

Section 5: Références et ressources listées par module

Il existe deux normes ISO spécifiques pour les laboratoires et CLSI possède deux documents qui sont très importants pour les laboratoires cliniques.

Le module de formation se réfère à ces 4 documents tout au long des 18 modules, ils ne sont donc pas cités dans la liste séparée des différents modules ci-dessous :

- ISO 15189:2007. Laboratoires médicaux – Exigences particulières pour la qualité et la compétence. Genève : International Organization for Standardization.
- ISO/IEC 17025:2005. Exigences générales pour la compétence des laboratoires de tests, essais et calibrations. Genève : International Organization for Standardization.
- CLSI/NCCLS. *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition*. GP26-A3. Wayne, PA: NCCLS; 2004.
- CLSI/NCCLS. *A Quality Management System Model for Health Care; Approved Guideline—Second Edition*. HS1-A2. Wayne, PA: NCCLS; 2004.

Module 1 Introduction

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ISO 9000:2005. *Systèmes de management de la qualité -- Principes essentiels et vocabulaire*. Genève : International Organization for Standardization.

ISO 9001:2008. *Systèmes de management de la qualité -- Exigences*. Genève : International Organization for Standardization.

Shewart WE. *Economic control of quality of manufactured product*. New York (NY): D. Van Nostrand Company; 1931.

Shewart WE. *Statistical methods from the viewpoint of quality control* (WE Deming [ed.]) Washington, DC: The Graduate School, the Department of Agriculture; 1939. Reprinted New York (NY): Dover Publications Inc; 1986.

Walton M. *The Deming management method*. New York (NY): Perigee Books; 1986.

WHO. *Fifty-eighth World Health Assembly. Resolutions and decisions annex*. Genève : World Health Organization; 2005. Disponible à : http://www.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf (CD-ROM : document pdf de XX pages).

Module 2 Bâtiments et sécurité

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

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

Howard Hughes Medical Institute, Office of Laboratory Safety. Laboratory safety study 1993-1997. Disponible à : <http://www.hhmi.org/>

ISO 15190:2003 Laboratoires de médecine -- Exigences pour la sécurité. Genève : International Organization for Standardization. (CD-ROM : document Word d'une page faisant la liste des points couverts ans cette norme)

ISO 3864-1:2002. Symboles graphiques -- Couleurs de sécurité et signaux de sécurité -- Partie 1: Principes de conception pour les signaux de sécurité sur les lieux de travail et dans les lieux publics. Genève : International Organization for Standardization.

ISO 3864-3:2006. Symboles graphiques -- Couleurs de sécurité et signaux de sécurité -- Partie 3: Principes de conception des symboles graphiques utilisés dans les signaux de sécurité. Genève : International Organization for Standardization.

Labels: internationally recognized. Disponible à :
http://www.ehs.cornell.edu/lrs/lab_dot_labels/lab_dot_labels.cfm
<http://ehs.unc.edu/labels/bio.shtml>
<http://www.safetylabel.com/safetylabelstandards/iso-ansi-symbols.php>

OMS. Manuel de sécurité biologique en laboratoire. Troisième édition. Genève : Organisation Mondiale de la Santé; 2003.

PHAC (Canada). The laboratory biosafety guidelines, 3rd ed. Ch. 9 Biological safety cabinets. Ottawa: Public Health Agency of Canada. 2004. Disponible à : <http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch9-eng.php> (Voir les graphiques de PSM)

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. Healthcare Epidemiology. Clinical Infectious Diseases 2004;39:702–9. (CD-ROM : document pdf de 8 pages) Disponible à : http://www.hpci.ch/files/documents/guidelines/hh_gl_disinf-sterili-cid.pdf

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

WHO. Guidance on regulation for the transport of infectious substances 2007-2008. Genève : World Health Organization; 2007.

Module 3 Equipement

King B. NIOSH Health Hazard Evaluation Report No. 2004-0081-3002. New York University School of Medicine, New York (NY); 2006. p. 11. (CD-ROM : document pdf de 18 pages) Disponible à : <http://www.cdc.gov/niosh/hhe/reports/pdfs/2004-0081-3002.pdf>

Richmond JY, McKinney RW, editors. Primary containment for biohazards: selection, installation and use of biological safety cabinets. 2nd ed. U.S. Government Printing Office. U.S. Department of Health and Human Services Public Health Service. Centers for Disease Control and Prevention and National Institutes of Health; 2000. (CD-ROM : document pdf de 54 pages)

WHO. Guidelines for health care equipment donations. Genève : World Health Organization; 2000. (CD-ROM : document pdf de 26 pages) Disponible à : http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf

Module 4 Achats et gestion des stocks

Biological Safety Cabinet Class II Purchasing Requirements (CD-ROM : document Word de 2 pages).

Guidelines for health care equipment donations. Genève : WHO; 2000. (CD-ROM : document pdf de 26 pages). Disponible à : http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf

Module 5 Contrôle des processus : gestion de l'échantillon

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. Emballage -- Codes à barres et symboles bidimensionnels pour l'expédition, le transport et les étiquettes de réception. Genève : International Organization for Standardization.

ISO 21067:2007. Emballages -- Vocabulaire. Genève : International Organization for Standardization.

UN. Recommendations on the transport of dangerous goods: model regulations. 15th rev. ed. New York; Genève : United Nations; 2007.

(CD-ROM : information sur le transport des échantillons, incluant 9 pages de figures, formulaires, diagrammes et étiquettes :

- 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
- Packing and Labeling of Category A Infectious Substances
- Packing and Labeling of Category B Infectious Substances
- Packing and Labeling of Exempt Substances
- Thermal Control Shipping Unit
- Dry Ice Shipping Label)

Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. Archives of Pathology and Laboratory Medicine 2006;130(11):1662–1668. (CD-ROM : document pdf de 7 pages)
Disponible à : [http://arpa.allenpress.com/pdfserv/10.1043%2F1543-2165\(2006\)130%5B1662:PSITCL%5D2.0.CO%3B2](http://arpa.allenpress.com/pdfserv/10.1043%2F1543-2165(2006)130%5B1662:PSITCL%5D2.0.CO%3B2)

WHO. Guidance on regulation for the transport of infectious substances 2007-2008. Genève : World Health Organization; 2007.

Module 6 Contrôle des processus: Introduction au contrôle de la qualité

ISO 9000:2005. Systèmes de management de la qualité -- Principes essentiels et vocabulaire. Genève : International Organization for Standardization.

WHO. External quality assessment of health laboratories report on a WHO working Group. Genève : World Health Organization; 1981.

Module 7 Contrôle des processus: CQ des tests quantitatifs

CLSI. C24-A3—Statistical quality control for quantitative measurement procedures: principles and definitions; Approved Guideline—Third Edition. C24-A3. Wayne (PA): Clinical and Laboratory Standards Institute; 2006.

ISO 15198:2004. Laboratoires d'analyses de biologie médicale -- Dispositifs médicaux de diagnostic in vitro -- Validation des recommandations du fabricant pour la maîtrise de la qualité par l'utilisateur. Genève : International Organization for Standardization.

Module 8 Contrôle des processus: CQ des tests qualitatifs et semi quantitatifs

CLSI. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition. EP12-A2 (Electronic Document). Wayne (PA): Clinical and Laboratory Standards Institute; 2008.

CLSI. Abbreviated Identification of Bacteria and Yeast; Approved Guideline - Second Edition. M35-A2. Wayne (PA): Clinical and Laboratory Standards Institute; 2008.

CLSI. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standards- Eighteenth 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, Baron EJ, Jorgensen JH, Landry ML, Pfaller MA, editors. Manual of Clinical Microbiology. 9th ed. Washington, DC: ASM Press; 2007. p. 1152-72.

Turnidge JD, Ferraro MJ, Jorgensen JH. Susceptibility test methods: general considerations. *ibid.* p. 1146-51.

Westgard Multirule System. Disponible à : <http://www.westgard.com/>

Module 9 Evaluation: Audits

Cochran C. The five keys to a successful internal audit program. The Auditor 2:1. Chico (CA): Paton Press; 2007. Disponible à : <http://www.dnvcert.com/DNV/Certification1/Resources1/Articles/NewsletterInfo/FiveKeystoaSuccessful/>

ISO 9000:2005. Systèmes de management de la qualité -- Principes essentiels et vocabulaire. Genève : International Organization for Standardization.

ISO 19011:2002. Lignes directrices pour l'audit des systèmes de management de la qualité et/ou de management environnemental. Genève : International Organization for Standardization.

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. (CD-ROM : document pdf de 66 pages) Disponible à : http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4__2_.pdf

Module 10 Evaluation: Evaluation externe de la qualité

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.

CDC/WHO HIV Rapid Test Training Package. Atlanta: Centers for Disease Control and Prevention/Genève : World Health Organization; 2005. Disponible à : <http://wwwn.cdc.gov/dls/ila/hivtraining/>

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CLSI. Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition. GP27-A2. Wayne (PA): Clinical and Laboratory Standards Institute; 2007.

CLSI. Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline—Second Edition. GP29-A2. Wayne (PA): Clinical and Laboratory Standards Institute; 2008.

ISO 15189:2007 (5.6.4). Laboratoires d'analyses de biologie médicale -- Exigences particulières concernant la qualité et la compétence. Genève : International Organization for Standardization.

ISO/IEC 17000:2004. Évaluation de la conformité -- Vocabulaire et principes généraux. Genève : International Organization for Standardization.

ISO/IEC Guide 2:2004. Normalisation et activités connexes -- Vocabulaire général. Genève : International Organization for Standardization.

ISO/IEC Guide 43-1:1997. Essais d'aptitude des laboratoires par intercomparaison -- Partie 1: Développement et mise en oeuvre de systèmes d'essais d'aptitude. Genève : International Organization for Standardization.

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.

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WHO. Principes et procédures du Programme OMS/NICD d'Évaluation Externe de la Qualité en microbiologie en Afrique, Années 1 à 4, 2002-2006. Genève : World Health Organization;

2007. (CD-ROM : document pdf de XX pages) Disponible à : http://www.who.int/ihr/publications/policy_procedures_eqa/fr/index.html, accédé le 19 septembre 2012.

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Module 11 Evaluation: Normes et Accréditation

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. (CD-ROM : document pdf de 12 pages)

Deutscher Akkreditierungs Rat (DAR) Acronyms, links, and e-mail addresses. Disponible à : <http://www.dar.bam.de/indexe.html>

ISO/IEC 17011:2004 Évaluation de la conformité -- Exigences générales pour les organismes d'accréditation procédant à l'accréditation d'organismes d'évaluation de la conformité. Genève : International Organization for Standardization.

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, SEA-HLM-386. (CD-ROM : document pdf de 66 pages) Disponible à : http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4__2_.pdf

Kusum M, Silva P. *ibid.* Checklist standard for medical laboratory (pages 45-56) (CD-ROM : document pdf de 12 pages)

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. (CD-ROM : document pdf de 203 pages)

Silva P. Guidelines on establishment of accreditation of health laboratories. World Health Organization Regional Office for South-East Asia; 2007. (CD-ROM : document pdf de 49 pages)

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. (CD-ROM : document pdf de 20 pages)

WHO. Handbook: Good laboratory practice. Quality practices for regulated non-clinical research and development. UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. Genève : World Health Organization; 2001. (CD-ROM : 226-

page pdf document) Disponible à : <http://www.who.int/tdr/svc/publications/training-guideline-publications/good-laboratory-practice-handbook>

WHO. National Polio Laboratory Check List for Annual WHO Accreditation. Genève : World Health Organization; 2003. (CD-ROM : 12-page pdf document) Disponible à : http://www.searo.who.int/LinkFiles/Laboratory_Network_NPLchecklist.pdf

Module 12 Personnel

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

ISO 10015:1999. Management de la qualité -- Lignes directrices pour la formation. Genève : International Organization for Standardization.

Module 13 Service Clients

ISO 10001:2007. Management de la qualité -- Satisfaction du client -- Lignes directrices relatives aux codes de conduite des organismes. Genève : International Organization for Standardization.

Module 14 Gestion des erreurs

Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. *Clinical Chemistry*; 2002;48:691-698. Disponible à : <http://www.clinchem.org/cgi/content/full/48/5/691>

ISO/TS 22367:2008. Laboratoires médicaux -- Réduction d'erreurs par gestion du risque et amélioration continue. Genève : International Organization for Standardization.

Khoury M, Burnett L, Mark A Mackay MA. Error rates in Australian chemical pathology laboratories. *Medical Journal of Australia*. 1996; 165: 128-130. Disponible à : <http://www.mja.com.au/public/issues/aug5/khoury/khoury.html>

Module 15 Amélioration des processus

Brown MG. Baldrige Award Winning Quality-15th ed.: How to interpret the Baldrige criteria for performance excellence. Milwaukee (WI): ASQ Quality Press; 2006.

Brown MG. Using the right metrics to drive world-class performance. New York (NY): American Management Association; 1996.

Crosby PB. Quality management: the real thing, on perfection (essays); 1962. (CD-ROM : document pdf de 2 pages) Disponible à :

<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. (CD-ROM : document pdf de 4 pages)
Disponible à : <http://www.wppl.org/wphistory/PhilipCrosby/TheMythsOfZeroDefects.pdf>

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Disponible à : http://cdc.confex.com/cdc/qlm2005/techprogram/paper_9086.htm

ISO 9001:2008. Systèmes de management de la qualité -- Exigences. Genève : International Organization for Standardization.

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 (WI): ASQ Quality Press; 2001.

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

Module 16 Documents et Enregistrements

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

ISO 9000:2005. Systèmes de management de la qualité -- Principes essentiels et vocabulaire. Genève : International Organization for Standardization.

Module 17 Gestion de l'information

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

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

Module 18 Organisation

ISO 9001:2008. Systèmes de management de la qualité -- Exigences. Genève : International Organization for Standardization.

Glossaire

Les définitions fournies dans le glossaire sont issues des références ci-dessus et des ressources listées ci-dessous.

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>, accédé le 14 septembre 2012).

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

ISO 3534-2:2006. Statistique -- Vocabulaire et symboles -- Partie 2: Statistique appliquée. Genève : International Organization for Standardization.

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

ISO/IEC 17020:2012. Évaluation de la conformité -- Exigences pour le fonctionnement de différents types d'organismes procédant à l'inspection. Genève : International Organization for Standardization.

ISO/IEC Directives, Partie 2 : Règles de structure et de rédaction des Normes internationales, 6^{ème} édition. Genève : International Organization for Standardization.

ISO/IEC Guide 51:1999. Aspects liés à la sécurité -- Principes directeurs pour les inclure dans les normes. Genève : International Organization for Standardization.

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

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

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Quality Glossary, Program Office for Laboratory Quality Management, Department of Pathology and Laboratory Medicine, University of British Columbia
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