

References and resources by module

There are two International Organization for Standardization (ISO) standards that are specific to laboratories and the Clinical and Laboratory Standards Institute (CLSI) has two documents that are very important in the clinical laboratory. These four documents are referred to throughout each of the 18 chapters and are therefore not cited in the individual chapters listed below.

- ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva, International Organization for Standardization, 2007.
- ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories*. Geneva, International Organization for Standardization, 2005.
- CLSI/NCCLS. *Application of a quality management system model for laboratory services; approved guideline—3rd ed. GP26-A3*. Wayne, PA, NCCLS, 2004.
- CLSI/NCCLS. *A quality management system model for health care; approved guideline—2nd ed. HS1-A2*. Wayne, PA, NCCLS, 2004.

Module 1 Introduction

Crosby PB. *Quality without tears: the art of hassle-free management*. New York, McGraw-Hill, 1995.

Deming WE. *Out of the crisis*. Cambridge, MIT Press, 1982.

ISO 9000:2005. *Quality management systems—Fundamentals and vocabulary*. Geneva, International Organization for Standardization, 2005.

ISO 9001:2008. *Quality management systems—Requirements*. Geneva, International Organization for Standardization, 2008.

Shewart WE. *Economic control of quality of manufactured product*. New York, D. Van Nostrand Company, 1931.

Shewart WE. *Statistical methods from the viewpoint of quality control*, WE Deming, ed., Washington, DC, Graduate School, Department of Agriculture, 1939. Reprinted New York, Dover Publications Inc, 1986.

Walton M. *The Deming management method*. New York, Perigee Books, 1986.

WHO. Fifty-eighth World Health Assembly. Resolutions and decisions annex. Geneva, World Health Organization, 2005 (http://www.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf, accessed 11 April 2011).

Module 2 Facilities and safety

CDC and NIH. *Biosafety in microbiological and biomedical laboratories*, 4th ed. United States Government Printing Office, United States Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, 1999.

Collins CH, Kennedy DA. Laboratory-acquired infections. In: *Laboratory-acquired infections: history, incidence, causes and preventions*, 4th ed. Oxford, United Kingdom, Butterworth- Heinemann, 1999:1–37.

Harding AL, Brandt Byers K. Epidemiology of laboratory-associated infections. In: Fleming DO, Hunt DL, eds. *Biological safety: principles and practices*. Washington, DC, ASM Press, 2000:35–54.

Howard Hughes Medical Institute, Office of Laboratory Safety. Laboratory safety study 1993–1997 (<http://www.hhmi.org/>).

ISO 15190:2003. *Medical laboratories—Requirements for safety*. Geneva, International Organization for Standardization, 2003.

ISO 3864-1:2002. *Graphical symbols—Safety colours and safety signs—Part 1: Design principles for safety signs in workplaces and public areas*. Geneva, International Organization for Standardization, 2002.

ISO 3864-3:2006. *Graphical symbols—Safety colours and safety signs—Part 3: Design principles for graphical symbols for use in safety signs*. Geneva, International Organization for Standardization, 2006.

Internationally recognized labels:

- http://www.ehs.cornell.edu/lrs/lab_dot_labels/lab_dot_labels.cfm (accessed 11 April 2011)
- <http://ehs.unc.edu/labels/bio.shtml> (accessed 11 April 2011)
- <http://www.safetylabel.com/safetylabelstandards/iso-ansi-symbols.php> (accessed 11 April 2011).

PHAC. Chapter 9: Biological safety cabinets. In: *The laboratory biosafety guidelines*, 3rd ed. Ottawa, Public Health Agency of Canada, 2004 (<http://www.phac-aspc.gc.ca/publicat/lbgldmbl-04/ch9-eng.php>, accessed 11 April 2011).

Reitman M, Wedum AG. Microbiological safety. *Public Health Report*, 1956,71(7):659–665.

Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: what clinicians need to know. *Clinical Infectious Diseases*, 2004, 39:702–709 (http://www.hpci.ch/files/documents/guidelines/hh_gl_disinf-sterili-cid.pdf, accessed 11 April 2011).

Sewell DL. Laboratory-associated infections and biosafety. *Clinical Microbiology Reviews*, 1995, 8:389–405.

WHO. *Laboratory safety manual*, 3rd ed. Geneva, World Health Organization, 2003.

WHO. *Guidance on regulation for the transport of infectious substances 2007–2008*. Geneva, World Health Organization, 2007.

Module 3 Equipment

King B. NIOSH Health Hazard Evaluation Report No. 2004-0081-3002. New York University School of Medicine, New York, 2006:11 (<http://www.cdc.gov/niosh/hhe/reports/pdfs/2004-0081-3002.pdf>, accessed 11 April 2011).

Richmond JY, McKinney RW, eds. *Primary containment for biohazards: selection, installation and use of biological safety cabinets*, 2nd ed. United States Government Printing Office, United States Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, 2000.

WHO. *Guidelines for health care equipment donations*. Geneva, World Health Organization, 2000 (http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf, accessed 11 April 2011).

Module 4 Purchasing and inventory

WHO. *Guidelines for health care equipment donations*. Geneva, World Health Organization, 2000 (http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf, accessed 11 April 2011).

Module 5 Process control—sample management

ICAO. Technical instructions for the safe transport of dangerous goods by air, 2007–2008 ed. (Doc 9284). Montreal, Canada, International Civil Aviation Organization, 2006.

ISO 15394:2000. *Packaging—bar code and two-dimensional symbols for shipping, transport and receiving labels*. Geneva, International Organization for Standardization, 2000.

ISO 21067:2007. *Packaging—vocabulary*. Geneva, International Organization for Standardization, 2007.

UN. *Recommendations on the transport of dangerous goods: model regulations*, 15th revised ed. New York, Geneva, United Nations, 2007. These recommendations include:

- UN 2900 Infectious substances affecting humans—infectious substances included in Category A in any form unless otherwise indicated;
- UN 2900 Infectious substances affecting animals only—"Exempt" human or animal samples;
- Shipper's Declaration for Dangerous Goods Form;
- Flowchart for Classification of Infectious Agents for Transport;
- Packaging and Labeling of Category A Infectious Substances;
- Packaging and Labeling of Category B Infectious Substances;
- Packaging and Labeling of Exempt Substances;
- Thermal Control Shipping Unit;
- Dry Ice Shipping Label.

Wagar EA et al. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. *Archives of Pathology and Laboratory Medicine*, 2006, 130(11):1662–1668 ([http://arpa.allenpress.com/pdfserv/10.1043%2F15432165\(2006\)130%5B1662:PSITCL%5D2.0.CO%3B2](http://arpa.allenpress.com/pdfserv/10.1043%2F15432165(2006)130%5B1662:PSITCL%5D2.0.CO%3B2)).

WHO. *Guidance on regulation for the transport of infectious substances 2007–2008*. Geneva, World Health Organization, 2007.

Module 6 Process control—introduction to quality control

ISO 9000:2005. *Quality management systems—Fundamentals and vocabulary*. Geneva, International Organization for Standardization, 2005.

WHO. *External quality assessment of health laboratories: report on a WHO Working Group*. Geneva, World Health Organization, 1981.

Module 7 Process control—quality control for quantitative tests

CLSI. C24-A3—*Statistical quality control for quantitative measurement procedures: principles and definitions*, approved guideline—3rd ed. Wayne, PA, Clinical and Laboratory Standards Institute, 2006.

ISO 15198:2004. *Clinical laboratory medicine—In vitro diagnostic medical devices—Validation of user quality control procedures by the manufacturer*. Geneva, International Organization for Standardization, 2004.

Module 8 Process control—quality control for qualitative and semiquantitative procedures

CLSI. *User protocol for evaluation of qualitative test performance*, approved guideline—2nd ed. EP12-A2 (electronic document). Wayne, PA, Clinical and Laboratory Standards Institute, 2008.

CLSI. *Abbreviated identification of bacteria and yeast*, approved guideline—2nd ed. M35-A2. Wayne, PA, Clinical and Laboratory Standards Institute, 2008.

CLSI. *Performance standards for antimicrobial disk susceptibility tests*, approved standards—18th informational supplement. M100-S18. Wayne, PA, Clinical and Laboratory Standards Institute, 2008.

Jorgensen JH, Turnidge JD. Susceptibility test methods: dilution and disk diffusion methods. In: Murray PR et al. (eds). *Manual of Clinical Microbiology*, 9th ed. Washington, DC, ASM Press, 2007:1152–1172.

Turnidge JD, Ferraro MJ, Jorgensen JH. Susceptibility test methods: general considerations. In: Murray PR et al. (eds). *Manual of Clinical Microbiology*, 9th ed. Washington, DC, ASM Press, 2007:1146–1151.

Westgard Multirule System. (<http://www.westgard.com>, accessed 11 April 2011).

Module 9 Assessment—audits

Cochran C. The five keys to a successful internal audit programme. *The Auditor* 2:1. Chico, CA, Paton Press, 2007 (<http://www.dnvcert.com/DNV/Certification1/Resources1/Articles/NewsletterInfo/FiveKeystoaSuccessfulI/>).

ISO 9000:2005. *Quality management systems—Fundamentals and vocabulary*. Geneva, International Organization for Standardization, 2005.

ISO 19011:2002. *Guidelines for quality and/or environmental systems auditing*. Geneva, International Organization for Standardization, 2002.

Kusum M, Silva P. *Quality standards in health laboratories implementation in Thailand: a novel approach*. World Health Organization Regional Office for South-East Asia, 2005 (http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4__2_.pdf, accessed 11 April 2011).

Module 10 Assessment—external quality assessment

APHL. External quality assessment for AFB smear microscopy. Silver Spring, MD, Association of Public Health Laboratories, 2002 (<http://wwwn.cdc.gov/mlp/pdf/GAP/Ridderhof.pdf>, accessed 11 April 2011).

CDC/WHO. *HIV rapid test training package*. Atlanta, Centers for Disease Control and Prevention/Geneva, World Health Organization, 2005 (<http://www.cdc.gov/dls/ila/hivtraining>, accessed 11 April 2011).

Chaitram JM et al. The World Health Organization's external quality assurance system proficiency testing programme has improved the accuracy of antimicrobial susceptibility testing and reporting among participating laboratories using NCCLS methods. *Journal of Clinical Microbiology*, 2003, 41:2372–2377.

CLSI. *Using proficiency testing to improve the clinical laboratory*, approved guideline—2nd ed. GP27-A2. Wayne, PA, Clinical and Laboratory Standards Institute, 2007.

CLSI. *Assessment of laboratory tests when proficiency testing is not available*, approved guideline—2nd ed, GP29-A2. Wayne, PA, Clinical and Laboratory Standards Institute, 2008.

ISO 15189:2007 (5.6.4). *Medical laboratories—requirements for quality and competence*. Geneva, International Organization for Standardization, 2007.

ISO/IEC 17000:2004. *Conformity assessment—Vocabulary and general principles*. Geneva, International Organization for Standardization, 2004.

ISO/IEC Guide 2:2004. *Standardization and related activities—General vocabulary*. Geneva, International Organization for Standardization, 2004.

ISO/IEC Guide 43-1:1997. *Proficiency testing by interlaboratory comparisons—Part 1: Development and operation of proficiency testing schemes*. Geneva, International Organization for Standardization, 1997.

Martinez A et al. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid-fast bacilli smears in a pilot project setting in Mexico. *International Journal of Tuberculosis and Lung Diseases*, 2005,9(3):301–305.

WHO. *Accreditation of health laboratories in the countries of the SEA region: report of a regional consultation, Bangkok, Thailand, 6–10 October, 2003*. WHO Project: ICP BCT 001, World Health Organization Regional Office for South-East Asia, 2004.

WHO. *Policy and procedures of the WHO/NICD microbiology external quality assessment programme in Africa, years 1 to 4, 2002–2006*. Geneva, World Health Organization, 2007 (http://www.who.int/csr/ihr/lyon/Policy_procedures_eqa_en.pdf, accessed 11 April 2011).

WHO,CDC. *Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach*. Geneva, World Health Organization/Atlanta, Centers for Disease

Control and Prevention, 2005 (<http://www.phppo.cdc.gov/dls/ila/default.aspx> and <http://www.who.int/hiv/topics/vct/toolkit/components/supply/en/index8.html>).

Module 11 Assessment—norms and accreditation

Dawson D, Kim SJ and the Stop Tuberculosis (TB) Unit at the Western Pacific Regional Office (WPRO). *Quality assurance of sputum microscopy in DOTS programmes*. World Health Organization Regional Office for the Western Pacific, 2003. Deutscher Akkreditierungs Rat (DAR). Acronyms, links, and e-mail addresses (<http://www.dar.bam.de/indexe.html>).

ISO/IEC 17011:2004. *Conformity assessment—general requirements for accreditation bodies accrediting conformity assessment bodies*. Geneva, International Organization for Standardization, 2004.

Kusum M, Silva P. *Quality standards in health laboratories, implementation in Thailand: a novel approach*. World Health Organization Regional Office for South-East Asia, 2005, SEAHLM-386 (http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4__2_.pdf, accessed 11 April 2011).

Kumari S, Bhatia R. *Guidelines for peripheral and intermediate laboratories in quality assurance in bacteriology and immunology*. World Health Organization Regional Office for South-East Asia, Series No. 28, 2003.

Silva P. *Guidelines on establishment of accreditation of health laboratories*. World Health Organization Regional Office for South-East Asia, 2007.

WHO. *Accreditation of health laboratories in the countries of the SEA region: report of a regional consultation, Bangkok, Thailand, 6–10 October 2003*. WHO Project ICP BCT 001. World Health Organization Regional Office for South-East Asia, 2004, SEA-HLM-379.

WHO. *Handbook: Good laboratory practice—quality practices for regulated nonclinical research and development*. UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. Geneva, World Health Organization, 2001 (<http://www.who.int/tdr/svc/publications/training-guidelinepublications/good-laboratory-practice-handbook>).

WHO. *National Polio Laboratory check list for annual WHO accreditation*. Geneva, World Health Organization, 2003 (http://www.searo.who.int/LinkFiles/Laboratory_Network_NPLchecklist.pdf).

Module 12 Personnel

Bello M. *Employee handbook*. eScholarship Repository, University of California, 2008 (<http://repositories.cdlib.org/lbnl/LBNL-937E>).

ISO 10015:1999. *Quality management—guidelines for training*. Geneva, International Organization for Standardization, 1999.

Module 13 Customer service

ISO 10001:2007. *Quality management—customer satisfaction: guidelines for codes of conduct for organizations*. Geneva, International Organization for Standardization, 2007.

Module 14 Occurrence management

Bonini P et al. Errors in laboratory medicine. *Clinical Chemistry*, 2002, 48:691–698 (<http://www.clinchem.org/cgi/content/full/48/5/691>).

ISO/TS 22367:2008. *Medical laboratories—reduction of error through risk management and continual improvement*. Geneva, International Organization for Standardization, 2008.

Khoury M et al. Error rates in Australian chemical pathology laboratories. *Medical Journal of Australia*, 1996, 165:128–130 (<http://www.mja.com.au/public/issues/aug5/khoury/khoury.html>).

Module 15 Process improvement

Brown MG. *Baldrige award winning quality, 15th ed.: How to interpret the Baldrige criteria for performance excellence*. Milwaukee, ASQ Quality Press, 2006.

Brown MG. *Using the right metrics to drive world-class performance*. New York, American Management Association, 1996.

Crosby PB. *Quality management: the real thing; on perfection (essays)*, 1962 (<http://www.wppl.org/wphistory/PhilipCrosby/OnPerfection.pdf> and www.wppl.org/wphistory/PhilipCrosby/QualityManagementTheRealThing.pdf).

Crosby PB. *The myths of zero defects (essay)*, 1979 (<http://www.wppl.org/wphistory/PhilipCrosby/TheMythsOfZeroDefects.pdf>).

Crosby PB. *Quality is free: the art of making quality certain*. New York, McGraw-Hill, 1979.

Deming WE. *Out of the crisis*. Cambridge, MIT Press, 1982.

Hilborne L. Developing a core set of laboratory based quality indicators. Presented at: Institute for Quality in Laboratory Medicine Conference, 29 April 2005, Atlanta, GA, United States of America (http://cdc.confex.com/cdc/qlm2005/techprogramme/paper_9086.htm).

ISO 9001:2008. *Quality management systems—Requirements*. Geneva, International Organization for Standardization, 2008.

Jacobson JM et al. Lean and Six Sigma: not for amateurs. *Laboratory Medicine*, 2006, 37:78–83.

Pande P, Holpp L. *What is Six Sigma?* Milwaukee, ASQ Quality Press, 2001.

Spanyi A. Six Sigma for the rest of us. *Quality Digest*, 2003, 23(7):22–26.

Module 16 Documents and records

Microbiology Laboratory Manual Online. Department of Microbiology, Mount Sinai Hospital Joseph and Wolf Lebovic Health Complex, Toronto, Ontario, Canada (<http://www.mountsinai.on.ca/education/staff-professionals/microbiology>).

ISO 9000:2005. *Quality management systems—Fundamentals and vocabulary*. Geneva, International Organization for Standardization, 2005.

Module 17 Information management

Laboratory Quality Management System Training Toolkit – Current Laboratory Practice Series - 2009

APHL. *Guidebook for implementation of laboratory information systems in resource poor settings*. Association for Public Health Laboratories, 2006 (<http://www.aphl.org/aphlprogrammes/global/initiatives/Pages/lis.aspx>).

Bentley D. *Analysis of a laboratory information management system (LIMS)*. University of Missouri, St Louis, MO, 1999 (http://www.umsl.edu/~sauterv/analysis/LIMS_example.html#BM1_).

Module 18 Organization

ISO 9001:2008. *Quality management systems—Requirements*. Geneva, International Organization for Standardization, 2008.

Glossary

The definitions provided in the glossary come from the references above and from the sources listed below.

ANSI/ASQC Standard A3. *Quality Systems Terminology*. American National Standards Institute/American Society for Quality Control, 1987.

Basem S. El-Haik, Khalid S. Mekki. *Medical device design for six sigma: a road map for safety and effectiveness*. John Wiley & Sons, Inc. Hoboken, NJ, 2008.

Glossary of QC Terms, Westgard QC (<http://www.westgard.com/glossary.htm>, accessed 14 September 2012).

Glossary of Terms, Six Sigma Forum, American Society for Quality (<http://asq.org/sixsigma/quality-information/termsa-sixsigma.html>, accessed 14 September 2012).

ISO 3534-2:2006. *Statistics—Vocabulary and symbols—Part 2: Applied statistics*. Geneva, International Organization for Standardization, 2006.

ISO 9000, 9001, and 9004 plain English definitions, Praxiom Research Group Limited (<http://www.praxiom.com/iso-definition.htm>, accessed 14 September 2012).

ISO/IEC 17020:2012. *Conformity assessment—Requirements for the operation of various types of bodies performing inspection*. Geneva, International Organization for Standardization, 2012.

ISO/IEC Directives, Part 2. *Rules for the structure and drafting of International Standards*, 6th edition. Geneva, International Organization for Standardization, 2011.

ISO/IEC Guide 51:1999. *Safety aspects—Guidelines for their inclusion in standards*. Geneva, International Organization for Standardization, 1999.

Mosby's Medical Dictionary, 8th edition. Elsevier, 2009 (<http://medical-dictionary.thefreedictionary.com/>, accessed 14 September 2012).

NSF/ANSI 49-2011. *Biosafety Cabinetry: Design, Construction, Performance, and Field Certification*. NSF International, 2011.

Quality Assurance Terms Glossary, The Elsmar Cove Web Site (http://elsmar.com/wiki/index.php/Quality_Assurance_Terms_Glossary/, accessed 14 September 2012).

Laboratory Quality Management System Training Toolkit – Current Laboratory Practice Series - 2009

Quality Glossary, Program Office for Laboratory Quality Management, Department of Pathology and Laboratory Medicine, University of British Columbia
(http://www.polqm.ca/glossary_lqm_a_i.htm, accessed 14 September 2012).

Tague NR. *The quality toolbox*. American Society for Quality, Quality Press, Milwaukee, WI, 2005.