

Implementing Quality Management System in Medical Laboratories

Consistent Quality despite the Adversity

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Goal:

- To provide an overview on how to implement Quality Management System in Medical Laboratories using ISO 15189 International Standards.

International
Standard



15189:2012

Medical laboratories -Requirements
for quality and competence

“This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for quality and competence that are particular to medical laboratories.

(ISO 15189:2012(E) Introduction Page)



ISO Quality Basics



Designing a Continuously Improving QMS.



Commit to making quality a priority.



ISO 15189:2012

Medical laboratories -- Requirements for quality and competence

What is **QUALITY** ?

Can you recognize **QUALITY** ?



A

QUALITY -

degree to which a set of inherent characteristics fulfills

requirements

ISO15189 3.17

B

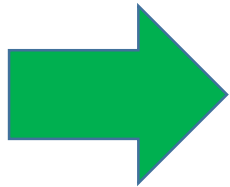




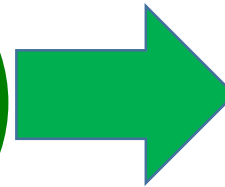
Is this a **QUALITY** lab result?

Patient X FBS: 180 mg/dL

Normal Value: 80 – 120 mg/dL



Request



Report

Clinical Decision-making
Clinical Outcomes

Information

- Accurate
- Reliable
- Timely
- Interpretable

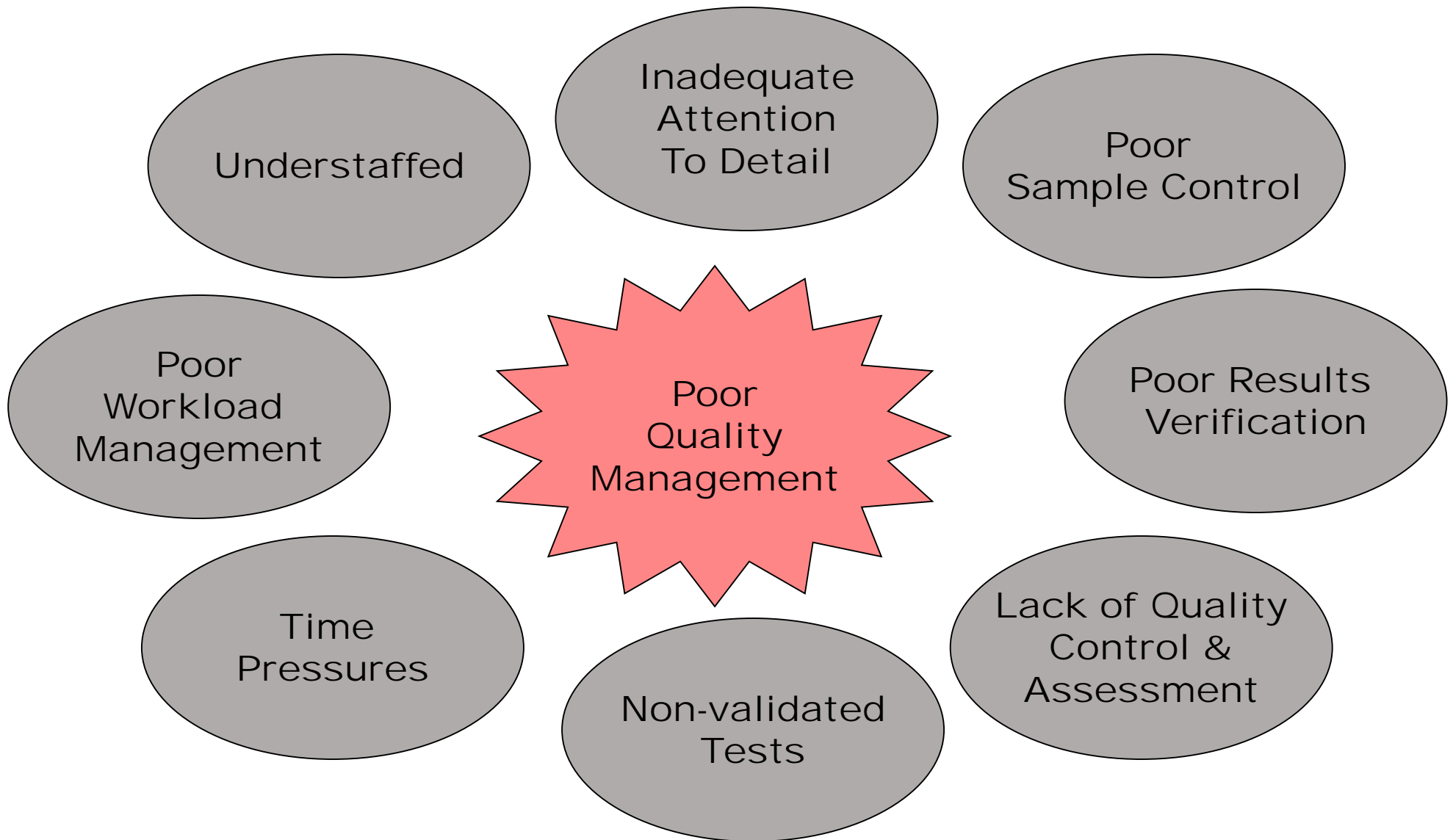
To meet the needs and requirements of the customers (e.g. patients and users), medical laboratory testing must:

Consistently provide clinical value at the decision points within a healthcare system

Clinical Decision Points in a Healthcare System

- Preventing disease
- Detecting disease early
- Establishing of an accurate diagnosis
- Selecting the right treatment
- Avoiding delays in treatment
- Facilitating recovery
- Reducing disability
- Preventing relapse
- Inhibiting progression

Why do laboratory ERRORS occur?





Quality Management System (QMS)

ISO Definition - A management system to direct and control an organization with regard to quality. ISO 15189:2012 3.20

Purpose - to define the **organizational structure** and essential tasks that are necessary to achieve quality in routine laboratory services. Westgard & Westgard, (2014), p1

3.20 quality management system

INTERNATIONAL
STANDARD

ISO
15189

Third edition
2012-11-01

Medical laboratories — Requirements for
quality and competence

*Laboratoires de biologie médicale — Exigences concernant la qualité et
la compétence*

NOTE 1 – The term “quality management system” referred to in this definition relates to:

- ✓ general management activities,
- ✓ the provision and management of resources,
- ✓ the pre-examination, examination and post examination processes and
- ✓ evaluation and continual improvement.

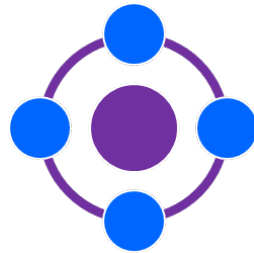


Implementing
Quality
Management
System **DOES NOT**
guarantee an
ERROR-FREE
Laboratory

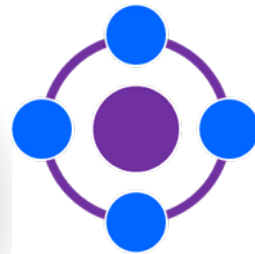
But it detects
errors that may
occur and
prevents them
from recurring



Quality Management Principles



serve as the underlying foundation for the ISO quality requirements

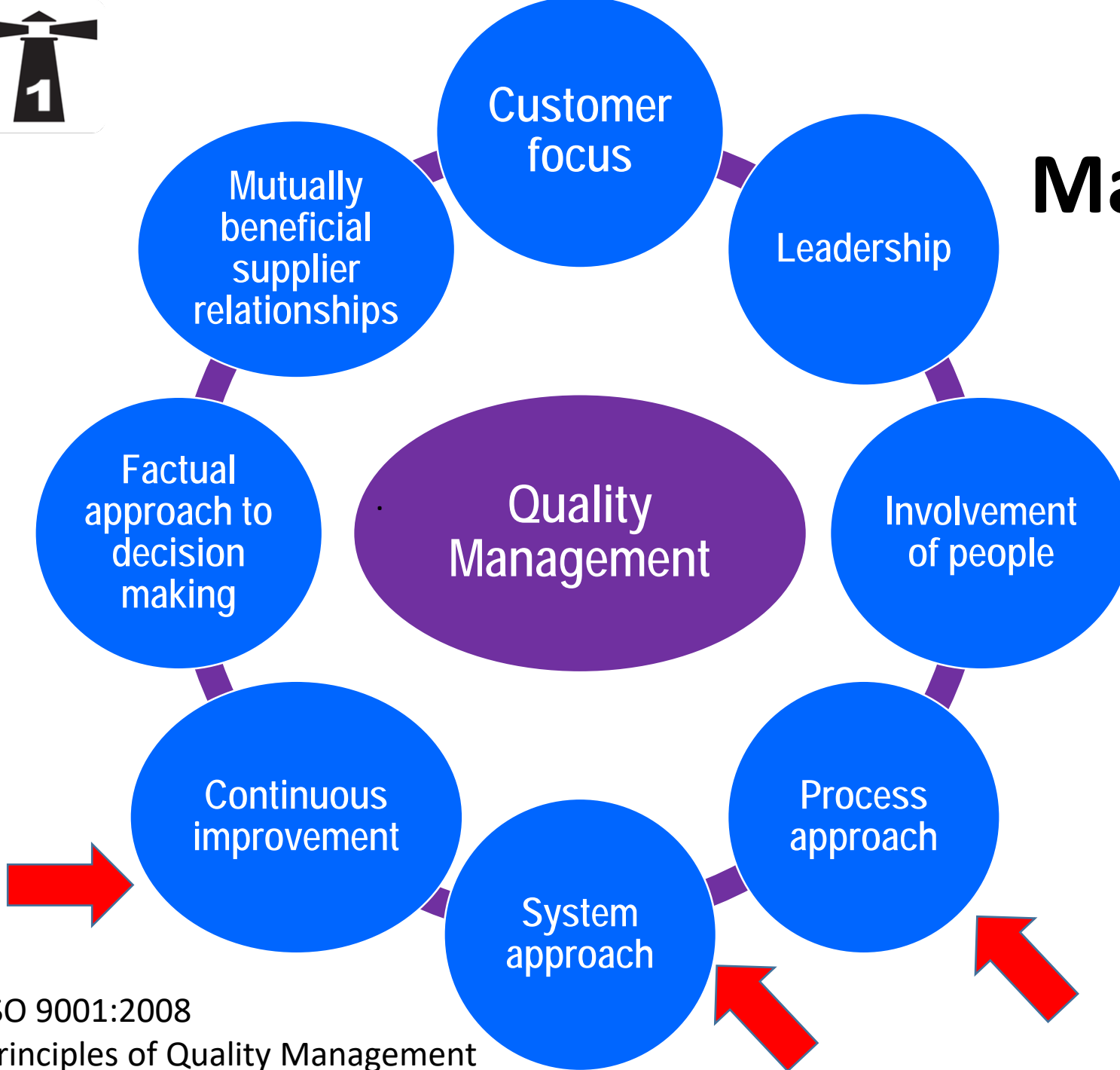


ISO 15189 is based upon which two other ISO standards?

ISO/IEC 17025 and ISO 9001



Quality Management Principles



Facilitate the achievement of quality objectives and form the foundation of effective quality management.



ISO 15189: 4.2 Quality management system 4.2.1 General requirements

The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

Process (system) approach



ISO Quality Basics



Designing a Continuously Improving QMS.



Commit to making quality a priority.



4 Management Requirements

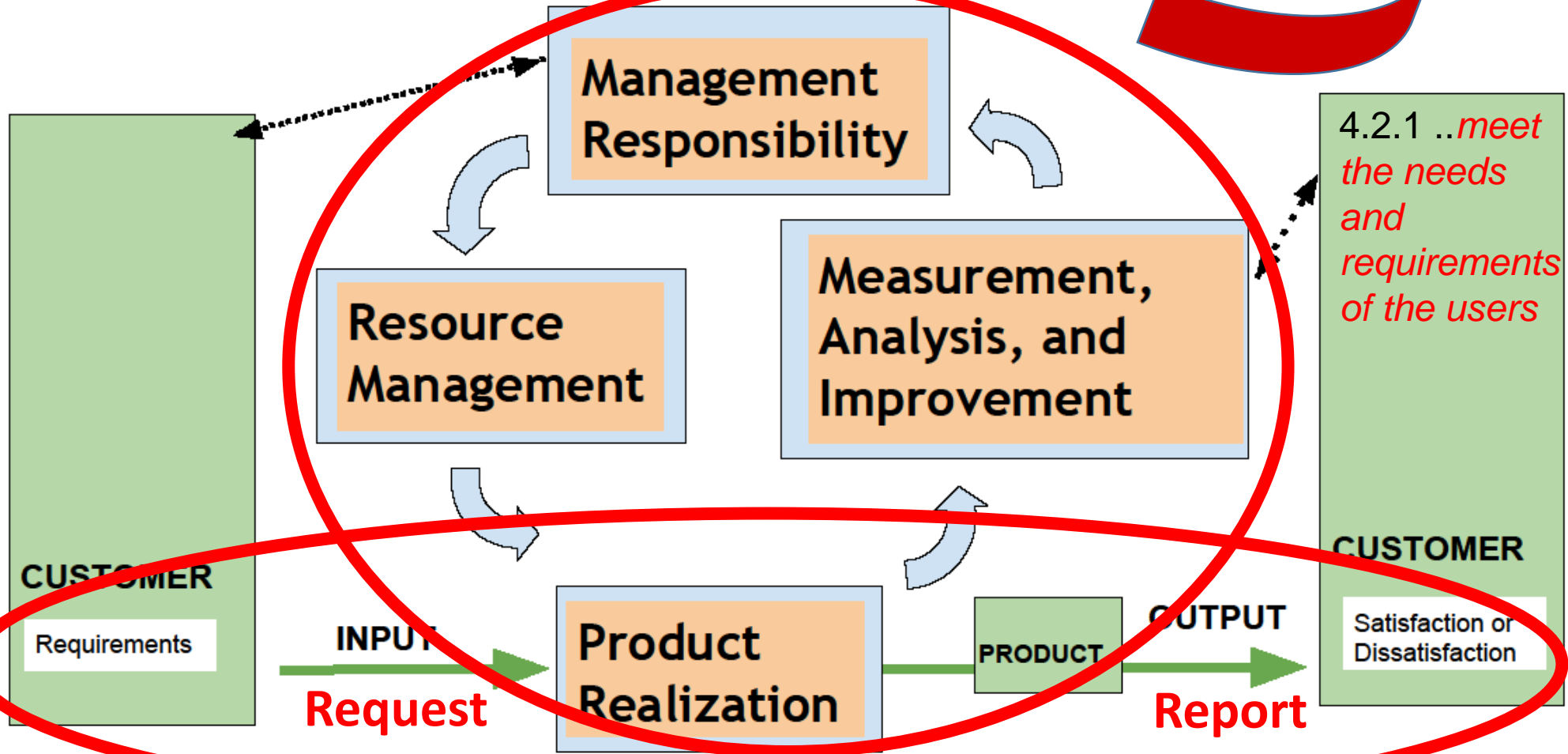
- 4.1 Organization and management responsibility
- 4.2 Quality management system
- 4.3 Document control
- 4.4 Service agreements
- 4.5 Examination by referral laboratories
- 4.6 External services and supplies
- 4.7 Advisory services
- 4.8 Resolution of complaints
- 4.9 Identification and control of nonconformities
- 4.10 Corrective action
- 4.11 Preventative action
- 4.12 Continual Improvement
- 4.13 Control of records
- 4.14 Evaluation and audits
- 4.15 Management review

5 Technical Requirements

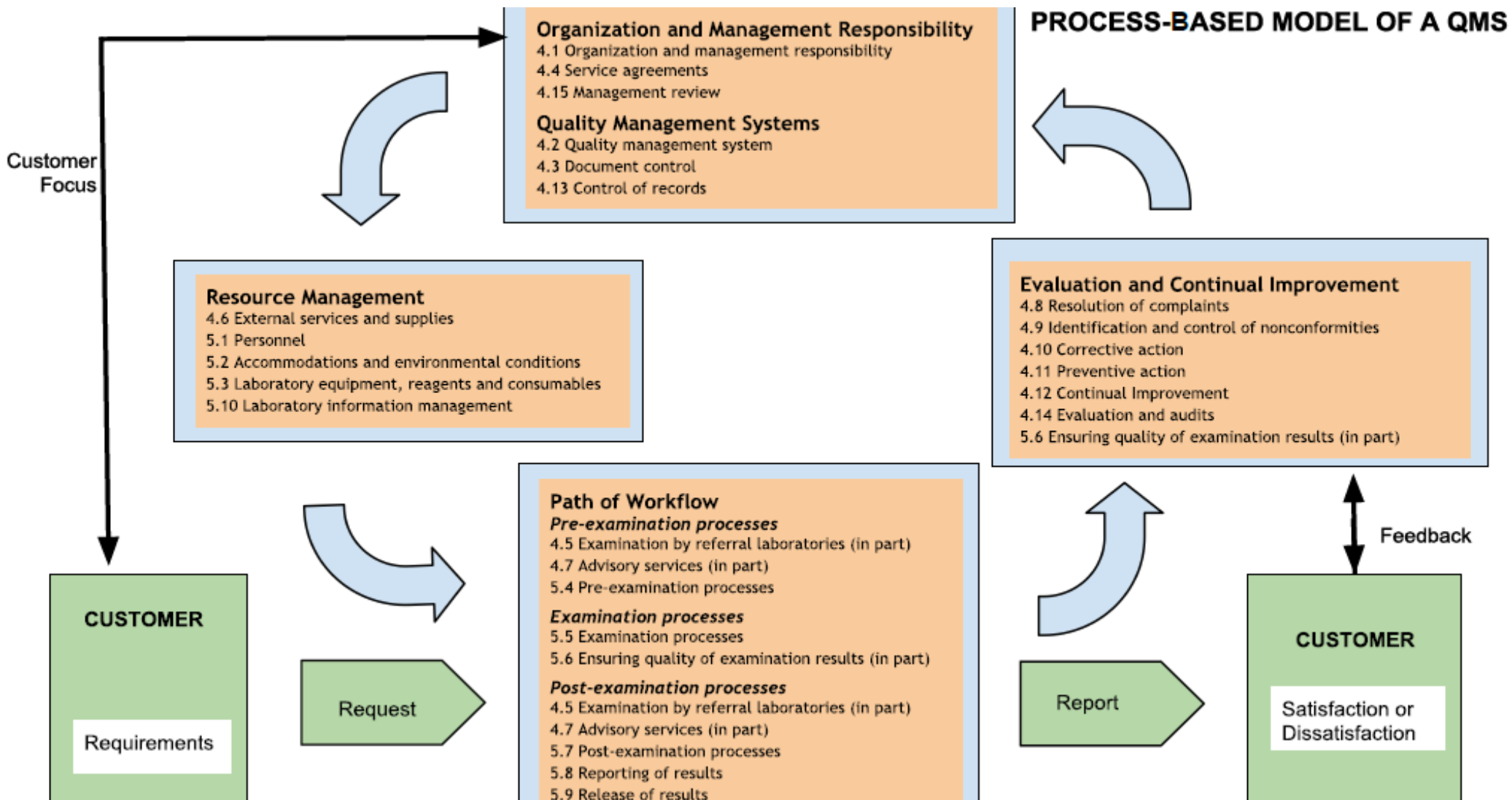
- 5.1 Personnel
- 5.2 Accommodations and environmental conditions
- 5.3 Laboratory equipment, reagents and consumables
- 5.4 Pre-examination processes
- 5.5 Examination processes
- 5.6 Ensuring quality of examination results
- 5.7 Post-examination processes
- 5.8 Reporting of results
- 5.9 Release of results
- 5.10 Laboratory information management

4.2.1 .. *Continually improve its (QMS) effectiveness*

Continual Improvement of the Quality Management System



PATH OF WORKFLOW





ISO Quality Basics



Designing a Continuously Improving QMS.



Commit to making quality a priority.



Management commitment to making quality a priority

ISO 15189 4.1.2.1 Management Commitment

“Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management and continually improve its effectiveness...”

“Strategic Leadership”

“create a unity of purpose and quality culture through action and example”



Management commitment to making
“**quality a priority**”

$$\text{Value} = \frac{\text{Quality}}{\text{Cost}}$$

The Cost of Quality is NOT the cost of creating a quality product or service. Instead, the Cost of Quality is a FAILURE to create a quality product or service.



Cost of Quality

PREVENTION COST

cost of developing and implementing quality management system

APPRAISAL COST

Cost of activities associated with measuring, evaluating or auditing to assure processes are fit-for-purpose and in conformance to quality standards.

Internal FAILURE COST

Cost of rework (sample recollection, repeat testing) and material or consumable losses.

External FAILURE COST

Cost of failure at customer site, including misdiagnosis or mistreatment.

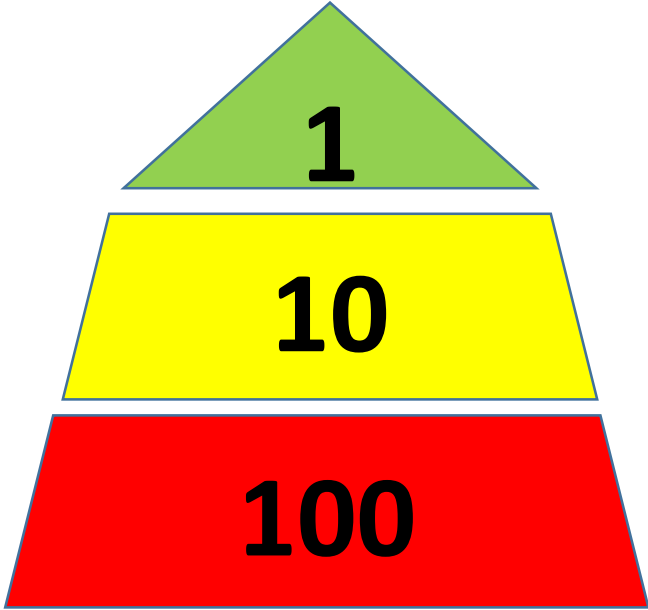


1-10-100 Rule

PREVENTION COST

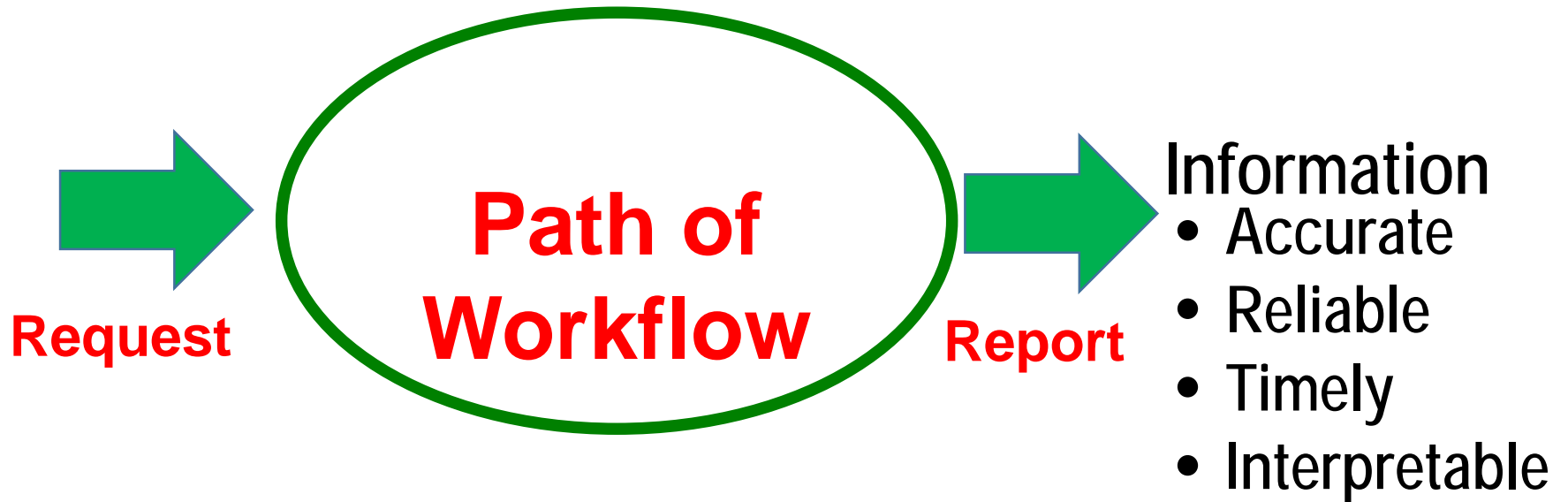
CORRECTION COST

FAILURE COST





WHY commit to making Quality a Priority in Your Laboratory???



A test result can change the way a clinician thinks about a patient.

This change in thinking can alter the way the clinician manages the patient.

This change in patient management can affect the clinical outcome (i.e. mortality/morbidity).

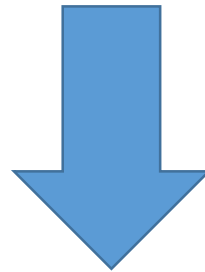
International
Standard



15189:2012

Medical laboratories -Requirements
for quality and competence

“A medical laboratory’s fulfillment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results”.



LABORATORY ACCREDITATION



What is my Why?



Despite the Adversity, the Medical
Laboratories has to maintain

Quality

LAB RESULTS ALWAYS
MATTER!!!

If you are interested in improving the quality of your medical laboratory, or you decided to take that journey towards laboratory accreditation, you don't have to do it alone.

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