



Terms of Reference

International consultancy for training and implementation of ISO 15189 (Essential Requirements for Clinical Laboratories) and ISO 9001 (Quality Management Systems – Requirements) standards in public, veterinary, and public health clinical laboratories in Cabo Verde

Technical supervisor
National Institute of Public Health

set, 2025

Table of contents

1. Framework	Erro! Marcador não definido.
2. General objectives of individual consultancy	Erro! Marcador não definido.
3. Consultancy tasks	Erro! Marcador não definido.
4. Consultancy profile and qualifications	5
5. Consultancy results and products	Erro! Marcador não definido.
6. Methodology	Erro! Marcador não definido.
7. Place where service is provided	Erro! Marcador não definido.
8. Duration	9
9. Expected results	Erro! Marcador não definido.
10. Supervision	Erro! Marcador não definido.
11. General information	Erro! Marcador não definido.
12. Application	Erro! Marcador não definido.

1. Framework

The National Institute of Public Health (INSP), established by resolution no. 21/2014 of March 14, is a public institute integrated into the indirect administration of the State, as a personalized service, inserted in the structure of the Ministry of Health, endowed with administrative, financial and patrimonial autonomy, whose mission is to “generate, develop and disseminate scientific and technological knowledge about health and its determinants and, also, coordinate and promote the adoption of health promotion policies in the country, from a multisectoral and multidisciplinary perspective”.

The INSP plays an important role in health research, laboratories, health promotion and risk communication, health surveillance, capacity building and training of human resources in public health, without neglecting its assignment as the headquarters of the **National Coordination Body (INC) within the framework of the “One Health” approach according to the Official Gazette published in 2019**. The INC is responsible for coordinating health-related actions and policies, involving various stakeholders, including the INSP, the Ministry of Health, other government institutions, non-governmental organisations and representatives of civil society. Through this coordination, it seeks to strengthen the capacity to respond to health emergencies, improve epidemiological surveillance and promote the effective implementation of public health programmes.

The adoption of the “One Health” approach, aligned with the strategy promoted by the United Nations, recognizes that human health is inseparable from animal health and the environment, requiring coordinated actions between different sectors. However, for this approach to be effective and produce reliable and sustainable results, it is essential that it be supported by a robust quality management system, in accordance with the requirements of the ISO 9001 and ISO 15189 version 2024 standards. This implies ensuring the traceability of processes, the technical competence of teams, the validation of analytical methods and the continuous improvement of services. Thus, INSP’s efforts in the surveillance, diagnosis, control and response to diseases that affect humans and animals will be carried out based on solid evidence, promoting the confidence of partners and society in the institutional response.

The benefits of adopting a robust Quality Management System (QMS) based on ISO 9001 and ISO 15189 standards will be advantageous, namely because: 1) it increases the ability to consistently provide products and services that satisfy both customer requirements and applicable statutory and regulatory requirements;

2) facilitates opportunities to increase customer satisfaction; 3) allows risks and opportunities associated with its context and objectives to be addressed; and 4) increases the ability to demonstrate compliance with specified quality management system requirements, thus operating in accordance with international standards.

In this regard, the National Institute of Public Health, as the National Coordinating Body for the “One Health” approach, is requesting support for specialised international consultancy to train professionals (technicians, quality managers) and assist in the implementation of ISO 15189 (Essential Requirements for Clinical Laboratories) and ISO 9001 (Quality Management Systems - Requirements) in public clinical, veterinary and public health laboratories in Cabo Verde.

2. General objectives of individual consultancy

The aim of the consultancy under consideration will include the following:

- 1) Train health professionals (in departments and services of human, animal and environmental health, quality managers and internal auditors):
 - a) understanding the requirements of the ISO 9001 and ISO 15189 standards;
 - b)) developing competences for internal audits of the two standards;
 - c) practical application of quality management concepts.
- 2) assist in the implementation of a Quality Management System (QMS) based on ISO 9001 and ISO 15189 standards in public clinical, veterinary and public health laboratories in Cabo Verde.

3.Consultancy tasks

The consultancy should carry out the following tasks:

- 1) Carrying out two training courses on ISO 9001 and ISO 15189 standards and training in internal auditing of the respective standards.

1. Presentation of the work plan for implementing the QMS based on ISO 9001 and ISO 15189 standards, containing the proposed phases, subsequent activities and products, the methodology adopted, the schedule, and the monitoring and evaluation mechanisms that will be subject to negotiation and approval by INSP, as the body that coordinates the Multisectoral Commission of the “One Health” Approach, and by the financing entity.

4. Consultancy profile and qualifications

The consultant must have proven skills and work experience in the areas of the consultancy. It must also have proven international experience and good knowledge and experience of the health sector, particularly in the areas of biology, auditing and laboratory.

The following qualifications and competences are required:

Academic qualifications:

- a) Higher education, preferably master's or doctorate, in areas such as: Engineering (Industrial, Production, Chemical, Biomedical and related); Management or Administration; Health Sciences or Biological Sciences; in Quality or related areas.

Experience:

- a) At least 15 (fifteen) years' professional experience;
- b) At least 10 (ten) years' proven experience in planning and drawing up QMS implementation documents;
- c) Proficiency in the requirements of ISO 9001 and ISO 15189 and in carrying out internal audits of the respective standards;
- d) Proven professional work experience in and/or with international and national health organisations (human, animal and environmental) or related institutions.

e) Skills:

- a) Interpretation and practical application of ISO 9001 and ISO 15189;

- b) Ability to perform gap analysis (compliance diagnosis);
- c) Preparation of quality manuals, procedures, work instructions and forms;
- d) Structuring documentation in accordance with regulatory requirements;
- e) Definition and monitoring of quality performance indicators;
- f) Conducting internal audits and supporting external audits;
- g) Identification of non-conformities and proposal of corrective actions;
- h) Application of tools such as PDCA, 5 Whys, Ishikawa, FMEA, among others;
- i) Analysis of organizational, laboratory and process risks;
- j) Planning of preventive actions;
- k) Training and awareness raising of quality professionals;
- l) Clear communication of regulatory requirements to technical and administrative areas;
- m) Knowledge of complementary standards such as ISO 17025, ISO 31000, ISO 35001, Good Laboratory Practices (GLP) and biosafety;
- n) Good analytical skills for processing qualitative and quantitative information, formulating reports and systematizing information;
- o) Excellent interpersonal skills and good communication skills;
- p) Leadership and teamwork skills.

Language skills required:

- a) Proficiency in Portuguese, both oral and written.

5. Consultancy results and products

It is proposed that the consultancy deliver the following results and products to INSP and the funding organisation/UGPE.

Results		Produto	
R1	Presentation of the consultancy work plan and methodology.	P1	Work plan and methodology presented and approved.
R2	Presentation of the training plan and methodology for ISO 9001 and ISO 15189	P2	Plan and methodology for training in ISO 9001 and ISO 15189 standards and training

	standards and training in internal auditing of the respective standards.		in internal auditing of the respective standards presented and approved.
R3	Health professionals (in departments and services of human, animal and environmental health, quality managers and internal auditors) trained in the implementation, maintenance and continuous improvement of the ISO 9001 and ISO 15189 standards, and in carrying out internal audits of the respective standards.	P3	Reports on the training of health professionals (from human, animal and environmental health departments and services, quality managers and internal auditors) in the implementation, maintenance and continuous improvement of the ISO 9001 and ISO 15189 standards, and in carrying out internal audits of the respective standards.
R4	Presentation of the proposal/first draft of the QMS implementation plan for public clinical, veterinary and public health laboratories in Cabo Verde, including resource mapping, budget and follow-up plan.	P4	First draft of the QMS implementation plan in public clinical, veterinary and public health laboratories in Cabo Verde prepared and presented.
R5	Submission of the final version of the QMS Implementation Plan in public clinical, veterinary and public health laboratories in Cabo Verde, with integration of any subsidies, for validation.	P5	Final version of the QMS implementation plan in public clinical, veterinary and public health laboratories in Cabo Verde approved and validated.
R6	Monitoring the implementation of the QMS in public clinical, veterinary and public health laboratories in Cabo Verde.	P6	3 (three) audit reports on the QMS under implementation, after 30, 60 days; and 1 (one) final compiled report on

			monitoring the implementation of the QMS.
--	--	--	---

The documents must be written in Portuguese and submitted in digital format.

The consultancy is responsible for organising the product validation workshops with the partners. The products must be submitted to the INSP for appraisal, input and comments and it is expected that between the receipt of subsequent versions of the products by the INSP and its reaction, there will be a period (4 working days) for analysing and preparing any comments to be sent by email for integration and sharing in the final version.

The final products of the consultancy must be approved by a multisectoral follow-up team that will be set up for this purpose.

6. Methodology

The following methodology is suggested for training to both standards:

- ✓ Training programme format: hybrid (in-person and online).
- ✓ Teaching methods (theoretical presentations, case discussions, practical exercises, group activities, and internal audit simulations).
- ✓ Teaching resources (handouts, presentations, support material).
- ✓ Time limit: 24 hours (3 days) for the ISO 9001 standard; and 40 hours (5 days) for the ISO 15189 standard.

The implementation of a Quality Management System (QMS) based on the ISO 9001 and ISO 15189 standards in clinical public, veterinary and public health laboratories in Cabo Verde must take place:

- ✓ Meetings with Ministry of Health officials;
- ✓ Meetings with Ministry of Agriculture and Environment officials;
- ✓ Meetings with the head of the National Laboratory Network;
- ✓ Meetings of heads of public clinical, veterinary and public health laboratories in Cabo Verde;
- ✓ Identifying and mapping of their resources;

- ✓ Set up a work schedule;
- ✓ Organise a planning workshop;
- ✓ Preparation of the 1st (first) version of the QMS implementation plan for public clinical, veterinary and public health laboratories in Cabo Verde;
- ✓ Facilitate a workshop in order to validate the QMS implementation plan with the INSP and *stakeholders* and gather input;
- ✓ Preparation of the general report of the plan validation workshop;
- ✓ Integration of the input gathered and preparation of the subsequent version of the QMS implementation plan;
- ✓ Submission of subsequent versions to the INSP and stakeholders for consideration and comments;
- ✓ Submission of the final version of the plan;
- ✓ Preparation of 3 (three) QMS audit reports - at 30. 60 days after the start date of the consultancy;
- ✓ Preparation of 1 (one) final report compiled from the monitoring of the implementation of the QMS by national public, veterinary and public health clinical laboratories.

7. Place where service is provided

8. This consultancy will be carried out at the facilities of the National Institute of Public Health, with headquarters at Largo do Desastre de Assistência, Chã de Areia, CP 719, Praia, Republic of Cabo Verde T: (+ 238) 261 21 67; and remotely, when justified.

9. Duration

This work is to be carried out in 60 working days and is scheduled to begin in November 2025. The work will be carried out in hybrid form (in person and virtually).

Therefore, it is estimated that the 60 working days will be used as shown in the table below:

Product	Delivery time
Work plan, indicative consultancy schedule and detailed methodological proposal	15 working days after signing the contract

Report on the training of health professionals (in departments and services of human, animal and environmental health, quality managers and internal auditors) in the implementation, maintenance and continuous improvement of the ISO 9001 and ISO 15189 standards, and in carrying out internal audits of the respective standards.	25 working days after signing the contract
First <i>draft</i> of the QMS implementation plan in the public clinical, veterinary and public health laboratories of Cabo Verde	40 working days after signing the contract
Final version of the QMS implementation plan for public clinical, veterinary and public health laboratories in Cabo Verde approved and validated	50 working days
Compiled final report on monitoring the implementation of the QMS	60 days

The products must be in line with the work schedule set out in the contract and must be presented in Portuguese with clear and objective language.

10. Expected results

A product of this consultancy is expected to be delivered to the monitoring team that was set up for this purpose and to the funding entity:

- 1) Professionals in the departments and services of human, animal and environmental health laboratories, quality managers and internal auditors trained in the implementation, maintenance, continuous improvement and internal audits of the ISO 9001 and ISO 15189 standards.
- 2) Final compiled report on the monitoring of the implementation of the QMS in Cabo Verde's public clinical, veterinary and public health laboratories.

The documents must be written in Portuguese and submitted in electronic version (Microsoft Word, USB stick or CD).

11. Supervision

The consultancy will report to the National Institute of Public Health (INSP). Similarly, the consultancy will report to the Special Projects Management Unit (UGPE) for contract administration issues.

12. General information

- A. The consultancy should present and discuss the draft proposals in meetings with the INSP and the Monitoring Team.
- B. The consultancy must carry out the activities contained in these Terms of Reference in accordance with the highest standards of competence, ethics and professional integrity and within the stipulated deadlines.

13. Application

The application dossier must include the following documents:

- ✓ Candidates' individual curriculum vitae and proof of qualifications and professional experience;
- ✓ Cover letter confirming interest and immediate availability for the consultancy.

Candidates should only submit information (CV and proof of qualifications) demonstrating that they are qualified and experienced for the job. The best-qualified candidate will then be invited to submit a technical and financial proposal for the contract.

Availability

Availability must be immediate, according to the timetable defined in point 8 above.