



Quality in Medical Diagnostic Laboratory

(Personnel, Reagents and Consumables, Examination Processes)

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Outline



PERSONNEL

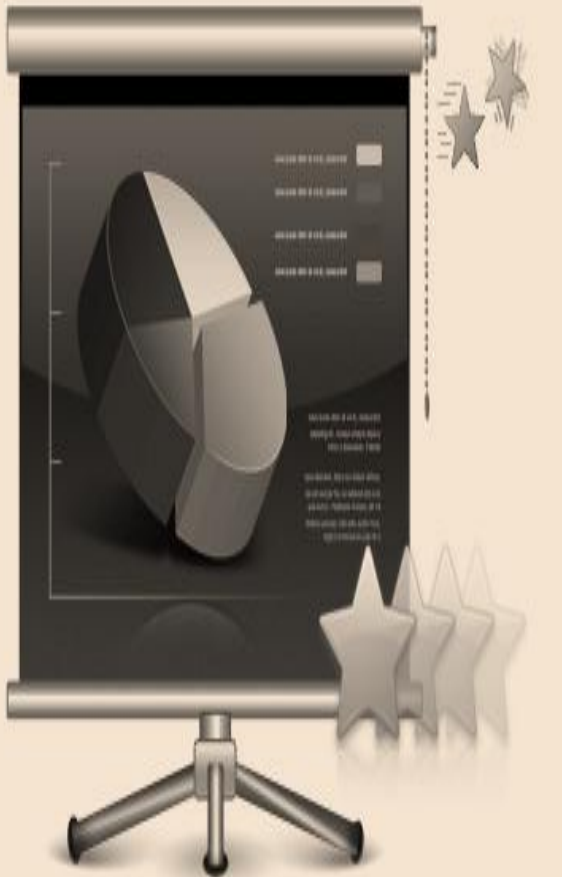
1. *'Secondary School Economics'- the most important factor of production*
2. *Continuous Improvement Cycle*

REAGENTS AND CONSUMABLES

1. *Reception and storage*
2. *Inventory management and records*
3. *Instructions for use*
4. *In-house prepared reagents*

EXAMINATION PROCESSES

1. *Selection of examination procedures*
2. *Verification of examination procedures*
3. *Validation of examination procedures*





PERSONNEL

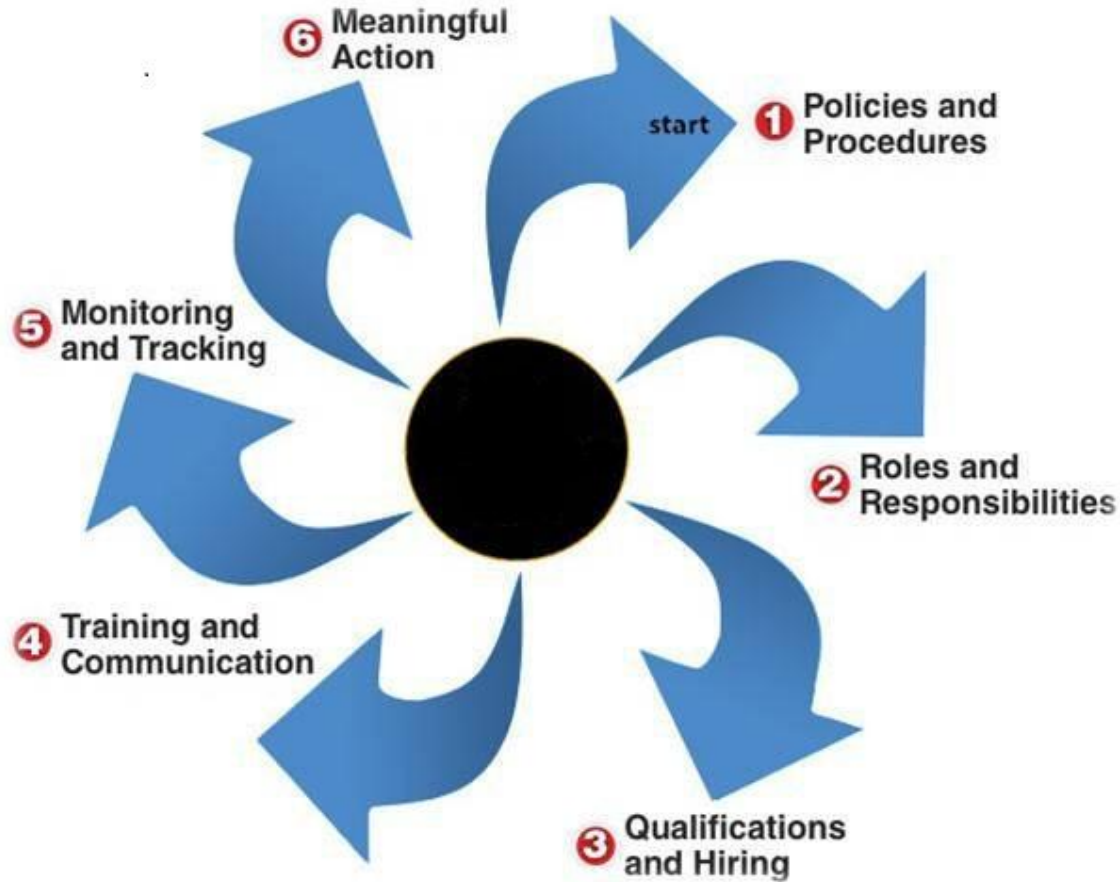
CLAUSE 5.1

PERSONNEL

The factors of Labour/Production

1. Land
2. Labour
3. Capital
4. ENTREPRENEUR – the most important factor

PERSONNEL cont'd



Continuous Improvement Cycle

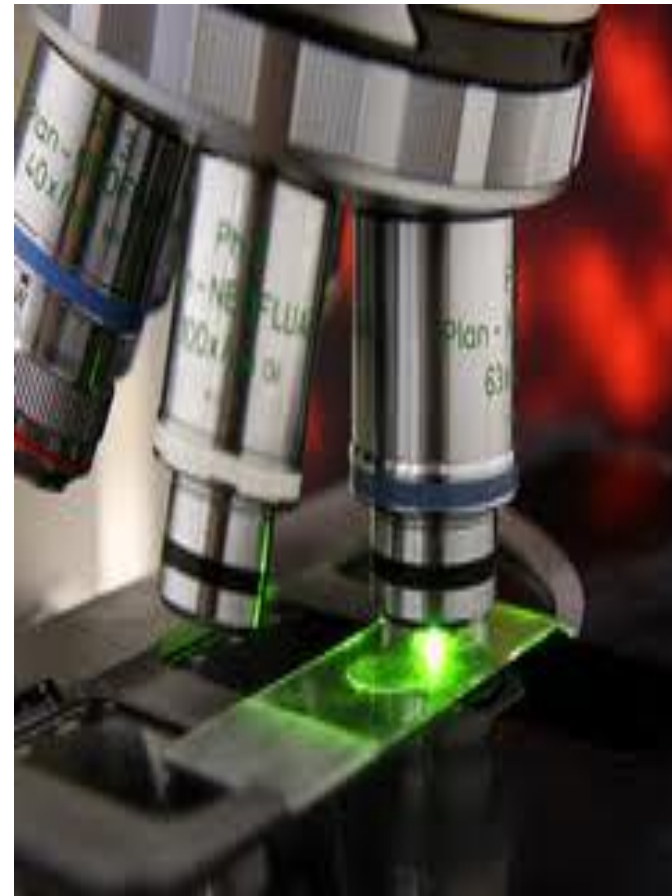
□ Personnel Qualification/Selection

1. MLSCN, MDCAN, RN/RM etc
2. Temperament assessment – Sanguine, Choleric, Phlegmatic and Melancholy



PERSONNEL cont'd

- Job description
- Training and competence assessment
- Performance review
- Continuing education and professional development





REAGENTS AND CONSUMABLES

CLAUSE 5.3.2

REAGENTS AND CONSUMABLES cont'd



- Reception and storage

REAGENTS AND CONSUMABLES cont'd



REAGENTS AND CONSUMABLES cont'd



- ❑ Inventory management and records



Attachment 7.4

REAGENT/KIT/CONTROL/CALIBRATOR BENCH LOG

LABORATORY: PCN VI DEPARTMENT: ENDOSCOLOGY

TEST: LH MANUFACTURER: BECKMAN

DATE OPENED	LOT NO.	EXPIRY DATE	DATE USED UP	REMARKS	SIGNATURE
17/09/13	370038	28/02/15	20/09/13	not used up	Ⓚ
20/09/13	370038	28/02/15	28/09/13	✓	Ⓚ
28/09/13	370038	28/02/15	03/10/13	✓	Ⓚ
03/10/13	370038	28/02/15	07/10/13	✓	Ⓚ
07/10/13	370038	28/02/15	09/10/13	used up	Ⓚ
09/10/13	370038	28/02/15			Ⓚ

1. Date reagent received
2. Expiry dates
3. Batch/Lot number
4. Condition when received
5. Date reagent put to use

REAGENTS AND CONSUMABLES cont'd

- **Instructions for use**
 - pre-dilution
 - on-board temperature
 - stability dates

- **In-house prepared reagents**

Reagent:	
Concentration:	
For Analysis:	
Store loc.:	
Expiry date:	
Prepared by:	Sign.:
Date:	



EXAMINATION PROCESSES

CLAUSE 5.5

EXAMINATION PROCESSES (ANALYTICAL PHASE)



❑ Selection of examination procedures

The preferred procedures are those:

- specified in the equipment manual
- published in established/authoritative textbooks
- peer-reviewed texts or journals
- international consensus standards
- national or regional regulations

EXAMINATION PROCESSES (ANALYTICAL PHASE)

Verification of examination procedures

This is the fulfilment of specific requirements or performance characteristics of a selected testing method.

- Measurement of accuracy
- Measurement of precision (repeatability)
- Measurement of sensitivity
- Measurement of specificity

Validation of examination procedures

The laboratory shall validate methods derived from

- Non-standard methods
- Laboratory –developed methods
- Standard methods used outside intended scope
- Modified validated methods

EXAMINATION PROCESSES (ANALYTICAL PHASE)

The specified requirements for each examination procedure **MUST** relate to the intended use.

THANK YOU

