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Proposal of a quality management design based on the ISO 17025-2005 standard in the clinical laboratory of the "Enrique Ponce Luque" Health Center belonging to the health district 12d01 of the city of Babahoyo - Los Ríos - Ecuador.

Propuesta de un diseño de gestión de calidad basado en la norma ISO 17025- 2005 en el laboratorio clínico del Centro de Salud "Enrique Ponce Luque" perteneciente al distrito de salud 12d01 de la ciudad de Babahoyo – Los Ríos – Ecuador.

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Abstract
The authors conducted a clinical laboratory diagnosis through observation, followed functioning of the laboratory on separate days to assess specific aspects included in a checklist based on ISO 17025-2005, plus its own analysis interviews were conducted to all workers to collect data from their perspective and obtain verifiable data, this information was subsequently processed and analyzed in a cause-and-effect diagram ISHIKAWA. Results: 80% of the requirements from the checklist are not meted, partially implemented requirements were 14.29 % and finally 5.71% implemented requirements are met. Conclusions: Overall compliance was low; this allows us to conclude that in terms of calibration and traceability clinical laboratory Enrique Ponce Laquez does not have the minimum requirements for operation in accordance with international standards.

key words Agency, Law, quality, laboratory.

Resumen
Los autores realizaron un diagnóstico del laboratorio clínico a través de la observación, siguieron el funcionamiento del laboratorio clínico en días separados para evaluar aspectos específicos incluidos en una lista de chequeo basada en la norma ISO 17025-2005, además de su propio análisis se realizó entrevistas a todos los trabajadores para recolectar datos desde su perspectiva y obtener datos verificables, esta información fue posteriormente procesada y analizada en un diagrama causa efecto ISHIKAWA. En los requisitos que conforman la lista de verificación, el 80% de los requisitos no se encuentran implementados, los requisitos parcialmente implementados fueron el 14,29% y finalmente se encontró un 5,71% de requisitos implementados. El cumplimiento general fue bajo, esto nos permite concluir que en cuanto a calibración y trazabilidad el laboratorio clínico Enrique Ponce Luque no posee los requerimientos mínimos para su funcionamiento acorde a las normas internacionales.

Palabras clave Organismo, Ley, calidad, laboratorio.

1. Introduction

Internationally, regulatory bodies for clinical laboratories vary from country to country. However, organizations such as the Clinical and Laboratory Standards Institute (CLSI) and associations such as the Research Quality Association (RQA) exist to promote a more global approach to the regulation of clinical laboratories [1] .

Adicionalmente existen los estándares de buena práctica Additionally, there are the good laboratory practice standards, originated in 2002 and adopted since then by the WHO. This tells us that there are non-governmental organizations and research institutions around the world that provide guidelines for implementing correct practices that are essential for the operations performed by laboratories around the world..

The WHO is responsible for advising countries on the creation or access to laboratory services, specimen transportation systems, biological risk management and laboratory quality systems, so that they can fulfill the commitments they have contracted under the International Health Regulations (IHR) [2].

The IHR is a legally binding international instrument, involving 194 countries, all those member states of the WHO; whose objective is to collaborate with the international community for the prevention and confrontation of acute public health risks that have the ability to cross borders and endanger populations worldwide [3].

In Ecuador, we have the Ecuadorian Accreditation Service (SAE), which is the official body for accreditation matters. SAE is a public law technical entity, which has legal status, autonomy in its

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administration, economy, finances and operations; and is non-profit. Its headquarters is in the city of Quito and its powers are nationwide, this organization is governed by international guidelines and practices, those mentioned above [4].

The SAE grants accreditation, in accordance with the standards of international bodies, the technical competence of those organizations that request it in the field of conformity assessment, in addition it is responsible for the coordination of the signing of mutual recognition agreements, supervision of accredited entities and determination of technical conditions required to provide services to third parties. In the same way, it has the function of promoting accreditation in all scientific and technological areas, disseminating the advantages of accreditation [5].

The SAE [6] also uses the ISO 17025-2005 standard for the accreditation of clinical laboratories. The ISO 17025-2005 standard is an international standard created by the International Organization for Standardization (ISO), which establishes the necessary requirements that testing and calibration laboratories must meet, this standard is used by laboratories to demonstrate their technical competence and ability to provide valid results [7].

At present Ecuador has 1419 Health Centers that provide free services to the community, these are distributed as follows: 648 in the urban sector and 771 in the rural sector, within these we can find 88 clinical laboratories that provide their services to health centers which are located between Coast, Highlands and East in order to provide quality and warmth care to all users and meeting their needs. All these centers are under the Rectorship, regulation, planning, coordination, control and management of the Ministry of Public Health of Ecuador (MSP).

In Ecuador there are three clinical laboratories accredited by SAE:

- Pazmiño and Narváez Clinical Laboratory in the city of Quito, the accredited field is chemistry and immunochemistry.
- Matlab S.A Laboratory in the city of Quito, the accredited field is hematology, chemistry, immunochemistry and coagulation.
- Illingworth Center Laboratory S.A in the city of Guayaquil, its accredited field is hematology, chemistry and immunochemistry.

The Enrique Ponce Luque Health Center has been providing health services to patients since it started operating on June 2, 1989, being accredited as an inclusive health center on December 6, 2015. In its beginnings it only provided general medical services and it was on March 3, 2002 when the construction of an area destined to clinical laboratory began due to the large influx of users, in this way it began to function on February 2, 2003 with a work team made up of 4 employees. It currently has 12 people; 1 pharmacist, 7 licensed in clinical laboratory, 3 assistants and 1 technologist.

1.1 Quality in clinical laboratories

The importance of quality in the operation of health laboratories in developing countries has been universally recognized. Laboratories practicing quality assurance principles generate relevant, reliable and cost-effective results [8].

Quality means meeting standards. Standards are requirements for a particular substance or service predetermined. Quality is extremely important in laboratories, reliable results produced by a clinical laboratory help improve physicians' decision-making ability which in turn affects public health [9].

The consequences of poor quality could be serious; it could lead to appropriate or inappropriate action or lack of action in a treatment, or research, lack of treatment or inadequate research generates late or suboptimal responses, as a consequence of poor quality laboratory services could negatively affect the credibility of the laboratory and also invite legal action [10].

A well-defined quality system that is part of the overall management of a health organization is intended to ensure consistency, reproducibility, traceability and effectiveness of products or services. Consequently, a quality system is defined as the organizational structure and resources needed to implement quality requirements [11].

The International Organization for Standardization (ISO) defines that a quality system consists of the organization of the structure, responsibilities, procedures, processes and resources for the implementation of quality management [12].

A quality system has the following five key elements:

- Management and organizational structure
- Documentation
- Monitoring and Evaluation
- Training
- Quality standards [13].

2. Materials and methods

In order to obtain the data for this research, the authors make a diagnosis of the clinical laboratory through the

observation of the areas related to it, the assessment is considered essential to verify the need to implement an international standard, in addition to their own analysis the authors conduct interviews with all the workers of this laboratory to obtain their diagnosis on the deficiencies of the place, this information is subsequently processed and analyzed [14].

2.1 Research instrument

Checklist
The authors observed the operation of the clinical laboratory on several separate days, to determine its shortcomings in specific aspects included in a checklist based on the ISO 17025-2005 standard. This list is divided into the following criterio:

Aspects evaluated in the organization
- Management System
- Document Control
- Review of orders, bids and contracts. Subcontracting and calibration tests.
- Purchasing services and supplies.

These requirements were classified as; implemented, partially implemented and not implemented according to what was observed by the authors at the Enrique Ponce Luque laboratory.

2.2 Interview
All collaborators were interviewed to collect this data from the worker's perception, this information was processed to obtain relevant and verifiable data.

2.3 Cause and effect diagram
This was the beginning of the research with an ISHIKAWA or cause and effect diagram where all data is recorded once analyzed.

2.4 Population and Sample
The Enrique Ponce Luque clinical laboratory has a population of 12 people. Since it is a small population, the entire population is selected as a sample.

Table 1. Distribution of staff in the laboratory

Distribution of staff at the clinical laboratory at the "Enrique Ponce Luque" health center		
Profession	**Male**	**Femaler**
Pharmacist	1	0
Clinical laboratory technician	3	4
Lab assistant	0	2
High school graduate	0	1
Laboratory technologist	0	1

2.5 Advantages of the management design proposal based on the ISO 17025-2005 standard

With the management design proposal of the ISO 17025-2005 standard in the laboratory, we can achieve advantages that help change many processes that are not aligned with the requirements established by the MSP.

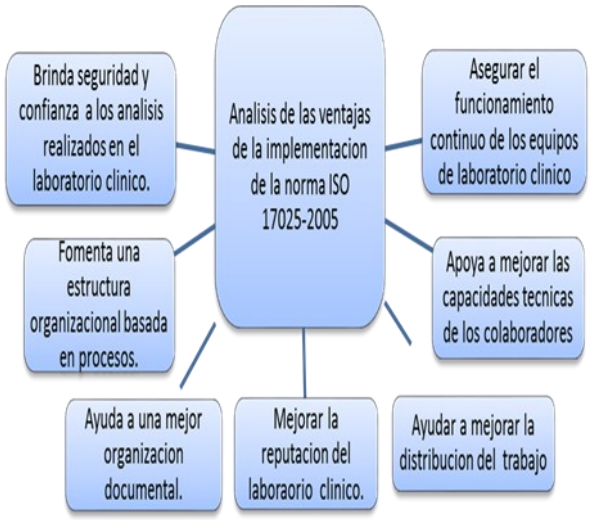

Fig. 1. *Advantages of implementing the ISO 17025 standard*

3. Results
After the analysis carried out with the checklist, the following results were obtained that verify the current state of the Enrique Ponce Luque laboratory. This list is divided into 2 criteria; organization and technical requirements which in turn are divided.

The criteria observed in the organization are; management system, document control, review of orders, bids and contracts, subcontracting of tests and calibrations, purchasing of services and supplies, customer service, complaints, control of nonconforming testing or calibration work, improvement, corrective actions, preventive actions, risk control internal audits and management review. The aspects assessed in technical requirements are; personnel, facilities and environmental conditions, test and calibration methods and method validation, equipment, traceability of measurements, sampling, handling of test or calibration items, assurance of test and calibration results quality and reporting results. These requirements were classified as; implemented, partially implemented and not implemented using observation and survey methods for collaborators.

Making a global assessment of all the requirements that make up the checklist, it can be seen that most of the criteria are not implemented, these being 80%, followed by partially implemented requirements obtained a percentage of 14.29% and finally 5.71% of requirements were found implemented.

Fig. 2. *General compliance*

3.1 Requirement results:

3.1.1 Organization

Based on the comparison of section 4.1 and laboratory processes, it can be seen that only 30.77% of the requirements are implemented in the laboratory, 23.08% are partially implemented requirements and finally 46.15% of the requirements are not implemented.

Compliance with the requirements reaching 30.77% originates from:

- The legal obligations of the laboratory, since these are kept up-to-date and in order, taking into account that said laboratory belongs to a public body (MSP).
- Evidence of the organization chart, and description of the person in charge of the laboratory.
- Definition of backups for all laboratory staff and constant training on the impact that malpractice in the laboratory can cause.

The partially implemented requirements consist of:

- Although key staff responsibilities were established, these are not documented and are communicated verbally.
- The laboratory has management and technical staff, but not everyone has the appropriate profile to carry out the assigned activities.
- It has policies to ensure the protection of confidential information and customer rights, communication is done verbally, since there are no documented policies.

Fig. 3. *Organization*

3.1.2 Management system

At this point it can be seen that the laboratory does not execute any of these requirements.

It partially complies with 14.29%, since management informs its collaborators how important it is to comply with customer, legal and regulatory requirements, but there is no evidence of training records to comply with said requirements.

Finally, the unimplemented requirements make up 85.71%..

Fig. 4. *Management System*

3.1.3 Document control

In the requirements related to Document Control, it can be seen that the laboratory does not have any implemented requirements.

The partially implemented requirements cover 14.29% since they have documents that are identified by issue date, etc., however, these formats are filled out discontinuously because they are not always available due to lack of resources.

85.71% of the requirements are not implemented because changes to the documentation are made by the person in charge of the laboratory under their own criteria, the modifications are made verbally and procedures are not defined to assign those responsible for the documents.

Fig. 5. *Documentary control*

3.1.4 Review of orders, bids and contracts

With regard to the review of orders, bids and contracts, it can be seen that 100% of the requirements of this section are not implemented.

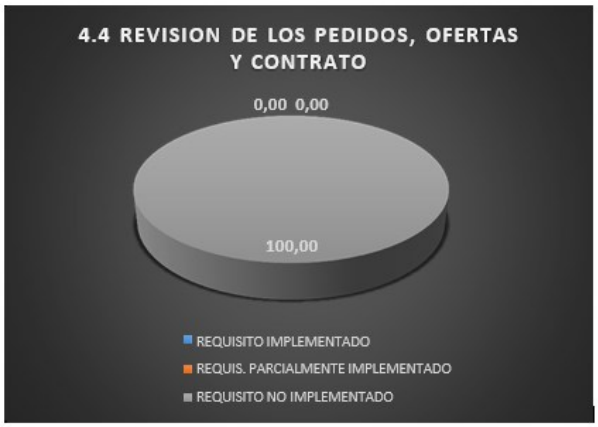

Fig. 6. *Review of orders and contracts*

3.1.5 Subcontracting tests and calibration

This graph shows that 100% of the requirements of this section are not implemented in the laboratory.

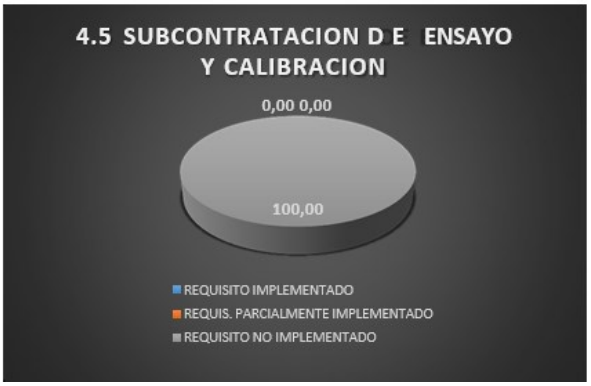

Fig. 7. *Subcontracting tests and calibration*

3.1.6 Purchase of services and supplies

The results in this section show that the laboratory complies with 25% of the requirements for purchasing services and supplies; they make the requisitions in the presence of requested supplies for the laboratory; once they arrive, a review is made of; batches, code, description, name and expiration date, additionally they review that any reagent arriving at the laboratory must have a certificate of analysis.

Fig. 8. *Purchasing services and supplies*

3.1.7 Customer service

We can see that the laboratory does not comply with any of the requirements corresponding to customer service, therefore 100% of requirements are not implemented.

Fig. 9. *Customer service*

3.1.8 Corrective actions

In the requirements that include Corrective Actions, it can be seen that the laboratory does not have any implemented or partially implemented requirements, as we can see in Graph 10.

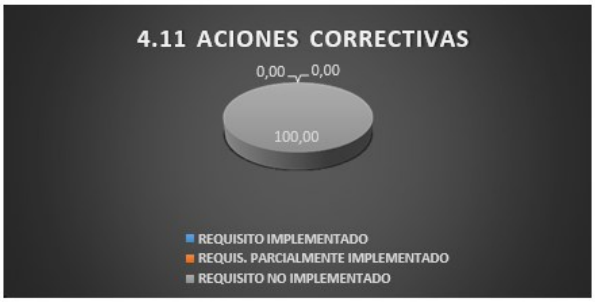

Fig. 10. *Corrective actions*

3.1.9 Preventive actions

In Graph 11 we can see the requirements regarding preventive actions carried out by the laboratory, the percentage corresponding to unimplemented requirements is 100%.

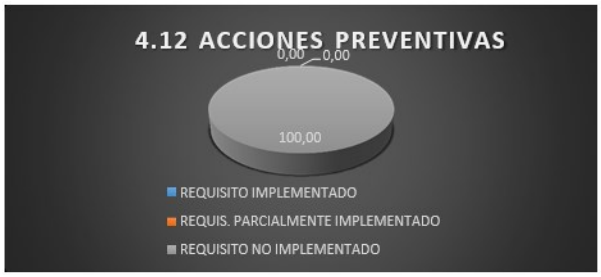

Fig. 11. *Preventive actions*

3.1.10 Control de riesgos

In Graph 11 corresponding to section 4.13 of the ISO 17025-2005 standard, it reflects that 33.33% of the requirements are partially implemented since:

- The records are stored after being generated or handled, but all are exposed to future damage and deterioration because these documents are not in an adequate environment.
- The records are kept on shelves, but these are not safe sites that guarantee preservation and confidentiality.
- Graph 4.13 reflects 66.67% which is caused by the following reasons:
- The laboratory does not have procedures to protect and safeguard electronically stored records and prevent unauthorized access.
- When there is a mistake in any record they repeat it since for them it is essential to keep the records legible but they eliminate the data that is corrected.

Fig. 12. *Risk control*

3.1.11 Internal audit

Graph 13 shows the absence of implemented requirements related to internal audits, with 100% not implemented.

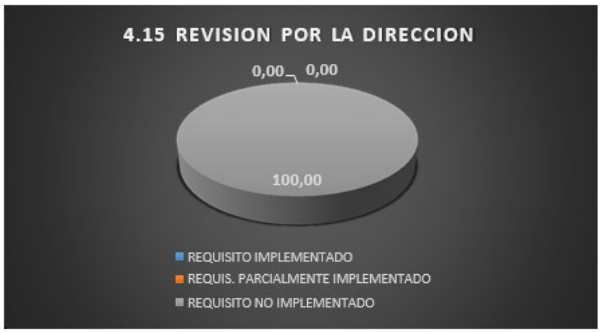

Fig. 13. *Management review*

3.1.12 Staff

In section 5.2 referring to staff you can see that most of the sections partially comply, occupying 80% of the pie chart, all this happens:

- Since the collaborators who operate the equipment have experience, but management does not carry out evaluations to ensure that operators can easily handle certain equipment.
- Job profiles have been created for the laboratory, but there are still people without adequate training occupying positions that do not match the required profile.
- The person in charge of the laboratory is directed and controlled by a supervisor, but there are no indicators that measure their competence.
- It is evident that the laboratory has job profiles, but the last time they were updated was in 2013.

Fig. 14. *Staff*

3.1.13 Facilities and environmental conditions

Since this is a laboratory that has to keep in mind the conditions and facilities arranged to carry out its activities, it is possible to identify that of all the requirements of section 5.3 of the 17025-2005 standard, partial compliance is reflected, being 20%, since the laboratory has environmental conditions in which activities can be carried out such as: lighting and space, but there are gaps that do not help privacy, running the risk of cross-contamination of samples in processes.

80% of the requirements on facilities and environmental conditions are not implemented.

Fig. 15. *Facilities and environmental conditions*

3.1.14 Test and calibration methods and method validation

In the laboratory, test methods are carried out, but it does not have the necessary equipment for handling and performing the tests.

In these criteria corresponding to the calibration and test method and method validation, they partially comply with 66.67% and the criteria that are not met are focused on 33.33%

Fig. 16. *Test, calibration and method validation*

3.1.15 Equipment

In the laboratory it is evident that the equipment is identified with the respective name of the equipment and its code, for complying with this requirement of section 5.5, it is reflected that in the pie chart it occupies 8.33%.

The partially implemented requirements are observed in graph 5.5 which occupy it. In the laboratory it is evident that the equipment is identified with the respective name of the equipment and its code, for complying with this requirement of section 5.5, it is reflected that in the pie chart it occupies 8.33% . since the equipment has the authorization sheet which mentions the people authorized to use them, but does not include instructions for handling the equipment.

The requirements that are not implemented make up 83.33% since the equipment is subjected to overload, because they are not recorded as out of service, but continue to be used regardless of whether the useful life has expired.

Fig. 17. *Equipment*

3.1.16 Traceability of measurements

In the section on traceability of measurements, 100% of the requirements are not implemented.

Fig. 18. *Traceability of measurements*

3.1.17 Sampling

The laboratory does not have a plan and procedures for sampling and data recording, therefore, unimplemented requirements cover 100% of graph 5.7.

Fig. 19. *Sampling*

3.1.18 Handling test or calibration items

In Graph 20 we can see that no requirement is implemented.

Fig. 20. *Handling test or calibration items*

3.1.19 Assurance of test and calibration results quality

100% of the requirements in this section are not implemented.

Fig. 21. *Quality assurance of test and calibration results*

3.1.20 Reporting results

The results reports made by the laboratory do not comply with the guidelines required by this section, which reflects that 100% of the requirements are not implemented.

Fig. 22. *Results reports*

4. Conclusions

Based on the work carried out in the Enrique Ponce Luque clinical laboratory, it was concluded that:

These are some of the characteristics required by the ISO 17025-2005 standard, as we could observe, general compliance was low, this allows us to conclude that in terms of calibration and traceability, the Enrique Ponce Luque clinical laboratory does not have the minimum requirements for its operation according to international standards.

Although in our study the standard was not implemented, a notorious difference can be seen and we can expect great benefits for the institution and the community it serves.

The implemented requirements cover 5.71% and make up the responsibilities of key personnel, but these are communicated in a verbal way, that is, they are not documented, there is sufficient management and technical staff, however, not all staff have the appropriate profile to carry out these activities. In this institution there are policies to ensure the protection of confidential information and customer rights, but only verbally, it was not evident that they have been documented.

In the requirements related to the management system; management verbally informs workers of the importance of complying with customer requirements, legal and regulatory, but there is no evidence in which employees have been trained to comply with these requirements.

14.29% belongs to the partially implemented requirements, obtaining the result based on document management, documents are identified with issue date and page numbering, however, when there are no resources, these formats cease to be generated. Most of the requirements are not implemented, highlighting 80%, since changes to the documentation are made by the person in charge of the laboratory under their own criteria, and modifications are made verbally and no procedures are defined to authorize a person to make changes to these. The review of supplies is done biweekly; batches, code, expiration date are observed, every reagent must arrive with a certificate of analysis.

The clinical laboratory does not have the correct environmental conditions to carry out the processes that take place in it, cross contamination may occur. Test and calibration methods are not planned in the laboratory, since the necessary resources are not available.

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