disclosure on the developer's website.

Where a hyperlink is not feasible (for example, in non-visual media), the developer may use another appropriate method to direct the recipient of the marketing material, communication, or assertion to the complete disclosure on its website.

8 SLI Compliance and ONC Health IT Certified Marks, Usage Guidelines

The customer may begin using the SLI and the ONC Health IT Certified marks upon notification by SLI that certification has been issued. Use of one or both marks is optional; however, they must be used in accordance with their respective usage guidelines and terms and conditions, which are provided to the customer in electronic format after certification is granted.

The ONC Health IT Certified status applies to the specific product that was certified, and not to the developer company as a whole; therefore, use of these marks must be clearly attributed to the product that received certification. Use of these marks must include your product name, version number and all marketing details required by the final rule (see 45 CFR 170.523(k)(1) under ONC Guidelines - Transparency and Disclosure Requirements above). This includes any additional costs a customer may be required to incur when implementing the certified health IT product in an effort to meet requirements for incentives attestation.

9 Conditions of Certification, Maintenance of Certification

The ONC has specified certain conditions for initial certification and maintenance of certification. These include:

- Information Blocking
- Assurances
- Communications
- Application Programming Interfaces (APIs)
- Real World Testing
- Attestations

The ACB responsible for a certification collects certain information from the developer according to timelines published by the ONC. ACBs are asked to review this information for completeness, respond to the developer if there are any gaps, and provide the information to the ONC. This information is in the form of Attestations (twice per year starting in 2022) as well as annual Real World Test Plans and Real World Test Reports that cover each calendar year starting with 2022. Developers will be notified of the specifics and provided materials, which may include guidance and/or templates. Developers are responsible for preparing the required items and presenting them to the ACB in time to meet ACB-imposed deadlines that allow time for ACB review and feedback. See https://www.healthit.gov/curesrule/, including the latest updates, for more details.

10 Press Releases

All marketing materials related to certified products must adhere to the guidelines posted in the "ONC Guidelines" section above. Any press release that includes information about SLI must undergo a review and approval process by SLI. *The review may take 5 business days or longer.* The Account Manager can provide assistance and additional information. These requirements also apply to organizations that sell a certified product under a private label.

11 Additional Resources

Please review the following sources for additional information:

• SLI Compliance website – Certification (http://www.slicompliance.com/services/testing-certification-health/)
• ONC FAQs on the Health IT Certification Program (https://www.healthit.gov/faq/faqs)
• Additional information about the ONC's Certified Health IT Product List (CHPL) (https://www.healthit.gov/topic/certified-health-it-products-list-chpl)
• 2015 Edition Test Methods (https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method)
• 2015 Cures Edition Test Methods (https://www.healthit.gov/topic/certification-ehrs/2015-edition-cures-update-test-method)
• Criteria and Terms of Usage for the ONC Health IT Certification Mark (https://www.healthit.gov/sites/default/files/hit_certificationterms_of_use_final.pdf)
• ONC Regulations related to the Health IT Certification Program (https://www.healthit.gov/topic/certification-ehrs/certification-standards-and-regulations)
• ONC Program Guidance (https://www.healthit.gov/topic/certification-ehrs/onc-health-it-certification-program-guidance)
• ONC Conditions and Maintenance of Certification (https://www.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification)
• ONC Real World Testing website (https://www.healthit.gov/topic/certification-ehrs/real-world-testing)

12 SLI Compliance Contact Information

For more information about SLI's ONC Health IT Certification Program, contact us at info@slicompliance.com. For ACB specific inquiries, contact acb@slicompliance.com.

SLI Compliance

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