Overview of ISO 15189

Requirements for Quality and Competence in the Medical Laboratories

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Overview of discussion…

- What is quality?
- Why do we need quality in Medical Laboratories?
- How do we ensure quality in Medical Laboratories?
- What is ISO?
- The importance of ISO
- Why ISO 15189?
- The history of ISO 15189
- Certification vs Accreditation
- ISO 15189, The context
- ISO 15189, Creating a practical tool for managing quality and competence in the Medical Laboratory

What is quality…

- Quality is a complex notion and means different things to different people.

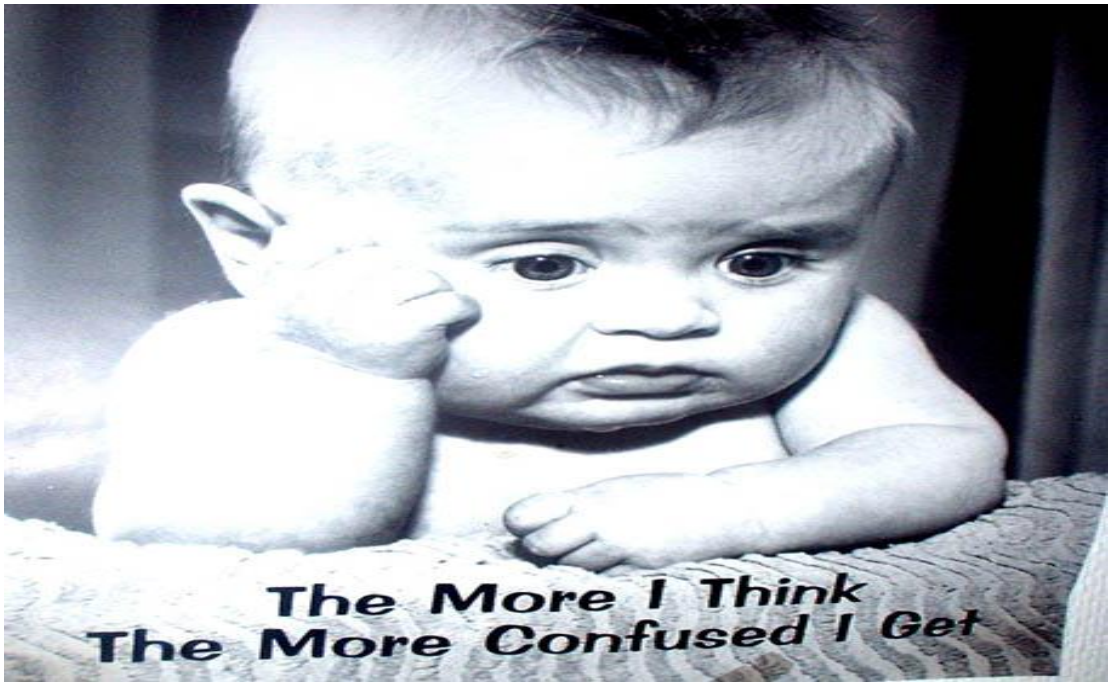
- Many vague definitions of quality exists…

What is quality… answers

- Quality is not an act it is a habit…
- To do things right the first time…
- Quality are tools and techniques…
- Quality itself is just a word…
- Quality is a perceptual and somewhat subjective attribute…
- It is an approach…
- Its value for money…

What is quality…confusion?

- Big confusion among experts



- If this is the definition of quality you will not be able to manage it at all

What is quality…
What is the alternative?

- Quality is always associated with something
- We call this "something" an object

What is quality…
For example coffee

- What is the quality of coffee?

- Color
- Taste
- Aroma
- Temperature

What is quality… defining quality

- Quality is the set of attributes of an object
- This attributes can be managed.
- One can manage the color, taste, aroma and temperature of coffee.

What is quality…
Quality in Medical Laboratories

- In Medical Laboratories there are far more "objects" than just coffee

- If this is not managed and measured the output will not be satisfactory

Why do we need quality in Medical Laboratories?

- A medical laboratory is a laboratory where tests are done on clinical specimens in order to get information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.

- *Seventy* percent of clinical medicine decision making is predicated upon, or confirmed by, or documented by medical laboratory test results.

- Medical Laboratories…

  Highly complex operations
  Individuals doing complex tasks
  Absolute need for Accuracy
  Absolute need for Confidentiality
  Absolute need for Time Effectiveness
  Absolute need for Cost Efficiency

What is quality…How do we ensure quality in Medical Laboratories

- Through the introduction of international recognized standards.
- What Standards… are available?

ISO…

- **What is ISO?**
- ISO (International Organization for Standardization) is the world's largest developer of voluntary International Standards.
- International Standards give state of the art specifications for products, services and good practice.
- **The Importance of ISO**
- The importance of ISO certification / accreditation is that it provides assurance of Quality management which in turn provides assurance to customers.
- ISO certification / accreditation forces an organization to focus on "how they do business".
- Each procedure and work instruction must be documented and thus, becomes the springboard for Continuous Improvement.

Why is ISO the next step?

The 8 eight Quality Management Principles that form the basis of all ISO Standards

- 1. Customer Focus
- 2. Leadership
- 3. Involvement of people
- 4. Process approach
- 5. System approach to management
- 6. Continual improvement
- 7. Factual approach to decision making
- 8. Mutually beneficial supplier relationships

Why ISO 15189…

- Created specifically for Medical Laboratories
- Written by medical laboratory professionals
- States the specific requirements for quality and competence in medical laboratories

History of ISO 15189

- It has its origins in two ISO Standards:

ISO9001 - Quality management systems — Requirements

ISO17025 - General requirements for the competence of testing and calibration laboratories

- ISO15189:2003 (1st Edition)
- ISO15189:2007 (minor changes, 2nd Edition)
- ISO15189:2012(a revision focused on improving the presentation as well as update of content)

- To be used for Accreditation not Certification

ISO Certification VS Accreditation

- Certification is defined in ISO/IEC Guide 2 as a procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements. (Management)

- Accreditation is defined in ISO/IEC Guide 2 as a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

- Certification gives written assurance / confirmation of specified requirements.
- Accreditation confirms TECHNICAL competence.

Sector specific aspects of ISO 15189 (1)

- focuses on the patient outcome without downgrading the need for accuracy of measurements

- emphasizes not only the quality of the measurement but of the total service of a medical laboratory

Sector specific aspects of ISO 15189 (2)

- uses a language and terms that are familiar in the profession
- highlights important features of pre and post examination issues
- addresses ethics and information needs of the medical laboratory.

ISO 15189 - The overall context

International Standard
(ISO 15189 Medical Laboratories - Requirements for quality and competence)

A – used by a medical laboratory for **SELF ASSESMENT**

B - used by the Accreditation Body as a basis for assessing a medical laboratory and grant accreditation **(VOLUNTARY ACCREDITATION)**

Medical Laboratory

C - Government or a designated regulator mandates accreditation to a chosen standard.
MANDATORY ACCREDITATION

National Accreditation Body
(An independent authoritative Body)

Regulation by Government
(of Medical laboratories)

Why accreditation?

- It is in the interest of patients, of society and governments that medical laboratories operate at high standards of professional and technical competence.

- It is also in the interest of competent laboratories that their competence is verified through a process of inspection, comparison against appropriate standards, as confirmation of their good standing.

Overview - ISO 15189:2012

- 15 Management Requirements (Section 4)

- 10 Technical Requirements (Section 5)

ISO 15189 Requirements

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 Preventive action
4.12 Continual improvement
4.13 Control of records
4.14 Evaluation and audits
4.15 Management review

5 Technical requirements

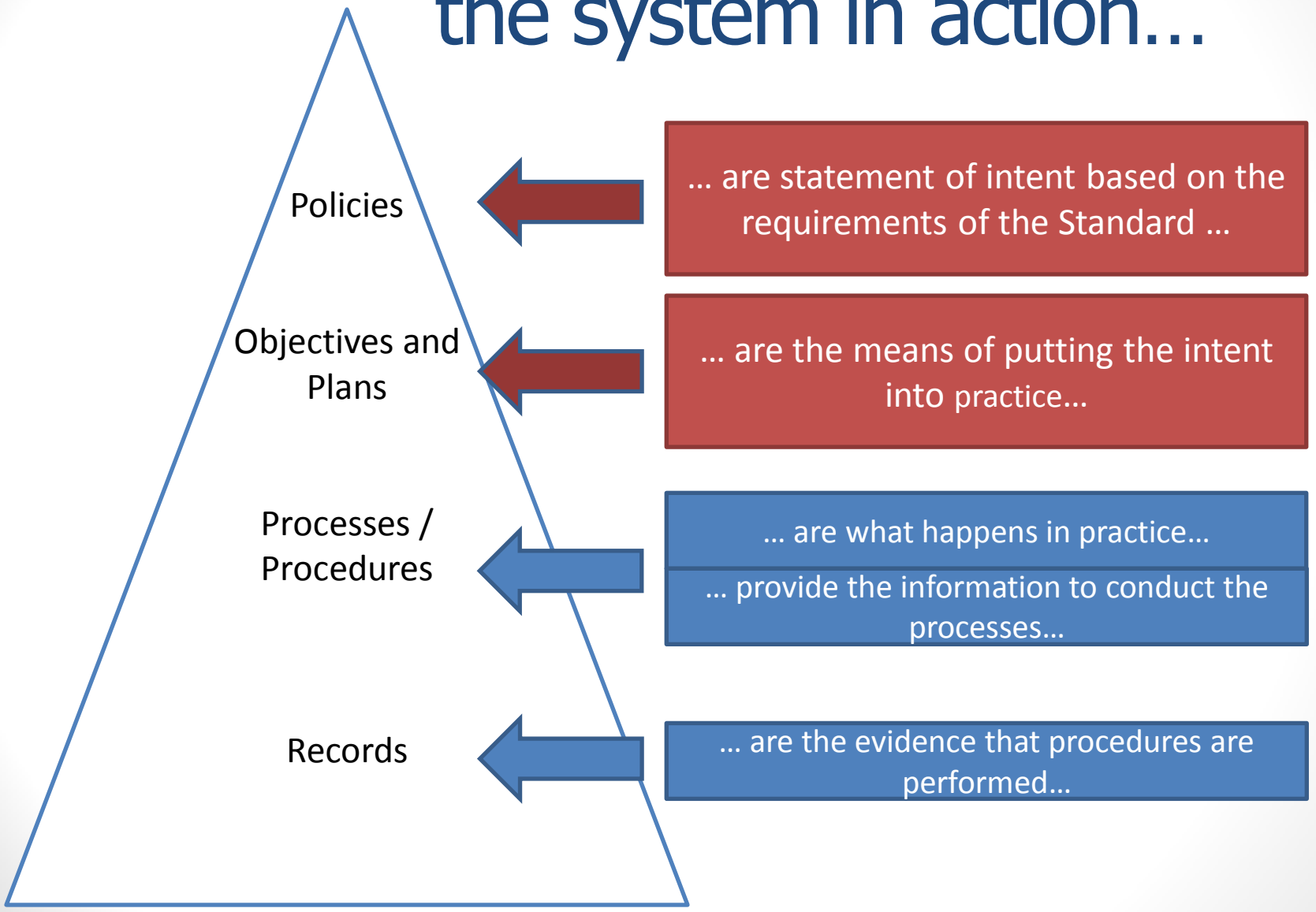
5.1 Personnel
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment, reagents, and consumables
5.4 Pre-examination processes
5.5 Examination processes
5.6 Ensuring quality of examination results
5.7 Post-examination processes
5.8 Reporting of results
5.9 Release of results
5.10 Laboratory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

ISO 15189 – The Practical context

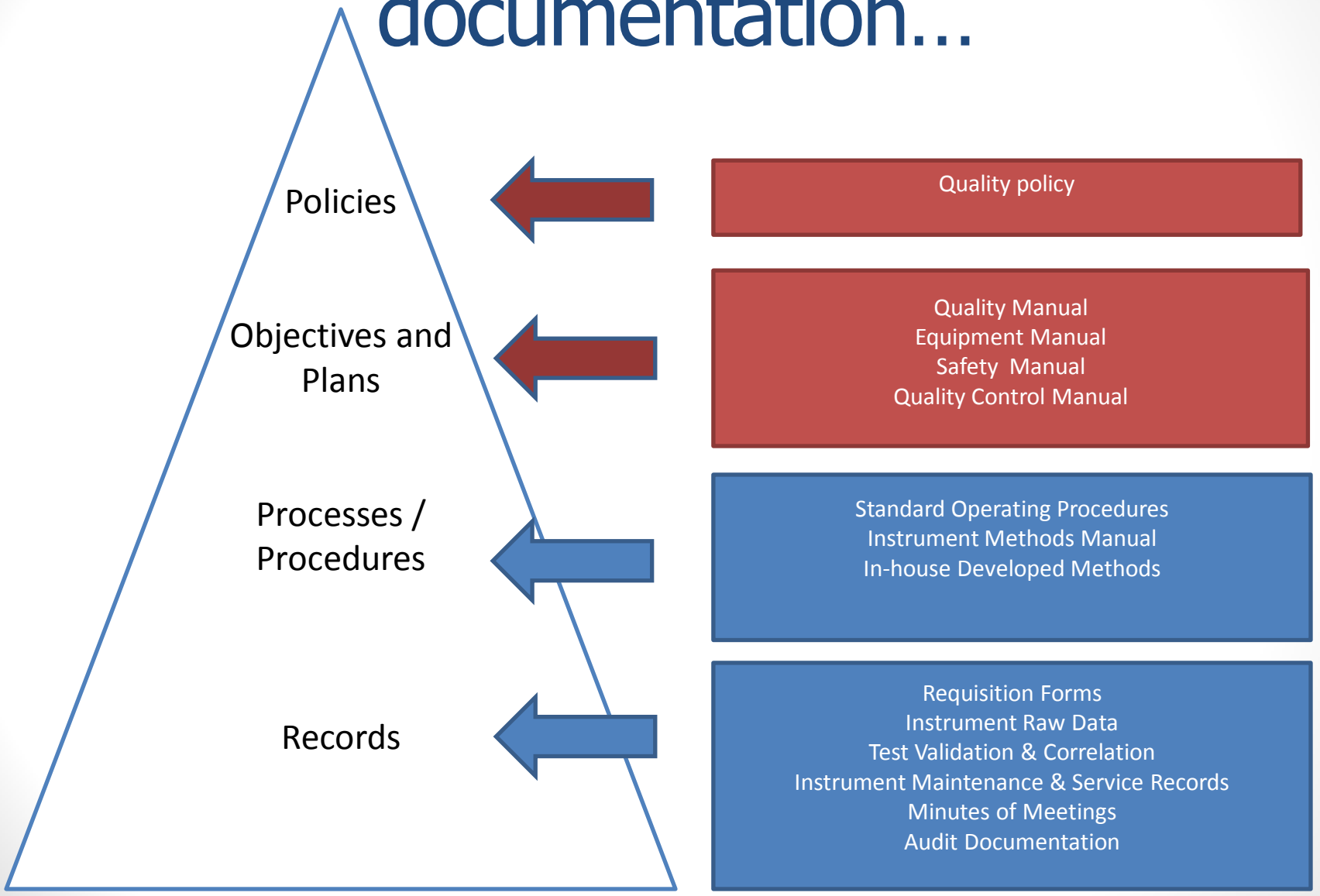
- How can ISO 15189 be used in practice?
- ISO 15189 = Total quality management tool

Four Components of a Quality Management System

ISO 15189 – Put the system in action…



Evidence through documentation…



How to apply ISO 15189 – to creating a practical tool…

- Re-ordering of the ISO 15189 packages of information
- Using the packages of information to examine…

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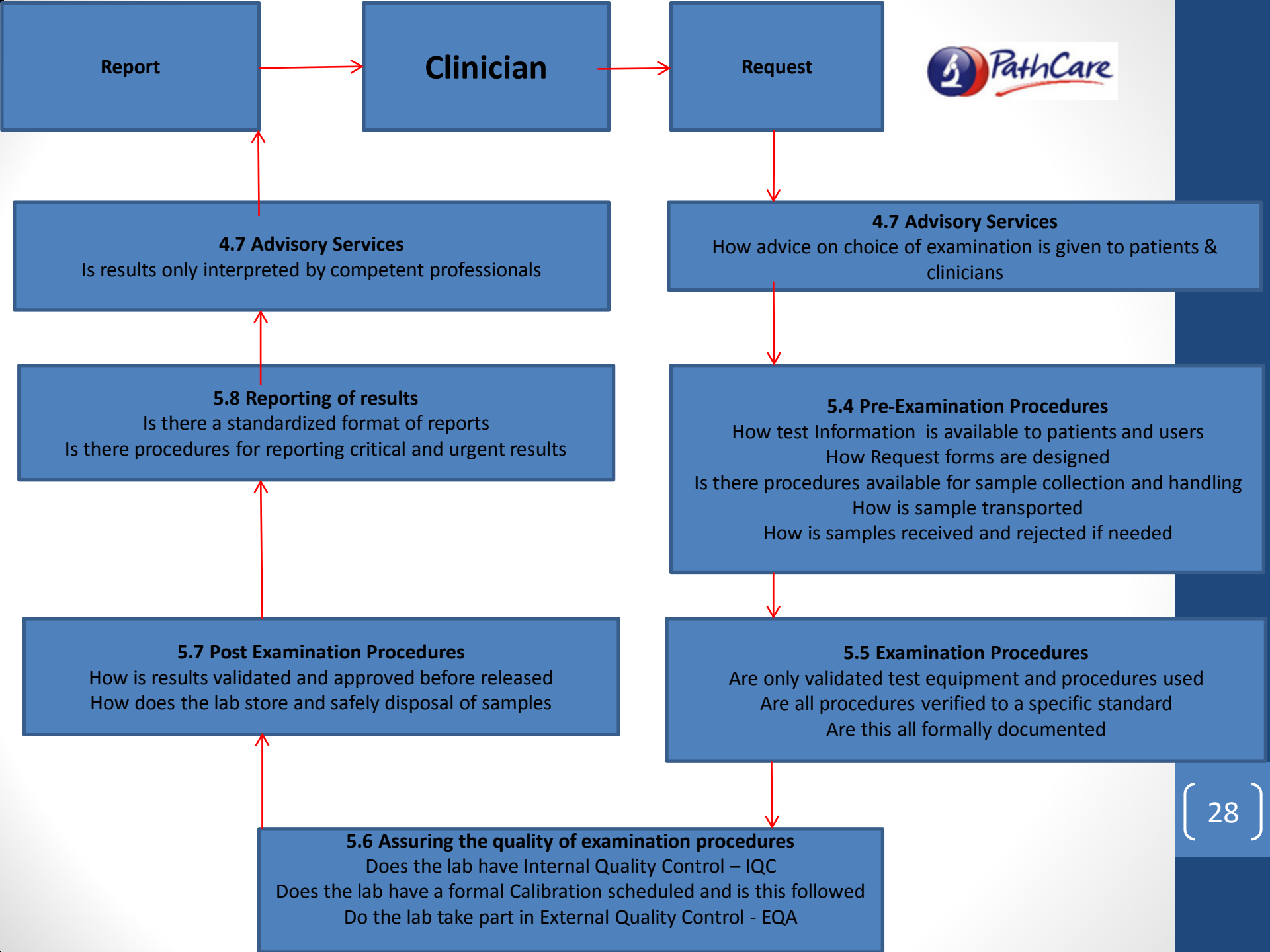
Report
Clinician
Request
4.7 Advisory Services
Is results only interpreted by competent professionals
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How advice on choice of examination is given to patients & clinicians
5.8 Reporting of results
Is there a standardized format of reports
Is there procedures for reporting critical and urgent results
5.4 Pre-Examination Procedures
How test Information is available to patients and users
How Request forms are designed
Is there procedures available for sample collection and handling
How is sample transported
How is samples received and rejected if needed
5.7 Post Examination Procedures
How is results validated and approved before released
How does the lab store and safely disposal of samples
5.5 Examination Procedures
Are only validated test equipment and procedures used
Are all procedures verified to a specific standard
Are this all formally documented
5.6 Assuring the quality of examination procedures
Does the lab have Internal Quality Control – IQC
Does the lab have a formal Calibration scheduled and is this followed
Do the lab take part in External Quality Control - EQA

Thank you …


The Quality Assurance Cycle
Pre-Analytic
Patient/Client Prep
Sample Collection
Personnel
Competency
Test
Evaluations
Sample
Receipt and
Accessioning
Sample
Transport
Quality Control
Testing
Analytic
Record
Keeping
Reporting
Post-Analytic
•Data and Lab Management
•Safety
•Customer Service