

**L'URGENZA EMERGENZA
in MEDICINA
DI LABORATORIO**
*Complessità Diagnostica
e Responsabilità Professionale*

Sabato 10 Settembre 2005

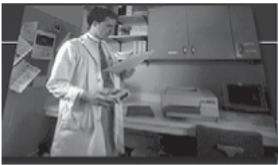
Certificazione del POCT: possibilità o
necessità?
Romolo M. Dorizzi (Verona)

Regolamentazione del POCT
a livello internazionale

Paese	Legge	LG	VEQ
Argentina	NO	NO	SI
Australia	SI	SI	SI
Belgio	NO	NO	NO
Canada	SI	SI	NO
Cina	NO	NO	NO
Danimarca	NO	SI	NO
Francia	NO	SI	NO
Germania	NO	SI	SI
Israele	NO	SI	SI
Italia	NO	NO	NO
Norvegia	NO	SI	SI
Nuova Zelanda	NO	SI	SI
Regno Unito	NO	SI	SI
Stati Uniti	SI	SI	SI
Svezia	NO	SI	SI

Price CP, et al Point-of-Care Testing AACCC 2004

Laboratory



any location where
any testing occurs

**Voluntary accrediting
agencies**

 Joint Commission on
Accreditation of
Healthcare Organizations

 Laboratory Accreditation
Program of the College
of American Pathologists

 COLA Commission of Office
Laboratory Accreditation

CAP 

Compliance with
checklist 1,
LABORATORY GENERAL,
AND checklist 30,
POINT-OF-CARE
TESTING

COLA 

- ✳ Inspection philosophy based on education and problem solving
- ✳ Provides educational training materials for waived testing programs
- ✳ Initial self-inspection with follow-up COLA inspection using the same checklist
- ✳ No accreditation for waived testing

ISO TC 212/SC N118
Date: 2003-07-25
ISO/PDTR 22869

ISO 9000
Quality management system
Fundamentals and vocabulary

ISO 9001:2000
Quality management system
Requirements

ISO/IEC 17025/1999 General requirements for the
competence of testing and calibration laboratories

ISO 15189:2003 Medical Laboratories
Particular requirements for quality and competence

ISO/PTDR 22869
Guidance on laboratory implementation of ISO 15189

DRAFT INTERNATIONAL STANDARD ISO/DIS 22870

ISO/TC 212 Secretariat: ANSI
Voting begins on: 2004-07-12 Voting terminates on: 2004-12-13

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Point-of-care testing (POCT) — Requirements for quality and competence

Analyses de biologie délocalisées (ADB) — Exigences concernant la qualité et la compétence

ISO/DIS 22870 

Point-of-care testing (POCT) — Requirements for quality and competence

A health professional grouping

shall be responsible to the governing body, for defining the scope of POCT to be made available. This shall take into consideration the *clinical need* for POCT, its *financial implications*, *technical feasibility*, and the ability of the organization to fulfil the need.

DRAFT INTERNATIONAL STANDARD ISO/DIS 22870

EQUIVALENT QC OPTIONS				
Equivalent QC Option	Test System Description	Evaluation Process:		Equivalent QC Procedure Testing Frequency
		Internal Monitoring Systems*	Test Two Levels of External Controls	
Option 3	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar week

HCFA

 **wait and**

 **see**

 **approach**

32 January 2005 ■ MLO

L'URGENZA EMERGENZA
in MEDICINA
DI LABORATORIO

*Complessità Diagnostica
e Responsabilità Professionale*

Sabato 10 Settembre 2005

Certificazione del POCT: possibilità o necessità? **NECESSITA'!**

Romolo M. Dorizzi (Verona)