

D 65v22

Management of a medical biology laboratory – ISO 15189:2022

Goal

1 Medical biology laboratory

- 1.1 History
- 1.2 Scope
- 1.3 Benefits
- 1.4 Principles and steps

2 Definitions, standards and books

- 2.1 Definitions
- 2.2 Standards
- 2.3 Books

3 Process approach

- 3.1 Types of processes
- 3.2 Mapping
- 3.3 Process approach

4 General requirements

- 4.1 Impartiality
- 4.2 Confidentiality
- 4.3 Patient requirements

5 Structure and governance

- 5.1 Legal entity
- 5.2 Laboratory director
- 5.3 Laboratory activities
- 5.4 Structure and authority
- 5.5 Policy and objectives
- 5.6 Risk management

6 Resources

- 6.1 General
- 6.2 Personnel

6.3 Facilities

6.4 Equipment

6.5 Calibration and traceability

6.6 Reagents and consumables

6.7 Contracts

6.8 External providers

7 Processes

7.1 Process requirements

7.2 Pre-examination processes

7.3 Examination processes

7.4 Post-examination processes

7.5 Nonconforming work

7.6 Data control

7.7 Complaints

7.8 Business continuity

8 Management system

8.1 General requirements

8.2 Documentation

8.3 Document control

8.4 Record control

8.5 Actions to address risks

8.6 Improvement

8.7 Nonconformities

8.8 Evaluations

8.9 Management review

Annex A POCT

Annexes

Goal of the module: Master the management of a medical biology laboratory (ISO 15189 accreditation) in order to:

- understand and assimilate the requirements and specificities of the ISO 15189 standard
 - build patient confidence and optimize operational processes
 - improve sample collection, analysis and the reporting of results

1 Medical Biology Laboratory

1.1 History

A people that forgets its past condemns itself to relive it. — Winston Churchill

Medical biology laboratories (MBLs) play a critical role in the diagnosis, monitoring and prevention of diseases.

Prior to the 2000s, MBLs primarily used:

- ISO 9001 (general quality management)
- ISO/IEC 17025 (requirements for calibration and testing laboratories, though not well-suited to medical specifics)

A need for a specific standard arose to address the unique challenges faced by MBLs:

- patient safety (risk of diagnostic errors)
- traceability of samples and results
- staff competence (biologists, technicians)
- local regulations (European directives, national laws)

The first edition of ISO 15189 was published in 2003 under the title: Medical biology laboratories — Particular requirements for quality and competence.

With the following objectives:

- to harmonize MBL practices internationally
- to integrate Good Laboratory Practice (GLP) and quality requirements
- to facilitate the mutual recognition of results between countries

The structure is based on ISO/IEC 17025 (for the technical component) and ISO 9001 (for quality management).

Rapidly adopted by accreditation bodies (COFRAC in France, UKAS in the United Kingdom), the standard became a global benchmark for MBL accreditation. The first revision (2007) included:

- stronger alignment with ISO 9001 (process approach)
- method validation
- risk management (introduction of patient safety concepts)
- traceability of samples and results
- the addition of Annexes to guide implementation (examples of quality documents)

The second revision (2012) included:

- the risk approach: risk management (inspired by ISO 31000)
- a focus on patient safety:
 - requirements to identify and control risks associated with laboratory errors (incorrect sampling, contamination)
- process improvement:
 - pre-examination: strengthened requirements for sample receipt and processing

- post-examination: result validation and communication with users

The current version (2022) - Medical laboratories – Requirements for quality and competence - includes several changes:

- management system requirements are located in Clause 8
- requirements related to point-of-care testing (POCT) are in Annex A (withdrawal of the ISO 22870 standard)
- increased emphasis on risk management (Sub-clauses 5.6 and 8.5)
- addition of conflict of interest management
- transparent communication with patients and easy access to results

Under Ordinance No. 2010-49 of January 13, 2010, on medical biology - ratified by Law No. 2013-442 of May 30, 2013, reforming medical biology - accreditation is mandatory in France for:

- medical biology laboratories (LBMs)
- EFS (French Blood Establishment) facilities that perform biological qualification of donations, for activities involving medical biology testing
- facilities performing medical assistance biological activities related to reproduction

1.2 Scope

**An expert is someone who has made every possible mistake in a very narrow field.
Niels Bohr**

The scope of this module applies to the quality (management system) and competence of medical laboratories, including POCTs.

The requirements are presented in the following sections:

- 4 (General requirements)
- 5 (Structure and governance)
- 6 (Resources)
- 7 (Processes)
- 8 (Management system)
- Annex A (POCT)

1.3 Benefits

Profit is not the goal of the company, but rather a signal that the company is well managed. Peter Drucker

The benefits of ISO 15189 accreditation for a laboratory are often:

- improved diagnostic accuracy:
 - reduced errors
 - validation of examination methods
 - enhanced quality control
- complete traceability:
 - sample tracking
 - secure archiving

- proactive risk management:
 - risk identification
 - action plans
- process optimization:
 - reduced turnaround times
 - automation
 - inventory management (reduced reagent waste)
- continual improvement:
 - key performance indicators (KPIs)
 - internal audits
- international recognition:
 - accreditation = quality label
 - patient and prescriber trust
 - transparency and ethics
- competitive advantages:
 - market differentiation
 - strategic partnerships
- compliance with legal obligations:
 - compliance with local regulations
 - alignment with other standards (ISO 9001, ISO 17025, GDPR)
 - audit preparation (ANSM in France, FDA in the United States)
- legal security:
 - reduced risk of lawsuits
 - professional liability insurance (preferential rates)
- cost reduction:
 - less waste
 - fewer claims
- increased revenue:
 - attracting new users
 - access to new markets
- funding and subsidies:
 - access to public funding
 - easier investment
- training and skills:
 - skills development
 - motivation and pride
- workplace safety:
 - reduced accidents

Examples of benefits of ISO 15189:2022 accreditation:

- improved quality and reliability of results:
 - ISO 15189 accreditation establishes strict procedures for each stage of the examination process: pre-examination, examination and post-examination
 - sample traceability, equipment calibration and scientific validation of the methods used are guaranteed
 - the laboratory reduces errors and improves the reliability of results
- increased trust among patients and healthcare professionals:
 - ISO 15189 accreditation assures patients, physicians and health authorities that the analyses performed are accurate and comply with international standards
 - accreditation demonstrates the laboratory's technical competence and its commitment to patient safety

- it strengthens cooperation between laboratories and healthcare facilities
- promoting safety and risk management in the laboratory:
 - one of the major contributions of ISO 15189 is the implementation of a risk management system applied to laboratory activities
 - it encourages the prevention of nonconformities, cross-contamination and safety incidents
 - in addition to ISO 15190, it reinforces the culture of safety and health vigilance
- developing staff competence and continuing education:
 - ISO 15189 accreditation recognizes the technical and scientific competence of laboratory staff
 - it imposes requirements for qualifications, training and regular evaluation
 - this approach promotes skills development and team motivation
- improving document management and traceability:
 - the ISO 15189 standard emphasizes the rigorous management of documents, records and analysis reports
 - every action, from sample receipt to results transmission, is documented and verifiable
 - this transparency facilitates internal audits, inspections and interlaboratory comparisons
 - ISO 15189 guarantees unambiguous traceability and continual quality improvement

1.4 Principles and step

Quality is anything that can be improved. — Masaaki Imai

The quality approach is a mindset that originates with top management as a priority strategic decision and extends to the entire staff. Top management defines the quality policy, which sets out quality objectives applicable to all activities. The quality management system is the tool used to achieve these objectives. The concept of prevention is applied across the board.

Quality costs almost nothing when the patient (or user) is satisfied: they remain loyal to us. It is only when the patient is not entirely satisfied that quality comes at a high price: sooner or later, the patient will turn to a competitor.

Price is forgotten; quality remains

The seven quality management principles (cf. figure 1-1) will help us achieve sustained performance (cf. ISO 9000:2026, § 4.2)

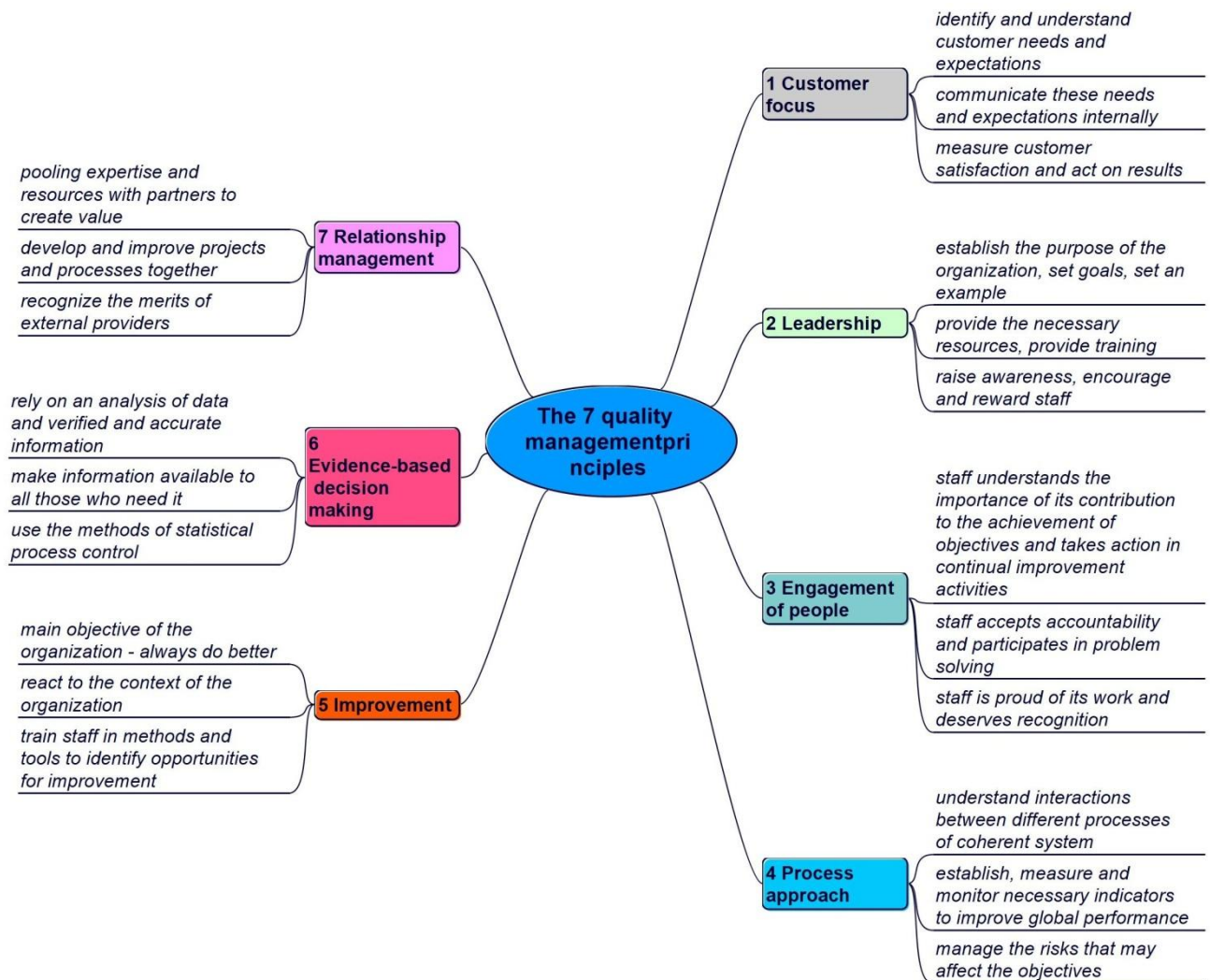


Figure 1-1. The 7 quality management principles

A well-prepared approach is half the battle won.

The process of implementing management for a medical biology laboratory (MBL) involves several stages. An example of preparation is shown in figure 1-2; cf. also [Annex 01](#). 

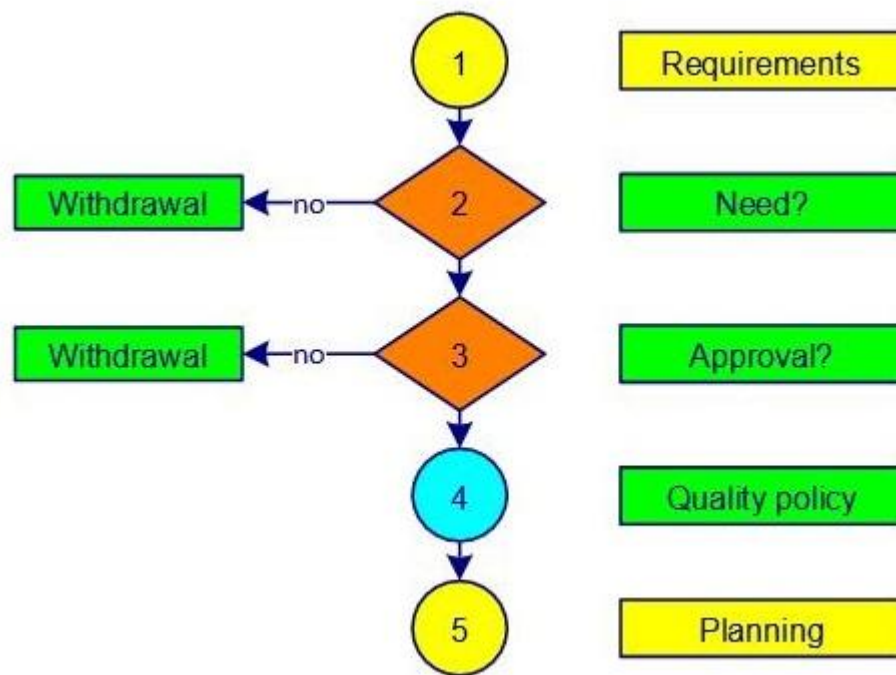


Figure 1-2. Preparation for managing an LBM

Step 1 involves identifying the needs and expectations (requirements) of stakeholders (both internal and external). Top-level management involvement is absolutely essential. Consultant advice is often sought. Contact the accreditation body (COFRAC in France).

One key question that arises very early on (Step 2) is the necessity of the decision itself. If it is not truly necessary, or if the estimated cost of the accreditation process exceeds available resources, it is best to abandon the project immediately.

The benefits of implementing a management system often include:

- improved company image
- a competitive edge
- better financial results
- increased day-to-day efficiency
- staff who are informed, consulted, motivated and proud
- promotion of best practices
- formalization of know-how
- process control
- up-to-date compliance with applicable regulations
- reduced production costs
- a mutually beneficial commitment

True story

Cerba, a private laboratory with a national network of over 100 sites, decided early on to obtain ISO 15189 accreditation. Challenges prior to accreditation:

- each site used its own methods
- no centralized system for tracking samples
- average turnaround times of 48 to 72 hours for certain analyses

Actions implemented:

- *harmonization of protocols across all sites (standardizing processes)*
- *centralized staff training (1,500 employees trained over two years)*
- *implementation of a unified Laboratory Information System (LIS) for sample traceability*
- *100% of analyses verified prior to validation*
- *participation in External Quality Assessment (EQA) programs for 90% of tests*
- *risk management for critical processes (sample collection, transport)*

Following ISO 15189 accreditation, the laboratory:

- *reduced errors by 30%*
- *cut turnaround times by 40%*
- *increased the number of examination orders by 25%*
- *won public contracts (hospitals, clinics)*
- *reduced reagent waste (improved inventory management)*
- *improved patient satisfaction (4.6/5 rating in surveys)*

The internalizing of the spirit of the principles and requirements of an ISO standard significantly improves the overall performance of your business - especially when it is not considered as a constraint, even if it is a legal obligation.

The **third step** involves determining whether the initiative has staff buy-in. An internal communication campaign regarding the management system's objectives is launched. Staff members are made aware of the process and come to understand that the project cannot succeed without their participation.

Have confidence - success will come with the involvement and effort of all!

Define the vision (what we want to be), the mission (why we exist) and the company's strategic plan. The **next step (4)** involves incorporating regulatory requirements specific to medical laboratories into the **quality policy**. If you do not yet have a copy of the ISO 15189 standard, now is the time to obtain one.

Planning is the **final step (5)** in preparing for ISO 15189 accreditation. Top management confirms the necessary resources (financial and personnel). A top management representative (often the quality manager) is appointed to lead the project. Top management's commitment is formalized in a document communicated to all staff.

The establishment and implementation of the management system (MS) are illustrated in figure 1-3.

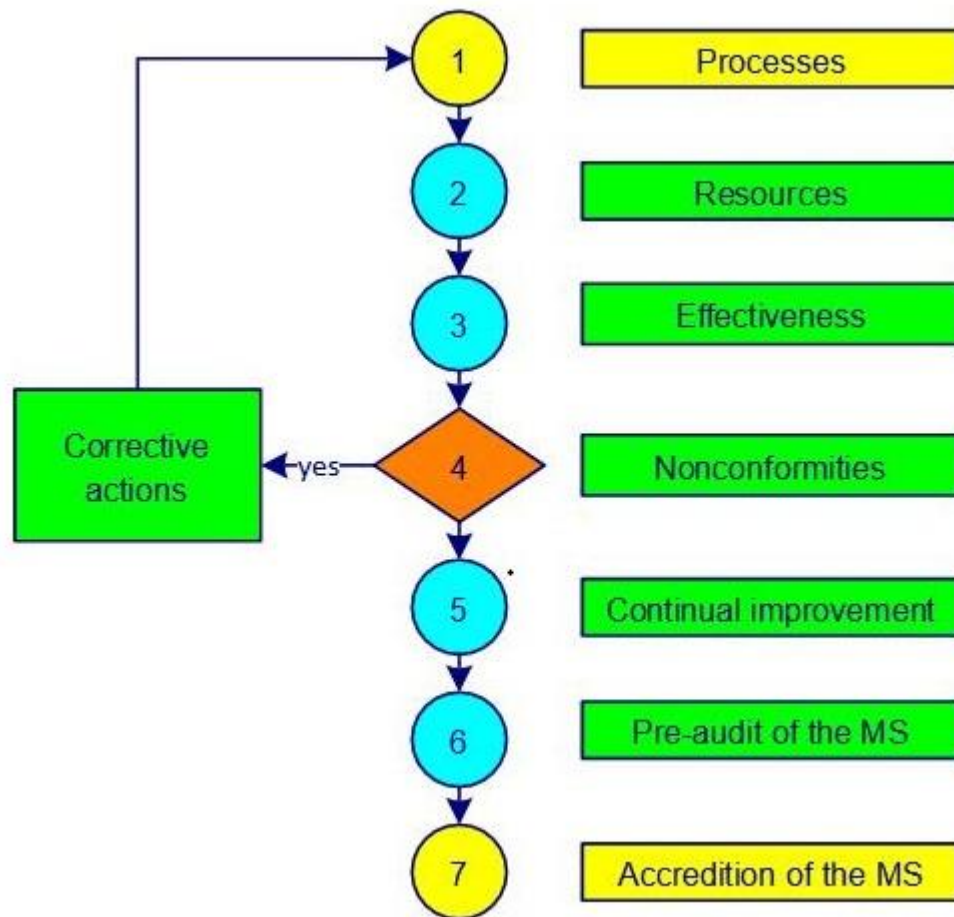


Figure 1-3. MS implementation

Step 1 involves identifying and defining processes, as well as establishing specific requirements within those **processes** and documents. New documents are created and the quality manual is updated.

In **Step 2**, the new **resources** required to achieve quality objectives are determined. A plan covering tasks, responsibilities and deadlines is established and internal auditor training is arranged.

Step 3 focuses on defining and implementing methods to measure the effectiveness and efficiency of each process (using **indicators**). Internal audits are conducted to assess the extent to which specific requirements have been implemented.

Step 4 involves cataloging all types of **nonconformities** and identifying various forms of waste. Corrective actions are implemented and documented and an approach is established to prevent nonconformities and eliminate their root causes.

An initial assessment based on data analysis is conducted in **Step 5**. A table detailing the main Costs of Quality (COQ) is completed by the individuals with access to the relevant figures. Patient feedback and other data are analyzed to evaluate the relevance and effectiveness of the management system.

To conduct the mock audit (**Step 6**), documents such as the quality manual and procedures are verified and approved by the appropriate personnel. A management review assesses compliance with applicable regulatory requirements and the quality policy and objectives

are finalized. A quality manager from another company or an external consultant can provide valuable insights, suggestions and recommendations.

Once the system is properly implemented and adhered to, obtaining COFRAC **accreditation** for the management system becomes a formality (**Step 7**).

A relevant method for assessing your management system's performance level is the RADAR logic used in the [EFQM](#) (European Foundation for Quality Management) Excellence Model, which features nine criteria and an overall score out of 1,000 points.

The PDCA cycle, or Deming cycle (figure 1-4), applies to the control of any process. PDCA cycles (Plan, Do, Check, Act) serve as a universal foundation for continuous improvement.

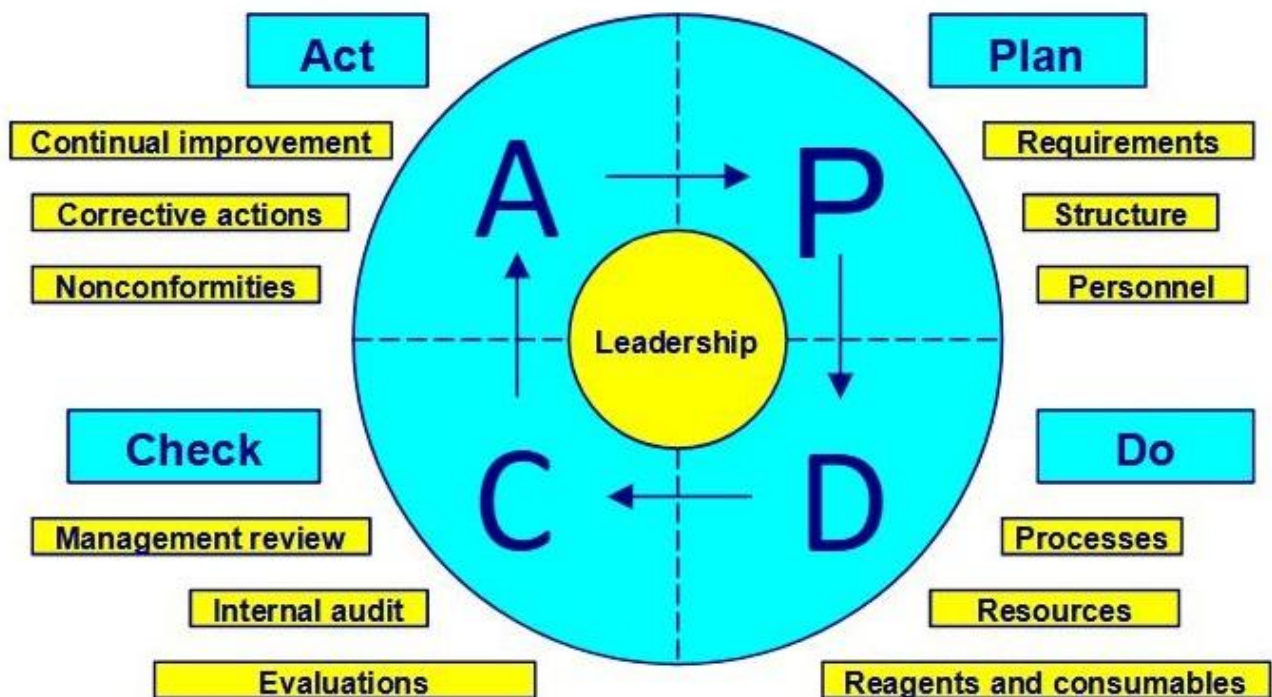


Figure 1-4. The Deming cycle

- Plan – Plan, define requirements, demonstrate leadership, manage patient rights, plan the management system and POCT activities, address risks, manage personnel (Clauses 4, 5, 6, 8 and Annex A)
- Do – Implement, manage processes, manage personnel, manage facilities, manage equipment, manage reagents and consumables, manage samples, control quality internally and within POCT activities (Clauses 6, 7, 8 and Annex A)
- Check – Compare, verify, compare performance, validate examination methods, audit, conduct management reviews, govern POCT activities (Clauses 7, 8 and Annex A)
- Act – Act, improve, control nonconformities, implement corrective actions, govern POCT activities (Clause 8 and Annex A)



To deepen your knowledge of the Deming cycle and his 14 points of management theory, you can consult the book **Out of the Crisis** by W. Edwards Deming (Economica, 2002; originally published in 1982).

2 Definitions, standards and books

2.1 Definitions

The beginning of wisdom is the definition of terms. Attributed to Socrates

Some definitions and acronyms:

Accreditation: attestation issued by a third party constituting formal recognition of competence to perform specific activities

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road

AFNOR: French Standardization Association

Analyte: substance or chemical product that is the subject of an examination procedure

ANSM: French National Agency for the Safety of Medicines and Health Products

Audit: methodical and independent examination to determine whether activities and results meet pre-established provisions and are capable of achieving objectives

Benchmarking: comparative analysis technique vis-à-vis one or more competitors

Business continuity management: method aimed at ensuring that, in the event of a crisis, critical functions remain operational or are restored as quickly as possible (see also resilience)

Business Continuity Plan (BCP): planning for business continuity management, including the approach, stages, methods and resources

COFRAC: French Accreditation Committee

Competence: personal aptitudes, knowledge and experience

Complaint: expression of dissatisfaction made to a laboratory

Conformity: fulfillment of a specified requirement

COQ: Costs of Obtaining Quality

Corrective action: action to eliminate the causes of nonconformity or any other undesirable event and prevent their recurrence

CSF: cerebrospinal fluid

Effectiveness: ability to carry out planned activities with minimum effort

Efficiency: financial ratio between the result obtained and the resources used

EFQM: European Foundation for Quality Management

EFS: French Blood Establishment

EPS: Public health institution (France)

External Quality Assessment (EQA): performance relative to criteria based on interlaboratory comparisons

FIFO: first in, first out

FMEA: Failure Mode, Effects and Criticality Analysis

GDPR: General Data Protection Regulation

GLP: Good Laboratory Practice

HIV: Human Immunodeficiency Virus

IEC: International Electrotechnical Commission

Impartiality: absence of bias and absence of conflict of interest

Inspection: actions involving measurement, testing and examination of a product, service, process, or equipment to determine conformity with requirements

Internal Quality Control (IQC): activities to verify and validate the reliability of results

ISO: International Organization for Standardization

Kaizen: from the Japanese *kai* (change) and *zen* (better). Continuous, step-by-step improvement to create more value and less waste. Approach based on common sense and staff motivation

KPI: Key Performance Indicator

MBL: medical biology laboratory

LIS: *Laboratory Information System*

LNE: *National Metrology and Testing Laboratory (France)*

Management System (MS): *set of processes enabling objectives to be achieved*

MCT: *multiple-choice test*

Measurand: *specific physical, chemical, or biological quantity subjected to a measurement process*

Measurement uncertainty (MU): *dispersion of the values attributed to a measurand*

Medical device (MD): *product or service used for the diagnosis, prevention, monitoring, treatment, or alleviation of a disease or injury*

Medical laboratory: *entity responsible for analyzing sample related to a disease or health condition*

MPE: *Maximum Permissible Error*

MS: *Management System*

Nonconformity: *failure to meet a specified requirement*

OBP: *Online Browsing Platform*

Patient: *person from whom the sample is obtained*

PCR: *Polymerase Chain Reaction*

PDCA: *Plan, Do, Check, Act*

Performance: *measurable and expected results of a management system*

POCT: *Point-of-Care Testing*

Poor quality: *gap between expected quality and perceived quality*

PPE: *Personal Protective Equipment*

Procedure: *document describing the actions to be taken to carry out a process*

Process: *activities that transform inputs into outputs*

Quality indicator: *value of a parameter, linked to an objective, allowing for the objective measurement of effectiveness*

RACI: *Responsible, Accountable, Consulted, Informed*

Record: *document providing tangible evidence of results obtained*

Reference interval: *distribution of values within a population*

Requirement: *implicit or explicit need or expectation*

Resilience: *ability to resolve a crisis and continue functioning as before*

Responsibility: *ability to make a decision independently*

Risk: *likelihood of a threat or opportunity occurring*

Safety: *absence of unacceptable risk*

SMART: *Specific, Measurable, Achievable, Realistic, Time-bound*

Sample: *portion of biological origin for examination*

Strategy: *overall approach to achieving objectives*

SWOT: *Strengths, Weaknesses, Opportunities, Threats*

System: *set of interacting processes*

Threat: *uncertain event that could have a negative impact on objectives*

UPS: *Uninterruptible Power Supply*

User: *person or entity utilizing the services of the medical laboratory*

Validation: *confirmation that the application of a process, product, service, or piece of equipment achieves the expected results*

Verification: *actions involving measurement, testing and examination of a product, service, process, or piece of equipment to determine compliance with requirements*

Waste: *anything that adds cost but no value*

In the terminology of quality management systems, do not confuse:

- **accident and incident**
 - an accident is an unexpected serious event
 - an incident is an event that can lead to an accident

- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
 - anomaly is a deviation from what is expected
 - defect is the non-fulfillment of a requirement related to an intended use
 - dysfunction is a degraded function that can lead to a failure
 - failure is when a function has become unfit
 - nonconformity is the non-fulfillment of a requirement in production
 - reject is a nonconforming product that will be destroyed
 - waste is when there are added costs but no value
- audit program and plan
 - an audit program is the annual planning of the audits
 - an audit plan is the description of the audit activities
- audit, inspection, auditee and auditor
 - an audit is the process of obtaining audit evidence
 - an inspection is the conformity verification of a process or product
 - an auditee is the one who is audited
 - an auditor is the one who conducts the audit
- cause and symptom
 - the cause is the circumstance leading to a failure
 - the symptom is the characteristic associated with a state
- control and optimize
 - control is meeting the objectives
 - optimize is searching for the best possible results
- customer, supplier and subcontractor
 - a customer receives a product
 - a supplier provides a product
 - a subcontractor provides a service or product on which specific work is done
- effectiveness and efficiency
 - effectiveness is the level of achievement of planned results
 - efficiency is the ratio between results and resources
- follow-up and review
 - follow-up is the verification of the obtained results of an action
 - review is the analysis of the effectiveness in achieving objectives
- inform and communicate
 - to inform is to give someone meaningful data
 - to communicate is to pass on a message, to listen to the reaction and discuss
- objective and indicator
 - an objective is a sought after commitment
 - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
 - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
 - an enterprise, society and company are examples of organizations
- prevention and protection, see figure 2-1
 - prevention refers to measures that reduce the likelihood and frequency of a risk occurring (e.g., checking tire pressure)
 - protection refers to measures that limit the impact of a risk (e.g., fastening one's seatbelt)
- probability, uncertainty and likelihood
 - probability represents the quantitative analysis of uncertainty
 - uncertainty is the imprecision involved in making predictions
 - likelihood represents the qualitative analysis of uncertainty
- process, procedure, product, activity and task

- a process is how we satisfy the customer using people to achieve the objectives
- a procedure is the description of how we should conform to the rules
- a product is the result of a process
- an activity is a set of tasks
- a task is a sequence of simple operations

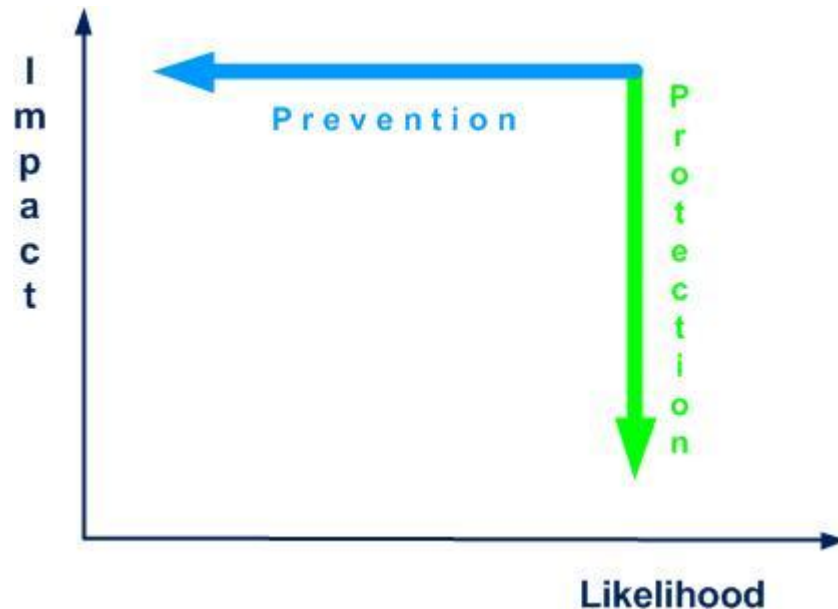


Figure 2-1. Prevention and protection

Note 1: Between "likelihood" and "probability," we prefer "likelihood" (of occurrence).

Note 2: Whenever you use the expression "opportunity for improvement" instead of "nonconformity," "malfunction," or "failure," you will further gain the trust of the person you are speaking with (patient or user).

Note 3: the use of ISO 9000 and ISO 15189 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

For other definitions, comments, explanations and interpretations not found in this module

or in [Annex 06](#) (Glossary), you may consult:



- [ISO Online Browsing Platform](#) (OBP)
- IEC [Electropedia](#)

2.2 Standards

There can be no improvements where there are no standards. Masaaki Imai



Standards related to medical biology laboratory (MBL) activities, in chronological order:

- BP Z74-700 (2011): [Business Continuity Plan](#) (BCP)

- CLSI GP36-A (2014): [Planning for Laboratory Operations During a Disaster](#)
- ISO 13485 (2016): [Medical devices](#) – Quality management systems – Requirements for regulatory purposes
- ISO/IEC 17025 (2017): [General requirements for the competence of testing and calibration laboratories](#)
- ISO 31000 (2018): [Risk management](#) – Guidelines
- ISO 14971 (2019): Medical devices – [Application of risk management to medical devices](#)
- ISO/TS 20914 (2019): Medical laboratories — [Practical guidance for the estimation of measurement uncertainty](#)
- ISO 35001 (2019): [Biorisk management for laboratories and other related organisations](#)
- IEC 31010 (2019): Risk management – [Risk assessment techniques](#)
- ISO 15190 (2020): Medical laboratories — [Requirements for safety](#)
- ISO/TR 24971 (2020): Medical devices — [Guidance on the application of ISO 14971](#)
- XP S99-223 (2020): Medical devices – [Benefit-risk ratio management](#)
- ISO 27001 (2022): Information security, cybersecurity and privacy protection — Information security management systems — [Requirements](#)
- SH REF 02 - Revision 08 (2023): [Requirements for accreditation according to standard NF EN ISO 15189:2022, COFRAC](#)
- ISO 20658 (2023): [Requirements for the collection and transport of samples for medical laboratory examination purposes](#)
- SH GTA 04 (2023): [Technical accreditation guide for the verification \(scope A\) / validation \(scope B\) of medical biology methods](#)
- ISO/IEC 17043 (2023): Conformity assessment — [General requirements for the competence of proficiency testing providers](#)
- ISO/TS 22583 (2024): [Requirements and recommendations for supervisors and operators of point-of-care testing \(POCT\) equipment](#)
- ISO 19011 (2026): [Guidelines for auditing management systems](#)
- ISO 9000 (2026): Quality management — [Fundamentals and vocabulary](#)
- ISO 15194 (2026): In vitro diagnostic medical devices — [Requirements for certified reference materials and the content of supporting documentation](#)
- ISO 22367 (2026): Medical laboratories — [Application of risk management to medical laboratories](#)
- ISO 9001 (2026): Quality management systems – [Requirements](#)

None of these standards is mandatory, but as Deming said:

There is no need to change. Survival is not mandatory.

2.3 Books



Books for further reading, in chronological order:



- Sushma Uttam Kanukale, Quality System Procedure for medical laboratories: [Complete set of QSP - ISO 15189 clauses, easy to edit template](#), Independently published, 2022

-  Gerardus Blokdyk, The Operational Excellence Library; [Mastering ISO 15189](#), 5STARCOoks, 2024
-  Tanmay Mehta, [NABL Handbook for Medical Laboratories](#): ISO 15189:2022 Simplified, Q world, 2025
-  Thierry Gatines, [Successful ISO 15189 certification](#), Thebookedition, 2025
-  David Ricketts, ISO 15189:2022 - [A Practical Guide](#), Independently published, 2026
-  David Hensley, [ISO 15189 Explained in Plain English](#): What the Medical Laboratory Quality and Competence Standard Actually Requires, Independently Published, 2026

When I think of all the books still left for me to read, I am certain of further happiness. Jules Renard

3 Process approach

3.1 Process

If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming

The word process comes from the Latin root *procedere* = go, development, progress (Pro = forward, *cedere* = go). Each process transforms inputs into outputs, creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs.



A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its external providers

A process is, among other things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documentation
- inputs
- outputs (intentional and not intentional)
- restraints
- people
- material resources
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for continual improvement

A process review is conducted periodically by the process owner (cf. [annex 02](#)).



The components of a process are shown in figure 3-1:



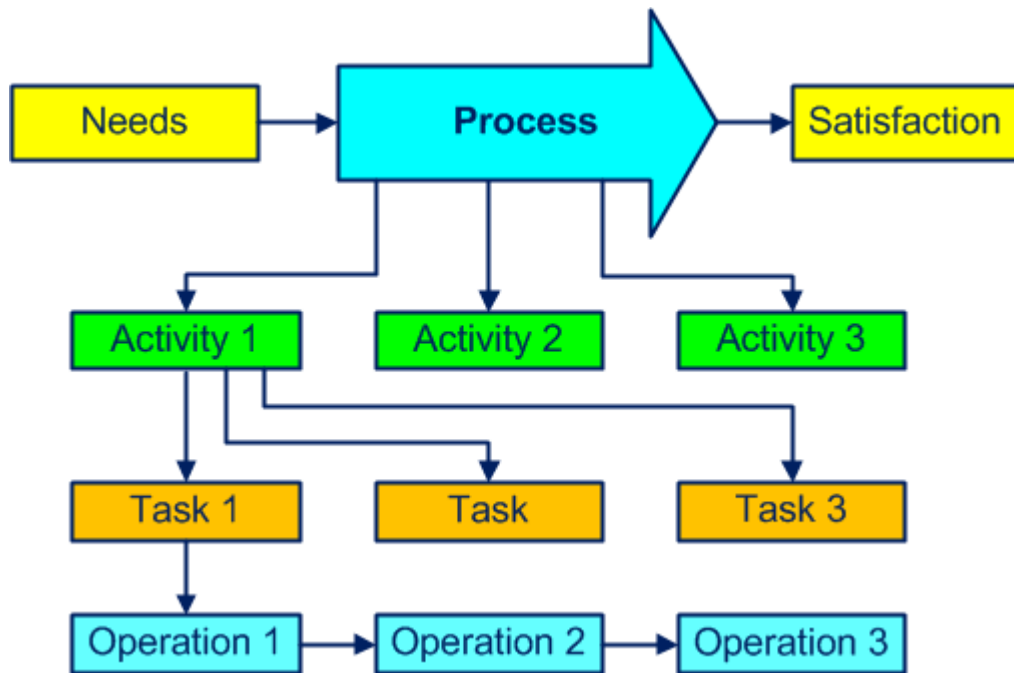


Figure 3-1. Components of a process

Figure 3-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, what objective, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

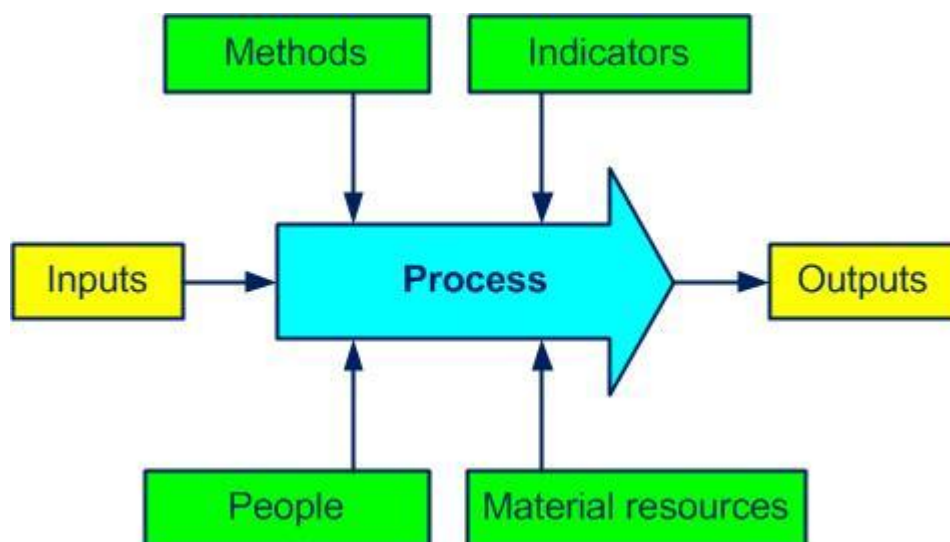


Figure 3-2. Some elements of a process

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack [D_02](#) and a list of processes in [annex 03](#). 

Any organization (company) can be considered to be a macro process, with a purpose, inputs (customer needs and expectations) and outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, production, sales) to differentiate the process from the company's department or procedure and recall the purpose of the process.

The processes are (as we shall cf. in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

3.1.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization and include elaboration of the policy, deployment of the objectives and all needed checks. They are the glue of all the realization and support processes.

The following processes can be part of this family, cf. [annex 03](#): 

- manage complaints
- address risks
- improve
- conduct an audit
- communicate
- establish process ownership
- develop strategy
- establish policy
- deploy objectives
- conduct management review

3.1.2 Realization processes

The realization (operational) processes are related to the product, increase the added value and contribute directly to customer satisfaction.

They are mainly (* mandatory):

- manage patient rights
- manage reagents and consumables
- manage suppliers
- collect samples
- transport samples
- receive samples
- secure samples
- validate examination methods
- control internal quality
- compare performance
- validate result reports
- store samples
- manage business continuity

- control nonconformities
- implement corrective actions
- govern POCTs

3.1.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- manage personnel
- manage facilities
- manage equipment
- control data
- manage documentation
- provide training
- manage inspection resources
- maintain accounts

3.2 Process mapping

Process mapping is not a drawing; it is a mirror of the organization. If the mirror is blurred, management is too

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of the ISO 15189 standard but is always welcome.

The three types of processes and some interactions are shown in figure 3-3.

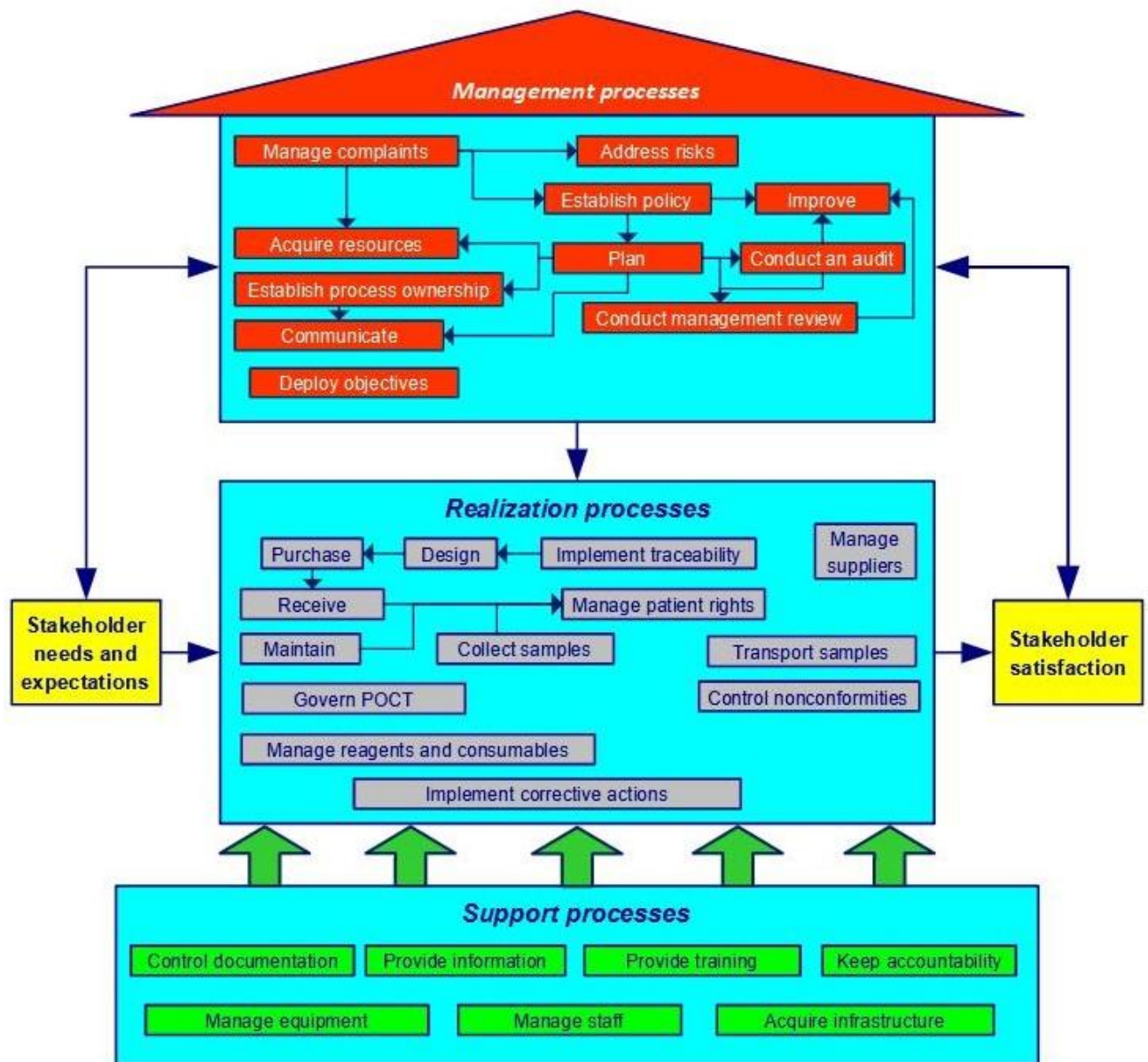


Figure 3-3. The process house

Mapping, among other things, allows you to:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process "develop the management system (MS)" can involve:

- develop strategy
- establish policy
- address risks
- manage complaints
- conduct management review
- deploy objectives

- establish process ownership
- improve
- audit

3.3 Process approach

Simple solutions for now, perfection for later

The fourth quality management principle is the "process approach" (cf. ISO 9000, 2.3.4). Some benefits include:

- gaining a comprehensive view of the organization through process mapping
- identifying and managing responsibilities and resources
- achieving effective organizational management based on process indicators
- managing risks that could impact objectives

Process approach: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

When the process approach is integrated during the development, implementation and continual improvement of an artificial intelligence management system, it allows one to achieve objectives that are related to customer satisfaction, as is shown in figure 3-4.

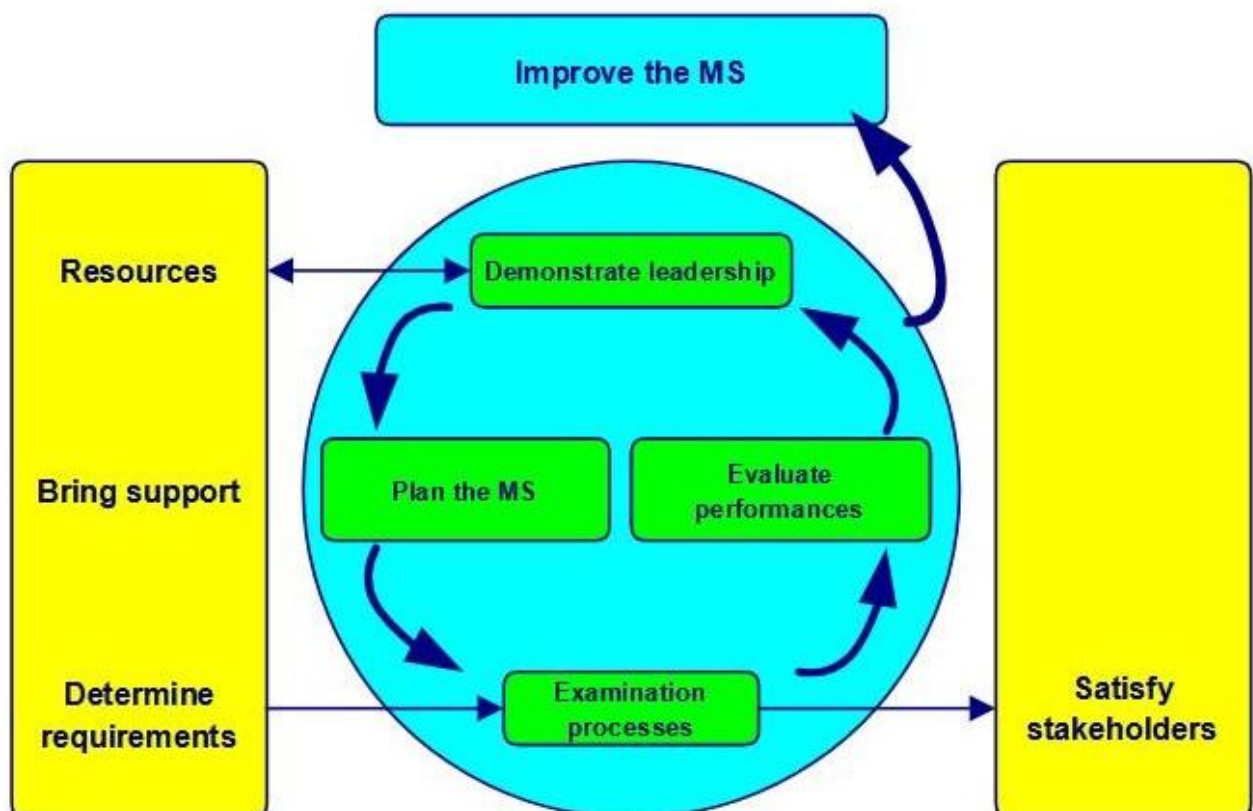


Figure 3-4. Model of an MS based on process approach and continual improvement

The process approach (cf. [annex 04](#)):

- emphasizes the importance of:
 - understanding and complying with patient requirements

- prevention so as to react to unwanted elements such as:
 - complaints
 - nonconformities
- measuring process performance, effectiveness and efficiency
- permanently improving objectives based on pertinent measurements
- process added value
- relies on:
 - methodical identification
 - interactions
 - the sequence and
 - process management, which consists of:
 - determining objectives and their indicators
 - piloting related activities
 - analyzing obtained results
 - permanently undertaking improvements
- allows one to:
 - better view inputs and outputs and their relationship
 - clarify roles and responsibilities
 - judiciously assign necessary resources
 - break down barriers between departments
 - decrease costs, delays and waste
- and ensures in the long run:
 - control
 - monitoring and
 - continual improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people ("Poor quality is the result of poor management." Masaaki Imai)
- prioritizing investments ("Use your brain, not your money." Taiichi Ohno)

4 General requirements



4.1 Impartiality

Requirements [1 to 9](#)

Quality is conformance to requirements. Philip Crosby

The 549 requirements of ISO 15189 found in the sub-clauses of clauses 4 to 8 and Annex A are shown in Figure 4-1:

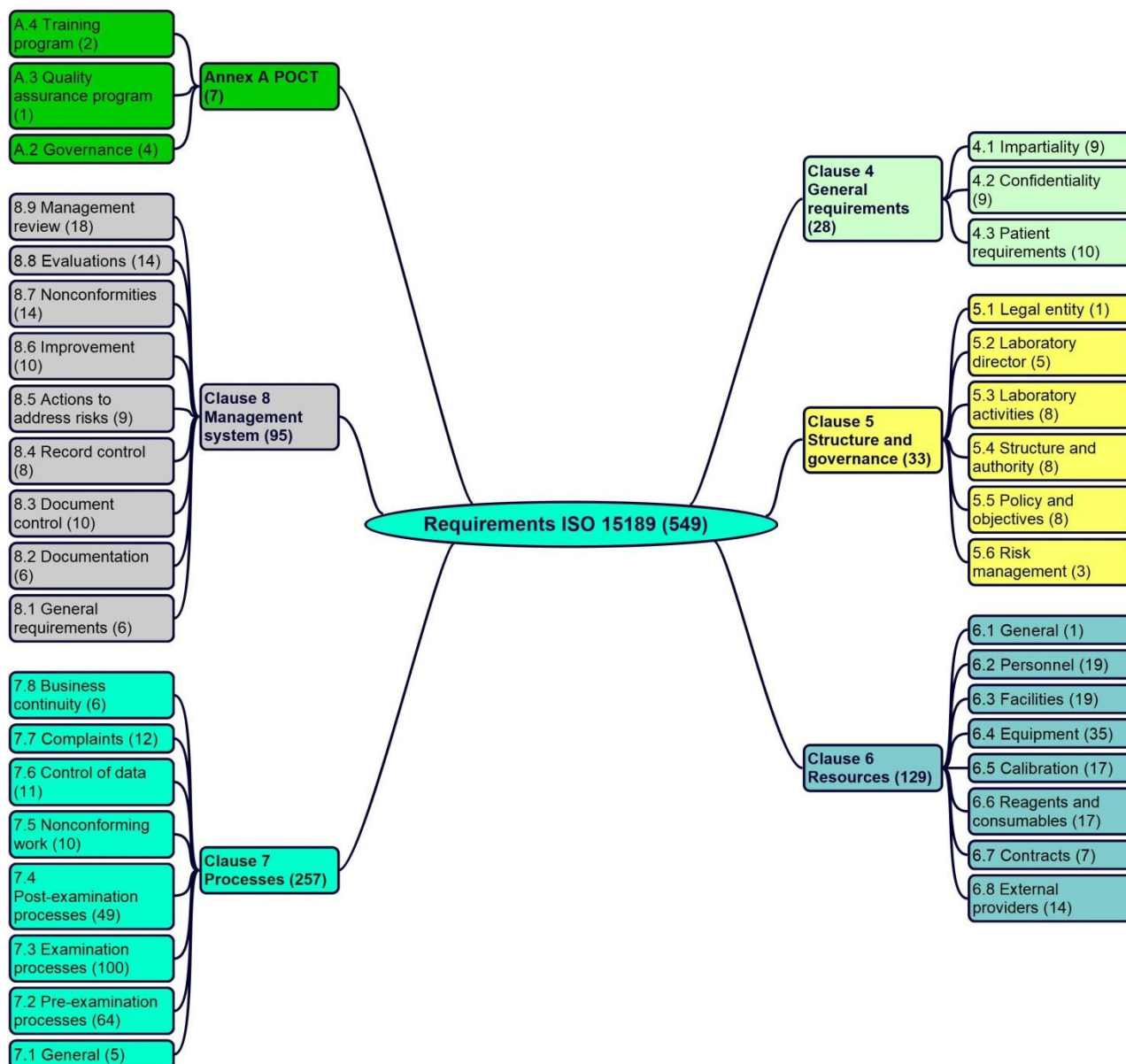


Figure 4-1. Requirements of ISO 15189

These requirements enable a medical biology laboratory to:

- improve patient care
- better satisfy laboratory users
- prevent risks
- seize opportunities for improvement

- increase the efficiency of the management system

Impartiality is like beauty: it is up to others to judge it. – Eric Dupont-Moretti

Impartiality is a fundamental principle ensuring that analysis results are:

- objective (uninfluenced by conflicts of interest)
- reliable (based solely on scientific and technical criteria)
- transparent (free from bias linked to commercial, financial, or personal pressures)

The laboratory demonstrates its impartiality in all its activities, particularly regarding:

- medical analyses (diagnostics, screening)
- quality-related decisions (result validation, nonconformity management)
- relationships with stakeholders (staff, patients, referring physicians, suppliers)

Impartiality is a non-negotiable requirement:

- all threats to impartiality are identified, documented and managed
- top management plays a central role in ensuring impartiality
- transparency and communication are essential to maintaining trust

Practical tools (code of conduct, ethics committee, conflict of interest register) help meet this requirement. Every employee signs a Declaration of No Conflict of Interest on their first day of work (cf. [annex 05](#)).

The laboratory identifies threats to impartiality by:

- identifying situations where its impartiality could be compromised
- documenting these threats (in the risk register or a SWOT analysis report)
- assessing their severity (high, medium, or low risk)

Examples of threats to impartiality:

Threat (source of risk)	Concrete example	Potential impact	Mitigation measure
Conflict of interest	A laboratory employee is also a reagent supplier	Bias in reagent selection (favoritism)	Establish an independent purchasing committee to select suppliers
Commercial pressure	A client (e.g., a clinic) demands unrealistic turnaround times for results	Errors or unreliable results	Train staff to resist pressure and clearly communicate limitations
Personal relationships	A biologist has a family connection to a referring physician	Influence on result interpretation	Exclude the staff member concerned from analyses linked to that physician
Unfair competition	The laboratory offers preferential rates to certain clients	Unequal treatment of patients	Apply the same rates and turnaround times to all clients
Supplier influence	An equipment manufacturer offers perks (e.g., free training)	Biased equipment selection	Establish objective criteria for equipment selection (performance, cost)
Insurer	A health insurer	Unreliable results	Establish an independent

pressure	mandates testing protocols that do not comply with GLP		committee to select insurers
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Examples of internal communication (posted on the premises):

"Our laboratory is committed to ensuring the impartiality of its analyses. Any conflict of interest must be reported to the Quality Manager."

True story

A laboratory purchases reagents from a supplier whose sales director is a former employee of the laboratory.

- *risk identified: conflict of interest (risk of favoritism in the selection of reagents). Severity: 4/5 (high risk to the quality of analyses)*
- *Documentation: the risk is recorded in the risk register*

Mitigation measures:

- *creation of an independent purchasing committee (comprising biologists and technicians)*
- *exclusion of the supplier in question from purchasing decisions*
- *transparent tendering process for all suppliers*
- *staff informed of the impartial purchasing procedure*
- *ethical guidelines displayed on the premises*

Good practices

- *gifts from suppliers comply with the laboratory's ethical rules*
- *a declaration of no conflict of interest is signed by every employee*
- *an ethics group oversees impartiality issues*
- *regular workshops featuring case studies on conflicts of interest, impartiality and ethics*
- *the audit program includes auditing compliance with impartiality requirements*

Bad practices

- *no documentation regarding the analysis of impartiality-related risks*
- *limited analysis of impartiality-related risks (covering only management)*
- *absence of an ethics policy (no rules governing gifts and benefits)*
- *staff unable to define a conflict of interest*
- *no management commitment to impartiality*

4.2 Confidentiality

Requirements [10 to 18](#)

You don't entrust chickens to a fox. Estonian proverb

Confidentiality is an ethical and legal cornerstone for medical biology laboratories, as they handle sensitive health data (examination results, diagnoses, personal information) belonging to patients, referring physicians and partners. Requirements to be met include:

- protecting data against unauthorized access, leaks, or misuse
- guaranteeing patient rights (right to be forgotten, data access)
- complying with local and international regulations (GDPR in the EU, HIPAA in the United States, the Data Protection Act in France)

Top management makes a written commitment to ensure that all information (regarding patients, referring physicians and results) is protected.

Example of a formal document outlining the confidentiality rules applied by the laboratory:

"Top management of [Name] Laboratory is committed to protecting the confidentiality of all medical and personal information in accordance with ISO 15189:2022 and the GDPR. Any unauthorized access or disclosure is strictly prohibited and subject to sanctions."

Example of a confidentiality matrix:

Level	Examples	Protection measures
Public	Quality policy, organizational chart	Open access, public distribution
Internal	Internal procedures, audit reports	Personnel-only access, authentication
Confidential	Patient results, medical data	Encryption, restricted access, logging
Secret	Genetic data, HIV tests	Enhanced encryption, highly restricted access, regular auditing

Personnel communication:

- mandatory training for all personnel (including temporary workers and external contractors) on:
 - legal obligations (GDPR, medical confidentiality)
 - internal confidentiality procedures
 - penalties for noncompliance
- signing of a confidentiality agreement by each employee

Information protection includes the following measures:

- technical:
 - data encryption
 - secure storage
- organizational:
 - information classification (public, internal, confidential, secret)
 - logging of access to patient records
 - securing of premises
- legal:
 - GDPR compliance
 - confidentiality agreements with external contractors

True story

To secure access to its premises and IT systems, a laboratory implemented the following measures to comply with ISO 15189 requirements:

- *physical access: personalized badges for all employees, restricted-access areas (server room, archives), logging (badge + camera)*
- *digital access: individual accounts for each employee, two-factor authentication for critical systems, automatic account deactivation after 3 failed login attempts*
- *access audit: monthly review of access logs to detect anomalies, automatic alerts for suspicious access (e.g., login from a foreign country)*

Good practices

- *a confidentiality agreement is signed by all employees*
- *a designated person is responsible for GDPR compliance*
- *data protection includes the management of unauthorized access*
- *regular training on GDPR, medical confidentiality and best practices*
- *access logs are monitored monthly*
- *secure destruction of data and documents*

Bad practices

- *screens visible to the public at the reception desk*
- *examination results announced aloud near the reception area*
- *a shared login ID used by several employees*
- *computers connected to the Laboratory Information System (LIS) left logged in without automatic locking*
- *disclosing sensitive results without verifying the exact identity of the person on the line*
- *documents containing personal data discarded in standard trash bins*

4.3 Patient requirements

Requirements [19 to 28](#)

A doctor's skill lies in discovering an ailment in a patient that both of them can live with. Albert Willemetz

Each medical biology laboratory places the patient at the heart of its management system in order to respect their rights, needs and expectations, while ensuring the safety, confidentiality and quality of the services provided.

The purpose of the "Manage patient rights" process is to safeguard patient well-being and safety and to ensure respect for patient rights, cf. [Annex 03](#), includes the requirement to

inform patients about: 

- services offered (examination methods, turnaround times, costs)
- communication channels (website, waiting room signage, patient information leaflets)
- results (format, interpretation, periodic review, delivery methods)
- incidents affecting patients and actions taken
- patient rights:
 - to information
 - to informed consent:
 - to access their data and results
 - to rectification
 - to protection
 - to be forgotten

- to confidentiality
- to lodge a complaint
- laboratory obligations (confidentiality, quality, safety, non-discrimination)
- communication tailored to specific patient needs (elderly, disabled, non-English speakers)

Good communication practices:

- simple language:
 - avoid medical jargon in patient-facing communications
 - use adapted explanations (diagrams, infographics for results)
- accessibility:
 - formats adapted for people with disabilities (Braille, audio, large print)
 - translation for non-English speaking patients (Spanish, Arabic, depending on the local population)
- multiple communication channels:
 - online patient portal (secure access to results)
 - mobile app (notifications for results)
 - dedicated customer service (telephone line or live chat)
- the laboratory informs patients of their rights, specifically:
 - right of access to their data (results, medical records)
 - right to rectification (correcting errors in their data)
 - right to be forgotten (data deletion after the statutory retention period)
 - right to consent (for genetic testing or research)
 - right to lodge a complaint (in the event of an error or delay)
- the laboratory must inform patients in the event of:
 - error in results (sample mix-up)
 - significant delay (turnaround time exceeded by more than 48 hours)
 - breach of confidentiality (data leak)

The laboratory identifies patient needs and expectations by:

- gathering patient feedback (satisfaction surveys, suggestion boxes, discussions)
- analyzing data to identify trends (excessive turnaround times, results that are difficult to understand)
- segmenting patients to tailor services (chronic patients, emergency cases, children)

Examples of responses to patient expectations:

- improving turnaround times:
 - automation of routine examinations (hematology, biochemistry)
 - workflow optimization (24/7 sample reception)
- clarifying results:
 - explanatory sheets for complex examinations (genetic tests)
 - interpretation by a biologist for abnormal results
- facilitating access:
 - home sample collection for patients with reduced mobility
 - extended hours for sample collection (early morning, weekends)
- personalizing care:
 - specific protocols for chronic patients (regular monitoring for diabetics)
 - tailored communication for children or the elderly

An audit at the laboratory revealed that some patients were dissatisfied with the transparency of public information.

Actions implemented:

- a dedicated patient webpage was launched: patients can view average result turnaround times, pricing and sample collection procedures; they can also complete a satisfaction survey*
- explanatory leaflets made available in waiting rooms, detailing examination procedures, average turnaround times for routine analyses (blood glucose, liver function tests) and contact details for inquiries*

Results:

- no complaints regarding public information at the subsequent audit*
- patient satisfaction survey showed 98% positive responses*

Good practices

- patient rights are fully upheld*
- results communicated to patients are validated and traceable*
- patient needs and expectations are identified and respected*
- communication with patients is clear and accessible*
- the complaints process is simple and accessible*

Bad practices

- results sent without explanation*
- turnaround time not communicated to patients*
- information sheets too technical for patients*
- lack of privacy during sample collection (partially open collection room)*
- written consent not requested for sensitive tests (HIV test, genetic testing)*
- patient not informed of common side effects (bruising, dizziness)*
- language barriers unaddressed (non-French speakers or the hearing impaired)*