ISO 15189: 2022

Medical laboratories — Requirements for quality and competence

La gestione del miglioramento e il monitoraggio dei processi secondo la revisione della Norma ISO 15189

Laura Sciacovelli

ISO 15189: 2022
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Gestione del miglioramento e monitoraggio dei processi

FOCUS ON ……

- ✓ **Quali requisiti**
- ✓ **Quali strumenti**

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Gestione del miglioramento e monitoraggio dei processi

1. Politica e Obiettivi che garantiscano la Sicurezza del Paziente

2. Definizione di criteri e modalità operative che garantiscano l'affidabilità delle procedure e dei processi

3. Efficaci strumenti per il monitoraggio dei processi (misurare, analizzare e valutare)

4. Efficaci azioni di miglioramento

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5.5 Objectives and policies

- **Meet the needs and requirements of its patients and users;**
- **Commit to good professional practice;**
- **Provide examinations that fulfil their intended use**
- **Conform to ISO 15189**

7.2 Pre-examination processes
7.3.2 Verification of examination methods
7.3.3 Validationof examination methods
7.3.4 Evaluation of measurement uncertainty (MU)
7.3.5 Biological reference intervals and clinical decision limits
7.4 Post-examination processes

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Gestione del miglioramento e monitoraggio dei processi

FOCUS ON ……

- ✓ **Quali requisiti**
- ✓ **Quali strumenti**

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3. Efficaci strumenti per il monitoraggio dei processi (misurare, analizzare e valutare)

5.5d	Objectives and policies
5.6	Risk management
7.3.7	Ensuring the validity of examination results
7.7	Complaint
8.7	Nonconformities and corrective actions
8.8.2	Quality Indicators
8.8.3	Internal Audit

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3. Efficaci strumenti per il monitoraggio dei processi (misurare, analizzare e valutare)

General (4)	Structural and Governance (5)	5.5d Objectives and policies 5.6 Risk management
Resource (6)	Process (7)	7.3.7 Ensuring the validity of examination results 7.7 Complaint
Management System (8)		8.7 Nonconformities and corrective actions 8.8.2 Quality Indicators 8.8.3 Internal Audit

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3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies → **Quality Indicators**

5.6 **Risk assessment**

7.3.7 Ensuring the validity of examination results

- ✓ **Internal Quality Control**
- ✓ **External Quality Assessment**
- ✓ **Comparability of examination results**

8.8.2 **Quality Indicators**

8.8.3 **Internal Audit**

- ✓ Complaints
- ✓ Nonconformities and corrective actions

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3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ Quality Indicators

5.6 Risk assessment

7.3.7 Ensuring the validity of examination results

- ✓ **Internal Quality Control**
- ✓ External Quality Assessment
- ✓ Comparability of examination results

8.8.2 Quality Indicators

8.8.3 Internal Audit

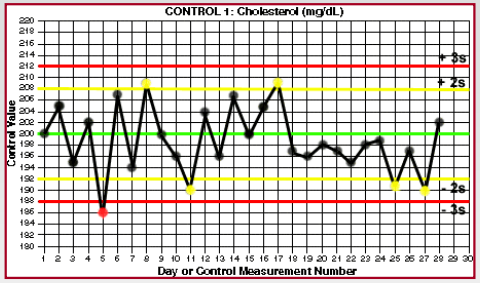
Gestione del Controllo di Qualità Interno

materiali di controllo

numero e livelli di concentrazione

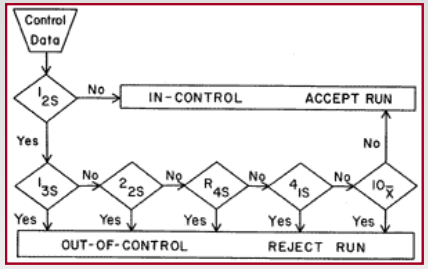
serie analitica

(sulla base del numero di campioni, tempo, ecc.)



carta di controllo

valore target e limiti di accettabilità



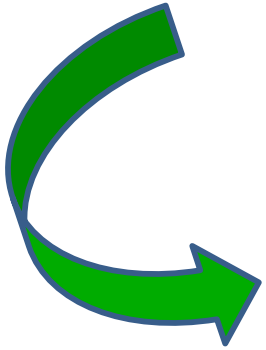
regole di controllo

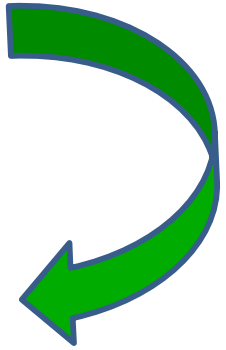
quali e di quante (motivare la scelta)

Gestione del Controllo di Qualità Interno

Validazione della calibrazione

Validazione della serie analitica





Risultati accurati

Gestione del Controllo di Qualità Interno

Gestione dei risultati non soddisfacenti

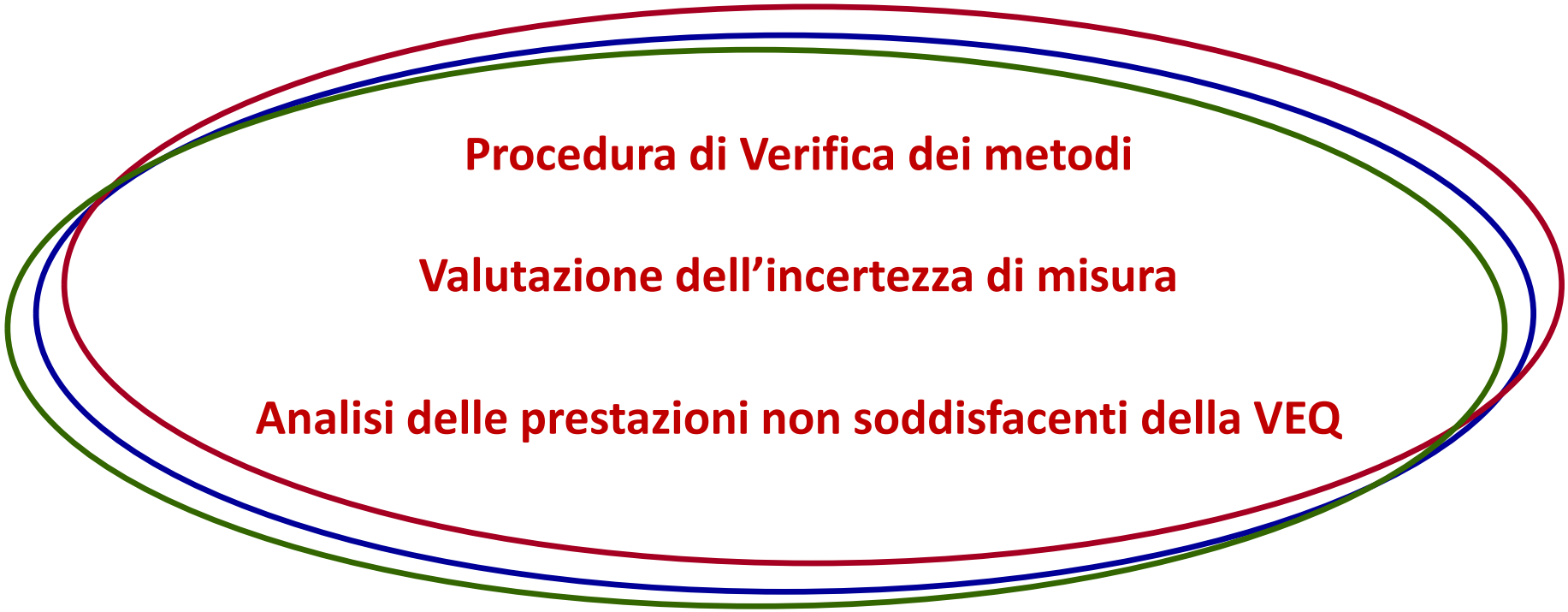
Validazione della calibrazione

Validazione della serie analitica

Azioni da attuare??

Gestione del Controllo di Qualità Interno

I risultati del CQI impattano sulle procedure per la:



Importanza dell'affidabilità dei risultati del CQI

Gestione del Controllo di Qualità Interno

Definire le differenze:

Obiettivo e procedura per la gestione del CQI

Obiettivo e procedura per la gestione dell'Interlab

Obiettivo e procedura per la gestione della VEQ

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7.3.7.2 Internal quality control (IQC)

a) The laboratory shall have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

1) The intended clinical application of the examination should be considered, as the performance specifications for the same measurand can differ in different clinical settings.

2) The procedure should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both.

3) The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.

NOTE Monitoring of interpretations and opinions can be achieved through regular peer review of examination results.

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7.3.7.2 Internal quality control (IQC)

b) The laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include:

1) stability with regard to the properties of interest;
2) the matrix is as close as possible to that of patient samples;
3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;
4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

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7.3.7.2 Internal quality control (IQC)

c) If appropriate IQC material is not available, the laboratory shall consider the use of other methods for IQC. Examples of such other methods may include:

   1) trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;

   2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511;

   3) retesting of retained patient samples.

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7.3.7.2 Internal quality control (IQC)

d) IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.

e) The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.

f) IQC data shall be reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance.

g) The laboratory shall prevent the release of patient results in the event that IQC fails the defined acceptability criteria.

   1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error has been corrected (see 7.5).

   2) The results from patient samples that were examined after the last successful IQC event shall be evaluated.

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Medical laboratories — Requirements for quality and competence

3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ Quality Indicators

5.6 Risk assessment

7.3.7 Ensuring the validity of examination results

- ✓ Internal Quality Control
- ✓ **External Quality Assessment**
- ✓ Comparability of examination results

8.8.2 Quality Indicators

8.8.3 Internal Audit

Valutazione Esterna della Qualità

Lo scopo primario della VEQ nella Medicina di Laboratorio è supportare il miglioramento della qualità delle prestazioni dei laboratori e dei sistemi diagnostici per il beneficio e la sicurezza del paziente.

Valutazione Esterna della Qualità

Laboratorio

Rendere **efficace la partecipazione** ai Programmi di VEQ, assicurando:

- ✓ l'appropriata **selezione e scelta** di affidabili Programmi di VEQ
- ✓ la tempestiva ed adeguata **valutazione delle informazioni** fornite nei rapporti di VEQ
- ✓ l'implementazione di **azioni correttive e di miglioramento**, quando necessario

Valutazione Esterna della Qualità

Affidabilità dei Programmi di VEQ

Ente Organizzatore di VEQ

- ★ **Ente Organizzatore**
- ★ **Qualità dei materiali di controllo**
- ★ **Specifiche di Qualità**:
  - definizione dei gruppi omogenei
  - valore assegnato
  - elaborazione dei risultati
  - valutazione delle prestazioni
- ★ **Informazioni nei Rapporti di VEQ**
- ★ **Assistenza e formazione ai Partecipanti ed alle Aziende del Diagnostico.**

Laboratorio

Affidabilità delle informazioni nei Rapporti di VEQ

22

Laboratorio

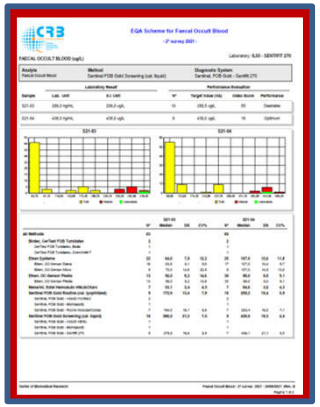
Valutazione Esterna della Qualità

Criteri per la selezione di un Programma di VEQ?

CRITERI

- ✓ Proprietà dei campioni di controllo (matrice, stabilità, range di concentrazioni clinicamente rilevanti)
- ✓ Numero di campioni e frequenza degli invii
- ✓ Numero dei partecipanti
- ✓ Criteri utilizzati per l'elaborazione dei dati (metodi parametrici e no parametrici, tutti i partecipanti, raggruppamenti per metodo o sistema diagnostico) e la valutazione delle prestazioni
- ✓ Informazioni nei Report di VEQ facilmente interpretabili
- ✓ Tempi dichiarati per il rilascio del report
- ✓ Disponibilità di assistenza su aspetti organizzativi e scientifici (interpretazione report, valutazione performance, ecc.)

Valutazione Esterna di Qualità (VEQ)



Identificazione dei problemi

Azioni Correttive

Miglioramento delle prestazioni

Le informazioni incluse nei Rapporti di VEQ devono essere usati per implementare il processo di miglioramento

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7.3.7.3 External quality assessment (EQA)

a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.
b) The laboratory shall establish a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available.
c) EQA samples shall be processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.
d) The EQA programme(s) selected by the laboratory shall, to the extent possible:
    1) have the effect of checking pre-examination, examination, and post-examination processes;
    2) provide samples that mimic patient samples for clinically relevant challenges
    3) fulfill ISO/IEC 17043 requirements.

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7.3.7.3 External quality assessment (EQA)

e) When selecting EQA programme(s), the laboratory should consider the type of target value offered. Target values are:
   1) independently set by a reference method, or
   2) set by overall consensus data, and/or
   3) set by method peer group consensus data, or
   4) set by a panel of experts.

NOTE 1 When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific.

NOTE 2 Where lack of commutability of EQA materials can hamper comparison between some methods, it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons.

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7.3.7.3 External quality assessment (EQA)

f) When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.

NOTE Acceptable alternatives include:

- participation in sample exchanges with other laboratories;
- interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material;
- analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material;
- analysis of microbiological organisms using split/ blind testing of the same sample by at least two persons, or on at least two analyzers, or by at least two methods;
- analysis of reference materials considered to be commutable with patient samples;
- analysis of patient samples from clinical correlation studies;
- analysis of materials from cell and tissue repositories

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7.3.7.3 External quality assessment (EQA)

g) EQA data shall be reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance.

h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.

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3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ Quality Indicators

5.6 Risk assessment

7.3.7 Ensuring the validity of examination results

- ✓ Internal Quality Control
- ✓ External Quality Assessment
- ✓ **Comparability of examination results**

8.8.2 Quality Indicators

8.8.3 Internal Audit

Comparabilità dei risultati

Comparabilità dei risultati determinati con procedure analitiche *identiche*

Comparabilità dei risultati determinati con procedure analitiche *differenti*

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7.3.7.4 Comparability of examination results

a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at different sites, a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals shall be specified.

   NOTE The use of patient samples when comparing different examination methods can avoid the difficulties linked to the limited commutability of IQC materials. When patient samples are either not available or impractical, see all options described for IQC and EQA.

b) The laboratory shall record the results of comparability performed and its acceptability.

c) The laboratory shall periodically review the comparability of results.

d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits shall be evaluated and acted upon.

e) The laboratory shall inform users of any clinically significant differences in comparability of results.

Comparabilità dei risultati

SIBioC DOCUMENTS DOCUMENTI SIBioC

Protocollo operativo per la verifica della comparabilità dei risultati di laboratorio ottenuti su più procedure analitiche

Matteo Vidali[1], Andrea Padoan[2,7], Ruggero Dittadi[3] per il Gruppo di Studio Statistica per il laboratorio, Duilio Brugnoni[4], Anna Carobene[5], Sonia Mattioli[6] per il Gruppo di Studio Qualità Analitica, Laura Sciacovelli[7], Ferruccio Ceriotti[8] per il Gruppo di Studio Qualità e Accreditamento.

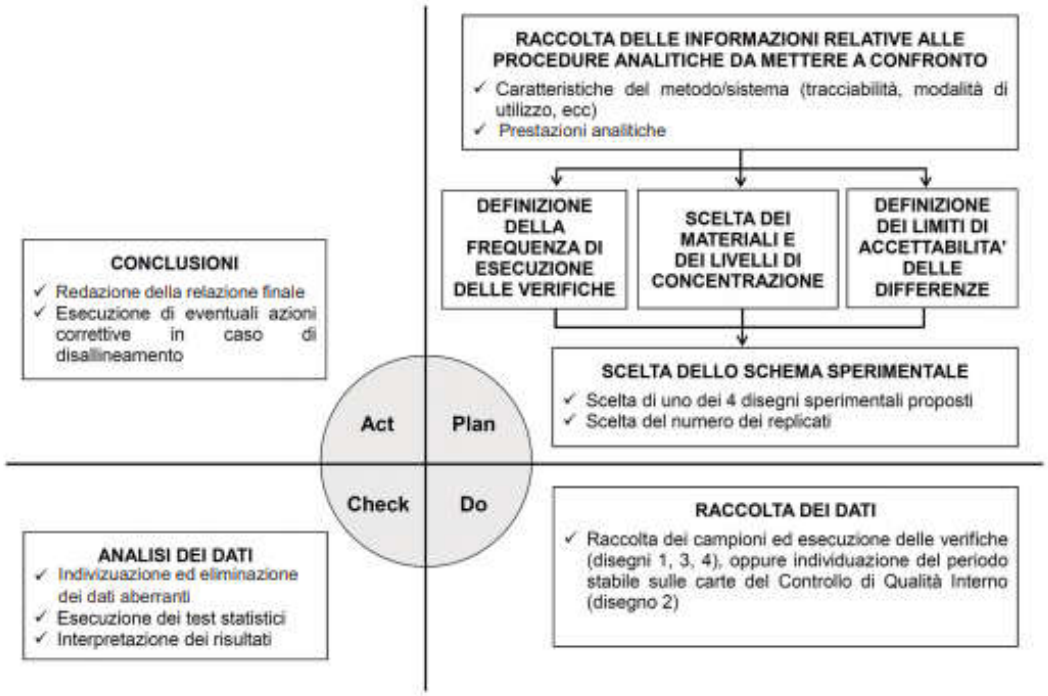

Figura 1
Sequenza delle fasi di pianificazione e implementazione delle attività.

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3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ **Quality Indicators**

5.6 **Risk assessment**

7.3.7 Ensuring the validity of examination results

- ✓ **Internal Quality Control**
- ✓ **External Quality Assessment**
- ✓ **Comparability of examination results**

8.8.2 **Quality Indicators**

8.8.3 **Internal Audit**

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5.5 Objectives and policies

a) ……;

b) ……;

c) ……;

d) The laboratory **shall establish quality indicators** to evaluate performance throughout key aspects of **pre-examination, examination, and post-examination processes** and monitor performance in relation to objectives (see 8.8.2)

NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.

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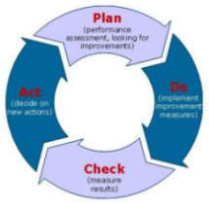
8.8 Evaluations

8.8.2 Quality indicators

The process of monitoring quality indicators [see 5.5 d)] shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring. The indicators shall be periodically reviewed, to ensure continued appropriateness.

Gestione degli Indicatori di Qualità



Sistema di valutazione interno

Prestazione del Laboratorio nel tempo.

Programmi Inter-laboratorio

Prestazione del Laboratorio in confronto a quella degli altri Laboratori.

Gestione degli Indicatori di Qualità

Sistema di valutazione interno

Prestazione del Laboratorio nel tempo !

Identificazione

Scheda Indicatore di Qualità		
Codice/ Identificazione → *definire il codice identificativo e descrivere l'indicatore*		
Scopo → *per esempio, descrivere:* - *perché è necessario monitorare lo specifico fenomeno (per esempio, Sicurezza del paziente, obiettivi della Direzione,necessità dell'utente, necessità organizzative interne, progetti di miglioramento, ecc.)* - *quale è il razionale per raccogliere questi dati piuttosto che altri ?* - *come la raccolta e l'analisi di questi dati aggiungerà valore agli sforzi per il miglioramento della qualità?*		
Processo e/o funzioni coinvolte → *Descrizione delle specifiche aree/processi/attività che sono misurate, ed i relativi legami. Mappare l'indicatore al Sistema di Gestione per la Qualità (per esempio fornitori, direzione) o alle unità organizzative, o fasi dell'analisi (fase pre-analitica)*		
Metodologia per la raccolta dati → *descrivere quali dati vanno raccolti (per esempio: tutti i campioni pervenuti, tutti i campioni con anticoagulante, ecc.) e come si devo raccogliere (per esempio: estrazione dei dati dal LIS utilizzando Qlik con specifica query che seleziona: anno, codice, provetta, tipologia di reparto, ecc; conteggio manuale delle richieste pervenute a San Massimo; indicare se è sufficiente solo il numero assoluto o se è meglio esprimere i dato con una misura relativa, (percentuale).*		
Frequenza di raccolta dati → *descrivere la frequenza di raccolta dati: quanto spesso (tutti i giorni, una settimana al mese, una volta l'anno, ecc.) e per quanto tempo (per esempio fino a nuova valutazione, per tre mesi, ecc.).*		
Modalità di calcolo dei dati → *per esempio: calcolo della percentuale; calcolo del sigma*		
Presentazione dei dati → *Grafico che visualizza l'andamento nel tempo disponibile nel sito intranet http://intra.labc.sanita.padova.it*		
Valore soglia per interventi → *il valore limite dell'indicatore che indica la necessità di intraprendere un'azione correttiva. Questo valore varia sulla base dell'indicatore e del rischio al quale è associato il fenomeno (attività, processo, area, ecc.) che stiamo misurando*		
Obiettivo per il miglioramento → *il valore dell'indicatore che suggerisce l'implementazione di un progetto di miglioramento. E' specifico dell'indicatore e può non essere definito qualora l'investimento di risorse sul progetto specifico non sia ritenuto strategico per la Direzione del Laboratorio.*		
Problematiche → *descrivere eventuali problemi che possono dar luogo ad errori nella raccolta dati e/o nell'analisi ed interpretazione dei dati raccolti*		
Classificazione ☐ Efficienza ☐ Efficacia ☐ Tempestività ☐ Sicurezza ☐ Professionali	☐ Struttura ☐ Attività/Processo ☐ Risultato ☐ Esito	☐ Fase pre-analitica ☐ Fase intra-analitica ☐ Fase post-analitica ☐ Processi di supporto .....
Note		

Modalità operativa

AZIENDA OSPEDALIERA DI PADOVA	Logo Dipartimento / Struttura complessa

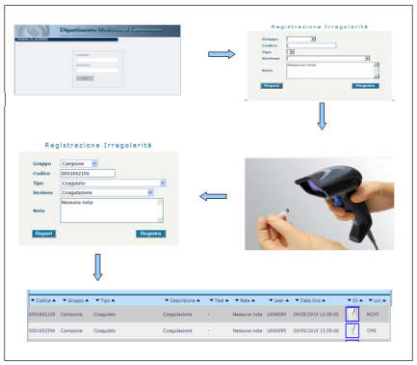
DIP/UOC/SSD
MEDICINA di LABORATORIO

PROCEDURA

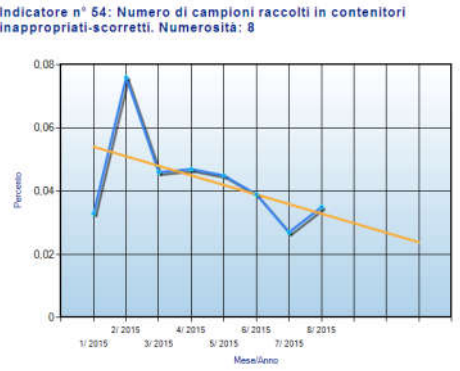
Gestione Indicatori di Qualità

Preparazione	**Referente GdL**
Verifica	**Referente Qualità e Accreditamento**
Approvazione	**Direttore**
Rev.	**Data**
Riconferma	**Responsabile** **Data**

Raccolta dei dati



Analisi dei dati

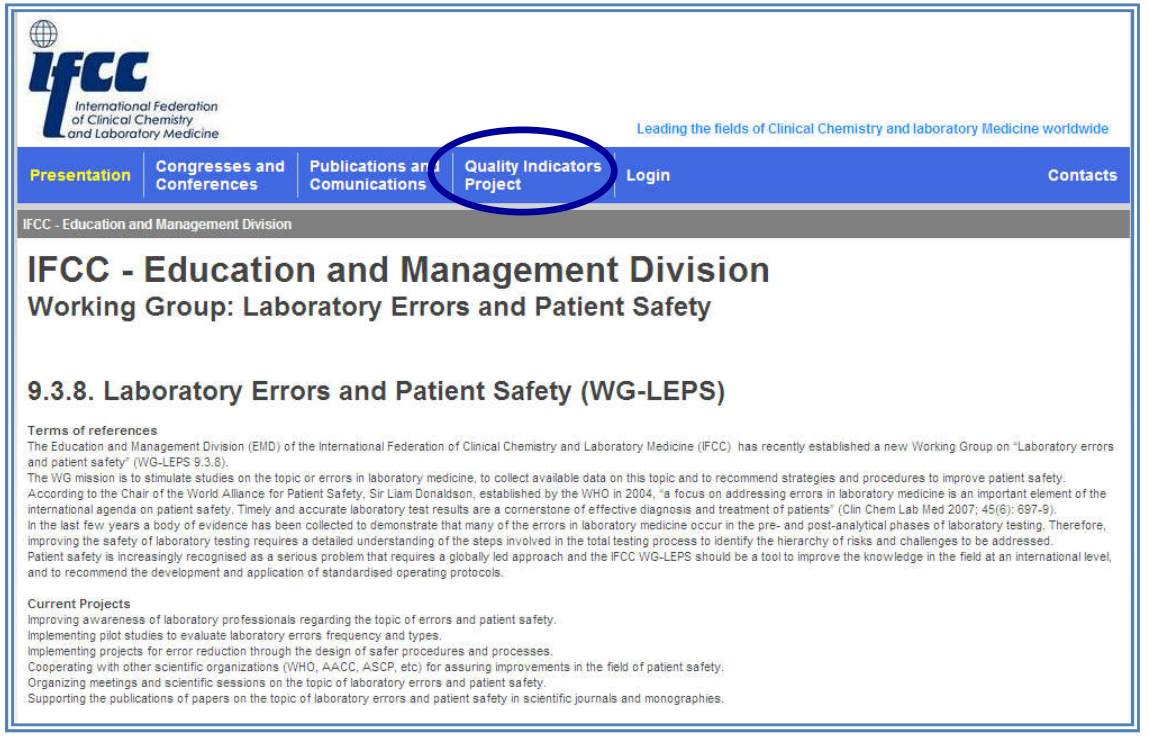


Gestione degli Indicatori di Qualità

Programma Inter-laboratorio

Prestazione del Laboratorio in confronto a quella degli altri Laboratori.

www.ifcc-mqi.com



Model of Quality Indicators

26 Indicators → **53** Measurements

	Indicators	*Measurements*
Key Processes	**20**	**43**
Pre-analytical phase	11	25
Intra-analytical phase	5	6
Post-analytical phase	4	12
Support Processes	**3**	**5**
Outcome Measures	**3**	**5**

Priority order

1 ***Mandatory***

2 ***Important***

3 ***Suggested***

4 ***Valued***

IFCC Working Group "Laboratory Errors and Patient Safety"

Project on Model of Quality Indicators

Model of Quality Indicators = 53 Measurements

Key Processes = 43

	Priority 1	2	3	4
Pre-analytical phase ⇨	19	2	2	2
Intra-analytical phase ⇨	6	0	0	0
Post-analytical phase ⇨	9	0	0	3

Support Processes = 5

Priority 1	2	3	4
0	4	1	0

Outcome Measures = 5

Priority 1	2	3	4
5	0	0	0

IFCC Working Group "Laboratory Errors and Patient Safety"

Project on Model of Quality Indicators

Reporting

QUALITY INDICATORS

Pre-Clot Percentage of: Number of samples clotted/ Total number of samples with an anticoagulant.

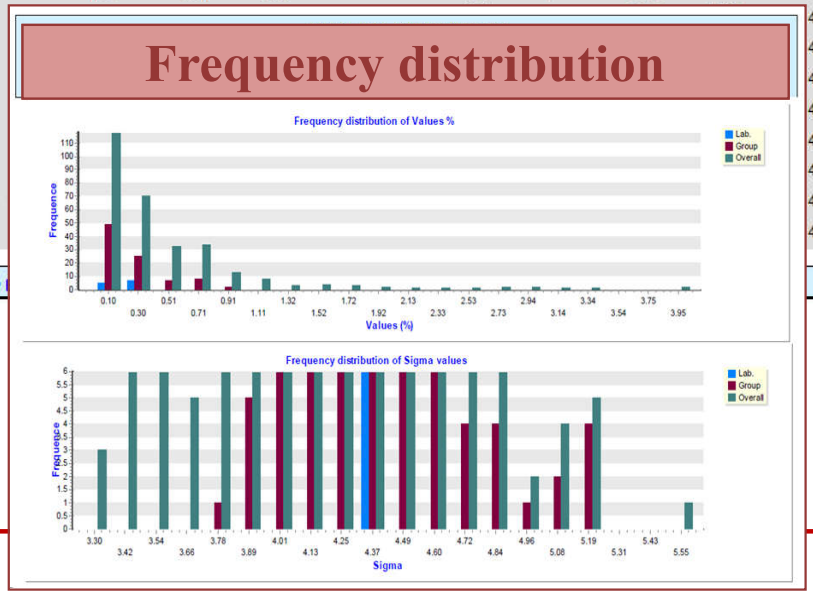
Statistical Data of Laboratory Results				Statistical Data of Category Results				Statistical Data of All Results			
Data Number	Mean (%)	Median (%)	Sigma Mean	Data Number	Mean (%)	Median (%)	Sigma Mean	Data Number	Mean (%)	Median (%)	Sigma Mean
12	0.22	0.21	4.36	91	0.26	0.20	4.38	299	0.48	0.29	4.24

	Laboratory Data				Participants Data							
	Laboratory Value (%)	Laboratory Sigma	Confidence Interval Sigma		Group Sigma		Confidence Interval Group Sigma		Overall Sigma		Confidence Interval Overall Sigma	
			Min.	Max.	Value	N.	Min.	Max.	Value	N.	Min.	Max.
January 2014	0.201	4.38	4.34	4.42	4.54	9	4.32	4.70	4.53	15	4.35	4.68
February 2014	0.197	4.38	4.34	4.43	4.52	10	4.30	4.72	4.52	15	4.33	4.68
March 2014	0.211	4.36	4.32	4.40	4.45	9	4.29	4.59	4.55	14	4.39	4.69
April 2014	0.246	4.31	4.27	4.35	4.29	7	4.19	4.39	4.18	31	4.04	4.32
									4.19	32	4.01	4.35
									4.22	30	4.02	4.38
									4.22	29	4.05	4.38
									4.15	27	3.99	4.30
									4.19	27	4.06	4.32
									4.23	26	4.10	4.36
									4.23	25	4.08	4.36
									4.19	28	4.05	4.31

Lab code:

Trend over time

Frequency distribution



IFCC Working Group "Laboratory Errors and Patient Safety"

Project on Model of Quality Indicators

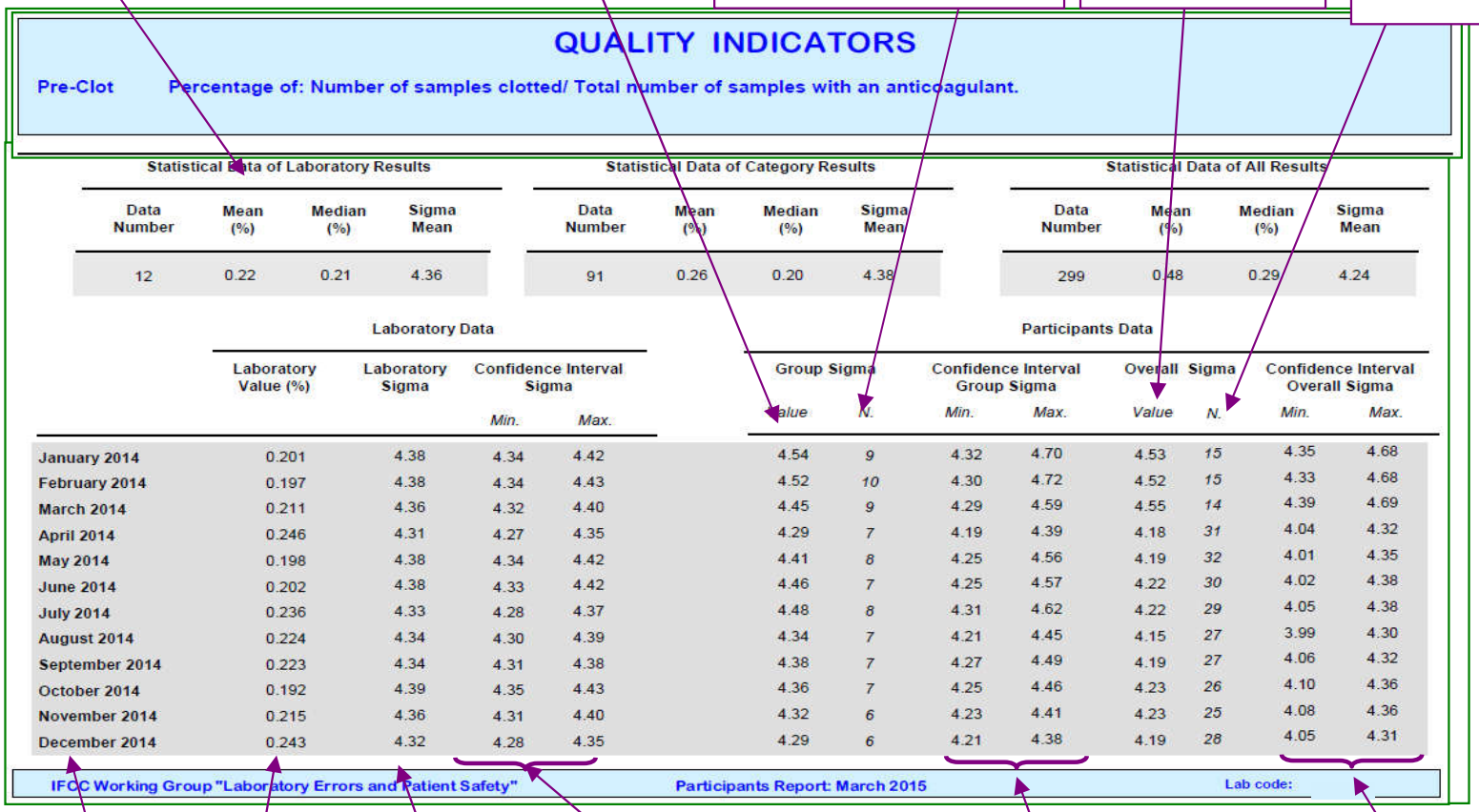
Dati statistici (numero di risultati, media, mediana, moda) calcolata sui risultati del laboratorio

Media calcolata sui valori sigma ottenuti dai laboratori appartenenti allo stesso gruppo

Numero di risultati sui quali è calcolata la media dei sigma appartenenti allo stesso gruppo

Media calcolata sui valori sigma ottenuti da tutti i laboratori

Numero di risultati sui quali è calcolata la media dei sigma tutti i laboratori



QUALITY INDICATORS

Pre-Clot Percentage of: Number of samples clotted/ Total number of samples with an anticoagulant.

Statistical Data of Laboratory Results

Data Number	Mean (%)	Median (%)	Sigma Mean
12	0.22	0.21	4.36

Statistical Data of Category Results

Data Number	Mean (%)	Median (%)	Sigma Mean
91	0.26	0.20	4.38

Statistical Data of All Results

Data Number	Mean (%)	Median (%)	Sigma Mean
299	0.48	0.29	4.24

	Laboratory Data				Participants Data							
	Laboratory Value (%)	Laboratory Sigma	Confidence Interval Sigma		Group Sigma		Confidence Interval Group Sigma		Overall Sigma		Confidence Interval Overall Sigma	
			Min.	Max.	Value	N.	Min.	Max.	Value	N.	Min.	Max.
January 2014	0.201	4.38	4.34	4.42	4.54	9	4.32	4.70	4.53	15	4.35	4.68
February 2014	0.197	4.38	4.34	4.43	4.52	10	4.30	4.72	4.52	15	4.33	4.68
March 2014	0.211	4.36	4.32	4.40	4.45	9	4.29	4.59	4.55	14	4.39	4.69
April 2014	0.246	4.31	4.27	4.35	4.29	7	4.19	4.39	4.18	31	4.04	4.32
May 2014	0.198	4.38	4.34	4.42	4.41	8	4.25	4.56	4.19	32	4.01	4.35
June 2014	0.202	4.38	4.33	4.42	4.46	7	4.25	4.57	4.22	30	4.02	4.38
July 2014	0.236	4.33	4.28	4.37	4.48	8	4.31	4.62	4.22	29	4.05	4.38
August 2014	0.224	4.34	4.30	4.39	4.34	7	4.21	4.45	4.15	27	3.99	4.30
September 2014	0.223	4.34	4.31	4.38	4.38	7	4.27	4.49	4.19	27	4.06	4.32
October 2014	0.192	4.39	4.35	4.43	4.36	7	4.25	4.46	4.23	26	4.10	4.36
November 2014	0.215	4.36	4.31	4.40	4.32	6	4.23	4.41	4.23	25	4.08	4.36
December 2014	0.243	4.32	4.28	4.35	4.29	6	4.21	4.38	4.19	28	4.05	4.31

IFCC Working Group "Laboratory Errors and Patient Safety" Participants Report: March 2015 Lab code:

Periodo di raccolta dati

Risultato del Laboratorio

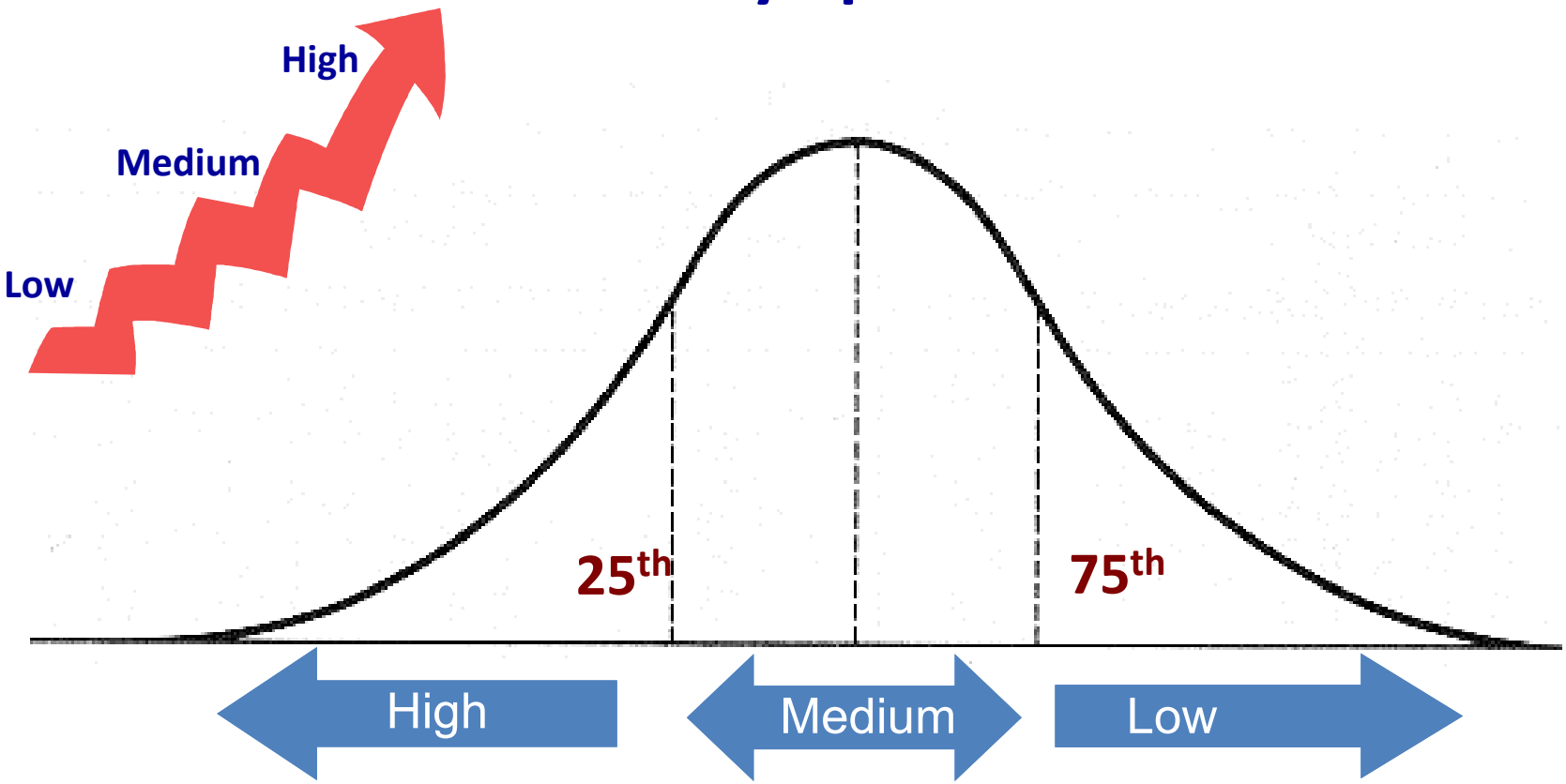
Sigma relativo al risultato del laboratorio

Intervallo di confidenza del valore sigma del laboratorio

Intervallo di confidenza relativo al sigma del gruppo

Intervallo di confidenza del sigma tutti I laboratori

Quality Specifications



State of the Art

IFCC Working Group "Laboratory Errors and Patient Safety"

Project on Model of Quality Indicators

*A **criterion** to define the **performance specifications** for each Quality Indicators has been proposed*

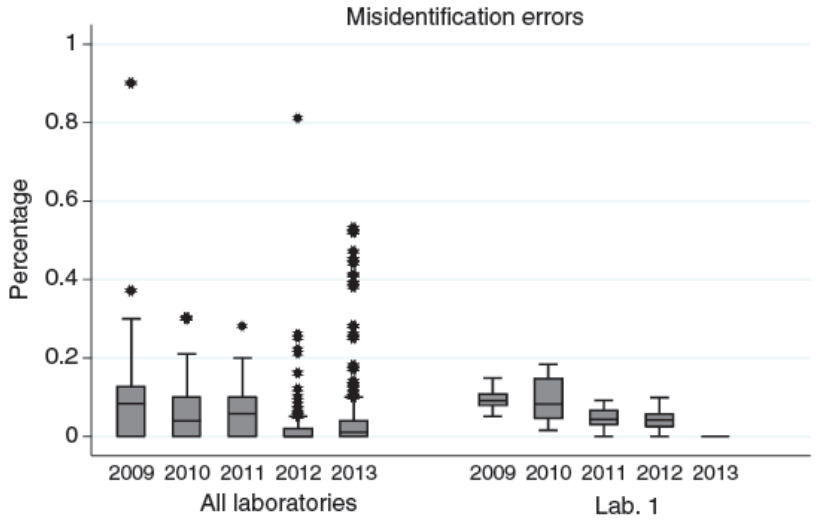
Opinion Paper

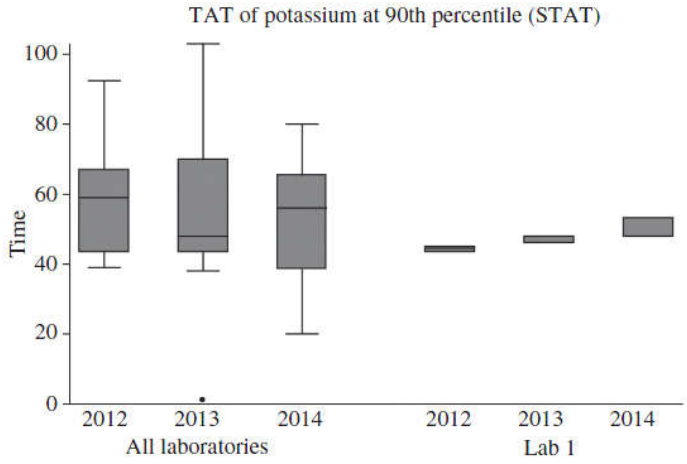
DE GRUYTER Clin Chem Lab Med 2015; 53(6): 943–948

Performance criteria and quality indicators for the pre-analytical phase

DE GRUYTER Clin Chem Lab Med 2015; aop

Performance criteria and quality indicators for the post-analytical phase





It is based on the results of participating laboratories: the lower percentiles represent the better performances; the higher percentiles the worst performances.

IFCC Working Group "Laboratory Errors and Patient Safety"

Project on Model of Quality Indicators

Three different goals *for each Indicator has been identified in order to allow laboratories to evaluate how they are placed in comparison with other labs and if improvement actions are possible.*

Opinion Paper

DE GRUYTER Clin Chem Lab Med 2015; 53(6): 943–948

Performance criteria and quality indicators for the pre-analytical phase

Table 2: Quality specifications for three QIs.

Quality indicators	Value	Quality specifications		
		Minimum	Desirable	Optimum
			(Based on 25th–50th–75th percentile)	
Misidentification errors	Percentage	0.040	0.010	0
	Sigma	4.54	5.04	5.25
Test transcription errors (added tests)	Percentage	0.240	0.070	0
	Sigma	4.26	4.59	4.74
Sample haemolysed	Percentage	0.852	0.440	0.120
	Sigma	3.84	4.09	4.39

Proposal of quality specifications based on percentiles values calculated on laboratories results (expressed as percentage and sigma) collected in the last year (2013).

Opinion Paper

DE GRUYTER Clin Chem Lab Med 2015; 53(6): 943–948

Performance criteria and quality indicators for the pre-analytical phase

Table 3: Proposal for quality specifications based on percentile values calculated on the basis of laboratories' results (expressed as percentages and, where appropriate, short term sigma) collected in 2014.

Quality indicators	Unit	Performance specifications based on 75th – 50th – 25th percentile		
		Low	Medium	High
Number of reports delivered outside the specified time/total number of reports	Percentage	0.22	0.060	0.006
	Sigma	3.904	4.5	4.795
Turnaround time (min) of potassium (K) at 90th percentile (STAT)	Time	66	53.2	39
Number of incorrect reports issued by the laboratory/total number of reports issued by the laboratory	Percentage	0.035	0.008	0.0002
	Sigma	4.7	5.1	5.4
Number of critical values of inpatients notified after a consensually agreed time (from result validation to result communication to the clinician)/total number of critical values of inpatients to communicate	Percentage	6.62	2.43[a]	0
Number of critical values of outpatients notified after a consensually agreed time (from result validation to result communication to the clinician)/total number of critical values of outpatients to communicate	Percentage	7.14	5.00[a]	0

[a]These values are different from those reported in Table 2 because, the median value is now calculated on data grouped by patient typology (inpatient and outpatient) on the basis of the improved formulation of the indicator introduced in 2014.

The use of 75th percentile, as a lower limit, seems to be the most practical approach so that no more than 25% of laboratories is considered to have a poor performance.

ISO 15189: 2022

Medical laboratories — Requirements for quality and competence

3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ **Quality Indicators**

5.6 **Risk assessment**

7.3.7 Ensuring the validity of examination results

- ✓ **Internal Quality Control**
- ✓ **External Quality Assessment**
- ✓ **Comparability of examination results**

8.8.2 **Quality Indicators**

8.8.3 Internal Audit

Audit Interni

8.8.3 Internal audits

8.8.3.1 laboratory shall conduct internal audits at planned intervals to provide information on wheter the management system:

a) conforms to the laboratory's own requirements for its management system, including the laboratory activities,

b) conforms to the requirements of this document and,

c) Is effectively implemented and maintained.

Audit Interni

8.8.3 Internal audits

8.8.3.2 laboratory shall plan, establish, implement and maintain an internal audit programme that includes:

a) **priority given to risk to patients from laboratory activities**;

b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of **nonconformities**, **incidents**, and **complaints**; and **changes** affecting the laboratory activities;

c) specified audit objectives, criteria and scope for each audit;

d) **selection of auditors who are trained, qualified and authorized** to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited;

e) ensuring objectivity and impartiality of the audit process;

f) ensuring that the results of the audits are reported to relevant personnel;

g) Implementation of appropriate corrections and corrective actions without undue delay;

h) Retentions of records as evidence of the implementation of audit programme and audit results.

NOTE ISO 19011 provides guidance for auditing management systems.

Audit Interni

Valutatori

Professionisti qualificati con competenza (conoscenze ed esperienza pratica) relativamente a:

- ✓ attività **pre-analitiche** e caratteristiche del campione che possono influenzare l'affidabilità dei risultati;
- ✓ **caratteristiche tecniche** delle procedure d'esame;
- ✓ attività **post-analitiche** che possono influenzare l'affidabilità delle informazioni di laboratorio;
- ✓ caratteristiche di performance che possono influenzare lo **scopo del test**;
- ✓ aspetti del **sistema di gestione per la qualità** necessari a supportare ed evidenziare i criteri e le procedure usate per garantire l'affidabilità delle informazioni di laboratorio.

Adeguatamente formati sulle procedure di audit al fine di garantire una **coerente**, **completa** ed **armonizzata valutazione** in relazione alle aree di competenza e al sistema di gestione per la qualità.

Audit Interni

ISO 19011: 2018

Linee guida per gli audit di sistemi di gestione

INDICE

ISO 15189: 2022

Medical laboratories — Requirements for quality and competence

3. Efficaci strumenti per il monitoraggio delle prestazioni (misurare, analizzare e valutare)

5.5d Objectives and policies ⟹ **Quality Indicators**

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7.3.7 Ensuring the validity of examination results

- ✓ **Internal Quality Control**
- ✓ **External Quality Assessment**
- ✓ **Comparability of examination results**

8.8.2 **Quality Indicators**

8.8.3 Internal Audit

ISO 15189: 2022
Medical laboratories — Requirements for quality and competence

5.6 Risk management

a) Laboratory management shall establish, implement, and maintain processes for **identifying risks of harm to patients and opportunities for improved patient care** associated with its examinations and activities, and **develop actions to address both risks and opportunities for improvement** (see 8.5).

b) The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective

NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.

NOTE 2 ISO 35001 provides details for laboratory biorisk management.

ISO 15189: 2022
Medical laboratories — Requirements for quality and competence

4. Efficaci azioni di miglioramento

General (4)

Structural and Governance (5)

5.6 Risk management

Resource (6)

Process (7)

Management System (8)

8.2.3. Evidence of commitment
8.5 Action to address risks and opportunities for improvement
8.6 Improvement
8.8 Evaluation

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Medical laboratories — Requirements for quality and competence

8.2 Managment system documentation

8.2.3 Evidence of commitment

Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving of its effectiveness.

ISO 15189: 2022

Medical laboratories — Requirements for quality and competence

8.6 Improvement

8.6.1 Continual improvement

a) The laboratory **shall** continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies.

b) The laboratory shall identify and select opportunities for improvement and develop, document, and implement any necessary actions. Improvement activities **shall** be directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5).

NOTE Opportunities for improvement can be identified through risk assessment, use of the policies, review of the operational procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and users, analysis of data and EQA results.

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Medical laboratories — Requirements for quality and competence

8.6 Improvement

8.6.1 Continual improvement

c) The laboratory **shall** evaluate the effectiveness of the actions taken.

d) Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.

e) Laboratory management shall communicate to personnel its improvement plans and related goals.

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Medical laboratories — Requirements for quality and competence

8.6 Improvement

8.6.2 Laboratory patients, user, and personnel feedback

The laboratory shall seek feedback from its patients, users, and personnel.

The feedback shall be analyzed and used to improve the management system, laboratory activities and services to users.

Records of feedback shall be maintained including the actions taken.

Communication shall be provided to personnel on actions taken arising from their feedback.

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Medical laboratories — Requirements for quality and competence

Gestione del miglioramento e monitoraggio dei processi

1. Obiettivi e Politica che garantiscano la Sicurezza del Paziente

2. Definizione di criteri e modalità operative che garantiscano l'affidabilità delle procedure e dei processi

3. Efficaci strumenti per il monitoraggio dei processi (misurare, analizzare e valutare)

4. Efficaci azioni di miglioramento

Grazie per l'attenzione