Società Italiana di Patologia Clinica e Medicina di Laboratorio
Componente della World Association of Societies of Pathology and Laboratory Medicine
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Commissione Nazionale Qualità ed Accreditamento
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Certificazione ISO

Versione 1.0
documento Q13-POCT in ISO 15189
giugno/2019

Raccomandazioni per l'inclusione dei requisiti degli esami eseguiti vicino al paziente (point-of-care testing, ISO 22870) nei requisiti dei laboratori medici (ISO 15189)

Codifica di questo documento:

Flusso Operativo Pre-esame Richiesta di esame A Raccolta del campione B Trasporto del campione C Ricezione e trattamento del campione D Esame Analisi E Revisione e flusso dei risultati F Interpretazione di laboratorio G Post-esame Trasmissione e archiviazione del risultato H Conservazione e smaltimento del campione I		**Elementi fondamentali del sistema qualità** Documenti e Registri L Organizzazione M Personale N Strumentazione O Acquisti e gestione scorte P Controllo del processo Q Gestione delle informazioni R Gestione degli inconvenienti S Verifiche T Miglioramento del processo U Servizio e Soddisfazione V Impianti e sicurezza Z	#

Riferimenti normativi

- UNI EN ISO 15189:2013 Laboratori medici - Requisiti riguardanti la qualità e la competenza. Milano: UNI 2013
- ISO 22870:2016 Point-of-care testing (POCT) -- Requirements for quality and competence. International Organization for Standardization, Geneva, Switzerland.
- ISO/DTS 22583:2019 Guidance for supervisors and operators of point-of-care testing (POCT) devices
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

Indice

Introduzione

ISO 15189:2012 ha avviato un processo importante di rinnovamento della medicina di laboratorio, esemplificato dal cambio di paradigma della presentazione dei risultati[1]. Ha influenzato anche i requisiti proposti in Italia per l'accreditamento istituzionale.[2] A differenza di altri paesi, tuttavia, non si è ancora imposta come unica norma di riferimento per l'accreditamento, probabilmente proprio a causa dell'interferenza dell'accreditamento istituzionale e del freno dei costi percepiti per la qualità dei laboratori.[3]
La revisione in corso di ISO 15189, norma per l'accreditamento dei laboratori medici che vedrà la luce nel 2022,[4] è elaborata dal WG1 di ISO/TC 212[5]

1 Pradella M. Risultati di esami nel laboratorio accreditato ISO 15189: il nuovo paradigma. La Rivista Italiana della Medicina di Laboratorio - Italian Journal of Laboratory Medicine June 2015, Volume 11, Issue 2, pp 118–121
2 Pradella, M. Requisiti Agenas e ISO 15189 per l'accreditamento dei Laboratori medici. La Rivista Italiana della Medicina di Laboratorio - Italian Journal of Laboratory Medicine, Volume 12 (2) – Feb 4, 2016
3 Pradella M. Experience with using ISO 15189 as an option for accrediting pathology laboratories. ECIBC Plenary 2016: When Science and Policy collaborate for Health. Ville Ponti, Varese 24 Nov 2016 - 25 Nov 2016. Available from https://snipurl.im/PradellaECIBC
4 SIPMeL. Avviata la revisione 2022 di iso 15189. Available from https://www.sipmel.it/it/comunicazione/notizie/112219
5 ISO/TC 212/WG 1 Quality and competence in the medical laboratory. In ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems.

seguendo le indicazioni di ISO's Committee on Conformity Assessment (CASCO)[6].

Le raccomandazioni espresse da CASCO a ISO/TC 212 sono di usare ISO/IEC 17025:2017[7] come modello e di seguire per la revisione il processo già usato per ISO/IEC17025, di costruire piccoli gruppi di redazione ma sottoporre il testo a tutto il gruppo di progetto, quindi al WG1 ed all'intero ISO/TC 212. Si dovrà inoltre incorporare ISO 22870 (la norma per i Point-of-care)[8] e stabilire collegamenti con ISO 15190 (salute e sicurezza, anche se ora in revisione)[9], ISO 22367 (gestione dei rischi, anche questa in revisione)[10] e ISO/TS 20658 (fase pre-esame)[11]. Sono stati individuati sette gruppi di redazione (requisiti generali, strutturali, personale, apparecchiature, processi pre-esame e di esame, qualità e post-esame, gestionali). Il cronoprogramma si svilupperà per tutto il 2019, il 2020 ed il 2021, per terminare con la pubblicazione nel gennaio 2022.

In questo documento vengono selezionate le parti di ISO 22870 che si raccomanda siano incorporate nella nuova ISO 15189, anche alla luce di ISO 22583[12].

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https://www.iso.org/committee/54916.html

6 ISO's Committee on Conformity Assessment (CASCO). International Organization for Standardization, Geneva, Switzerland. Available from https://www.iso.org/casco.html

7 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

8 ISO 22870:2016 Point-of-care testing (POCT) -- Requirements for quality and competence. International Organization for Standardization, Geneva, Switzerland.

9 ISO/DIS 15190:2019. Medical laboratories -- Requirements for safety. International Organization for Standardization, Geneva, Switzerland. Available from https://www.iso.org/standard/72191.html

10 ISO/DIS 22367:2019. Medical laboratories -- Application of risk management to medical laboratories. International Organization for Standardization, Geneva, Switzerland. Available from https://www.iso.org/standard/71254.html

11 ISO/TS 20658:2017, Medical laboratories — Requirements for collection, transport, receipt, and handling of samples. International Organization for Standardization, Geneva, Switzerland.

12 ISO/DTS 22583 Guidance for supervisors and operators of point-of-care testing (POCT) devices

Capitoli “introduzione”, “1. campo d'applicazione”, “3. glossario”

§	ISO 22870:2016	Modifiche ISO 15189:2022
Introduction	Advances in technology have resulted in compact, easy-to-use in vitro diagnostic (IVD) medical devices that make it possible to carry out some examinations at, or close to, the location of the patient. Point-of-care/near-patient testing may benefit the patient as well as healthcare facilities.	Addition Advances in technology have resulted in compact, easy-to-use in vitro diagnostic (IVD) medical devices that make it possible to carry out some examinations at, or close to, the location of the patient. Point-of-care/near-patient testing may benefit the patient as well as healthcare facilities.
1 Scope - Domaine d’application	This document gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. This document can be applied to transcutaneous measurements, the analysis of expired air, and in vivo monitoring of physiological parameters. Patient self-testing in a home or community setting is excluded, but elements of this document can be applicable.	Addition in 1 Scope (Domaine d’application) This document gives also specific requirements applicable to point-of-care testing. The requirements of this document apply when POCT is carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. This document can be applied to

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		transcutaneous measurements, the analysis of expired air, and in vivo monitoring of physiological parameters. Patient self-testing in a home or community setting is excluded, but elements of this document can be applicable.
2	Normative references	None
3.1	point-of-care testing POCT near-patient testing testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient	Addition X.X point-of-care testing POCT near-patient testing examination that is performed near or at the site of a patient with the result leading to possible change in the care of the patient

Clausola 4.1 "organizzazione e direzione" (4.1 Organization and management)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.1.1	... The management of laboratory services shall plan and develop the processes needed for POCT.	Addition

§	ISO 22870:2016	Modifiche ISO 15189:2022
	The following shall be considered, as appropriate: a) quality objectives and requirements for POCT; b) the need to establish processes and documents, and provide resources specific to POCT; c) required verification, validation, and monitoring of activities specific to POCT; d) records to provide evidence that POCT processes and procedures meet requirements. The governing body of the organization shall be ultimately responsible for ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization.	In 5 Structural requirements 5.5 The laboratory shall:… The management of laboratory services shall plan and develop the processes needed for POCT. The need to establish processes and documents, and provide resources specific to POCT shall be considered.
4.1.2.1	A health professional grouping (e.g. Medical Advisory Committee) shall be responsible to the governing body for defining the scope of POCT to be made available. This shall take into consideration the clinical need for POCT, its financial implications, technical feasibility and the ability of the organization to fulfil the need.	Addition In 5 Structural requirements 5.5 The laboratory shall:… A health professional grouping (e.g. Medical Advisory Committee) shall be responsible to the governing body for defining the scope of POCT to be made available. This shall take into consideration the clinical need for POCT, its financial implications, technical feasibility and the

§	ISO 22870:2016	Modifiche ISO 15189:2022
		ability of the organization to fulfil the need.
4.1.2.2	The laboratory director or designate shall appoint a multidisciplinary POCT management group with representation from the laboratory, administration and clinical programmes including nursing to advise on the provision of POCT.	Addition In 5 Structural requirements 5.5 The laboratory shall:… The laboratory director or designate shall appoint a multidisciplinary POCT management group with representation from the laboratory, administration and clinical programmes including nursing to advise on the provision of POCT.
4.1.2.3	The management group shall ensure that responsibilities and authorities are defined and communicated within the organization.	None (absorbed by 5.5 The laboratory shall: a) define the organization and management structure…
4.1.2.4	The management group shall assist in evaluating and selecting POCT devices and systems. Performance criteria for POCT devices should include consideration of trueness, precision, detection limits, use limits and interferences. Practicability should also be considered.	None (absorbed by 6.4 Equipment 6.4.1 The laboratory shall have access to equipment…)
4.1.2.5	The management group shall consider all proposals to introduce any	None

§	ISO 22870:2016	Modifiche ISO 15189:2022
	product, device or system for POCT.	(absorbed by 6.4 Equipment 6.4.1 The laboratory shall have access to equipment…)

Clausola 4.2 "gestione per la qualità" (4.2 Quality management system)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.2.2	The management of laboratory services shall establish, document, implement and maintain a quality management system and continually improve its effectiveness	None (absorbed by 8 Management system requirements 8.1 General requirements and options 8.1.1 General)
4.2.2.1	The management of laboratory services shall a) identify the processes needed for the quality management system for POCT throughout the organization, b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, f) implement actions necessary to achieve	None (absorbed by 8 Management system requirements 8.1 General requirements and options 8.1.1 General + Annex B Management system options)

§	ISO 22870:2016	Modifiche ISO 15189:2022
	planned results and continual improvement of these processes, and g) appoint a person with appropriate training and experience as quality manager responsible for POCT quality, which includes review of the requirements related to POCT. These processes shall be managed by the organization in accordance with the requirements of this document. Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, service provisions and measurement provisions.	
4.2.2.2	The management of laboratory services shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of POCT to the quality system.	None (absorbed by 8 Management system requirements 8.1 General requirements and options 8.1.1 General + Annex B Management system options)
4.2.3	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) quality manual, c) documented procedures required by this document, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this document.	None (absorbed by 8.2 Management system documentation)

§	ISO 22870:2016	Modifiche ISO 15189:2022
	NOTE Within this document, the term "documented procedure" means that the procedure is established, documented, implemented and maintained. The extent of the quality management system documentation may differ from one organization to another due to — the size of the organization and type of activities, — the complexity of processes and their interactions, and — the competence of personnel. The documentation may be in any form or type of medium that can be maintained and retrieved up to the specified retention times, which is dependent upon local, regional and national requirements.	
4.2.4	… The laboratory director or suitably qualified designate shall ensure that a) POCT quality objectives are established and are measurable, b) the planning of the quality management system is carried out in order to meet the requirements of the service, as well as the quality objectives, and c) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	None (absorbed by 8.2.2 Commitment. Laboratory management shall provide evidence of commitment to the planning, development and implementation of the management system and to continually improving its effectiveness.)
4.2.5	… The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, b) the	None (not compatible with 8.2 Management system

§	ISO 22870:2016	Modifiche ISO 15189:2022
	documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.	documentation 8.2.1 Policies and objectives

Clausole 4.3-4.8 (documenti, accordi, laboratori esterni, consulenza, reclami)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.3-4.8	4.3 Document control 4.4 Review of contracts 4.5 Examination by referral laboratories 4.6 External services and supplies 4.7 Advisory services 4.8 Resolution of complaints	None (absorbed by 8.3 Control of management system documents, 7.1 Review of requests, tenders and contracts, 6.6 Externally provided products and services, 7.8.7 Reporting opinions and interpretations, 7.9 Complaints

Clausola 4.9 "non conformità" (4.9 Identification and control of nonconformities)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.9.2	The organization shall ensure that POCT that does not conform to requirements is identified and controlled to prevent its unintended use. The controls and related responsibilities and authorities for dealing with nonconforming POCT shall be defined in a documented procedure.	None (absorbed by 7.12 NONCONFORMING WORK 7.12.1 Identification and control of nonconformities)

§	ISO 22870:2016	Modifiche ISO 15189:2022
	The organization shall deal with nonconforming POCT by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release and acceptance; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken shall be maintained.	
4.9.3	The organization shall determine, collect and analyse appropriate data to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement, as well as from other relevant sources.	None (absorbed by 8.6 Improvement 8.6.1 Continual improvement)
4.9.4	The analysis of data shall provide information relating to a) healthcare provider/patient/customer satisfaction (see 4.12), b) conformity to POCT requirements (see 4.2), c) characteristics and trends of POCT, including opportunities for preventive action, and d) suppliers.	None (absorbed by 8.6 Improvement 8.6.1 Continual improvement)

Clausola 4.10 "azioni correttive" (4.10 Corrective action)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.10.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered	None (absorbed by 8.7 Corrective Action 8.7.1 Actions when nonconformity occurs)
4.10.3	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including healthcare provider/patient/client complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken, and f) reviewing corrective action taken.	None (absorbed by 8.7.1 Actions when nonconformity occurs 8.7.2 Actions appropriate to effects 8.7.3 Records of nonconformities)

Clausole 4.11 "azioni preventive", 4.12 "miglioramento continuo", 4.13 "registrazioni" (4.11 Preventive action, 4.12 Continual improvement, 4.13 Quality and technical records)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.11.2	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.	None (absorbed by 8.6 Improvement)
4.11.3	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken, and e) reviewing preventive action taken.	None (absorbed by 8.6 Improvement) (documentazione discrezionale come da punto 8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.)
4.12.2	A quality assurance programme shall periodically review the relative benefits of POCT, monitor the test ordering patterns, carry out audits to verify record keeping and review critical value reports.	None (absorbed by 8.9 Management reviews)
4.13.2	Records shall be established and maintained to provide evidence of conformity to requirements and of effective operation of the quality	None (absorbed by 8.4 Control of records)

§	ISO 22870:2016	Modifiche ISO 15189:2022
	management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	(documentazione discrezionale come da punto 8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.)

Clausole 4.14 "audit interni", 4.15 "riesame della direzione" (4.14 Internal audits, 4.15 Management review)

§	ISO 22870:2016	Modifiche ISO 15189:2022
4.14	Internal audits ... a) The laboratory director, or designated suitably qualified person, and the multidisciplinary POCT management group shall receive and review the reports of the quality assurance programme. b) Suggested modifications arising from such reviews, if approved, shall be incorporated into the POCT policy, processes and procedures.	None (absorbed by 8.8 Internal audits)
4.15.2	The laboratory director, or a designated suitably qualified person, shall implement a periodic management review that includes — a cost-benefit analysis and an evaluation of the clinical need, — the clinical effectiveness and the cost efficiency of POCT activities, and — the	Addition 8.9.1 The laboratory management shall review… a cost-benefit analysis of POCT and the clinical effectiveness of POCT;

§	ISO 22870:2016	Modifiche ISO 15189:2022
	identification of opportunities for improvement	
4.15.3	Input to management review shall include information on a) results of audits, b) healthcare provider/patient/client feedback, c) process performance and service conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	None (absorbed by 8.9.2 The inputs to management review…)
4.15.4	The laboratory director, or designated suitably qualified person, shall make changes to policy, processes or procedures resulting from the management review.	None (absorbed by 8.9.3 The outputs from the management review)

Clausole 5.1 "personale", 5.2 "spazi e ambiente" (5.1 Personnel, 5.2 Accommodation and environmental conditions)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.1.1	The organization shall determine and provide the human resources needed to a) implement and maintain the POCT quality management	None (absorbed by 6.1 General 6.2 Personnel)

§	ISO 22870:2016	Modifiche ISO 15189:2022
	system and continually improve its effectiveness, b) ensure that required training is provided to personnel performing POCT from all services, programmes and departments, and c) enhance healthcare provider/patient/client satisfaction by meeting customer requirements.	
5.1.2	… The laboratory director, or other suitably qualified person, shall be responsible for a) procuring, evaluating and selecting all POCT devices, reagents and systems, including quality control material, and b) establishing documented quality policy and protocols for the performance of all POCT and associated quality control and quality assurance. Overall responsibility for the provision of POCT may be delegated to an appropriate laboratory specialist.	5.5 The laboratory shall: … b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; NOTE: management and verification include procuring, evaluating and selecting all POCT devices, reagents and systems, including quality control material, and establishing documented policy and protocols for the performance of all POCT and associated quality control and quality assurance
5.1.4	… The management group shall allocate responsibilities and designate staff undertaking POCT. The allocation of duties and responsibilities of different groups of staff shall be defined in the operating procedures.	Addition 6.2.7 The POCT management group (5.5) shall allocate responsibilities and designate staff undertaking POCT.

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.1.5	… The laboratory director, or other suitably qualified person, may appoint a person with appropriate training and experience to manage the training and competency assessment. a) The manager shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel. The manager may assign responsibility for training on a specific POCT instrument/system to an appropriate technical specialist or technologist. b) Only personnel who have completed the training and demonstrated competence shall carry out POCT. Records of training/attestation and of retraining and re-attestation shall be retained. c) The content of the training programme and the knowledge/skill level assessment process shall be documented. The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system (chemistry and detector) and appreciation of the pre-analytical aspects of the analysis, including — a sample collection, — its clinical utility and limitations, — expertise in the analytical procedure, — reagent storage, — quality control and quality assurance, — technical limitations of the device,— response to results that fall	Addition in 6.2.3 The laboratory shall ensure that the personnel have the competence… NOTE ISO/TS 22583 gives guidance for supervisors and operators of point-of-care testing (POCT) services where POCT is performed without medical laboratory training, supervision or support. It includes the key components that should be considered to provide safe and reliable POCT results. These are Operators (Training, Competence), equipment selection, process management (Pre-testing stage, Testing stage, Post-testing stage, External audits), Information management, Documentation and record keeping, Health and safety.

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	outside of predefined limits, — infection control practices, and — correct documentation and maintenance of the results. d) Retraining intervals and a continuing education programme shall be established by the management group. e) POCT operator performance shall be monitored as part of the quality assurance programme.	
5.2.2	The premises, in which POCT is undertaken and the equipment are used, shall conform to applicable national legislation or to regional or local requirements.	None (absorbed by 5.1 The laboratory shall be a legal entity… and 5.4 Laboratory activities shall be carried out… regulatory authorities and organizations providing recognition
5.2.3	The organization shall determine and manage the work environment needed to achieve good working conditions as well as conformity to POCT requirements and the device manufacturer's recommendations.	None (absorbed by 6.3 Facilities and environmental conditions)

Clausola 5.3 "apparecchiature" (5.3 Laboratory equipment)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.3.2	The laboratory director, or designated suitably qualified person, shall be responsible for the selection criteria and for the procurement of equipment, materials and reagents. a) An inventory shall be maintained of all POCT equipment including serial number and unique identification, manufacturer/supplier, date purchased and service history, including dates out-of-service. b) Reagents, kits and equipment shall be verified prior to routine use. c) There shall be written procedures for the maintenance and operation of POCT equipment. d) The management group shall recommend that any POCT device or system be withdrawn from service if critical requirements are not met or safety becomes an issue. e) A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed. f) Periodic and episodic maintenance of equipment shall be monitored and documented.	6.4.1 The laboratory and POCT shall have access to equipment (including, but not limited to, measuring systems, hardware and software of instruments, laboratory information systems, environmental monitoring system, measurement standards, reference materials, calibrators and quality control materials, reagents, consumables or auxiliary apparatus that is required for the correct and safe performance of laboratory activities and that can influence the results

Clausole 5.4 "procedure pre-esame" e 5.5 "procedure di esame" (5.4 Pre-examination procedures, 5.5 Examination procedures)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.4.2	The organization shall ensure identification of the sample and its clerical traceability to the patient.	None (absorbed by 7.3 Sampling and 7.x.x Sample reception)
5.4.3	The organization shall exercise care with samples obtained for POCT from its patients while such samples are under the organization's control or are being used by the organization. The organization shall identify and safeguard samples for analysis. If any sample is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the responsible healthcare professional and records maintained.	7.4 Pre-examination handling, preparation and storage The laboratory and POCT shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.
5.5.2	Procedure manuals for each POCT system shall be made available to all users.	None (absorbed by 7.2.1.2 ... manuals…readily available to personnel)
5.5.3	The manufacturer's recommendations regarding minimum quality control of a specific instrument system may be accepted, following documented review.	7.7.1 The laboratory and POCT shall have a procedure for monitoring… NOTE 1. monitoring of quality is scheduled verification

§	ISO 22870:2016	Modifiche ISO 15189:2022
		(3.8) capable of detecting results that fail to meet performance specifications. (ISO 15198 5.1)[13]. Quality control is a shared responsibility of IVD medical device manufacturers and users. The manufacturer of an IVD medical device recommends a quality control procedure for the user to monitor examination performance and provide sufficient information for the user to understand the basis for the recommendations. Based on the manufacturer's recommended quality control procedures, a user can establish a comprehensive quality control system for the specific setting in which the device is used. (ISO 15198 4.1).
5.5.4	Instrument-generated quality control shall be acceptable provided that regulatory authorities have accepted it.	Delete

13 ISO 15198 Clinical laboratory medicine -- In vitro diagnostic medical devices -- Validation of user quality control procedures by the manufacturer

Clausola 5.6 "monitoraggio della qualità" (5.6 Assuring the quality of examination procedures)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.6.2	The quality manager is responsible for the design, implementation and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory. The relationship between values obtained in the laboratory and POCT shall be established and published or available upon request.	7.7.1 The laboratory and POCT shall have a procedure for monitoring… 7.2.3 Comparability of examination results (*in selection and validation chapter 7.2)* 7.2.3.1 The laboratory and POCT shall define means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples… NOTE comparison should be done following published guidelines widely recognized (such as CLSI EP09[14], CLSI EP31[15]) 7.2.3.2 The laboratory and POCT management group shall notify users of any differences in comparability of results…

14 CLSI EP09 (2018) Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition
15 CLSI EP31 (2012) Verification of Comparability of Patient Results Within One Health Care System, Interim Revision

§	ISO 22870:2016	Modifiche ISO 15189:2022
		7.2.3.3 The laboratory and POCT shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed.
5.6.3	The quality manager may assign responsibility for quality control on a specific POCT instrument/system to an appropriately qualified person. When such activities are assigned, the quality manager shall remain accountable to the laboratory director, or designated person, for the quality of all POCT testing.	6.2.7 The POCT management group shall authorize personnel to perform specific activities, including but not limited to, the monitoring of method performances.
5.6.5	Where available, participation in an external quality assessment (EQA) shall be required (see ISO/IEC 17043). In the absence of an EQA scheme, the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of the test within the laboratory.	7.7.2 The laboratory and POCT shall monitor its performance by comparison with results of other laboratories,…
5.6.6	The laboratory director, or designated person, and the multidisciplinary POCT management group shall receive and review the external or internal quality assessment data. Suggested modifications arising from such review shall be incorporated into the POCT policy, processes, and procedures.	None (absorbed by 7.7.3 Data from monitoring activities shall be analysed…)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.6.8	… The laboratory director shall validate the following processes for service provision. a) Trueness and precision and, where appropriate, linearity of the instrument response shall be verified by the QC programme. b) Split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites.	None (absorbed by 7.7.1 The laboratory shall have a procedure for monitoring…, 7.2.3 Comparability of examination results)
5.6.8	c) Frequency of internal QC should be specified for each device.	7.7.2.1 … NOTE Quality control procedures should be based on widely recognized guidelines such as CLSI C24[16] and POCT07[17] and should contain the Definition of the Quality Requirements, the Selection of Control Materials, the Determination of Target Values and Standard Deviations for Quality Control Materials that Represent Stable Analytical Performance, the Setting of Goals for Quality Control Performance, the Selection of a Quality Control Strategy Based on Performance Goals, and Multiple Instrument Quality Control

16 CLSI C24-A4 (2016) Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition
17 CLSI POCT07 (2010) Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.6.8	d) Corrective action to be taken for out-of-control results shall be documented. e) Action taken on nonconforming QC results shall be documented.	None (absorbed by 7.10 Nonconforming work and 8.7 Corrective action)
5.6.8	f) QC results shall be recorded for regular review by the quality manager or designated person.	None (absorbed by 7.7.3 Data from monitoring activities shall be analysed)
5.6.8	g) Process control for consumable supplies and reagents shall be documented and monitored.	None (absorbed by 6.4.13 Records shall be retained for equipment)
5.6.8	h) In-patient self-testing using POCT devices, if allowed, shall be monitored to validate the accuracy and comparability of the results to those of the central laboratory.	7.2.3.4 In-patient self-testing using POCT devices, if allowed, shall be monitored for comparability of the results to those of the central laboratory

Clausole 5.7 "procedure post-esame" e 5.8 "presentazione dei risultati" (5.7 Post-examination procedure, 5.8 Reporting of results)

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.7.1	… The organization shall handle and dispose safely of all samples, reagents and kits according to local, regional or national regulations.	None (absorbed by 7.4.1 The laboratory shall have a procedure for the … storage, retention, and disposal…)
5.7.2	Where repeat testing is clinically indicated, the original sample shall be used where available. Otherwise, a new sample shall be obtained.	None (absorbed by 7.4.1 The laboratory shall have a procedure for the … storage, retention, and disposal…)
5.8.2	POCT results shall be reported with necessary details.	None (absorbed by ISO 17025 7.8.1.2 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.)
5.8.3	POCT results shall be permanently recorded in the patient's medical record.	Addition 7.10.2 Result reporting … POCT results shall be permanently recorded in the patient's medical record.

§	ISO 22870:2016	Modifiche ISO 15189:2022
5.8.3	The identity of the person performing the test should be recorded.	None (absorbed by 7.7 Technical records. 7.7.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information ... The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. ....
5.8.4	The record shall distinguish between POCT results and those from the central laboratory or its satellites.	Addition 7.7 Technical records. 7.7.1 The laboratory shall ensure that… NOTE The record shall distinguish between POCT results and those from the central laboratory or its satellites.

Conclusioni

In questo documento vengono selezionate le parti di ISO 22870 che da incorporare nella nuova ISO 15189, anche alla luce di ISO 22583 (guida per operatori e supervisori POCT)[18] e ISO/TS 20658 (fase pre-esame)[19]. Il testo della nuova ISO 15189 è ancora allo stadio embrionale, quindi il riferimento principale è costituito dalla norma in vigore ISO/IEC 17025:2017 (laboratori di prova e di taratura)[20].

Molti punti di ISO 22870 possono essere considerati assorbiti da ISO 17025 o da probabili modifiche introdotte per la nuova ISO 15189.

Alcuni elementi sono invece caratterizzanti della particolarità dei POCT, attività realizzate da una collaborazione gestionale tra laboratorio e reparti clinici, inquadrate in modo molto differente tra paesi diversi ed addirittura tra aziende sanitarie diverse. Tra questi elementi, innanzitutto il "Medical Advisory Committee" (Comitato consultivo medico, 4.1.2.1) ed il "POCT management group" (Gruppo di gestione POCT, 4.1.2.2), che ha il compito principale di "allocate responsibilities and designate staff undertaking POCT" (assegnare responsabilità e designare il personale che eroga POCT, 5.1.4). Inoltre appare opportuno evidenziare la necessità di "cost-benefit analysis of POCT" (analisi costi-benefici dei POCT, 4.15.2) e dettagliare tra le attività gestionali "procuring, evaluating and selecting all POCT devices" (acquisire, valutare e selezionare tutti i dispositivi POCT, 5.1.2) nonché "policy and protocols for the performance of all POCT" (politica e protocolli per l'esecuzione di tutti i POCT, 5.1.2), compreso "comparison with results of other laboratories" (confronto con i risultati di altri laboratori, 5.6.5). Il capitolo delle competenze del personale non può non avvalersi delle specifiche sviluppate in ISO/TS 22583[21] (guida per supervisori e operatori di POCT). Essendo locali e strutture organizzative diverse, il POCT va menzionato nei requisiti "access to equipment" (accesso alle attrezzature, 4.1.2.4) e "facilities for securing patient samples" (infrastrutture per la

18 ISO/DTS 22583 Guidance for supervisors and operators of point-of-care testing (POCT) devices
19 ISO/TS 20658:2017, Medical laboratories — Requirements for collection, transport, receipt, and handling of samples. International Organization for Standardization, Geneva, Switzerland.
20 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
21 ISO/DTS 22583:2019 Guidance for supervisors and operators of point-of-care testing (POCT) devices

sicurezza dei campioni dei pazienti, 5.4.3). Il monitoraggio delle prestazioni dei metodi non può più prescindere dalle indicazioni di ISO 15198[22], richiamate anche dalle Raccomandazioni SIPMeL in tema[23], ovvero dal contributo fondamentale del fabbricante, già esplicitaente richiamato nella ISO 22870:2016. Comunque, il monitoraggio delle prestazioni non può eludere del tutto lo schema fissato dalle fondamentali linee guida come CLSI C24[24] e POCT07[25]. Tutto il capitolo della "Comparability of examination results" (Confrontabilità dei risultati degli esami, 5.6.2) deve tener conto in modo particolare dei POCT in confronto ai risultati del laboratorio centrale, utilizzando approcci secondo linee guida largamente riconosciute (CLSI EP09[26], CLSI EP31[27]).[28] Va considerato almeno in ambiente ospedaliero il tema del "self-testing" (auto-diagnosi, 5.6.8). Va inoltre prescritta la registrazione dei risultati nel "patient's medical record" (cartella clinica del paziente, 5.8.3), garantendo la distinzione dei risultati POCT da quelli del laboratorio.

22 ISO 15198:2004 Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer
23 SIPMeL Commissione Qualità. Documento Q11P1 raccomandazioni ISO 15198 e controllo di qualità. http://labmedico.blogspot.com/2019/05/sipmel-commissione-qualita.html
24 CLSI C24-A4 (2016) Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition
25 CLSI POCT07 (2010) Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition
26 CLSI EP09 (2018) Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition
27 CLSI EP31 (2012) Verification of Comparability of Patient Results Within One Health Care System, Interim Revision
28 SIPMeL Linee guida per il confronto di procedure di esami di laboratorio: utilizzo delle indicazioni di CLSI EP09-A3 ed EP31-A-IR. https://www.sipmel.it/it/lineeguida/approvate/110831 Riv Ital Med Lab 2016;12:26-35 https://link.springer.com/content/pdf/10.1007%2Fs13631-016-0110-1.pdf