

SCC SOFT COMPUTER REGULATORY AFFAIRS QUICK REFERENCE

SCC'S SOFTLAB® VERSIONS 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5, AND 4.5.8 RECEIVED ONC CERTIFICATION CRITERIA FOR HEALTH IT.

SCC Soft Computer is pleased to announce SCC's laboratory information system, SoftLab®, versions 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5, and 4.5.8 have all achieved ONC Certification Criteria for Health IT as Health IT Modules.

SoftLab versions 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5, and 4.5.8 were certified by Drummond Group, an Office of the National Coordinator-Authorized Certification Body (ONC-ACB)^{1, 2} in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services.

These certifications do not represent an endorsement by the U.S. Department of Health and Human Services.

CERTIFICATION DETAILS

Product Name	Certification Date	CHPL ID Number
SoftLab® 4.0.7	February 9, 2023	15.07.04.2287.SL40.07.1.1.230209
SoftLab® 4.0.8	February 9, 2023	15.07.04.2287.SL40.08.02.1.230209
SoftLab® 4.0.9	February 9, 2023	15.07.04.2287.SL40.09.03.1.230209
SoftLab® 4.5.4	February 9, 2023	15.07.04.2287.SL45.05.03.1.230209
SoftLab® 4.5.5	February 9, 2023	15.07.04.2287.SL45.04.04.1.230209
SoftLab® 4.5.8	June 6, 2023	15.99.04.2287.SL45.04.05.1.230606

CERTIFICATION CRITERIA

SoftLab versions 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5, and 4.5.8 achieved the following ONC Certification Criteria for Health IT:

- 170.315(b)(10): Electronic Health Information Export
- 170.315(d)(1): Authentication, Access Control, and Authorization
- 170.315(d)(2): Auditable Events and Tamper-Resistance (Cures Update)
- 170.315(d)(3): Audit Reports (Cures Update)
- 170.315(d)(7): End-User Device Encryption
- 170.315(d)(12): Encrypt Authentication Credentials (Cures Update)
- 170.315(d)(13): Multi-Factor Authentication (Cures Update)
- 170.315(f)(3): Transmission to Public Health Agencies – Reportable Laboratory Tests and Values/Results
- 170.315(g)(4): Quality Management System
- 170.315(g)(5): Accessibility-Centered Design

The additional software relied upon to comply with one or more of the certification criteria include:

- SCC Soft Computer ELR Interface

¹ Drummond Group offers vendor-neutral third-party testing and certification of security and health IT products, as well as network-connected devices, to measure product compliance, reliability, and performance for many of the world's top security vendors.

² ONC Certification Criteria for Health IT is granted to those technologies that are capable of meeting the more rigorous testing criteria developed to support providers and hospitals who wish to deliver higher quality patient care and exchange clinical information securely. Visit <https://www.drummondgroup.com/> for more information.

SoftLab is a registered trademark of SCC Soft Computer® in the United States and Canada.

GENERAL COSTS AND

1. User acquires access to the Software License paying a License Fee. User receives a perpetual license to use the software. The User may only use the Licensed Software in a production environment if under a valid Software Application Support and Maintenance Agreement. If the User terminates the Software Application Support and Maintenance Agreement, the User may only use the Licensed Software for archival purposes to look up prior tests. The User would no longer receive updates/upgrades to the licensed software if the maintenance agreement is terminated, and this could lead to a patient safety risk to health issue, as corrections to the Licensed Software are issued under the Software Application Support and Maintenance Agreement.
2. In addition to the License Fee, there is a onetime implementation fee and training fee quoted to help the user move from test system to production system in live operation.
3. Once Live Date occurs and the software is used in a production environment, software maintenance commences. Software Maintenance fee is a percentage of the Software License Fee. Updates to newer versions of the user's Licensed Software is offered for no license fee as part of the annual maintenance.

EDUCATION COURSES

SCC Soft Computer offers a variety of online or on-site training classes that are listed on the website.

THIRD PARTY FEES

1. SCC Soft Computer is an authorized reseller of IBM and Oracle products and services. IBM and Oracle products are offered as a pass-through courtesy to users and will be quoted when requested by the user.
2. SCC Soft Computer offers interfaces to laboratory and HIS vendors, as requested by the users. The interfaces are offered under an initial license fee and an annual maintenance fee.