NICOSIA
THURSDAY, FEBRUARY 2-2023

Η νέα έκδοση του CYS EN ISO 15189 - Βασικές Απαιτήσεις και οι αλλαγές σε σχέση με την προηγούμενη έκδοση

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ΕΙΣΑΓΩΓΗ ΣΤΑ ΣΥΣΤΗΜΑΤΑ ΔΙΑΧΕΙΡΙΣΗΣ

Τι είναι ένα πρότυπο;

Ένα πρότυπο:

- Προσδιορίζει απαιτήσεις
- Περιγράφει μεθόδους
- Δίνει συστάσεις (recommendations)
- Προσφέρει καθοδήγηση

Εξέλιξη των Προτύπων Διαχείρισης

Ο Διεθνής Οργανισμός Τυποποίησης (ISO) (International Organization for Standardization) είναι μια παγκόσμια Ομοσπονδία Εθνικών Φορέων Τυποποίησης (φορείς –μέλη του ISO). Η εργασία προετοιμασίας Διεθνών Προτύπων διεκπεραιώνεται κατά κανόνα από τις Τεχνικές Επιτροπές του ISO. Κάθε φορέας φορέας-μέλος που ενδιαφέρεται για ένα θέμα, για το οποίο έχει συσταθεί μια Τεχνική επιτροπή, έχει δικαίωμα να εκπροσωπείται σε αυτή την Επιτροπή. Στις εργασίες, επίσης, συμμετέχουν Διεθνείς Οργανισμοί κρατικοί και μη, που συνδέονται με το ISO, το οποίο συνεργάζεται στενά με τη Διεθνή Ηλεκτροτεχνική Επιτροπή (IEC) σε όλα τα θέματα ηλεκτροτεχνικής τυποποίησης

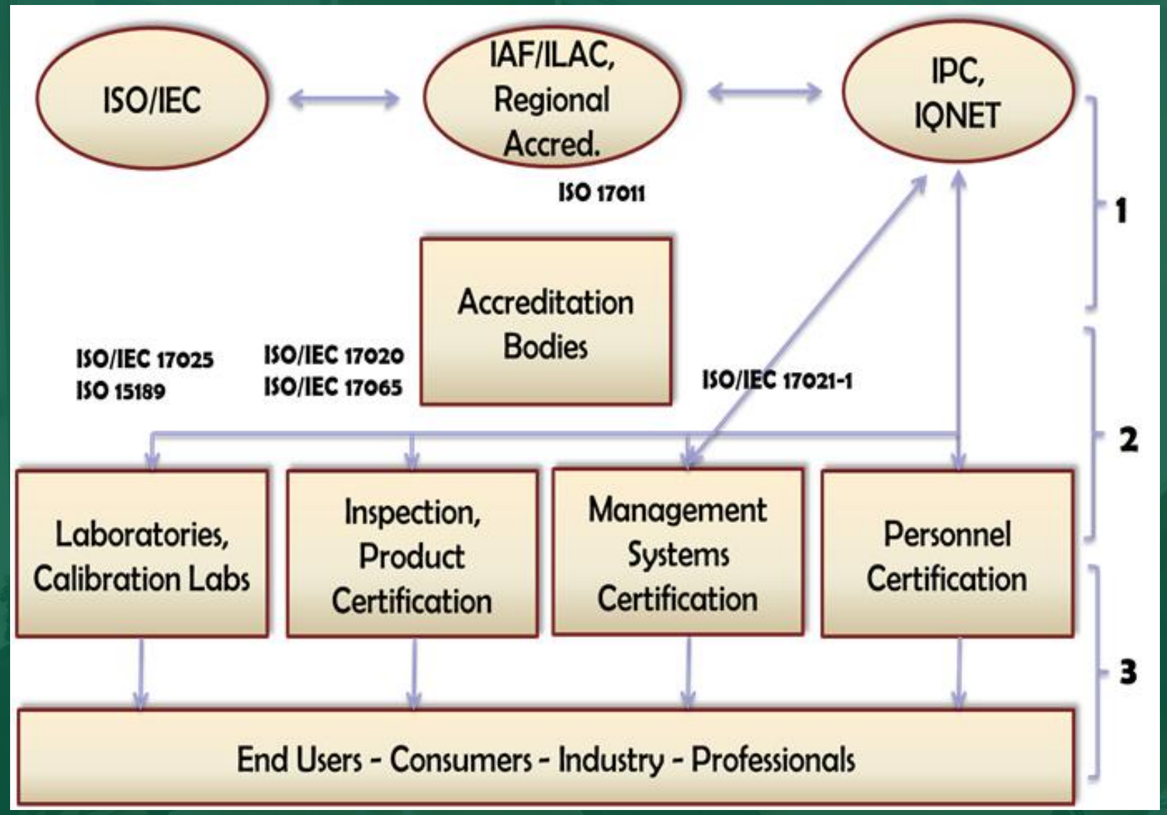
Conformity Assessment

Διαπίστευση - Πιστοποίηση

Πιστοποίηση: Έλεγχος επάρκειας και αμεροληψίας.
-Αναφέρεται σε οργανισμούς παροχής υπηρεσιών ή στην οργάνωση των υπηρεσιών ευρύτερων οργανισμών.
-Γίνεται από δημόσιους και ιδιωτικούς φορείς

Διαπίστευση: Έλεγχος επάρκειας, αμεροληψίας και ικανότητας.
-Αναφέρεται σε εργαστήρια δοκιμών και διακριβώσεων, φορέων πιστοποίησης κ.α.
-Γίνεται μόνο από φορείς διαπίστευσης.

Conformity Assessment Structure



ΓΙΑΤΙ ΔΙΑΠΙΣΤΕΥΣΗ ΚΛΙΝΙΚΩΝ ΕΡΓΑΣΤΗΡΙΩΝ;

Διότι αξιόπιστος έλεγχος και δοκιμές ζητούνται από:

- **Κρατικές Υπηρεσίες (Υπουργεία – βλ. COVID-19 κ.α.)**
- **Πολίτες (πρόληψη και διάγνωση)**
- **Υπηρεσίες Υγείας (αναλυτικές υπηρεσίες, ασφάλεια φαρμάκων, κλινικές μελέτες, κ.α.)**
- **Ερευνητικούς Φορείς (R&D, επικύρωση, κ.α.)**
- **Ασφαλιστικούς Οργανισμούς (ανάλυση αστοχίας, αξιολόγηση κινδύνων, κ.α.)**

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- Αξιοπιστία και εγκυρότητα αποτελεσμάτων
- Παγκόσμια αναγνώριση εκθέσεων/πιστοποιητικών
- Επίδειξη τεχνικής ικανότητας
- Εσωτερική οργάνωση
- Αποτελεσματικότητα των λειτουργιών
- Μείωση σφαλμάτων
- Διασφάλιση επάρκειας και ικανότητας προσωπικού
- Διασφάλιση αξιοπιστίας εργαστηριακού εξοπλισμού
- Διασφάλιση της Ποιότητας

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CYS EN ISO 15189:2022 - Ανάπτυξη του προτύπου

Το πρότυπο αυτό προετοιμάστηκε απο την Τεχνική Επιτροπή ISO/TC 212, Clinical laboratory testing and InVitro diagnostics test systems, σε συνεργασία με την Ευρωπαϊκή Επιτροπή για την Τυποποίηση (CEN), Τεχνική επιτροπή CEN/TC 140 σύμφωνα με τη συμφωνία μεταξύ ISO και CEN.

CYS EN ISO 15189:2022 - Ανάπτυξη του προτύπου

Αυτή είναι η τέταρτη έκδοση του προτύπου και αντικαθιστά την τρίτη έκδοση (ISO 15189:2012),η οποία έχει τεχνικά αναθεωρηθεί. Επιπλέον αντικαθιστά το πρότυπο ISO 22870:2016 για το Point of Care Testing (POCT).

CYS EN ISO 15189:2022

Requirements

Βασικές Αλλαγές

- Επικεντρωμένο περισσότερο στον κλινικό κίνδυνο και στην επίδραση των υπηρεσιών στους ασθενείς.
- Ενσωμάτωση των απαιτήσεων του προτύπου ISO 22870 (Point of Care Testing)
- Δομική αναδιοργάνωση των παραγράφων, ώστε να προσομοιάζει με τα υπόλοιπα πρότυπα της σειράς ISO 17000 που σχετίζονται με την πιστοποίηση και διαπίστευση.
- Πιο ευέλικτο ώς προς τον τρόπο εκπλήρωσης των απαιτήσεων που ζητούν τεκμηριωμένες πληροφορίες.

ΑΛΛΑΓΕΣ ΣΤΗΝ ΕΚΔΟΣΗ 2022

SERVICE AGREEMENTS

Χρήση του όρου "Examination Request" αντί για "Request Form"

Quality Control (QC)

Όχι πλέον απαίτηση να ακολουθούνται οι οδηγίες κατασκευαστή για ελάχιστα διαστήματα ελέγχων, αλλα θα πρέπει να ελέγχεται ο κινδυνος στον Ασθενή αν το QC αποτύχει.

Quality Manager & Quality Manual

Δεν υπάρχει πλέον συγκεκριμένη απαίτηση

Terminology

15 προσθήκες στο νέο πρότυπο.

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
Foreword	Foreword
Introduction	Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Management requirements 4.1 Organization and management responsibility 4.1.1 Organization 4.1.1.1 General 4.1.1.3 Ethical conduct [includes confidentiality in (e)]	4 General requirements 4.1 Impartiality 4.2 Confidentiality 4.2.1 Management of information 4.2.2 Release of information 4.2.3 Personnel responsibility

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.1.1.2 Legal entity 4.1.1.4 Laboratory director 4.1.2 Management responsibility 4.1.2.1 Management commitment	5 Structural and governance requirements 5.1 Legal Entity 5.2 Laboratory director 5.2.1 Laboratory director competence 5.2.2 Laboratory director responsibilities 5.2.3 Delegation of duties 5.3 Laboratory activities 5.3.1 General 5.3.2 Conformance with requirements 5.4.1 General 5.4.2 Quality management 8.2.3 Evidence of commitment
4.1.2.2 Needs of users	4.3 Requirements regarding patients 5.3.3 Advisory activities
4.1.2.3 Quality policy	5.5 Objectives and policies
4.1.2.4 Quality objectives and planning	5.5 Objectives and policies
4.1.2.5 Responsibility, authority, and interrelationships	5.4 Structure and authority
4.1.2.6 Communication	5.4.1 General b)

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.1.2.7 Quality manager	5.4.2 Quality management
4.2 Quality management system	8 Management system requirements
4.2.1 General requirements	8.1 General requirements and options 8.1.1 General 8.1.2 Fulfilment of management requirements 8.1.3 Management system awareness
4.2.2 Documentation requirements	8.2 Management system documentation
4.2.2.1 General	8.2.1 General
4.2.2.2 Quality manual	[optional, no longer a requirement, see 8.2.1 NOTE]
4.3 Document control	8.3 Control of management system documents 8.3.1 General 8.3.2 Management of documents
4.4 Service agreements 4.4.1 Establishment of service agreements 4.4.2 Review of service agreements	6.7 Service agreements

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.5 Examination by referral laboratories 4.5.1 Selecting and evaluating referral laboratories and consultants 4.5.2 Provision of examination results	6.8.2 Referral laboratories and consultants
4.6 External services and supplies	6.8 Externally provided products and services 6.8.3 Review and approval of externally provided products and services
4.7 Advisory services	5.3.3 Advisory activities
4.8 Resolution of complaints	7.7 Complaints 7.7.1 Process 7.7.2 Receipt of complaint 7.7.3 Resolution of complaint
4.9 Identification and control of nonconformities	7.5 Nonconforming work
4.10 Corrective action	8.7 Corrective action 8.7.1 Actions when nonconformity occurs 8.7.2 Corrective action effectiveness 8.7.3 Records of nonconformities

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.11 Preventive action	8.5 Actions to address risks and opportunities for improvement 8.5.1 Identification of risks and opportunities for improvement 8.5.2 Acting on risks and opportunities for improvement
4.12 Continual improvement	8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feedback
4.13 Control of records	8.4 Control of records 8.4.1 Creation of records 8.4.2 Amendment of records 8.4.3 Retention of records
4.14 Evaluation and audits 4.14.1 General	8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal audits
4.14.2 Periodic review of requests, and suitability of procedures, and sample requirements	7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.2.4.1 General 7.3 Examination processes 7.3.1 General e)

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.14.3 Assessment of user feedback 4.14.4 Staff suggestions	8.6.2 Laboratory user and personnel feedback
4.14.5 Internal audit	8.8.3 Internal audits
4.14.6 Risk management	5.6 Risk management 8.5 Actions to address risks and opportunities for improvement 8.5.1 Identifications of risks and actions taken 8.5.2 Acting on risks and opportunities for improvement
4.14.7 Quality indicators	5.5 Objectives and policies d) 8.8.2 Quality indicators
4.14.8 Reviews by external organizations	8.7 Nonconformities and corrective action
4.15 Management review	8.9 Management review
4.15.1 General	8.9.1 General
4.15.2 Review input	8.9.2 Review input
4.15.3 Review activities	[not specified]

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
4.15.4 Review output	8.9.3 Review output
5 Technical requirements	6 Resource requirements
5.1 Personnel 5.1.1 General 5.1.2 Personnel qualifications 5.1.3 Job descriptions 5.1.4 Personnel introduction to the organizational environment 5.1.5 Training 5.1.6 Competence assessment 5.1.7 Review of staff performance 5.1.8 Continuing education and professional development 5.1.9 Personnel records	6.2 Personnel 6.2.1 General 6.2.2 Competence requirements 6.2.3 Authorization 6.2.4 Continuing education and professional development 6.2.5 Personnel records
5.2 Accommodation and environmental conditions 5.2.1 General 5.2.2 Laboratory and office facilities 5.2.3 Storage facilities 5.2.4 Staff facilities 5.2.5 Patient sample collection facilities 5.2.6 Facility maintenance and environmental conditions	6.3 Facilities and environmental conditions 6.3.1 General 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities 6.3.2 Facility controls

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment and 6.6 Reagents and consumables
5.3.1 Equipment 5.3.1.1 General 5.3.1.2 Equipment acceptance testing 5.3.1.3 Equipment instructions for use 5.3.1.4 Equipment calibration and metrological traceability 5.3.1.5 Equipment maintenance and repair 5.3.1.6 Equipment adverse incident reporting 5.3.1.7 Equipment records	6.4 Equipment 6.4.1 General 6.4.2 Equipment requirements 6.4.3 Equipment acceptance procedure 6.4.4 Equipment instructions for use 6.4.5 Equipment maintenance and repair 6.4.6 Equipment adverse incident reporting 6.4.7 Equipment records 6.5 Equipment calibration and metrological traceability 6.5.1 General 6.5.2 Equipment calibration 6.5.3 Metrological traceability of measurement results
5.3.2 Reagents and consumables 5.3.2.1 General 5.3.2.2 Reagents and consumables – reception and storage 5.3.2.3 Reagents and consumables – acceptance testing 5.3.2.4 Reagents and consumables – inventory management 5.3.2.5 Reagents and consumables – instructions for use 5.3.2.6 Reagents and consumables – adverse incident reporting 5.3.2.7 Reagents and consumables – records	6.6 Reagents and consumables 6.6.1 Reagents and consumables – General 6.6.2 Reagents and consumables – Receipt and storage 6.6.3 Reagents and consumables – Acceptance testing 6.6.4 Reagents and consumables – Inventory management 6.6.5 Reagents and consumables – Instructions for use 6.6.6 Reagents and consumables – Adverse incident reporting 6.6.7 Reagents and consumables – Records

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
5.4 Pre-examination processes 5.4.1 General 5.4.2 Information for patients and users 5.4.3 Request form information 5.4.4 Primary sample collection and handling 5.4.4.1 General 5.4.4.2 Instructions for pre-collection activities 5.4.4.3 Instructions for collection activities 5.4.5 Sample transportation 5.4.6 Sample reception 5.4.7 Pre-examination handling, preparation, and storage	7.2 Pre-examination processes 7.2.1 General 7.2.2 Laboratory information for patients and users 7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.2.3.2 Oral requests 7.2.4 Primary sample collection and handling 7.2.4.1 General 7.2.4.2 Information for pre-collection activities 7.2.4.3 Patient consent 7.2.4.4 Instructions for collection activities 7.2.5 Sample transportation 7.2.6 Sample receipt 7.2.6.1 Sample receipt procedure 7.2.6.2 Sample acceptance exceptions 7.2.7 Pre-examination handling, preparation and storage 7.2.7.1 Sample protection 7.2.7.2 Criteria for additional examination requests 7.2.7.3 Sample stability
5.5 Examination processes	7.3 Examination processes
5.5.1 Selection, verification, and validation of examination procedures	7.3.1 General

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
5.5.1.2 Verification of examination procedures	7.3.2 Verification of examination methods
5.5.1.3 Validation of examination procedures	7.3.3 Validation of examination methods
5.5.1.4 Measurement uncertainty of measured quantity values	7.3.4 Evaluation of measurement uncertainty
5.5.2 Biological reference intervals or clinical decision values	7.3.5 Biological reference intervals and clinical decision limits
5.5.3 Documentation of examination procedures	7.3.6 Documentation of examination procedures
5.6 Ensuring quality of examination results 5.6.1 General	7.3.7 Ensuring the validity of examination results 7.3.7.1 General
5.6.2 Quality control 5.6.2.1 General 5.6.2.2 Quality control materials 5.6.2.3 Quality control data	7.3.7.2 Internal quality control (IQC)
5.6.3 Interlaboratory comparisons 5.6.3.1 Participation 5.6.3.2 Alternative approaches 5.6.3.3 Analysis of interlaboratory comparison samples 5.6.3.4 Evaluation of laboratory performance	7.3.7.3 External quality assessment (EQA)

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Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

ISO 15189:2012	ISO 15189:2022 (this document)
5.6.4 Comparability of examination results	7.3.7.4 Comparability of examination results
5.7 Post-examination processes	7.4 Post-examination processes
5.7.1 Review of results	7.4.1.2 Result review and release 7.4.1.3 Critical result reports
5.7.2 Storage, retention, and disposal of clinical samples	7.4.2 Post-examination handling of samples
5.8 Reporting of results 5.8.1 General 5.8.2 Report attributes 5.8.3 Report content	7.4.1 Reporting of results 7.4.1.1 General 7.4.1.4 Special considerations for results 7.4.1.6 Requirements for reports 7.4.1.7 Additional information for reports
5.9 Release of results	7.4.1.2 Result review and release
5.9.1 General	7.4.1.1 General
5.9.2 Automated selection and reporting of results	7.4.1.5 Automated selection, review, release and reporting of results

Σύγκριση μεταξύ ISO 15189:2012 & ISO 15189:2022

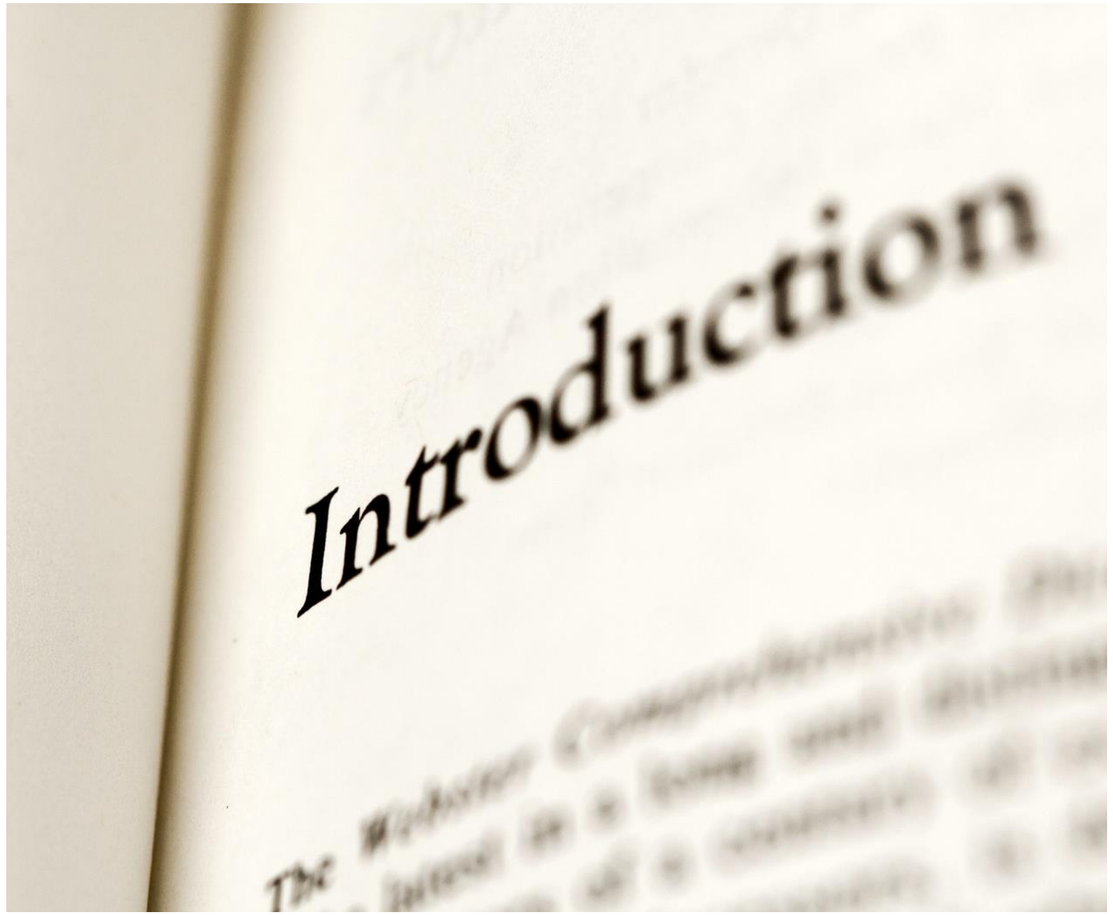
ISO 15189:2012	ISO 15189:2022 (this document)
5.9.3 Revised reports	7.4.1.8 Amendments to results reported
5.10 Laboratory information management 5.10.1 General 5.10.2 Authorities and responsibilities 5.10.3 Information system management	7.6 Control of data and information management 7.6.1 General 7.6.2 Authorities and responsibilities for information management 7.6.3 Information systems management 7.6.4 Downtime plans 7.6.5 Off site management 7.8 Continuity and emergency preparedness planning
Not specified	Annex A Additional requirements for Point-of-Care Testing
Annex A Table A.1 Correlation between ISO 9001:2008 and this document Annex A Table A.2 Correlation between and ISO/IEC 17025:2005 and this document	Annex B Table B.1 Comparison between ISO 9001:2015 and this document Annex B Table B.2 Comparison between ISO/IEC 17025:2017 and this document
Annex B Table B.1 Comparison of ISO 15189:2007 to ISO 15189:2012	Annex C Table C.1 Comparison between ISO 15189:2012 and ISO 15189:2022

Introduction (1/3)

The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories. This document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. Benefits of this approach include: increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment.

Introduction (2/3)

- The requirements for risk management are aligned with the principles of ISO 22367.
- The requirements for laboratory safety are aligned with the principles of ISO 15190.
- The requirements for sample collection and transport are aligned with ISO 20658.
- This document contains the requirements for point-of-care testing (POCT) and supersedes ISO 22870, which was withdrawn upon publication of this document.
- The format of this document is based on ISO/IEC 17025:2017.



Introduction (3/3)

While this document is intended for use throughout the currently recognized medical laboratory disciplines, it can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

The use of this document facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

Scope

This document specifies requirements for quality and competence in medical laboratories.

This document is applicable to medical laboratories in developing their management systems and assessing their competence. It is also applicable for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.
This document is also applicable to point-of-care testing (POCT)

THANK YOU

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