Beyond CLIA Regulation: Quality Management System International Guidelines & Standards

Introductory Information for February 2008 CLIAC Meeting

Devery Howerton, PhD
Division of Laboratory Systems, CDC
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Presentation Outline

- Overview of international QMS standards & guidelines
  - CLSI
  - ISO
- Comparison of CLSI, ISO and CLIA
- Questions to consider

Questions to Consider

- What international QMS standards/guidelines apply to clinical laboratories?
- How do these standards/guidelines differ from CLIA?
- How are they being used within and outside of the US?
- What are the advantages/facilitators and disadvantages/barriers for US laboratories to implementing international QMS standards?
- What incentives do US laboratories have/need to implement QMS?

Standards Organizations

- **Clinical and Laboratory Standards Institute (CLSI)**
  - Uses consensus process
  - Focus on health care services, especially laboratory
- **International Organization for Standardization (ISO):**
  - Guidance for quality in manufacturing and service industries
  - Broad applicability, many kinds of organizations can use

Quality Management System (QMS)

- A framework for managing and monitoring activities to address quality standards and achieve organizational goals (CLSI).

- Organizational structure, resources, policies, processes and procedures needed to implement quality management (ISO, CLSI).


Quality Management System
Quality Assurance
Quality Control

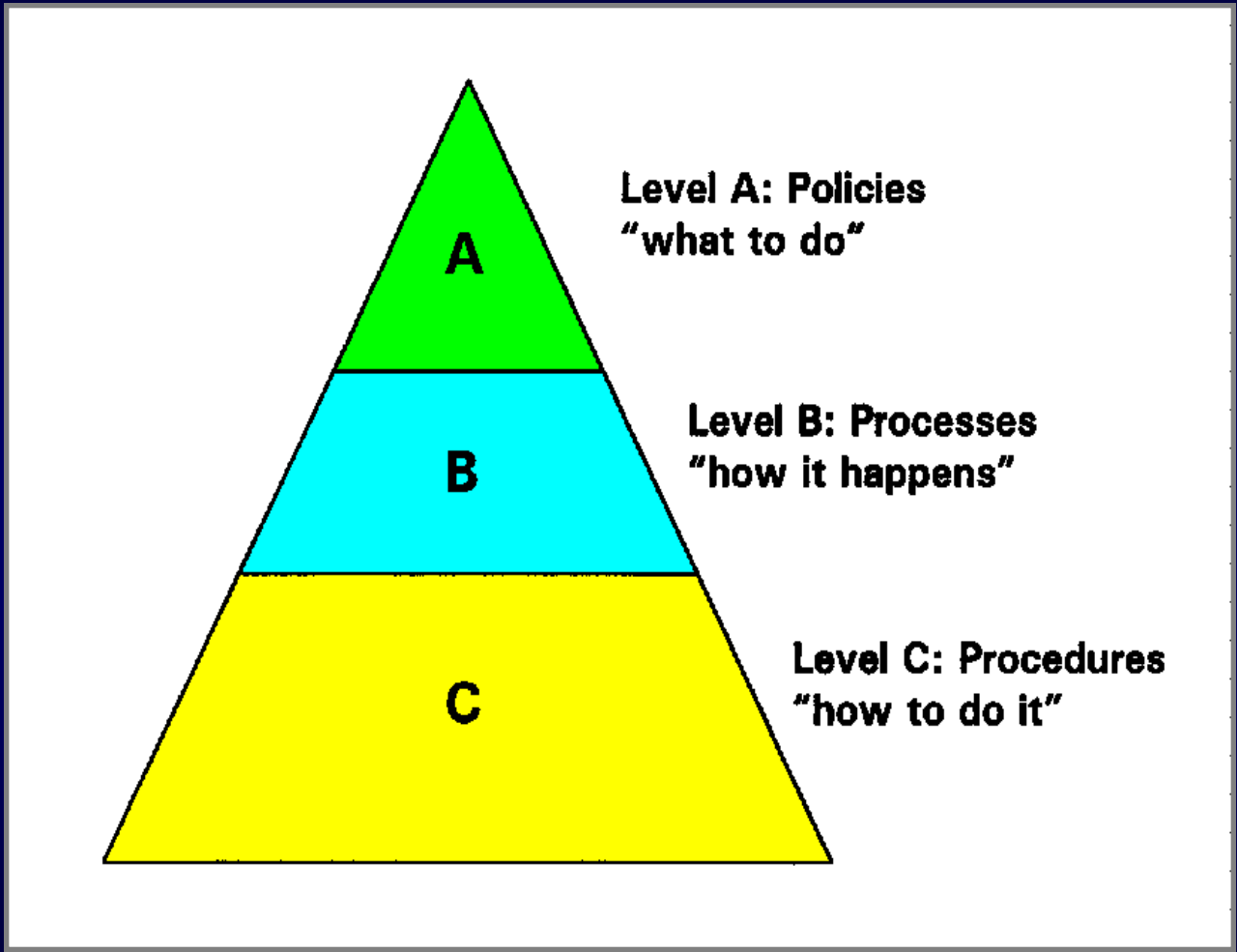
ISO Documents - Laboratory

Standard No.	Title
ISO 9001:2000	**Quality Management System Requirements** Model for QA in design, development production, installation, and servicing
ISO/FDIS 15189: 2003	**Medical Laboratories – Particular requirements for quality and competence**
ISO/IEC 17025	**General requirements for the competence of testing and calibration labs**

CLSI Quality Standards

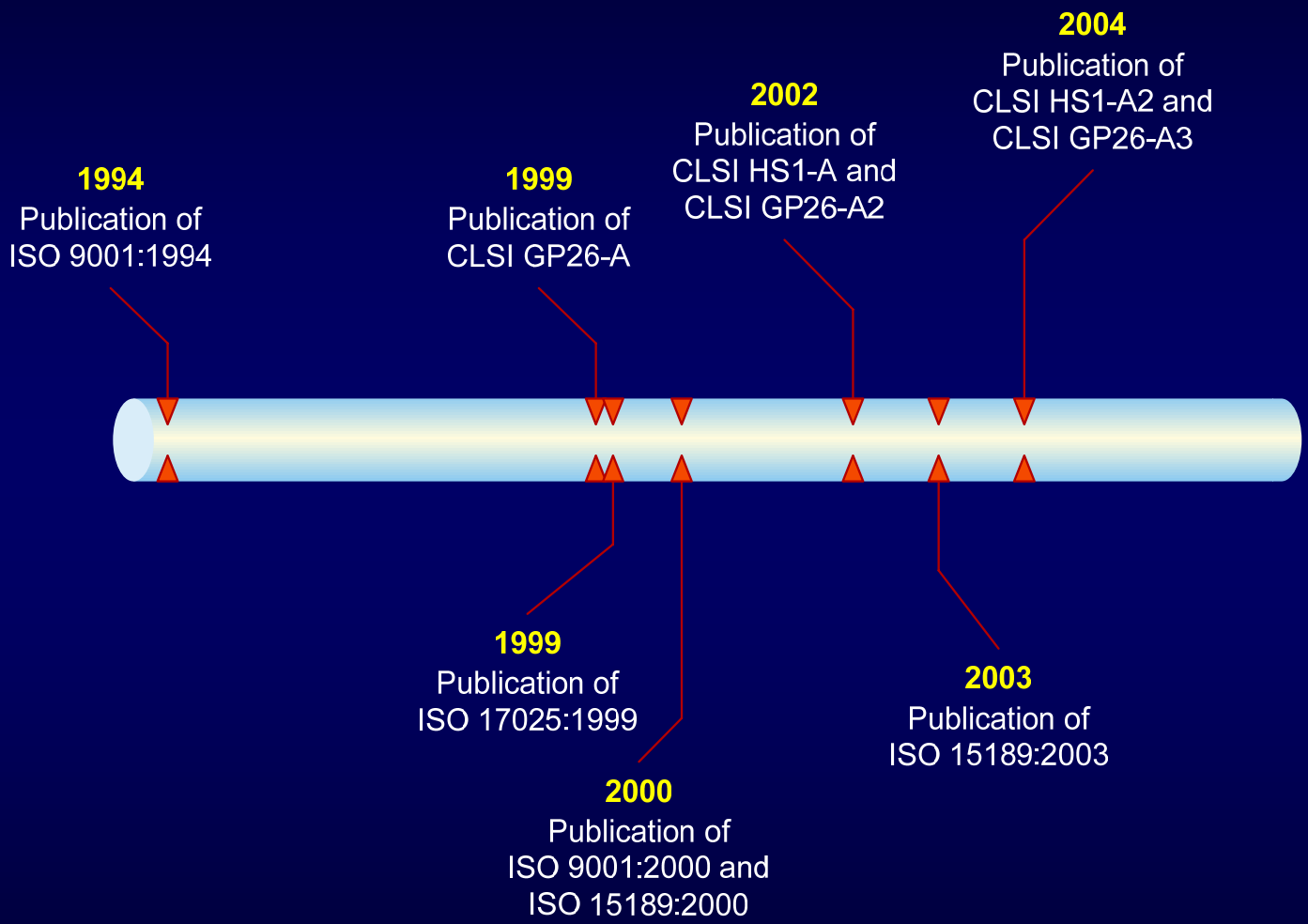
Standard No.	Title
HS1-A2	**A Quality Management System Model for Health Care** ▪ Describes quality system model, 12 essentials ▪ Applicable to all health care systems, ▪ Applies quality design consistent with ISO 9000 series
GP 26-A3	**Application of Quality Management System Model for Laboratory Services** ▪ Laboratory application document for quality system ▪ Describes path of workflow ▪ Assists lab in improving processes ▪ Relates to HS1-A

QMS Document Hierarchy

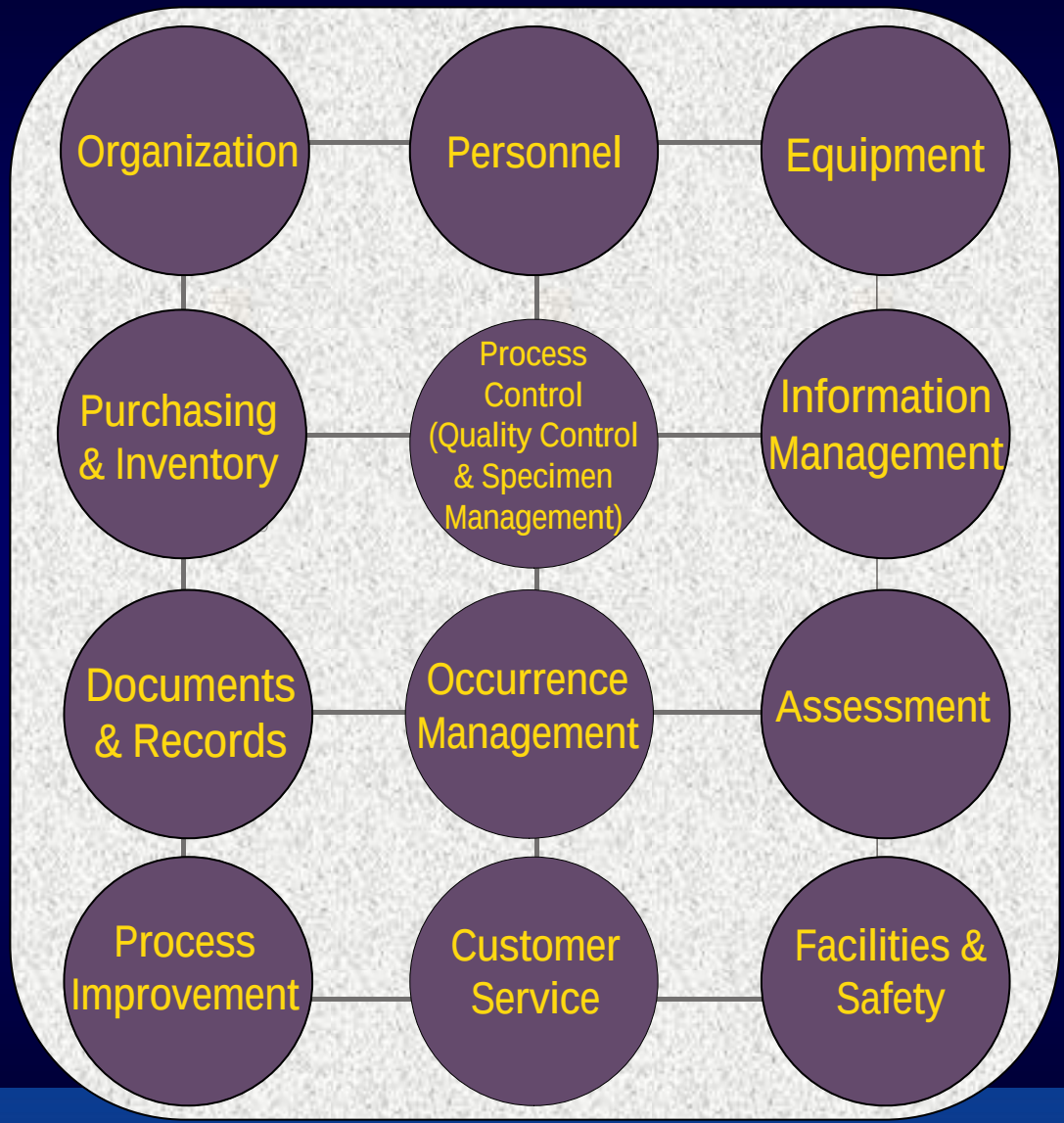


CLSI Document HS2-A, 2004

QMS Guidance - A Timeline



CLSI Quality System Essentials

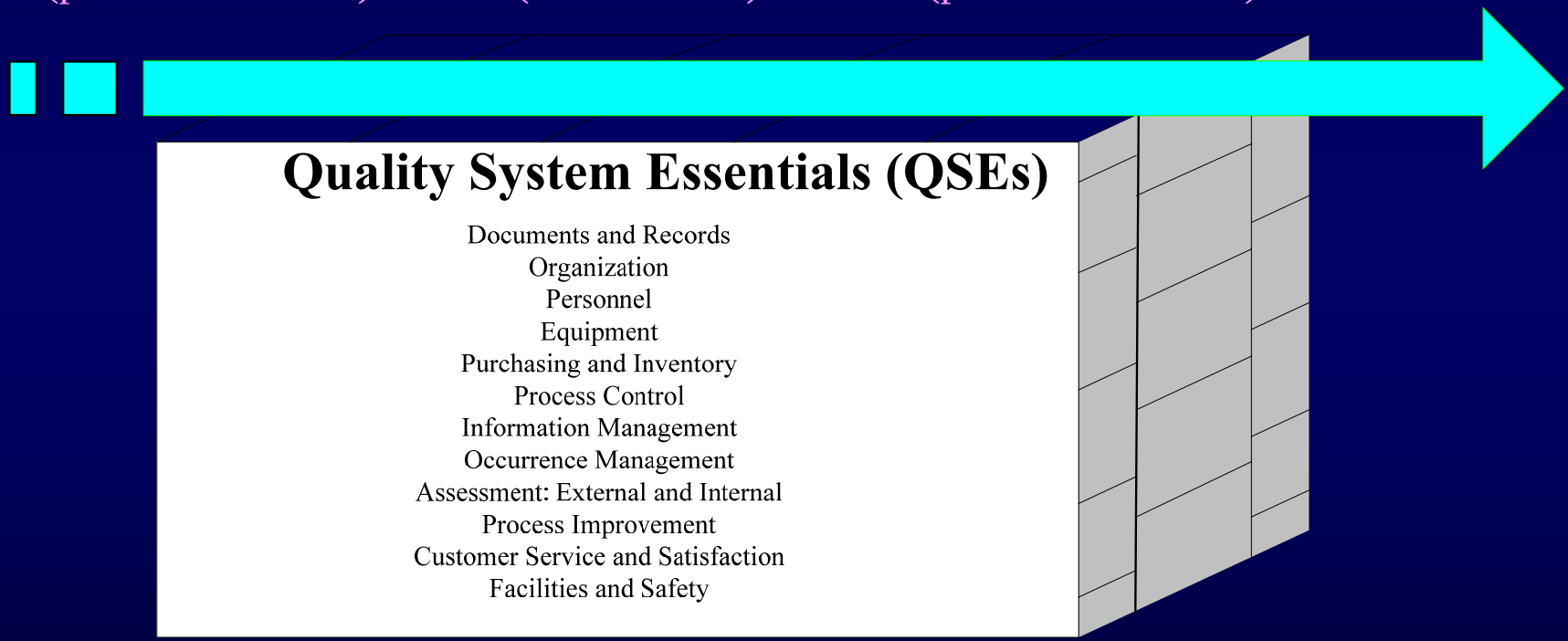


Laboratory Path of Workflow

Pre-analytic (pre- examination)

Analytic (examination)

Post-analytic (post-examination)



Medical Laboratories - Particular Requirements for Quality and Competence (ISO 15189:2003)

Management Requirements

1. Organization and management
2. QMS
3. Document control
4. Review of contracts
5. Referral laboratories
6. External services/supplies
7. Advisory services
8. Resolution of complaints
9. Control of nonconformities
10. Corrective action
11. Preventive action
12. Continual improvement
13. Quality and technical records
14. Internal audits
15. Management review

ISO 15189:2003, continued

Technical Requirements

1. Personnel
2. Accommodation and environmental conditions
3. Laboratory equipment
4. Pre-examination procedures
5. Examination procedures
6. Assuring quality of examination procedures
7. Post-examination procedures
8. Reporting of results

Annex A: Correlation with ISO 9001:2000 and ISO/IEC 17025:1999
Annex B: Recommendations for protection of LIS
Annex C: Ethics in laboratory medicine

CLIA Regulations

- Subpart A: General Provisions
- Subpart H: Participation in PT
- Subpart J: Facilities
- Subpart K: Quality Systems
  - Specialties/subspecialties
  - General laboratory systems
  - Pre-analytic
  - Analytic
  - Post-analytic
- Subpart M: Personnel
- Subpart Q: Inspection

Comparison: CLSI QMS Model to ISO 15189 and CLIA Regulations

CLSI QMS	ISO 15189	CLIA
QSE	Clauses	Sections
Organization	4.1 Organization and Management 4.2 Quality management system 4.15 Management review	§ 493.1200 – § 493.1299 Subpart K – Quality System for Non-Waived Testing
Personnel	5.1 Personnel	§ 493.1351 - § 493.1495 Subpart M – Personnel for Non-Waived Testing
Equipment	5.3 Laboratory Equipment	§ 493.1252 - § 493.1255 Equipment, performance verification, maintenance and function checks, calibration
Purchasing & Inventory	4.4 Contract review 4.5 Referral Laboratories 4.6 External Services and Supplies	§ 493.1242(8)(c) Specimen referral § 493.1252 Test systems, equipment, instruments, reagents, materials, and supplies

Comparison: CLSI QMS Model to ISO 15189 and CLIA Regulations

CLSI QMS	ISO 15189	CLIA
QSE	Clauses	Sections
Process control	5.4 Pre-examination procedures 5.5 Examination procedures 5.6 Assuring quality – examination 5.7 Post-examination procedures	§ 493.1240 - § 493.1249 Pre-analytic systems § 493.1250 - § 493.1289 Analytic Systems § 493.1290 - § 493.1299 Post-analytic systems
Documents and records	4..3 Document Control 4.13 Quality and Technical Records	§ 493.1101(e) Standard: Facilities 493.1105 Standard: Retention Requirements
Information management	5.8 Reporting of results Annex B: LIS Annex C: Ethics	§ 493.1290 - § 493.1291 Post-analytic Systems
Occurrence management	4.8 Resolution of complaints 4.9 Identification and control of nonconformities 4.10 Corrective action	§ 493.1299 Post-analytic systems quality assessment § 493.1256 - § 493.1282 Control procedures

Comparison: CLSI QMS Model to ISO 15189 and CLIA Regulations

CLSI QMS	ISO 15189	CLIA
QSE	Clauses	Sections
Assessments: Internal & External	4.11 Preventive action 4.14 Internal audits 5.6.4 External quality assessment	§ 493..1250 - § 493.1255 Analytic Systems § 493.801- § 493.865 Participation in Proficiency Testing Subpart Q - Inspection
Process improvement	4.12 Continual improvement	§ 493.1200, § 493.1239, § 493.1249, § 493.1289, § 493.1299 Quality Systems assessments
Customer service	4.7 Advisory services 4.8 Resolution of complaints Annex C: ethics	§ 493.1407, § 493.1419 Consultation § 493.1233 Complaint investigation § 493.1234 Communication
Facilities and Safety	4.6 External services and supplies 5.2 Accommodation and environmental conditions 5.3 Laboratory equipment	§ 493.1100 - § 493.1101 Facility Administration for Non-waived Testing § 493.1252 Standard: Test systems, equipment, etc.,

How do CLIA requirements differ from ISO and CLSI QMS standards/guidelines?

General Differences between CLIA and ISO/CLSI

- CLIA – more specific in some areas, e.g.
  - Personnel
  - Quality control
  - PT
  - Record retention
- ISO/CLSI – more comprehensive and general, e.g.
  - Applies to all laboratories, regardless of test complexity
  - Management system
  - Internal and external assessment

CLIA Requirements not Included in CLSI/ISO

- Complexity model, waived testing
- Specialties and subspecialties
- Specific retention requirements
- Establishment/verification of certain method performance specifications
- Quality control & calibration materials/frequency
- PT participation and grading criteria
- Personnel categories beyond Lab Director
- Specific personnel qualifications/responsibilities

CLSI/ISO Elements not Specified in CLIA

- Quality manager
- Management review
- Process improvement
- Quality manual (policy)
- Quality indicators
- Contract review
- Evaluation of referral laboratories, suppliers
- Continuing education for all personnel
- Internal audits
- PT for all tests (ISO compliant programs)
- Reports using internationally recognized standards
- Recommendations for LIS

Certification/Accreditation Bodies

- CLIA
  - CMS
  - Accrediting Organizations
  - Exempt States
- ISO: International Laboratory Accreditation Cooperation (ILAC)

International Laboratory Accreditation Cooperation (ILAC)

- International cooperation of laboratory and inspection accreditation bodies
- 46 full member economies
- Some countries mandate adherence to ISO 15189, others recognize/endorse ISO

ILAC: U.S. Representatives

- American Association for Laboratory Accreditation (A2LA)
- Assured Calibration and Laboratory Accreditation Select Services (ACLASS)
- International Accreditation Service, Inc. (IAS)
- National Voluntary Laboratory Accreditation Program (NVLAP)

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