Università degli Studi di Padova
Scuola di Specializzazione in Biochimica Clinica (A.A. 2005-2006)
INDIRIZZI: DIAGNOSTICO E ANALITICO TECNOLOGICO

Biochimica Clinica e Biologia Molecolare Clinica:
automazione ed informatica in Biochimica Clinica
area D SSD BIO/12 ex E05C ore 20 anno IV
-OBIETTIVO FORMATIVO: Acquisire le conoscenze informatiche per la gestione del laboratorio

correzione, verifica e validazione dei risultati

Marco Pradella
Castelfranco Veneto

correzione, verifica e validazione

- ciclo, cicli e deragliamenti
- verifica e validazione nel flusso operativo diagnostico
- verifiche e algoritmi
- autoverifica

Flusso operativo del laboratorio

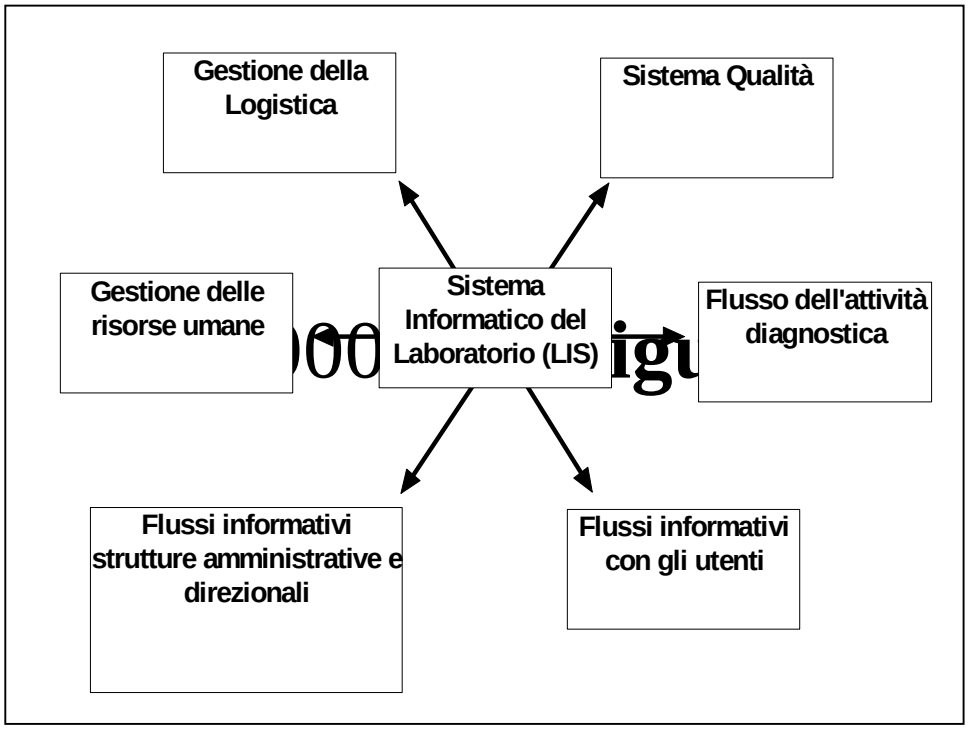
Pre-analitica	Analitica	Post-analitica
richiesta (order) preparazione paziente raccolta trasporto e conservazione ricezione	analisi e revisione interpretazione di laboratorio	**risposta** (***revisione formattazione, consulenza, ulteriori procedure...***) conservazione del campione

ISO 15189:2002

NCCLS GP26-A2

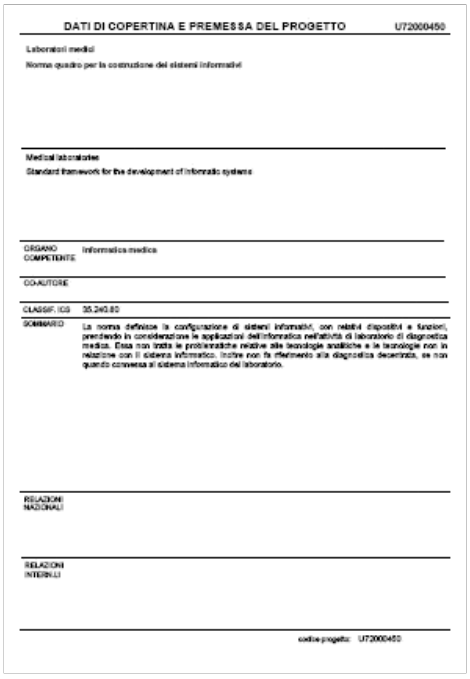
workflow

- quale flusso ??



Medical laboratories

Standard framework for the development of informatic systems



DATI DI COPERTINA E PREMESSA DEL PROGETTO U72000450

Laboratori medici

Norma quadro per la costruzione dei sistemi informativi

Medical laboratories

Standard framework for the development of informatic systems

ORGANO COMPETENTE Informatica medica

COAUTORE

CLASSIF. ICS 35.240.80

SOMMARIO La norma definisce la configurazione di sistemi informativi, con relativi dispositivi e funzioni, prendendo in considerazione le applicazioni dell'informatica nell'attività di laboratorio di diagnostica medica. Essa non tratta le problematiche relative alle tecnologie analitiche e le tecnologie non in relazione con il sistema informatico. Inoltre non fa riferimento alla diagnostica decentrata, se non quando connessa al sistema informatico del laboratorio.

RELAZIONI NAZIONALI

RELAZIONI INTERNAZ.

codice progetto: U72000450

U72000450

Laboratori medici

Norma quadro per la costruzione dei sistemi informativi

ISO 15189

- “Medical laboratory services ...include arrangements for ... validation, interpretation, reporting and advice, ...”.
- **4.2 Quality management system**
  - **4.2.4** A quality manual shall describe the quality management system
    - The table of contents of a quality manual
      - (p) Validation of results.

Validazione >< Verifica

- **Validation** Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. [1]
- **Validation** Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. [2]
  - *[1] FDA QSR*
  - *[2] ISO 8402 (reference only, obsoleted by [8] ANSI/ISO/ASQ Q9000-2000 (U.S. version ISO 9000:2000);*

Validazione >< Verifica

- **Verification** The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements. [1]
- **Verification** Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. [2]
- **Verification** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. [1]
  - *[1] Quality Management and Quality Assurance - Vocabulary-ISO 8402:1994 (reference only, obsoleted by [8] ANSI/ISO/ASQ Q9000-2000 (U.S. version ISO 9000:2000);*
  - *[2] FDA **Medical Device Quality Systems Manual - The Quality Systems regulation***

ISO 15189
3.9 Post-examination procedures

- Postanalytical phase
  - Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the examinations

CLSI GP26 – Laboratory Workflow

- Preanalytical
  - Patient assessment
  - Test request
  - Specimen collection
  - Specimen transport
  - Specimen receipt
- Analytical
  - Testing / **review**
  - **Interpretation**
- Postanalytical
  - Results reporting
  - Post-test specimen management
- Information management
  - Laboratory information system
  - Clinical application / consultation

10 QSEs apply to all stages of workflow path

CLSI AUTO10-P Vol. 26 No. 4
Autoverification of Clinical Laboratory Test Results; Proposed Guideline

- posizione nel flusso

AUTO10-P addresses the quality system essentials (QSEs) indicated by an "X."

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X						

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.*

AUTO10-P addresses the clinical laboratory path of workflow steps indicated by an "X."

Preexamination				Examination			Postexamination	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
					X	X	X	

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.*