

## References and Resources Listed by Module

There are two ISO standards that are specific to laboratories and CLSI has two documents that are very important in the clinical laboratory.

These four documents are referred to throughout each of the 18 modules and are therefore not cited in the individual modules listed below.

- ISO 15189:2007. Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization.
- ISO/IEC 17025:2005. General requirements for the competence of testing and calibration laboratories. Geneva: 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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## Module 2 Facilities and Safety

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<http://www.safetylabel.com/safetylabelstandards/iso-ansi-symbols.php>

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### **Module 3 Equipment**

WHO. Guidelines for health care equipment donations. Geneva: World Health Organization; 2000. (CD-ROM: 26-page pdf document) Available at URL: [http://www.who.int/hac/techguidance/pht/en/1\\_equipment%20donationbuletin82WHO.pdf](http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf)

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### **Module 4 Purchasing and Inventory**

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

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### **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.

ISO 21067:2007. Packaging—Vocabulary. Geneva: International Organization for Standardization.

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

(CD-ROM: Sample Transport information, including 9-pages with figures, forms, diagrams, and labels:

- 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)

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## **Module 6 Process Control: Quality Control Introduction**

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## **Module 7 Process Control: QC Quantitative Tests**

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.

## **Module 8 Process Control: QC Qualitative and Semi-Quantitative Procedures**

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## **Module 9 Assessment: Audits**

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## Module 10 Assessment: External Quality Assessment

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.

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## Module 12 Personnel

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## Module 14 Occurrence Management

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## Module 15 Process Improvement

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## Module 16 Documents and Records

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## Module 17 Information Management

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## Module 18 Organization

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