Gaming Laboratories International, LLC dba SLI Compliance (SLI)

ONC-ACB Certification Program

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4720 Independence St.
Wheat Ridge, CO 80033
303-422-1566
www.SLICompliance.com

Document History

Rev.	Date	Change
1.0	September 7, 2017	Initial Version
1.1	September 22, 2017	Changed company reference on cover page to Gaming Laboratories International, LLC dba SLI Compliance
1.2	November 27, 2017	Section 3: Clarified that test results from other ATLs must be reviewed and certifications are not transferrable among ACBs.
2.0	December 08, 2017	1. Changed name to ONC-ACB Certification Program and document ID to ACB-CERT-Prog 2. Section 1: Removed – "This manual applies to the SLI Compliance (SLI) Certification Body (CB) and is based on ISO/IEC 17065:2012 and ONC guidance." Added – "This document defines the requirements for the certification of healthcare IT products under the scope of accreditation issued by ANSI 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 vendor submitting a product(s) for certification."
2.1	February 26, 2019	1. Section 1: Added 2017 version of ISO/IEC 17025, added ANSI accreditation ID 2. Multiple sections: changed "logo" to "mark" 3. 6.2: Removed requirement for random surveillance of 2% of products 4. 11: Added URLs

Contents

1 About SLI Compliance

This document defines the requirements for the certification of healthcare IT products under the scope of accreditation issued by ANSI 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 vendor 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 (ONC) Health IT Certification Program. As an accredited ONC-ATL and ONC-ACB, SLI operates a Quality Management System that is compliant to ISO/IEC 17025:2005 (transitioning to the 2017 version) 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 American National Standards Institute (ANSI) for the certification of healthcare IT products (ANSI Accreditation ID# 1265)
- ISO/IEC 17025:2005 (transitioning to the 2017 standard) by National Voluntary Laboratory Accreditation Program (NVLAP) for Healthcare IT Testing (NVLAP Lab Code: 200733-0 - TESTING)
- ISO 9001:2015, Quality management systems – Requirements
- ISO/IEC 17025:2005 (transitioning to the 2017 standard) by NVLAP for Voting System Testing (NVLAP Lab Code: 200733-0 - TESTING)

For more information about the federal testing and certification program, please visit http://www.healthit.gov.

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 www.slicompliance.com. 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 is 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 "SLI Compliance ONC-ATL Testing Program Guide" available at www.slicompliance.com/solutions/health-it.

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 (SA), which includes pricing, the certification agreement and the Terms and Conditions.

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

2.2 Submission of Materials

Upon receipt of all 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 recordings of tests or screen captures 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 SA 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 vendor 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 Testing 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. At the conclusion of the certification process, SLI 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.

4.2 Gap Certification

If a product was tested and certified under earlier certification criteria, the customer's criteria may be eligible for Gap Certification. The SLI registration form denotes all gap eligible criteria.

4.3 Certification to Newer Versions of Certain Standards

ONC-ACBs may certify health IT products to a newer version of certain identified minimum standards as specified in the Final Rule and approved final test procedures if the Secretary has accepted a newer version of an adopted minimum 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 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 the ONC's page on the CHPL 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 documents the criteria under 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. SLI requests that a Product Update Form is submitted, along with any additional documentation, to facilitate the review. SLI will review these modifications and determine whether a 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.

If a product is no longer maintained 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 Private-Labeling, and/or Product Name Changes

The customer must report all company and/or product name changes to SLI using the Product Update Form, and follow the designated process—no changes will be processed without a completed Product Update Form. Company headquarters address and/or billing address changes may be submitted to SLI in writing and signed by an authorized official; in this case a Product Update Form is not required, but may be used.

All rebranded or private-labeled product certifications must be submitted to SLI using the Product Private-Label Form. The original manufacturer or company and the company rebranding the product must both sign the form as evidence that each is aware of the requested changes.

5.3 Resellers and Private-Labelers

EHR 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 (Note: this practice is specifically sanctioned under the ONC certification program).

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 Private-Labeling Form;
- Provide documentation of 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 SA 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 Director. All appeals/disputes must be submitted in writing (mail, fax, 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 17065:2012 requirements, SLI is required to prepare an annual Surveillance Plan. The plan includes reactive and proactive surveillance of certified EHR products. The current plan is available on the SLI web site. 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.
- 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 certified mark used must be from SLI and not from another authorized 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 EHR products certified by SLI that have complaints or questions about the certified product functionality may submit complaints to SLI by contacting SLI at info@slicompliance.com. All complaints will be reviewed for validity and relevance to a certified EHR product. The product certification may be suspended or withdrawn if the complaint is valid and compromises the integrity of the product certification. The customer,

any associated Accredited Testing Lab and any affected federal entity (e.g., the ONC) will be notified.

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;
- Withdrawal 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 resolve it or provide a reasonable explanation of why the breach cannot be corrected.

The SLI Director (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, making reference to the certification, and the product listing will be removed from both the SLI website and 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 meaningful use 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.)*
i. *And* where applicable, any limitations (whether by contract or otherwise) that a user may encounter in the course of implementing and using the health IT product's

capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification. *(Examples given include, but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology 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 Attestation Requirement

As a condition of certification, health IT developers must make one of the following attestations:

In the affirmative:
In support of enhanced marketplace transparency and visibility into the costs and performance of certified health IT products and services, and the business practices of health IT developers, **[Developer Name]** hereby attests that it will provide in a timely manner, in plain writing, and in a manner calculated to inform, any part (including all) of the information required to be disclosed under 45 CFR §170.523(k)(1)under the following circumstances:

- To all persons who request such information.
- To all persons who request or receive a quotation, estimate, description of services, or other assertion or information from [Developer Name] in connection with any certified health IT or any capabilities thereof.
- To all customers prior to providing or entering into any agreement to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an on-going agreement).

-OR –

In the negative:
[Developer Name] hereby attests that it has been asked to make the voluntary attestation described by 45 CFR § 170.523(k)(2)(i)in support of enhanced marketplace transparency and visibility into the costs and performances of certified health IT products and services, and the business practices of health IT developers and **[Developer Name]** hereby declines to make such attestation at this time.

-OR –

Self-developer exclusion:
[Developer Name] hereby attests that it is a self-developer exempt from the disclosure requirements at 45 CFR §170.523(k)(1)(iii) and 170.523(k)(2). **[Developer Name]** further attests that as a self-developer it does not and will not market, sell or license its certified Health IT Module(s).

The failure of a health IT developer to disclose the required information is a violation of an explicit certification program requirement and thus constitutes a non-conformity.

A developer's adherence to their attestations is voluntary; however, SLI is required to include the developer's attestations in the hyperlink submitted to the National Coordinator for inclusion in the CHPL so that the public can determine which developers have attested to taking the additional actions to promote transparency of their technologies and business practices. ONC notes that a developer's attestation under 45 CFR § 170.523(k)(2) does not broaden or change the scope of the information a developer is required to disclose under 45 CFR § 170.523(k)(1).

SLI administers the transparency attestation requirement by including it as part of new 2015 Edition certification registrations, the update process for previously certified products, and as part of the follow up that is required for quarterly reporting information.

9 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), including any additional costs that a customer is required to incur to implement a certified health IT product in an effort to meet Meaningful Use (MU) objectives and measures for attestation.

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)
- 2014 Edition Test Methods (https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method)
- 2015 Edition Test Methods (https://www.healthit.gov/topic/certification-ehrs/2015-edition-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)

12 SLI Compliance Contact Information

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

SLI Compliance

4720 Independence St., Wheat Ridge, CO 80033

Phone: (844) 754-8683

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