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3rd Edition

CLSI AUTO11™

Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems

CLSI AUTO11 provides a framework for communication of information technology security issues between the *in vitro* diagnostic system vendor and the health care delivery organization.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute

P: +1.610.688.0100

F: +1.610.688.0700

www.clsi.org

standard@clsi.org

Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems

Ed Heierman, PhD
Riccardo Benedetti, Dr.sc.techn.ETH, Dipl.El.Ing.ETH
Richard Y. Wang, DO
David Chou, MD
Thomas J.S. Durant, MD
Philip R. Foulis, MD, MPH
Anthony Gautier, BS

Derek Holzhauser, MAppSc, BSc
Sean Kocur, PhD, C(ASCP), D(ABFT)FT
James McLean, MBA, PMP, CSSLP
Niklaus Rümmele, BSc
Sheri Terrillion, MT(ASCP)^{CM}, CQA(ASQ), MAOL

Abstract

Clinical and Laboratory Standards Institute AUTO11—*Information Technology Security of In Vitro Diagnostic Instruments and Software Systems* specifies technical and operational requirements and technical implementation procedures related to security of *in vitro* diagnostic (IVD) systems (devices, analytical instruments, data management systems, etc.) installed at a health care delivery organization (HDO). The intended users for CLSI AUTO11 are medical device and IVD system manufacturers, users (eg, laboratory personnel), and information technology management of HDOs.

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Committee Membership

Consensus Council

The Consensus Council sets priorities for CLSI standards development and votes on Final Draft documents to confirm that process requirements have been met. Consensus Council members are listed on the CLSI website: <https://clsi.org/standards-development/consensus-council/>

Document Development Committee on Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems

Ed Heierman, PhD Chairholder Abbott USA	Thomas J.S. Durant, MD Yale University School of Medicine USA	James McLean, MBA, PMP, CSSLP Siemens Healthineers USA
Riccardo Benedetti, Dr.sc.techn.ETH, Dipl.El.Ing.ETH Vice-Chairholder Roche Diagnostics International Ltd Switzerland	Philip R. Foulis, MD, MPH James A. Haley Veterans' Hospital USA	Enrique Terrazas, MD, MS Quest Diagnostics USA
Richard Y. Wang, DO Committee Secretary Centers for Disease Control and Prevention USA	Anthony Gautier, BS Beckman Coulter USA	Sheri Terrillion, MT(ASCP) ^{CM} , CQA(ASQ), MAOL Sentara Healthcare USA
	Derek Holzhauser, MAppSc, BSc RCPA Quality Assurance Programs Pty Limited Australia	

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David Chou, MD
University of Washington Dept of Lab
Medicine and Pathology
USA

Sean Kocur, PhD, C(ASCP), D(ABFT)FT
Quest Diagnostics
USA

Niklaus Rümmele, BSc
Roche Diagnostics International Ltd.
Switzerland

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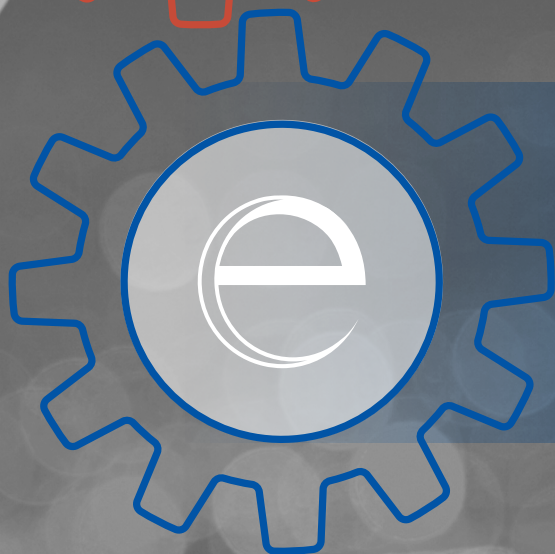
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