

Focus 2009
18th - 21st May 2009
Liverpool



ISO 22870 and CPA Accreditation for POCT

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CPA Regional Assessment Manager**

Definition of POCT



“... any analytical test performed for a patient by a healthcare professional outside the conventional laboratory.”



“...testing that is performed near or at the site of the patient with the result leading to possible change in the care of the patient.”

- *DoH Workshop - January 2009*

“... any diagnostic test performed on a person by a competent individual, where a result that can be interpreted is provided before the person leaves”

Advice on POCT

- 1995 Kost GJ. Guidelines for point-of-care testing. Improving patient outcomes
- 1997/8 European Community Confederation of Clinical Chemistry (EC4)
- 1999 The German Working Group on Medical Laboratory Testing (AML)
- 2000 The Joint Working Group on Quality Assurance (JWGQA)
- 2002 Medicines and Healthcare products Regulatory Agency (MHRA) Management and use of in vitro diagnostic devices for point of care testing
- 2006 ISO 22870:2006 Point-of-care testing (POCT) - Requirements for quality and competence

ISO 22870

- ISO 22870 designed to be used in conjunction with ISO 15189
- “This international standard gives specific requirements applicable to point of care testing and is intended to be used in conjunction with ISO 15189”
- Not intended to be used as a standalone standard – cross references to ISO 15189

CPA & POCT



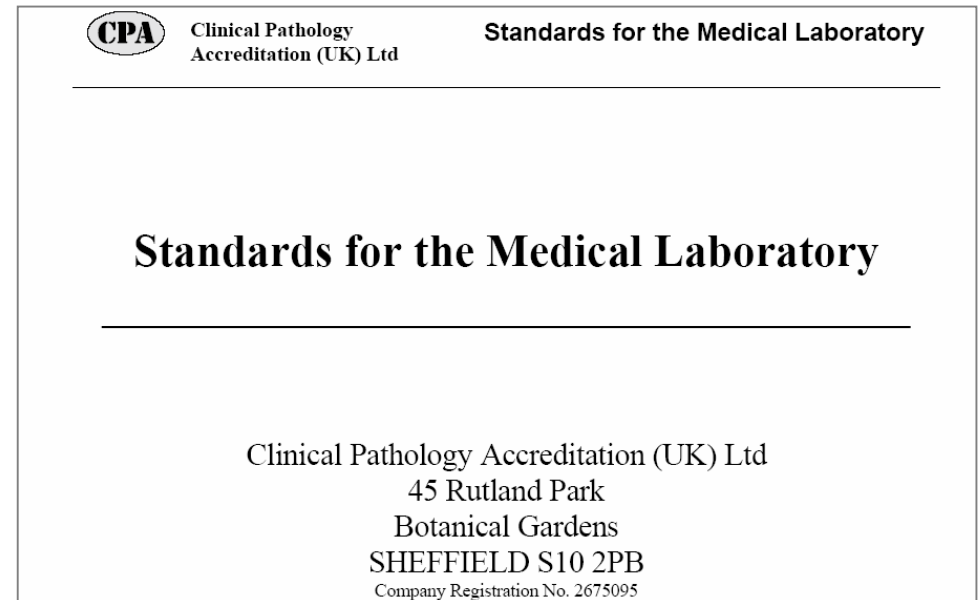
Standards for the Medical Laboratory

version 2.00 (September 2007)

No individual standard for:

- Mortuary
- Transfusion
- Control of infection

•or POCT



Gap analysis

- CPA carried out gap analysis between ISO 15189/ISO 22870 and CPA Standards for the Medical Laboratory



**Clinical Pathology
Accreditation (UK) Ltd**

**Standards for Point-of-Care Testing
(POCT) facilities**

Additional Standards for Point-of-Care Testing (POCT) facilities

Clinical Pathology Accreditation (UK) Ltd
45 Rutland Park
Botanical Gardens
SHEFFIELD S10 2PB
Company Registration No. 2675095

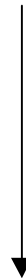
Tel: ++44(0)114 251 5800
Fax: ++44(0)114 251 5801
e-mail: office@cpa-uk.co.uk
www.cpa-uk.co.uk

Copyright

- Additional CPA Standards written in CPA type format and language
- Wording from ISO standard used -
Copyright issues
- Requires permission to use the modified standard from CEN

- ISO 15189

CPA Med Lab Std



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CPA addition Stds for POCT



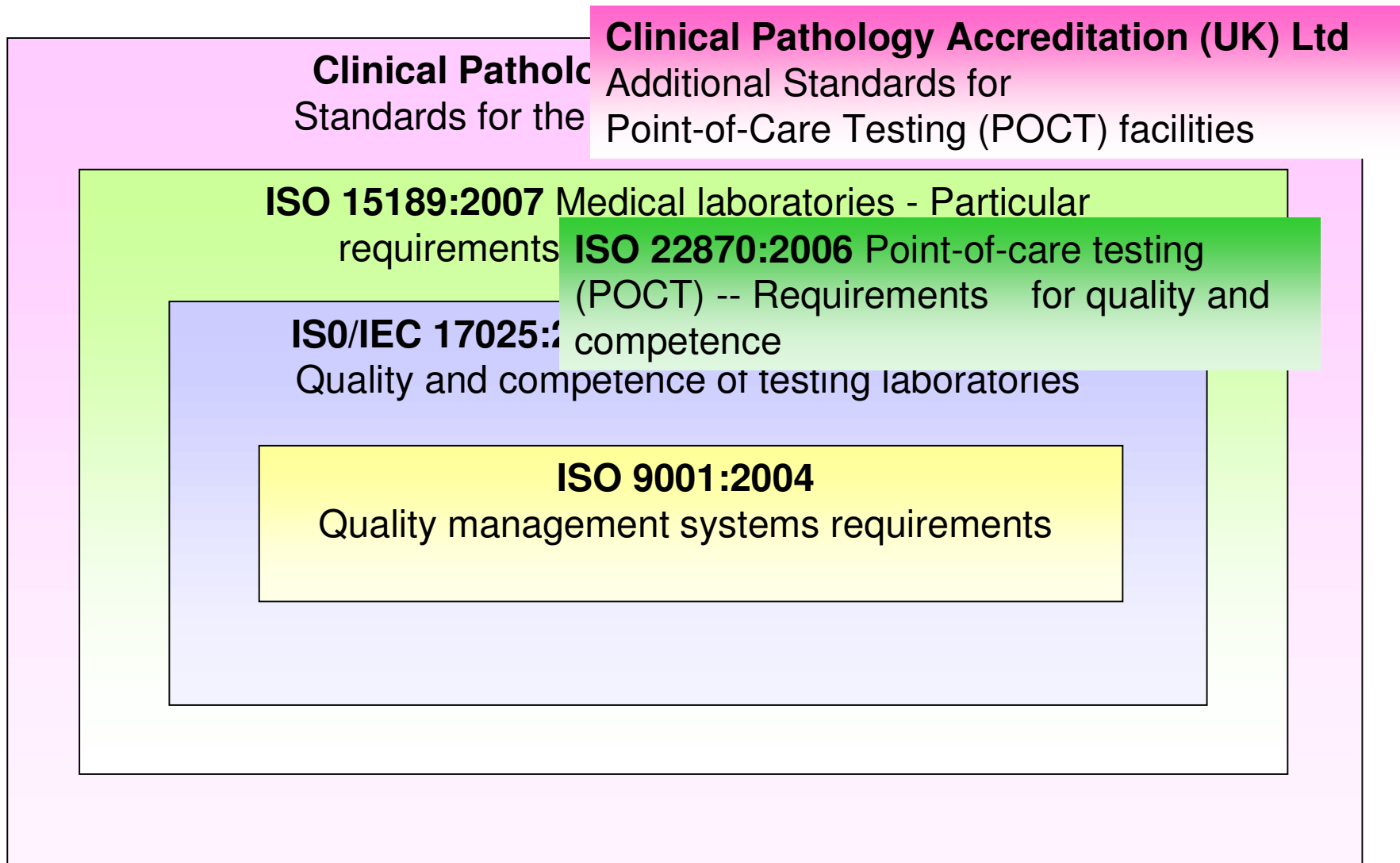
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Guidance to ISO Std

- ISO 22870



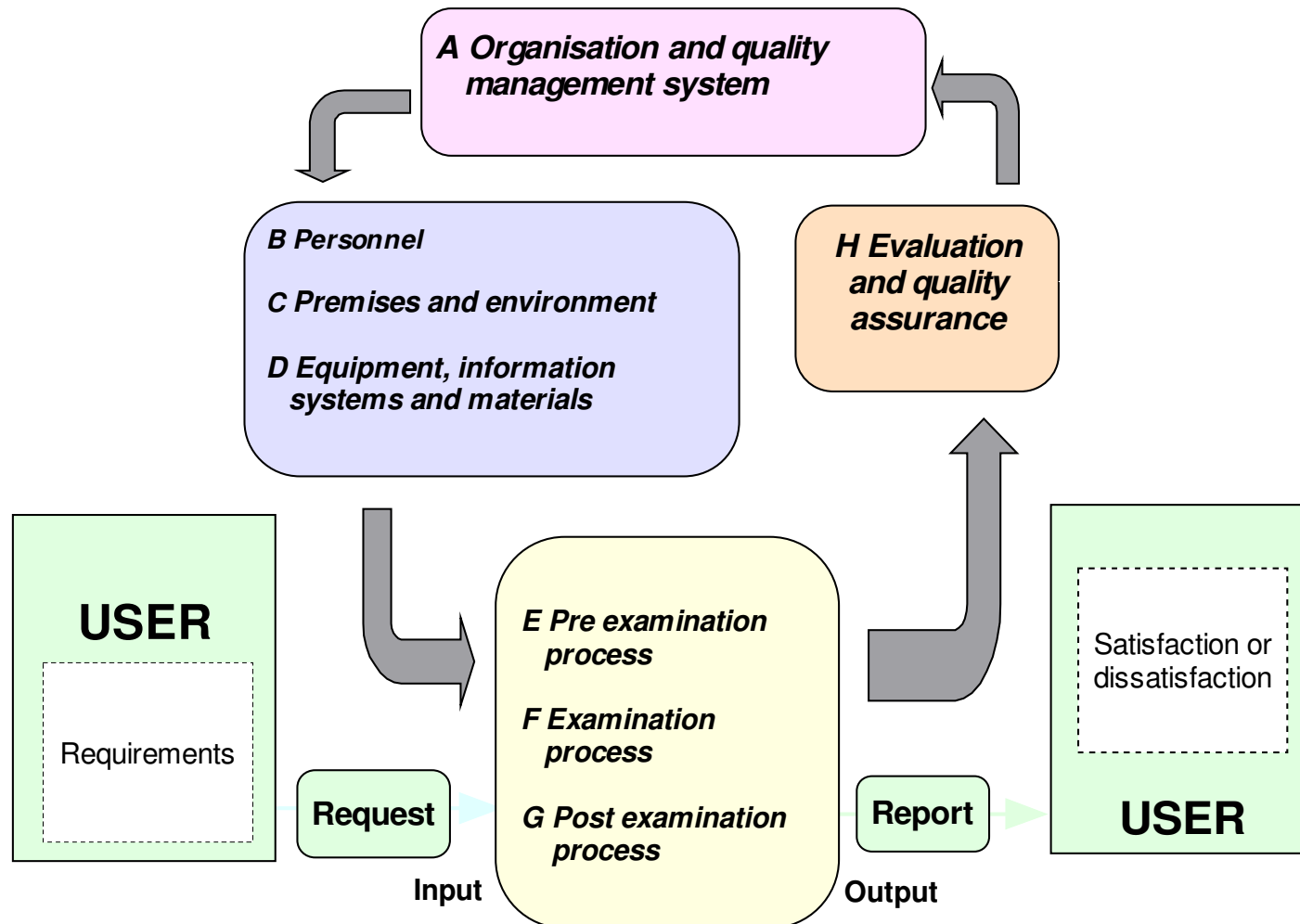
Relationships between standards



Application form

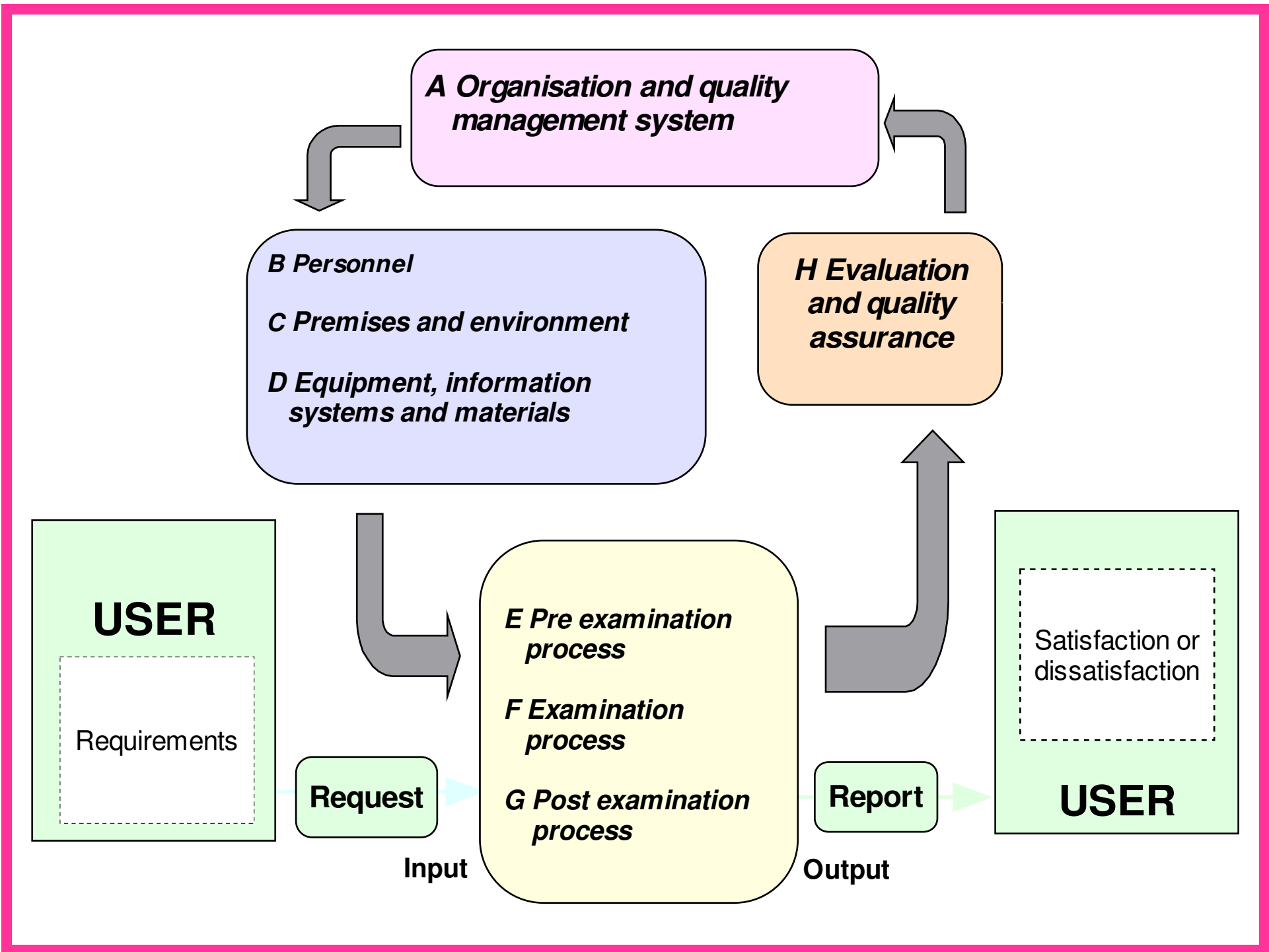
- Application form must be received from “base” laboratory
- Applications from Point of Care establishments e.g. GP surgery, clinic – not acceptable
- Must state scope and where POCT is used

CPA standards and a quality management system



A4 Quality management system

‘A quality management system provides the integration of organisational structure, processes, procedures, and resources needed to fulfil a quality policy and thus meet the needs and requirements of users’





A Organisation and quality management system

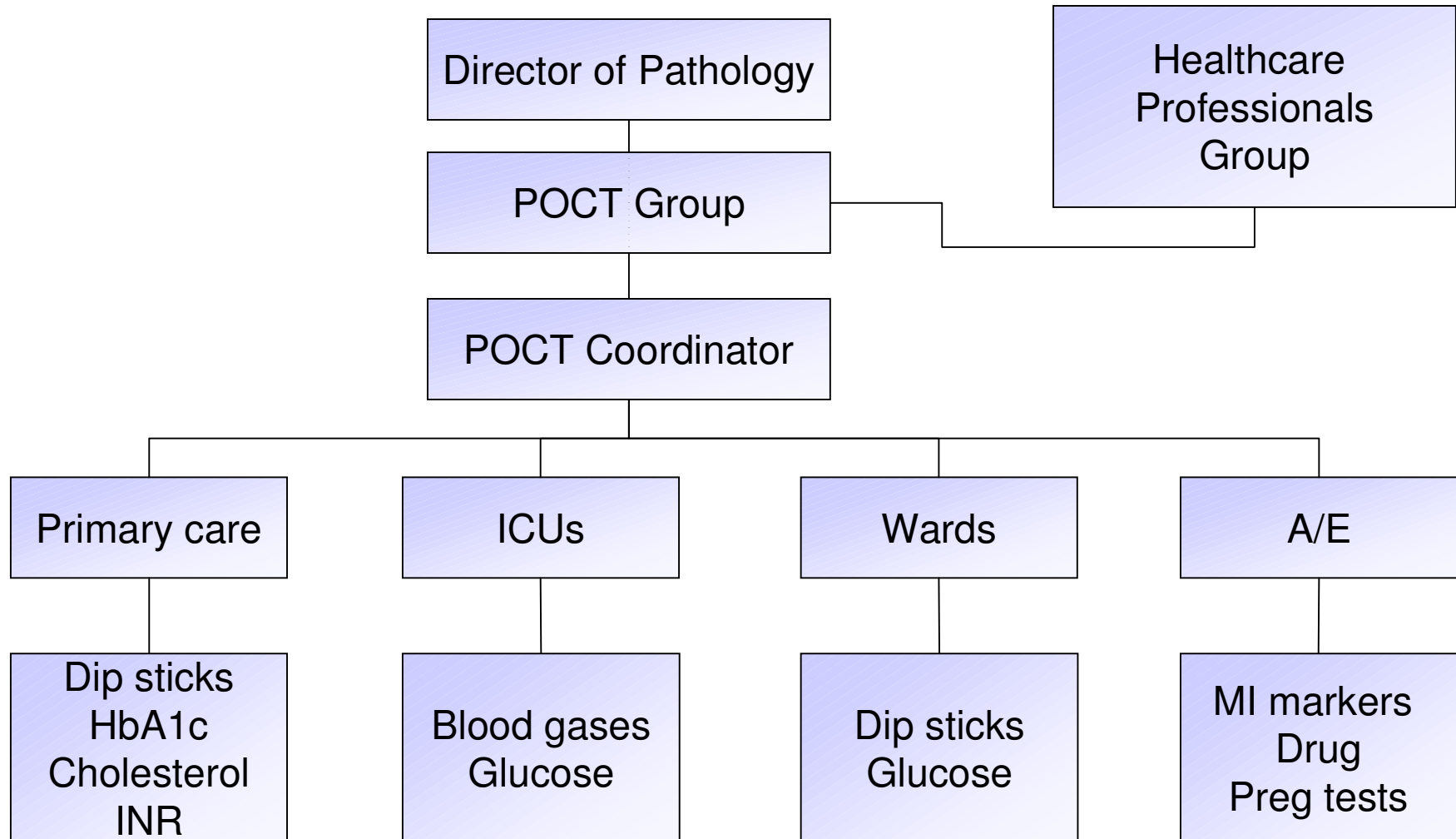
A. ORGANISATION & QUALITY MANAGEMENT SYSTEM

- A1 Organisation and management
- A2 Needs and requirements of users
- A3 Quality policy
- A4 Quality management system
 - A5 Quality objectives and plans
 - A6 Quality manual
 - A7 Quality manager (POCT Co-ordinator)
 - A8 Document control
 - A9 Control of process & quality records
 - A10 Control of clinical material
 - A11 Management review

Ultimate responsibility

- “The laboratory, or the parent organization of which it is a part, shall ultimately be responsible for ensuring that appropriate measures, including internal quality control and participation in EQA schemes, are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization.”

Management of POCT



Governance

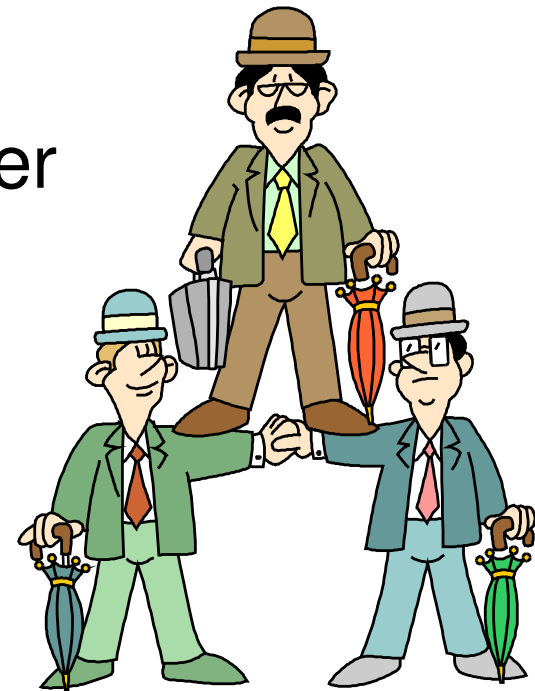
- A health professional grouping (e.g. Medical Advisory Committee) shall be responsible to the governing body, for defining the scope of POCT to be made available.
- This shall take into consideration:
 - clinical need for POCT
 - financial implications
 - technical feasibility
 - ability of the organization to fulfil the need.

Practical management

- The laboratory director or designate, in conjunction with management, shall appoint a multidisciplinary POCT management group with representation from the laboratory, administration, and clinical programmes including nursing to advise on the provision of POCT.

The multidisciplinary POCT mgt group

- Laboratory professional (Chair)
- POCT Co-ordinator(s)
- Nurse
- Clinicians
- Information Technology Manager
- Medical Equipment Manager
- Accountant
- Pharmacist
- Risk / Safety Officer



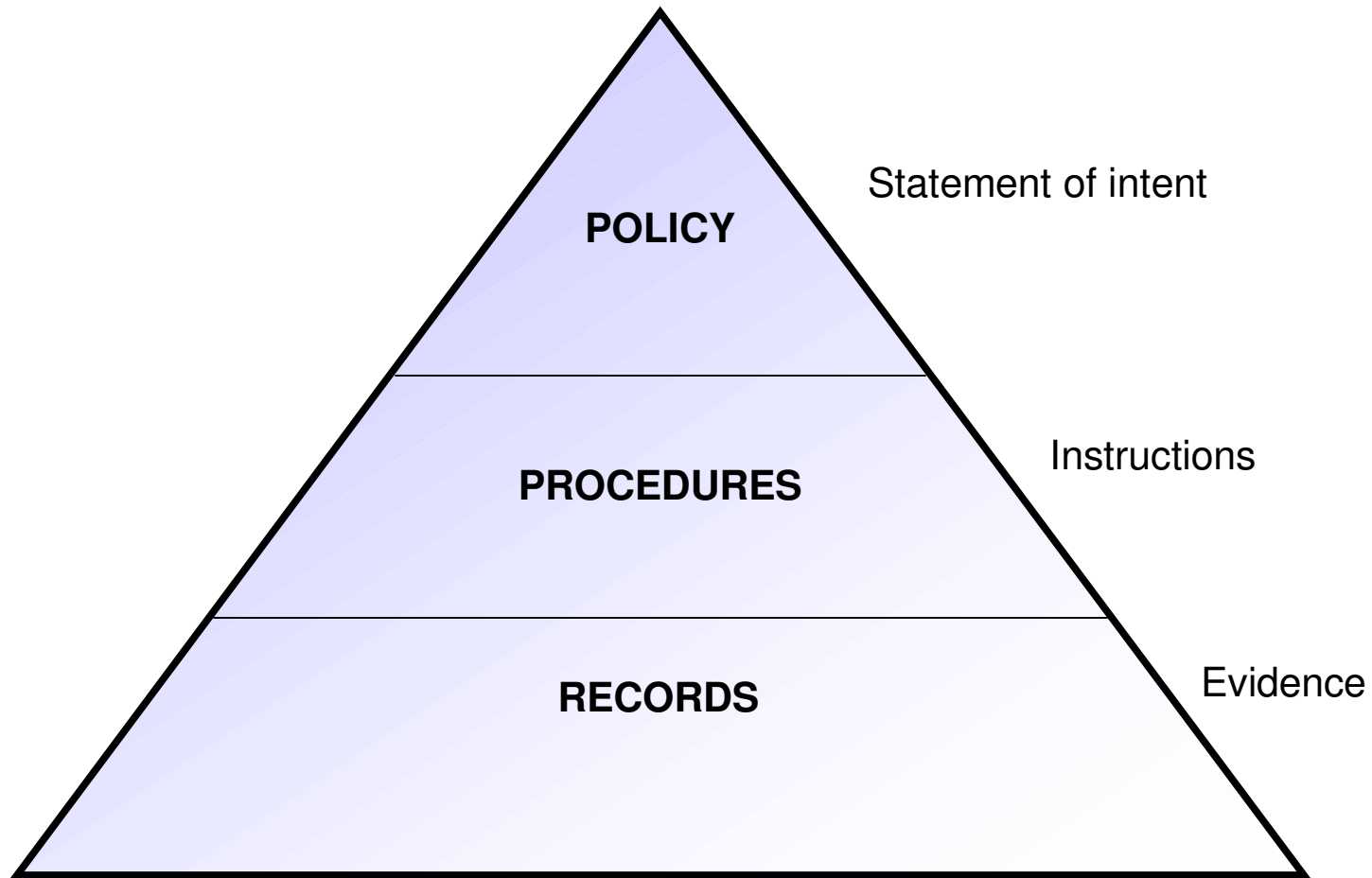
POCT group remit

- define and communicate responsibilities
- consider POCT proposals
- assist in evaluation & selection
- review quality
- training and competence testing.

Quality management

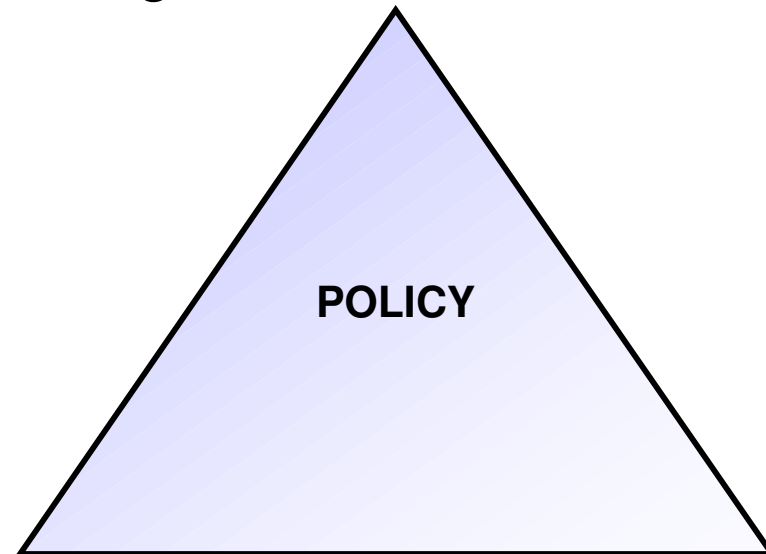
- Laboratory management shall appoint a person with appropriate training and experience, as quality manager responsible for POCT quality, which includes review of requirements related to POCT.
- POCT coordinator

Documentation



POCT Policy

- Needs and requirements of users
- Laboratory Support
- Selection and site of Equipment
- Validation (technical & diagnostic)
- Health, safety and risk management
- Training
- Procedures
- Quality Control
- Post analytical
- Patient records
- Other records
- Cost
- Audit



POCT Management Procedure

INTRODUCTION

Purpose and scope
Responsibilities
References
Definitions
Documentation

TRAINING AND CERTIFICATION

Trainers
Training courses
Register of certified users

ORGANISATION AND MANAGEMENT

Working Group on POCT
Membership
Agendas and minutes
Frequency of meetings

DOCUMENTATION

Procedures and working instructions
Manufacturer's information
Patient's records
Quality records

***IN VITRO* DIAGNOSTIC DEVICES (IVD)**

IVD inventory
IVD maintenance
Stock control

ASSURING THE QUALITY OF POCT

Internal quality control
External quality assessment
Internal quality audit

HAZARDS AND PRECAUTIONS

INTERPRETATION AND COMMUNICATION OF RESULTS

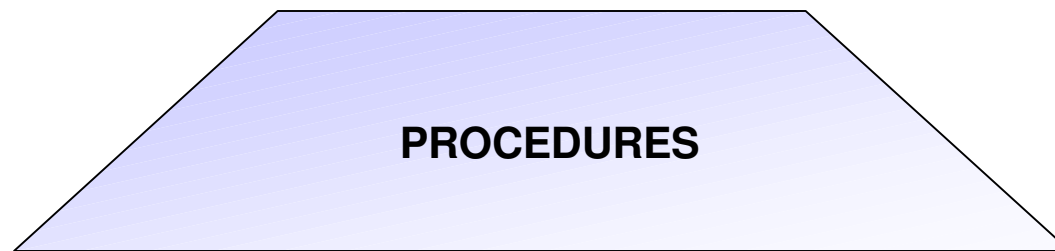


PROCEDURES

Procedures and instructions

- Sample collection
- Use of equipment
- Recording results

- Document control



Providing the evidence

- Application for POCT device
- Certificate of competence
- Maintenance log form
- Electronic logs
- QC records



A Organisation and quality management system

B Personnel
C Premises and environment
D Equipment, information systems and materials

B. PERSONNEL
B1 Laboratory Director
B2 Staffing
B3 Personnel management
B4 Staff orientation and induction
B5 Job descriptions and contracts
B6 Staff records
B7 Staff annual joint review
B8 Staff meetings and communication
B9 Staff training and education

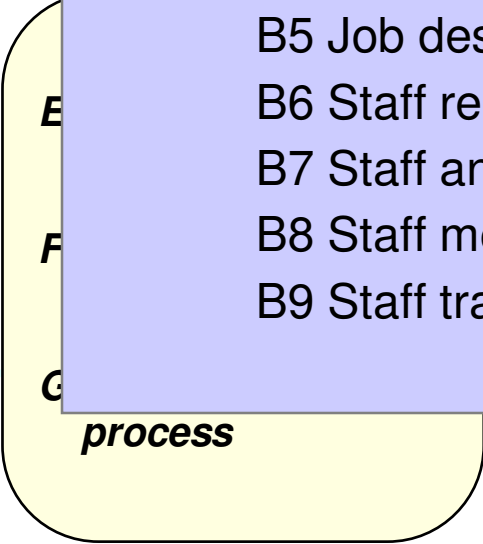
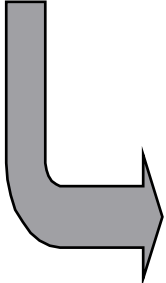
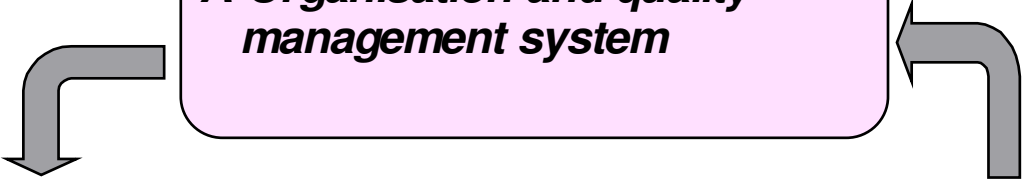
USER
Requirements

Request

Input

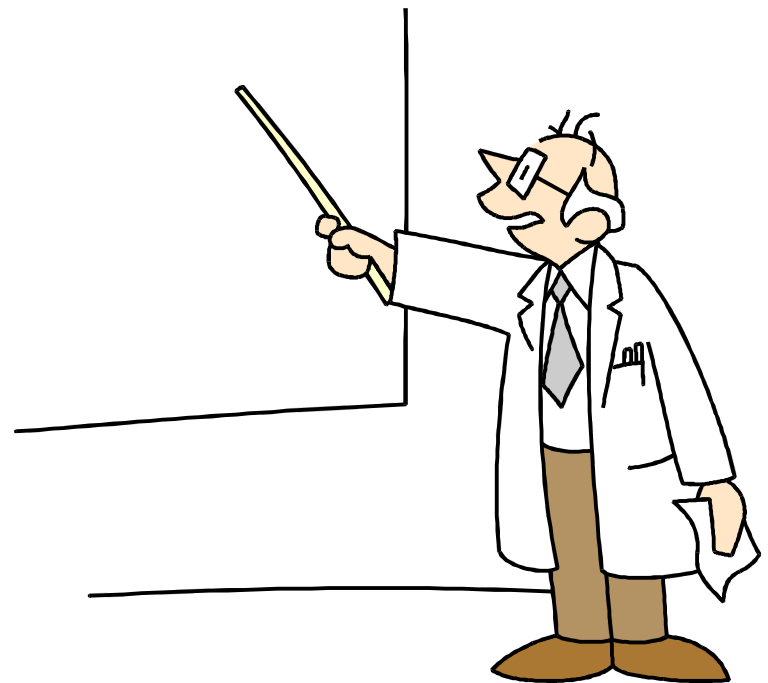
process

Output



Training

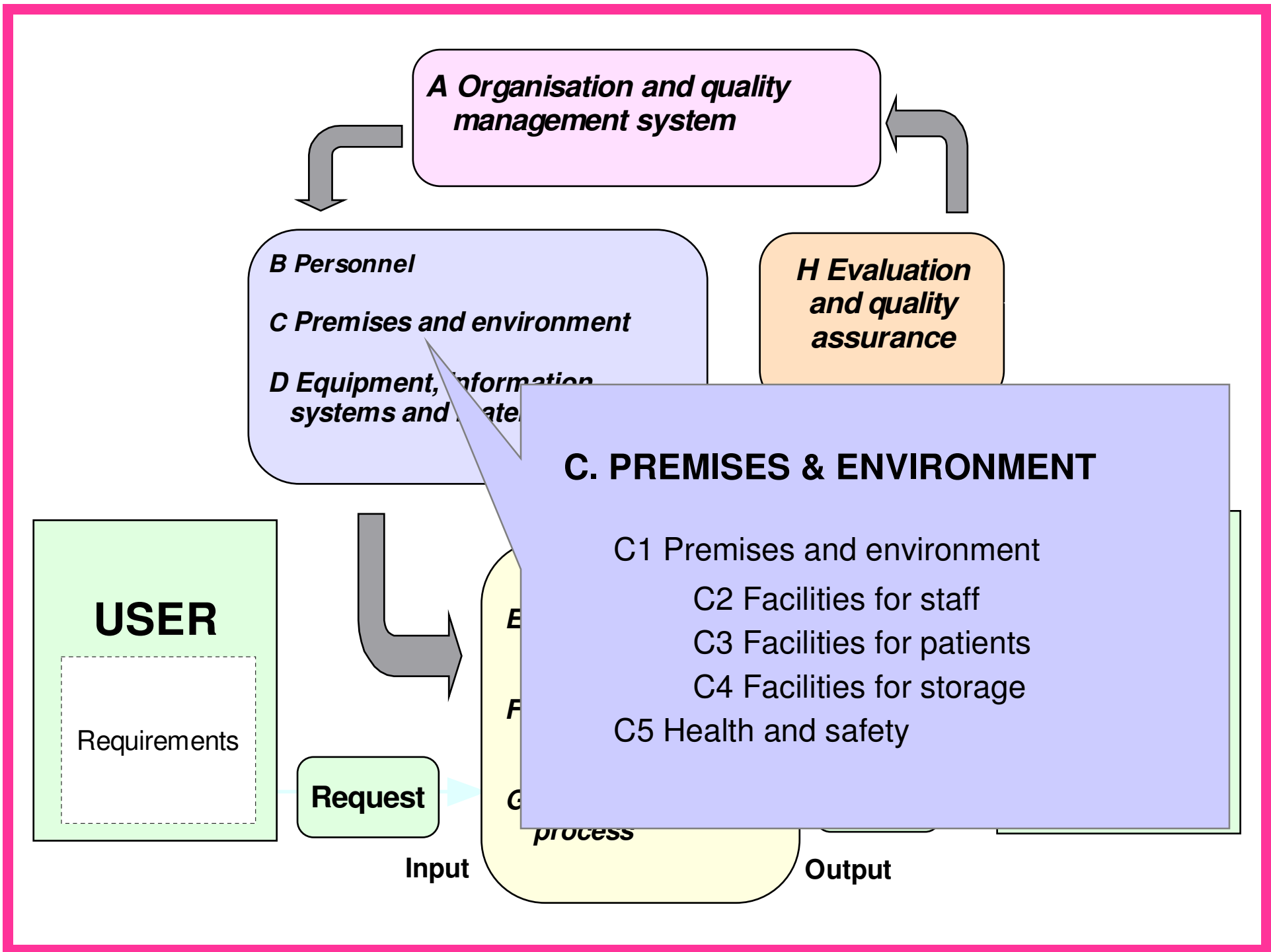
- Who is trained?
 - Nurses/Doctors
 - Medical assistants/MTO
- Who does the training?
 - Laboratory staff
 - Cascade trainers
- What is the content?
 - Knowledge
 - Practical skills
 - National Occupational Standards



Certification

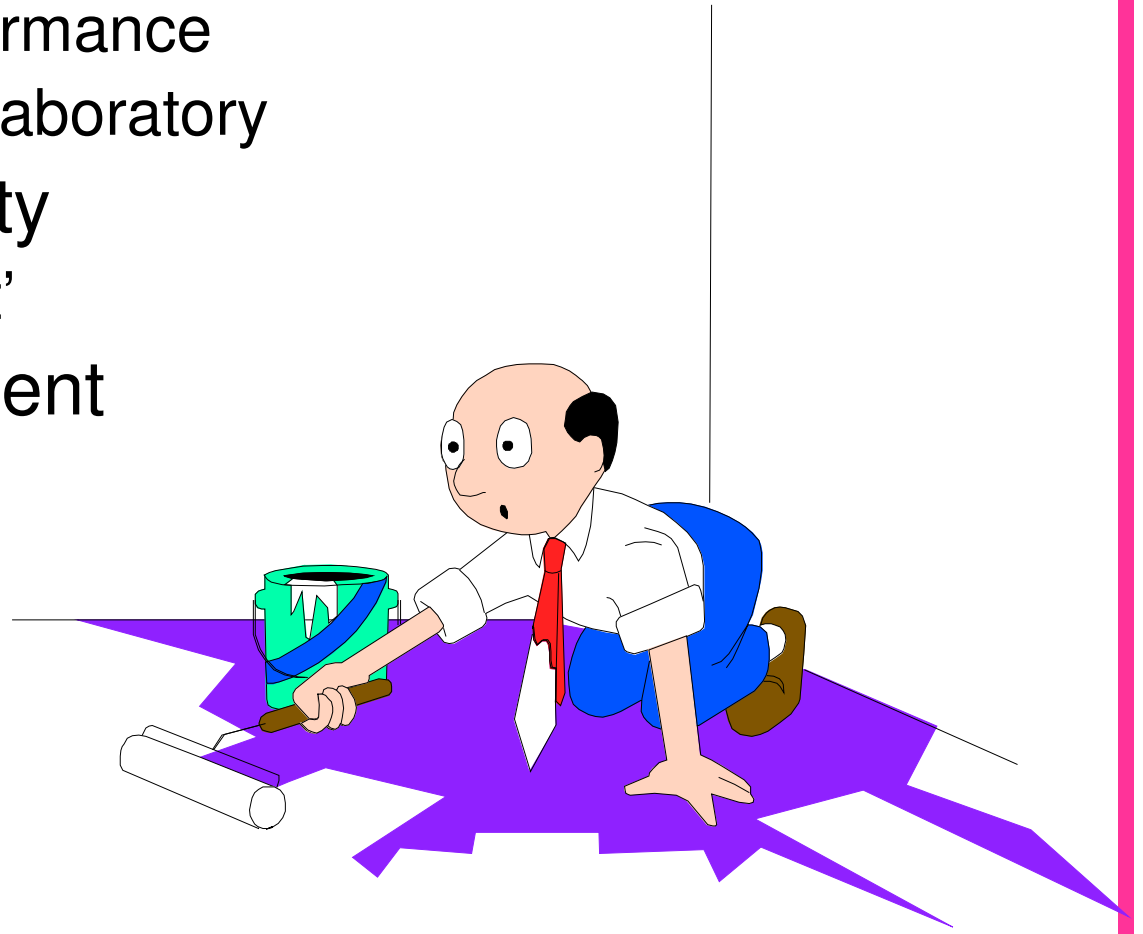
- Assessment of competence
 - Written test
 - Multiple choice questionnaire
 - Direct observation
- Update training
 - EQA
 - Updates
 - Self assessment
- Training records
 - Certificates
 - Central record





Selection of equipment

- Technical Validation
 - Underpinning performance
 - Concordance with laboratory
- Diagnostic capability
 - ‘Rule in’ or ‘rule out’
- Location of equipment
 - Power
 - Water
 - Drainage
 - Space
 - IT infrastructure



A Organisation and quality management system

B Personnel
C Premises and environment
D Equipment, information systems and materials

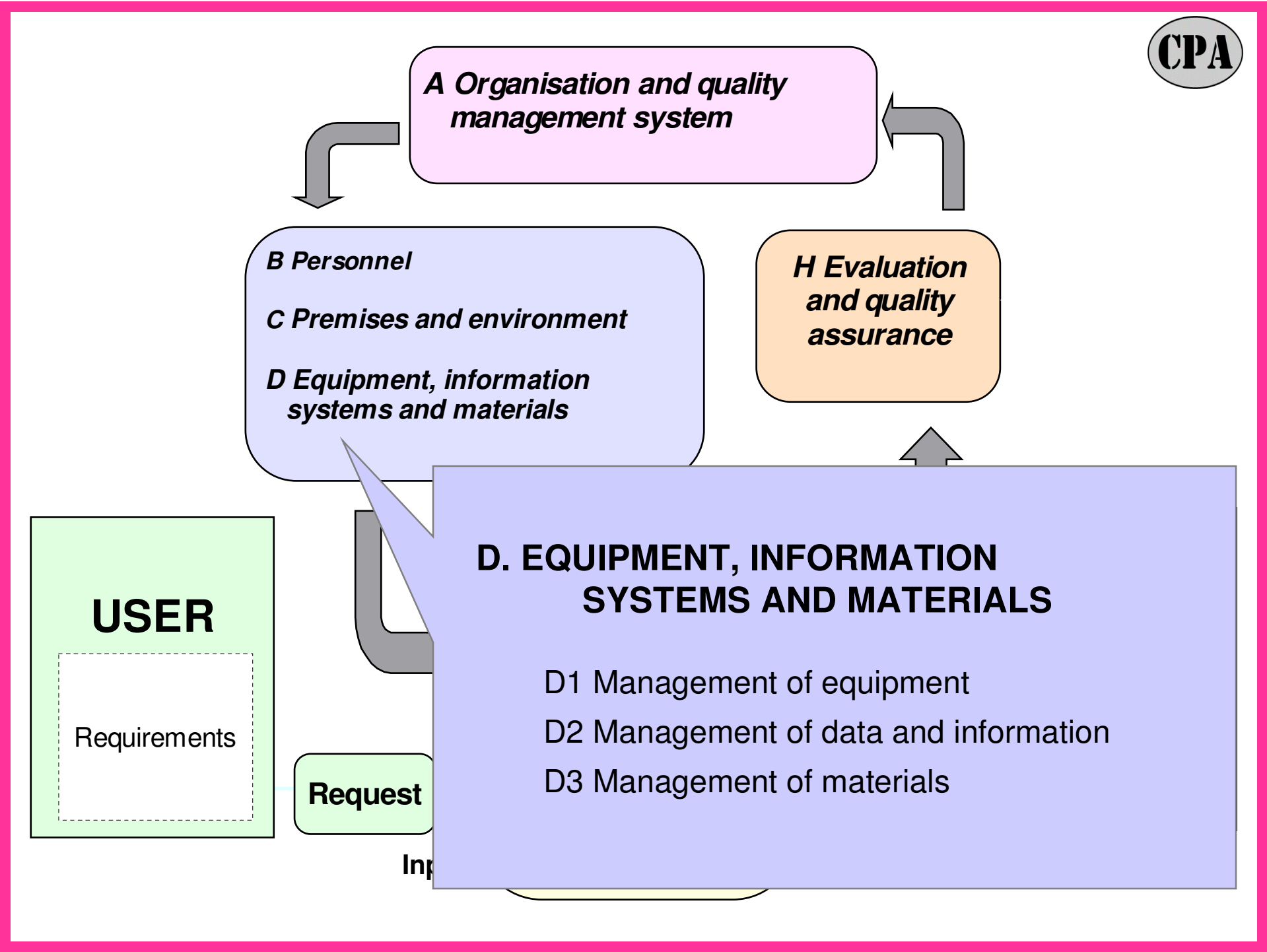
H Evaluation and quality assurance

USER
Requirements

Request

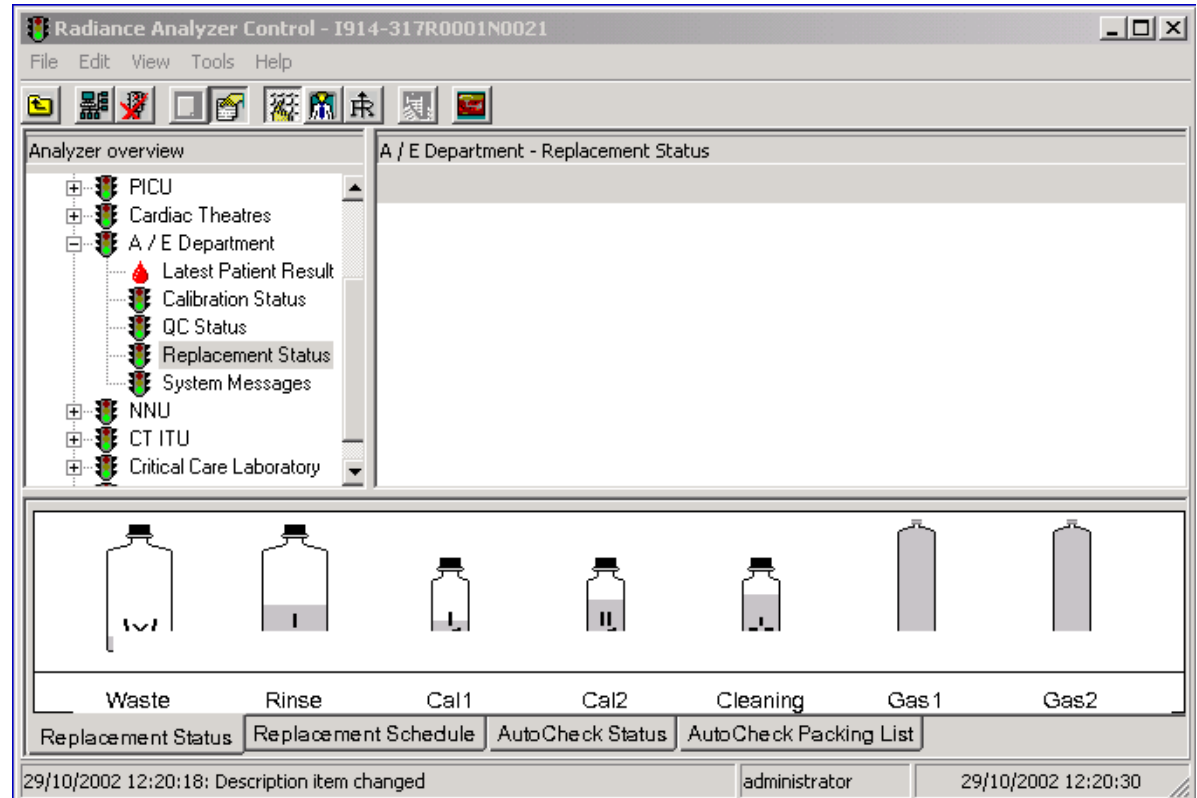
D. EQUIPMENT, INFORMATION SYSTEMS AND MATERIALS
D1 Management of equipment
D2 Management of data and information
D3 Management of materials

Inf



Equipment management

- Servicing
 - Laboratory
 - Supplier
 - PPM
- Records
 - Monitoring
- Remote control



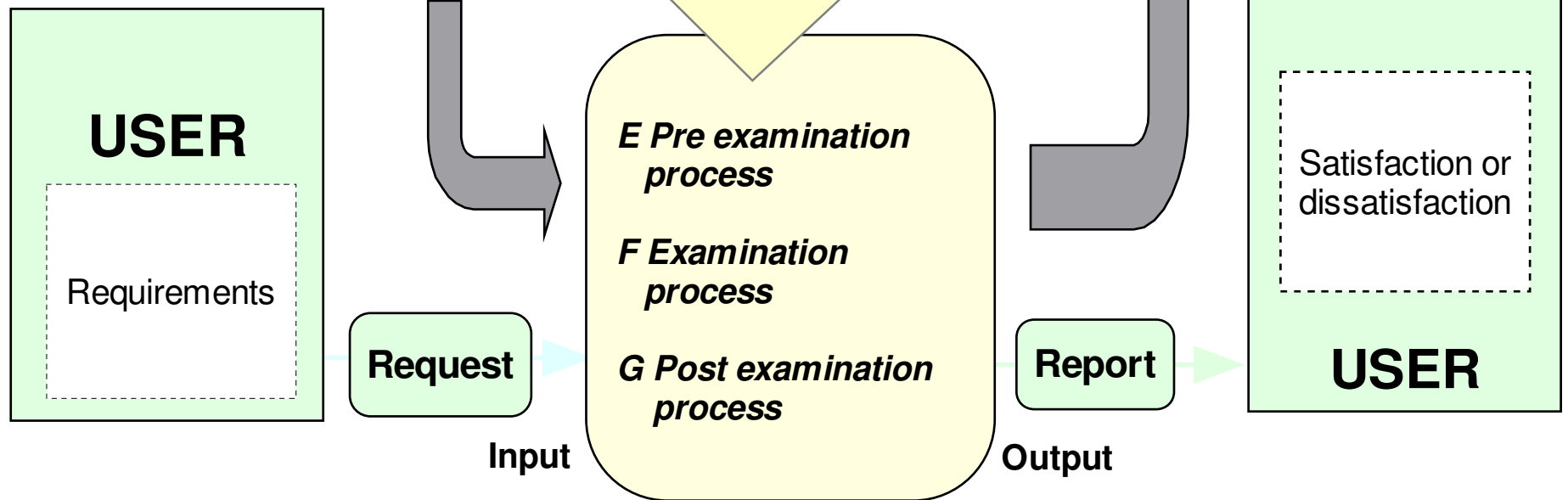
Data handling

- Patient demographics
- Results
- Audit trail
 - Who?
 - What?
 - When?
- bi-directionality
 - device connection commonality
 - security

E. PRE- EXAMINATION PROCESSES

- E1 Information for users and patients
- E2 Request form
- E3 Specimen collection and handling
- E4 Specimen transportation
- E5 Specimen reception
- E6 Referral to other laboratories

evaluation
and quality
assurance



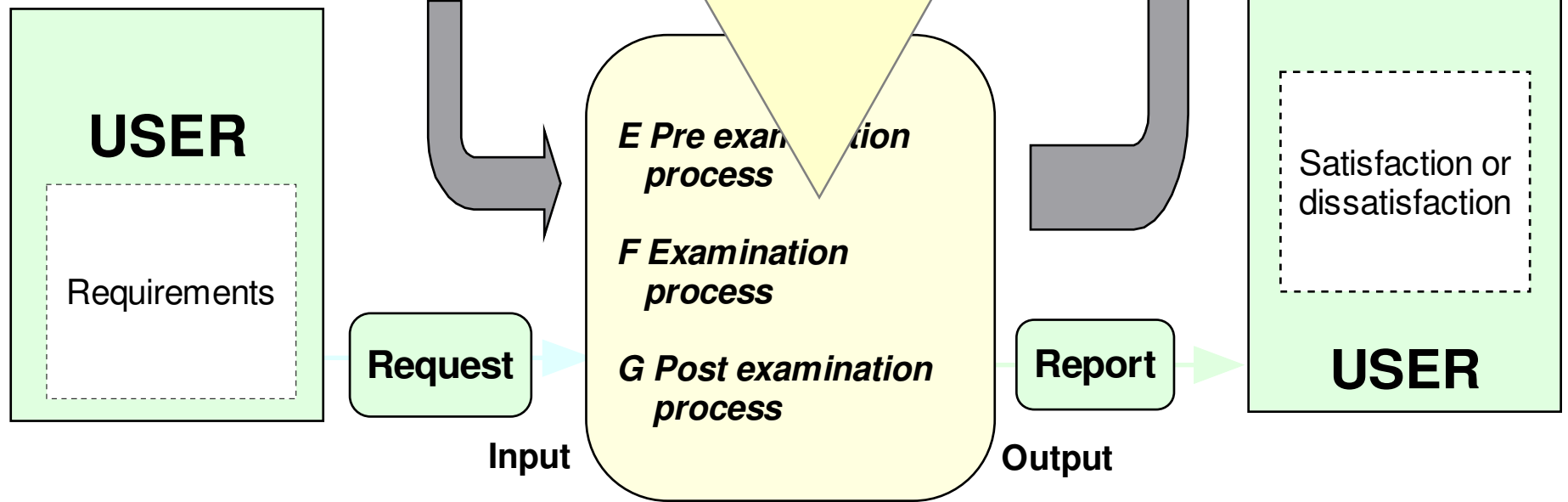
Pre examination

- Obtaining the correct specimen
- Sample identification
- Transportation
- Clinical contra-indications
 - Recently a hazard notice was issued following three critical incidents - including one fatality - due to a problem with bedside glucose meters overestimating glucose in patients whose treatment contained maltose

F. EXAMINATION PROCESSES

- F1 Selection and validation of examination procedures
- F2 Examination procedures
- F3 Assuring the quality of examinations

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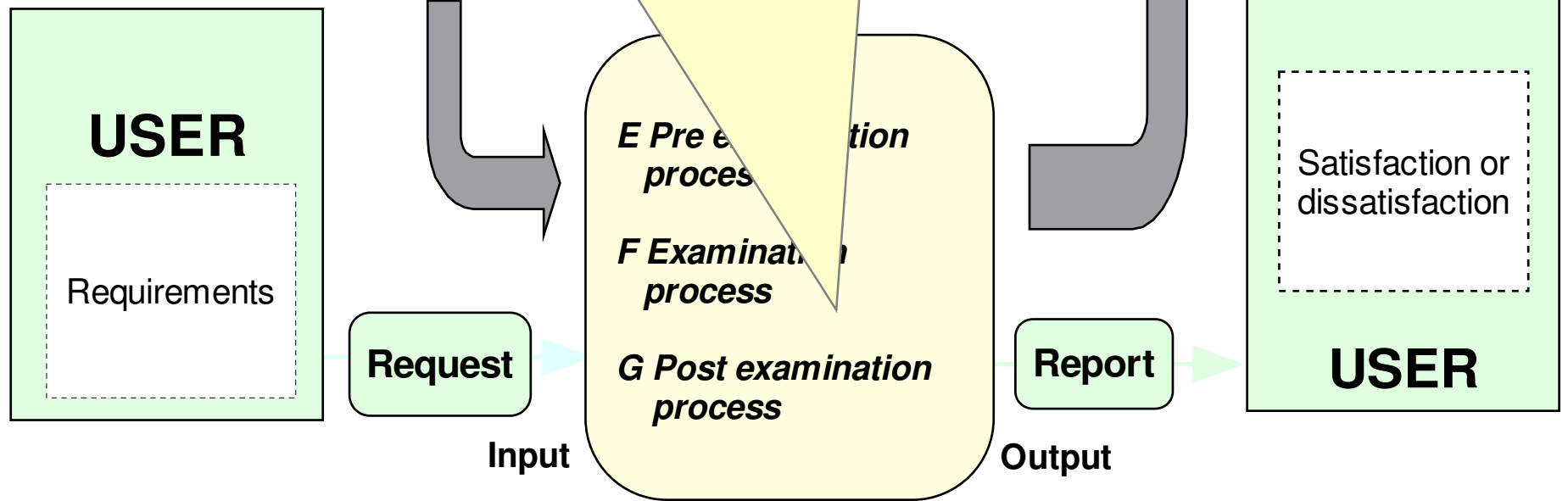
Examination

- Use of equipment
- Quality control
 - frequency
 - acceptance limits and actions
- Analytical limitations
- Traceability & uncertainty
- Health and safety
- Cleaning decontamination
- Disposal of clinical waste



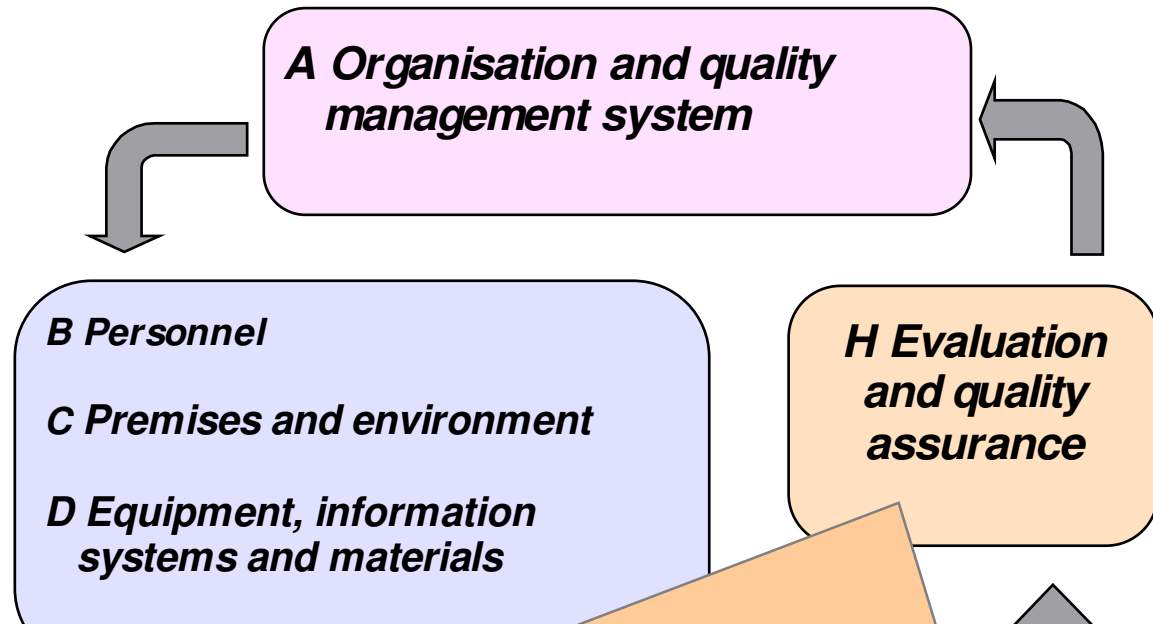
G. POST EXAMINATION PROCESSES

- G1 Reporting results
- G2 The report
- G3 The telephoned report
- G4 The amended report
- G5 Clinical advice & interpretation



Post examination

- Knowledge of reference ranges
- Action to be taken if outside analytical range
- Action to be taken if abnormal
 - pre-prescribed action, critical or alert limits, then who to contact, for example clinician or a senior nurse, must be clearly documented
- Accurate documentation



H. EVALUATION & QUALITY ASSURANCE

H1 Evaluation and improvement processes

H2 Assessment of user satisfaction and complaints

H3 Internal audit of quality management system

H4 Internal audit of examination processes

H5 External quality assessment

H6 Quality improvement

H7 Identification and control of nonconformities

Satisfaction or dissatisfaction

USER

External Quality Assurance

- WEQAS POCT schemes
 - Glucose
 - Urinalysis
 - Pregnancy testing
 - Hgb
- NEQAS
 - INR
 - Cholesterol

Management Review

- Internal audit
 - Vertical
 - Examination
 - Correction of non-conformities
- EQA
- User satisfaction
- Critical incident reporting
- Cost effectiveness
- External audit (CPA)
- Preventive & corrective action



The Carter Report

- Report of the Review of NHS Pathology Services in England (2006)
- POCT mentioned 24 times
 - “..fragmentation of parts of the service, particularly point-of-care services which are increasingly being undertaken by other members of the health care team, often with no reference to pathology services...”

The Carter Report

- Recommendations
 - (ix) the independent accreditation process is reviewed to ensure flexibility of approach and is extended to cover all providers of pathology services (including point-of care testing)..
 - (x) all pathology providers, including point-of-care testing providers, are accredited in accordance with a national independent accreditation process....
....and which requires full participation in external quality assurance schemes..

Manchester - 2007

- 22 pharmacies across Greater Manchester
- Regularly monitoring patients with diabetes and/or coronary heart disease and providing point of care testing.

“Let me single out the benefit that will come to the individual citizen if the local pharmacy is able to offer services... such as blood tests and anything that will make it more convenient for the patient...”

Prime Minister Gordon Brown

Source: Royal Pharmaceutical Society of Great Britain. September 2007

So which standard?

Hospital controlled POCT
Clinical Pathology Accreditation (UK) Ltd
Standards for the Medical Laboratory v 2 2007



Non Hospital POCT – Primary care
Clinical Pathology Accreditation (UK) Ltd
Additional Standards for
Point-of-Care Testing (POCT) facilities



Pharmacists & High Street
UKAS
Individual Licence



CPA Certificate

- Under EA rules:
- Certificate will have the name of the base laboratory
- Will have the POCT services accredited
- or
- GP practice that is supported by the laboratory

Thank you for listening

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