Traditional vs Individualized QC Plan:

The Good, The Bad and The Risky

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Knowing the Difference Between…

Traditional vs Conventional

Personalized vs Individualized

http://www.differencebetween.com/difference-between-conventional-and-vs-traditional/

Individualized QC Plan?

Traditional QC?

Risky

Who Dares Breaking the Rules?

The Good, the Bad and the Ugly (Italian title: *Il buono, il brutto, il cattivo*, lit. "The Good, the Ugly, the Bad") is a 1966 Italian epic Spaghetti Western film directed by Sergio Leone, starring Clint Eastwood, Lee Van Cleef, and Eli Wallach in the title roles respectively.[1]

http://en.wikipedia.org/wiki/The_Good,_the_Bad_and_the_Ugly

What's the Difference?

Traditional QC

↓

Equivalent QC

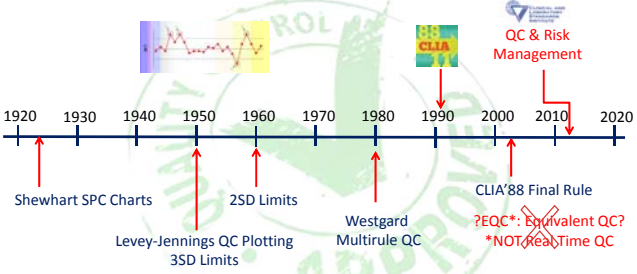
↓

Individualized QC Plan

CHANGE: ADAPT

Fail to Plan = Plan to Fail

Brief History of Traditional QC in Clinical Laboratories



The Center for Medicare and Medicaid Services (CMS) has developed a new Quality Control (QC) option under the Clinical Laboratory Improvement Amendments (CLIA) called the Individualized Quality Control Plan (IQCP). The IQCP educational and transitional period runs from January 1, 2014 to January 1, 2016.

A Risk-based QC Concept

Really Six Sigma Quality?

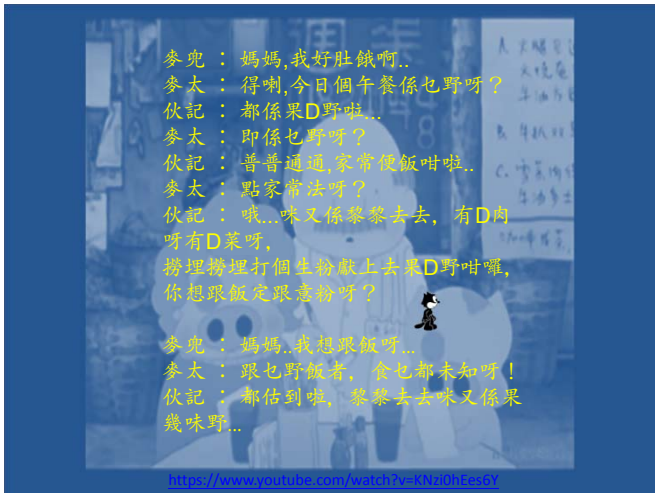
Nearly One Century…The Way Forward…?

Nowadays, we are on the edge of an era where 'one-size-fits-all' QC approach doesn't work all the time with different analytical systems.

Quality Assurance/Quality Control (in Medical Laboratories)

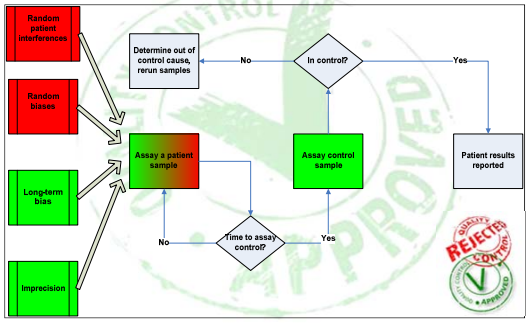
Quality must be designed from the front end, not tested on the back end

實驗室必須在一開始就做好質量設計，而不是最後才來分析質量



The Role of Traditional QC

What Causes Errors in Assays?



http://krouwerconsulting.com/Essays/Equivalent.htm

The Effect of Various QC Schemes on Detecting Errors

Systematic Errors vs Random Errors

Error Source	QC Scheme		
	Increased	Current (2 per day)	Reduced
Random patient interference	No effect	No effect	No effect
Short term bias	Catches more errors	Catches fewer errors	Catches even fewer errors
Long term bias	No effect	No effect	Catches fewer errors[1]
Imprecision	No effect	No effect	No effect

[1]For example, if a system is calibrated weekly, and there is calibration error, running QC monthly will frequently miss this error

很多變異和誤差用傳統的質控方法是無法檢出的

"Westgard Rules"

Traditional/Conventional QC

MULTIRULE AND "WESTGARD RULES": WHAT ARE THEY?

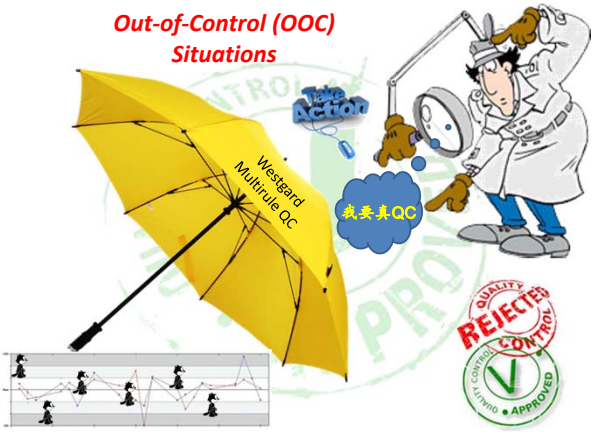
- What is Multirule QC?
- What are the "Westgard Rules"?
- What are other common multirules?
- How do you perform multirule QC?
- What is N?
- Why use a multirule QC procedure?
- Are there similar strategies for QC testing and diagnostic testing?
- Are there similar performance characteristics for QC and diagnostic tests?
- How can you use multiple tests to optimize performance?
- When should you use a multirule QC procedure?

Tips, Advice, Reference and more... for the "Westgard Rules"

- Abuses, misuses and "In-excuses" - a Top 10 list of inappropriate implementations of the "Westgard Rules"
- Best Practices - Optimizing the "Westgard Rules" in your lab for superior results
- The Original Multirule Paper - PDF files
- The "Westgard Rules" Minicourse
- Download a FREE Multirule Worksheet!
- QC - The Multirule Interpretation
- FAQ's about Multirule QC
- Multirules and QC Validator
- View Power Function Graphs of Multirules

http://www.quik.com.co/memorias/articulos/Westsgard/Multirule%20and%20westgard%20rules%20-%20what%20are%20they.pdf

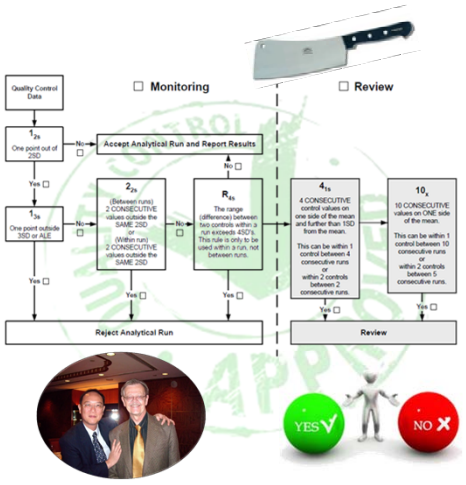
Out-of-Control (OOC) Situations



What is Multirule?

Out-of-Control (OOC) Situations

"Once is One Time Too Many"



Abuses, Misuses, and In-excuses

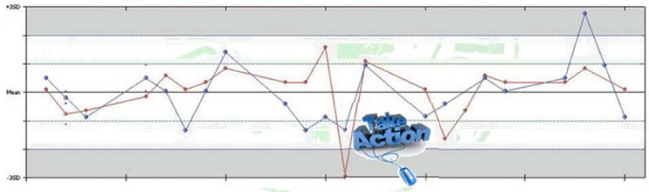
A Top 10 list of problems with QC and the "Westgard Rules"

And if you see a claim that they've "**modified**" the rules to make them better, be afraid....

http://www.westgard.com/lesson73.htm

Trends, Drifts and Shifts

- 5.6.2.3 Quality Control Data
  - *Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.*



NOTE Statistical and non-statistical techniques for process control should be used wherever possible to continuously monitor examination system performance.

"IQC To Detect Immediate Errors"

Myths or Facts?

- *This statement often leads laboratory personnel to incorrectly believe that QC will always catch errors, when in fact; it's the QC rule and frequency that determines if an out of control condition (OOC) will be caught.*
- *A poorly selected rule may not catch a smaller OOC condition until many many QC events have passed.*
- *The 2SD limits are generally not desirable because of the high Pfr, except occasionally they are necessary for low sigma analytes.*

Abuses, Misuses, and In-excuses

A Top 10 list of problems with QC and the "Westgard Rules"

- 10. Abuse of the term "Westgard Rules"
- 9. Misuse of "Westgard Rules" as a specific set of rules, namely $1_{2s}/2_{2s}/R_{4s}/4_{1s}/10_{x}$.
- 8. Misuse of the 12s "warning rule" in computer implementations.
- 7. "In-excuse" for using some inappropriate single-rules alone.
- 6. Misuse of the R_{4s} rule across runs.
- 5. "In-excuse" for illogical combinations of control rules.
- 4. Misuse of combinations of control rules whose error detection capabilities are not known.
- 3. "In-excuse" for not defining the details of rule implementation.
- 2. Misuse of "Westgard Rules" as a magic bullet.
- 1. Misuse of "Westgard Rules" when simpler QC will do.

http://www.westgard.com/lesson73.htm

CMS-CLSI Partnership

- CLSI convened the well-attended 'QC for the Future' meeting in 2005
  - Sponsored by accreditation bodies, industry, professional organizations & government agencies
  - Outcome: Stakeholder concern that manufacturers don't provide labs sufficient information
  - 'One-size-fits-all' QC doesn't work with new technology
- CLSI meeting directed the development of Evaluation Protocol (EP)-*23 - Laboratory Quality Control Based on Risk Management* published in October, 2011.
- CMS incorporated key EP-23 concepts into CLIA Interpretive Guidelines as QC policy, called **IQCP**.

Individualized Quality Control Plan (IQCP)

- The Centers for Medicare & Medicaid Services (CMS), Baltimore, which is implementing a new quality control option for labs based on risk management, has provided interpretive guidelines.
- The Individualized Quality Control Plan (IQCP) will give labs flexibility in customizing Quality Control (QC) policies and procedures depending on the test systems they are using and the individual characteristics of the labs themselves.

http://www.clpmag.com/2013/08/cms-provides-iqcp-interpretive-guidelines-for-labs/#sthash.RKjVO9B2.dpuf

CMS Provides IQCP Interpretive Guidelines for Labs

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-54-CLIA

DATE: August 16, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

http://cdn.clpmag.com/clpmag/2013/08/Survey-and-Cert-Letter-13-54.pdf

CMS.gov
Centers for Medicare & Medicaid Services

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure11.pdf

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

IQC Plan is *Voluntary*

- Only if
  - You want to reduce QC for a test or a device to less than 2 times per day
- Or
  - The manufacturer (product insert) recommends QC less than 2 times per day

Who dares breaking the rules?

Clinical Laboratory Improvement Amendments

CLIA's minimum QC of TWO levels per day should apply only to measurement procedures that demonstrate

- 5 sigma quality or higher.

Manufacturer's Recommendations

Question

廠商靠得住嗎？

Why Labs should perform Risk Assessment (Analysis and Evaluation)?

Currently Manufacturers of IVD Devices

Do NOT give much, if any information about Device Risk

IQC Plan is *Voluntary*

- Labs will continue to have the option of gaining compliance by following all Clinical Laboratory Improvement Amendments (CLIA) QC regulations as written.
- The lab director is responsible for ensuring that QC programs are established and maintained to guarantee the quality of lab services provided, and to identify failures in quality as they occur.

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Individualized QC Plan (Three Important Elements)

Risk Assessment (RA)

Quality Control Plan (QCP)

Quality Assessment/Assurance (QA)

Risk Assessment

- Risk assessment (RA) is the identification and evaluation of potential failures and sources of errors in a testing system. RA must include, at a minimum, an evaluation of the following five components in the laboratory:
  - ✓Specimen
  - ✓Environment
  - ✓Reagent
  - ✓Test System
  - ✓Testing Personnel

Adapted from the Centers for Medicare and Medicaid Services (CMS) Memo Dated August 16, 2013.

Conceptual Issue
一個非常基本的概念

Poor Performance
分析性能不理想

Root Cause Analysis
根本原因分析(RCA)

Risk Assessment
風險評估

多做QC質控就能保證品質了嗎？

儀器本身如果有先天的缺陷，哪多做質控也無補於事的！

選購儀器前一定要做足評估工作。

儀器招標規格

Tender Specifications

"天作孽猶可恕自作孽不可活"
是什麼意思?

- 《尚書·太甲中》：『天作孽猶可違，自作孽不可逭』
- 《詩》云：「永言配命，自求多福。」

孽，災也。違逭相通，避也，逃也。言天災可避，自作災不可逃。

The following list contains possible sources of information for conducting a Risk Assessment:

- ✓ Regulatory requirements
- ✓ Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- ✓ Manufacturer's operator manual
- ✓ Troubleshooting guide
- ✓ Manufacturer's alerts and bulletins
- ✓ Verification of establishment of performance specifications
- ✓ Testing personnel qualifications, training, and competency records
- ✓ QC data
- ✓ Proficiency testing data
- ✓ QA information, including corrective action
- ✓ Scientific publications
- ✓ Other information as appropriate

Adapted from the Centers for Medicare and Medicaid Services (CMS) Memo Dated August 16, 2013.

The Quality Control Plan (QCP)

- The Quality Control Plan (QCP), based on the identified risk(s), is a comprehensive strategy that includes all control procedures to reduce residual risk and methods to immediately detect errors, using both prevention and monitoring strategies.
- The QCP is intended to proactively address potential risks before they occur and result in failures, compared to the practice of addressing failures after they occur.

Fail to Plan = Plan to Fail

Quality Assessment

- Documents to consider for QA review may include, but are not limited to:
  - ✓ QC review
  - ✓ Proficiency testing records (scores, testing failures, trends)
  - ✓ Patient result review
  - ✓ Specimen rejection logs
  - ✓ Turnaround time reports
  - ✓ Records of preventive measures, corrective actions, and follow-up
  - ✓ Personnel competency records

Adapted from the Centers for Medicare and Medicaid Services (CMS) Memo Dated August 16, 2013.

Eligible for IQCP

- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- General Immunology
- Syphilis Serology
- Hematology
- Immunohematology
- Clinical Cytogenetics
- Radiobioassay
- Histocompatibility

Eligible for IQCP

- Microbiology
  - Bacteriology
  - Mycology
  - Mycobacteriology
  - Parasitology
  - Virology
- Alternative QC already acceptable to CMS

Not Eligible for IQCP

- Pathology
  - Histopathology
  - Oral pathology
  - Cytology
- 493.1256 (6)-(10)

(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.
(7) Over time, rotate control material testing among all operators who perform the test.
(8) Test control materials in the same manner as patient specimens.
(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.
(10) Establish or verify the criteria for acceptability of all control materials.

http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec493-1256.pdf

The CAP Laboratory Accreditation Program plans to introduce IQCP in its July 2015 checklist, subject to CMS approval. The CAP Checklists Committee, together with the Point-of-Care Testing Committee, is working on changes and will submit a plan for concept approval in early fall.

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http://www.captodayonline.com

cap

Risk management steps up labs' QC game under IQCP

Date : September 12, 2014

Anne Paxton

September 2014—Industrial risk management. It may not seem all that sexy as a concept, but in the field of laboratory quality control, risk management has become about as buzzworthy as is possible. One of the key reasons: The Centers for Medicare and Medicaid Services has embraced risk management as the foundation of a new option for meeting CLIA quality control standards called IQCP, or Individualized Quality Control Plan.

Four Key CMS Regulations for Moderately Complex Tests

- 493.1253 Test Method Verification
  - accuracy
  - precision
  - reportable range and
  - reference ranges
- 493.1254 Maintenance and Function Checks
- 493.1255 Calibration and Calibration Verification
- 493.1256 QC Procedures

CMS.gov
Centers for Medicare & Medicaid Services

CMS/CLIA Website:
http://www.cms.hhs.gov/clia/

5.6 Ensuring quality of examination results

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.6.H HOKLAS Policy on Ensuring quality of examination results

Each HOKLAS accredited laboratory shall adopt an appropriate set of quality control procedures suitable to the range of work done and to the number of testing staff available. The results of such procedures shall be fully recorded and be available for review during HOKLAS assessments. Where a standard specifies a quality control procedure, it shall be followed.

The laboratory shall participate in at least one proficiency testing programme annually for each discipline. The programme(s) shall cover all accredited test areas in each discipline. Specific requirements, if any, for each discipline are given in the respective HOKLAS Supplementary Criteria. Generally, laboratories shall perform the examinations and report the results to the organisers for all rounds of the programmes for all examinations that are within the Scopes of Accreditation of the laboratories.

When developing new examination procedures, the laboratory shall consider carefully their quality control requirements. This should be documented as part of the quality assurance plan for those examination procedures. Where necessary, the existing quality control procedures should be extended to cover the new work or new procedures. The adequacy of the quality control procedures will be examined critically during assessments. The quality control plan, together with the acceptable criteria and actions to be taken in out of control situations, shall be documented. Quality control plans shall include, where relevant, the use of control samples (positive and/or negative, relevant levels), duplicates, blanks, spikes, etc. Control samples shall be of a similar matrix as the patient samples. Correlation of results in a sample shall be reviewed, where relevant.

http://www.itc.gov.hk/en/quality/hkas/doc/common/publication/hoklas_pub_en.pdf

Detect Immediate Errors

- "Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance" (CLIA 493.1256)
  - Most importantly
- Perform corrective actions to "recover" before reporting of test results

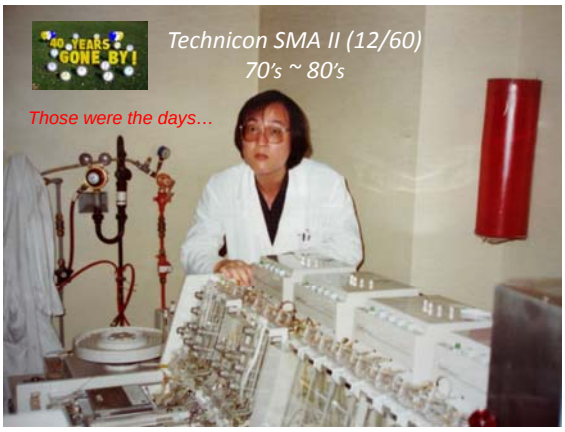
CMS.gov
Centers for Medicare & Medicaid Services

http://www.clinchem.org/content/51/10/1911.full

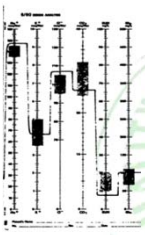
The Old Days

- The CLIA requirement for testing TWO levels of liquid QC every day a test is run comes from the days when labs ran just a few batches of patient samples a day.
- With the new, more automated analyzers (those so-called "black boxes"), there is no longer batch analysis and patient samples are analyzed continuously (or in discrete mode).

- CLIA's minimum QC of TWO levels per day should apply only to measurement procedures that demonstrate 5 sigma quality or higher.



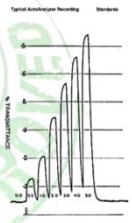
Detect Immediate Errors



SMA 6/60

Calibration/QC done every 10-15 samples

Those were the days...

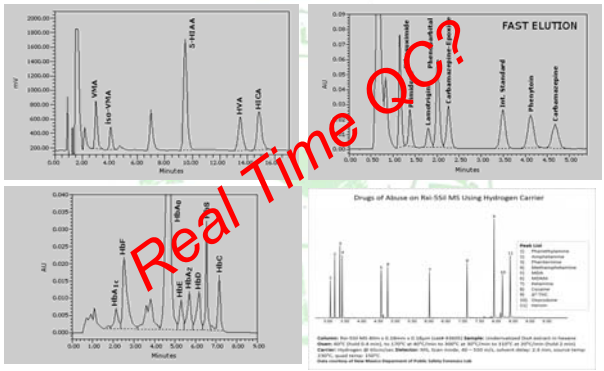


Curve Tracking

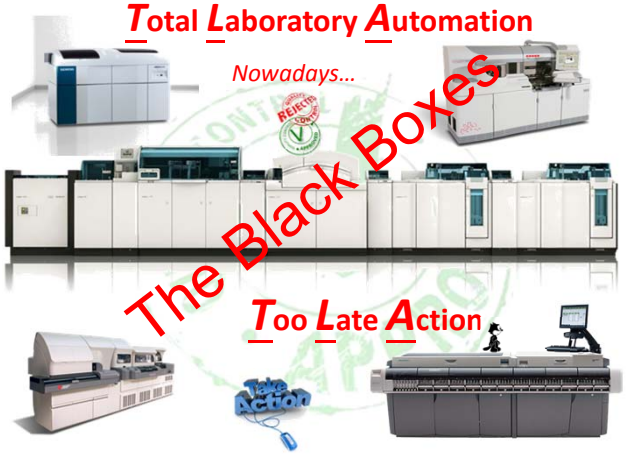
Technicon AutoAnalyzer I

**Real Time Monitoring*

HPLC/LC/GC/MS/MS



Total Laboratory Automation



Individualized QC Plan
More Emphasis on…

Risk Management

Patient Safety

NATA

ISO 15189

HKAS

cap

"Accreditation is, at its core, a Risk Reduction activity"

風險管理被定義為系統地應用管理政策、程式和做法，
分析, 評價、控制和監控風險

Risk Management
風險管理

Risk management is defined as the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971).

Medical devices – Application of risk management to medical devices. ISO14971:2007 (Geneva, Switzerland: International Organization for Standardization, 2007).

What is the Best Quality Management?
什麼是最好的品質管理？

More with Less?

(有自信)
可以少做質控QC

ISO 15189: 2012

4.14 Evaluation and Audits

4.14.6 Risk management

– *The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.*

4.14.6 風險管理(ISO 15189: 2012新要求)

– 實驗室應針對影響病人安全的工作流程與檢驗結果之潛在失效的衝擊進行評估，並應調整流程以減少或消除已鑑別的風險，並將決定及採行措施予以文件化。」

– 当检验结果影响患者安全时，实验室应评估工作过程和可能存在的问题对检验结果的影响，应修改过程以降低或消除识别出的风险，并将做出的决定和所采取的措施文件化。

Consensus?

簡單三行字，如何做？作多深？若AO不公布指引，在毫無共識之下，將來爭議必多

在CLIA框架下新的IQCP（Individualized Quality Control Plan；個別化品質管理計畫/个性化质量控制计划）是應用風險管理的品質管理/质量控制新概念，每一位評審員(Assessor)都會接受嗎？

AO: Accreditation Organization

HOKLAS 015 (Fifth Edition)

Abridged Version
(Requirements and notes of ISO 15189 are not included in this document. This document should be read in conjunction with ISO 15189 : 2012)

Technical Criteria for Laboratory Accreditation (Medical Laboratories)

http://www.itc.gov.hk/en/quality/hkas/doc/common/publication/hoklas_pub_en.pdf

4.14 Evaluation and audits

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.14.H HOKLAS Policy on Evaluation and audits

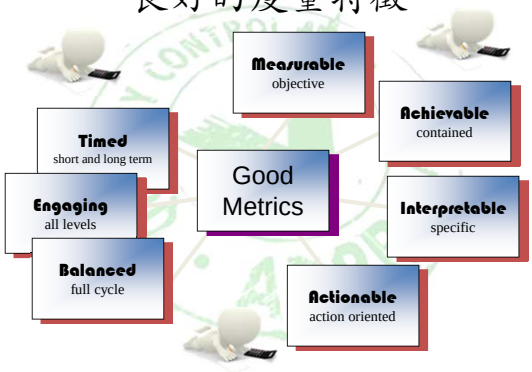
To solicit user feedback as required in 4.14.3 could be achieved in a number of ways, including but not limited to having annual customer feedback survey, holding regular customer liaison meetings or encouraging completion of readily available customer suggestion forms.

Laboratories are encouraged to take note of the examples of quality indicators given under 4.14.7 and in Note 1 and 2 for implementation and where measurable indicators are established, they shall be monitored.

HOKLAS policy on internal audits is detailed in HKAS Supplementary Criteria No. 5.

The Quality Toolbox

Characteristics of Good Metrics
良好的度量特徵



Occurrence Rating

CLSI EP23A Occurrence Rating

EP23 Rating	Definition	Ratio	Defect rate
Frequent	Once per week	1/7	0.1429
Probable	Once per month	1/30	0.0333
Occasional	Once per year	1/350	0.0029
Remote	Once every few years	1/1000	0.0010
Improbable	Once in lifetime of system	1/2000	0.0005

EP23-A 7.2.1
If probability estimates are not easily quantifiable, EP23 suggests using descriptive categories.

Estimation of Occurrence

Lab Process Description	Parameters
Samples/run	50
Runs/day	2
Workdays/week	6
Weeks/year	52
Months/year	12
Workdays/year	312
Samples/year	31200
3 year factor	0.33
5 year factor	0.20

Ranking Scale

Ranking	Description
Very frequent	1 sample/day
Very frequent	1 run/day
Frequent	1 sample/week
Frequent	1 run/week
Probable	1 run/month
Probable	1 day/month
Occasional	1 day/year
Remote	1 day/3 years
Improbable	1 day/5 years

Sigma-Metrics and Defect Rate

Ranking	Defects/ Year	Defect Rate	Defects/ Million
1 sample/day	312	0.0100	10,000
1 run/day	15,600	0.5000	500,000
1 sample/week	52	0.0017	1,667
1 run/week	2,600	0.0833	83,333
1 run/month	600	0.0192	19,231
1 day/month	1,200	0.0385	38,462
1 day/year	100	0.0032	3,205
1 day/3 years	33	0.0011	1,058
1 day/5 years	20	0.0006	641

DPM = Defects per Million

TABLE 1.1 Sigma Table

Sigma	Defects per Million	Yield
6.0	3.4	99.9997%
5.0	233.0	99.977
4.0	6,210.0	99.379
3.0	66,807.0	93.32
2.5	158,655.0	84.1
2.0	308,538.0	69.1
1.5	500,000.0	50.0
1.4	539,828.0	46.0
1.3	579,260.0	42.1
1.2	617,911.0	38.2
1.1	655,422.0	34.5
1.0	691,462.0	30.9
0.5	841,345.0	15.9
0.0	933,193.0	6.7

Choosing OWN QC Rules Based on Error Rates

$SE_c = [(TEa\text{-}bias)/s] - z$

ΔSE_c	QC Rule Low	Moderate	High
> 3	1-3.5s	1-3s	1-2.5s (D, I)
2-3	1-3s	1-2.5s	1-2s (D, I)
1-2	1-2.5s (D)	1-2s (D, +)	1-2s (D, +, I)
<1	1-2s (D, I)	1-2s (D, +, I)	1-2s (D, +, I)

D: examine QC chart Daily, **+**: Increase control frequency;
I: Initiate corrective action

Error Rate Categories
Low= method that experiences <3% QC flags/year
Moderate= method that experiences 3-10% QC flags/year
High= method that experiences >10% QC flags/year

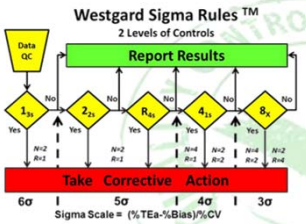
Frontiers in Clinical Biochemistry Symposium, 2012 Taipei
http://www.cacb.org.tw/

By courtesy of
Alan Wu, PhD, FACB

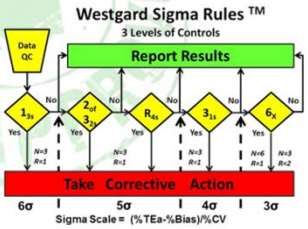
SPC Tools

- Power Function Graphs
  - Clin Chem 1979;25:863-9.
- Critical-Error Graphs
  - Clin Chem 1990;36:230-3.
- QC Selection Grids
  - Clin Lab Sci 1990;3:271-8.
- OPSpecs Chart
  - Clin Chem 1992;38:1226-33.
- QC Validator
  - Clin Chem 1997;43:400-3.
- EZ Rules 3 computer programs
  - Westgard JO. Assuring the Right Quality Right. Chapter 11. How to use the EZRules 3 computer program. Madison WI: Westgard QC, Inc., 2007.

Westgard Sigma Rules



To look for faster and simpler tools that will help laboratories select the right SQC for their own applications.



http://www.westgard.com/westgard-sigma-rules.htm

QC Frequency

(Collective Opinion Paper)

- >6σ (excellent performance) – evaluate with one QC per day (alternating levels between days) and a 1-3.5s rule.
- 4σ–6σ (suited for purpose) – evaluate with two levels of QC per day and the 1-2.5s rule.
- 3σ–4σ (poor performance) – use a combination of rules with two levels of QC twice per day.
- <3σ (problematic) – maximum QC, three levels, three times a day. Consider testing specimens in duplicate.

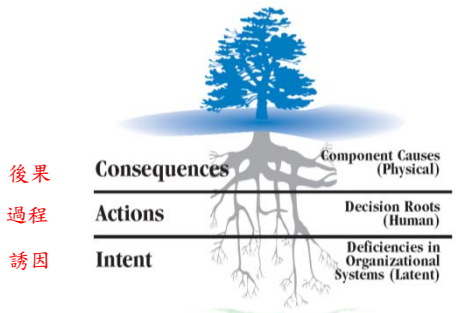
Clin Chem Lab Med 2011; 49: 793-802.

ISO 15189: 2012

4.11 Preventive Action

- *The laboratory 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.*
  - *Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (PT, proficiency testing).*

The Three Levels of Cause



American Society for Healthcare Risk Management

ASHRM Journal 2004 ; Vol 24 : No. 3

Preventive Action is a Proactive Process…

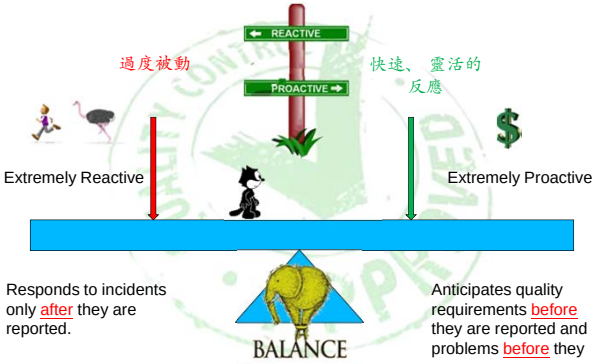
- *The Individualized Quality Control Plan (IQCP), based on the identified risk(s), is a comprehensive strategy that includes all control procedures to reduce residual risk and methods to immediately detect errors, using both prevention and monitoring strategies. The QCP is intended to proactively address potential risks before they occur and result in failures, compared to the practice of addressing failures after they occur.*

Relevant ISO 15189: 2012 Clauses:

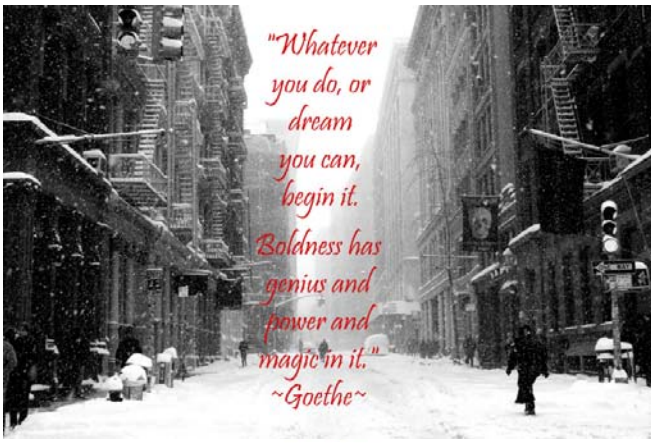
- 4.15.1. Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.
- 4.15.3. The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, also be objectively evaluated.

"Proactively"

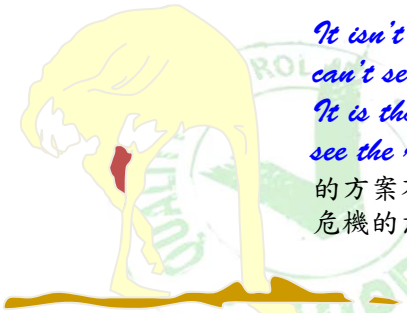
如何達到均衡點



被動和主動



Winter Storm in New York City – January 2015



It isn't that they can't see the solution. It is that they can't see the risk 沒有解決的方案不要緊。沒有危機的意識就麻煩了

"no eye see"

ISO 15189: 2012

5.6.2.2 Quality Control Materials

- Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

A White Paper on QC

Bio-Rad Laboratories ⟷ PATIENT RISK MANAGEMENT

Looking Ahead to Patient Risk Management

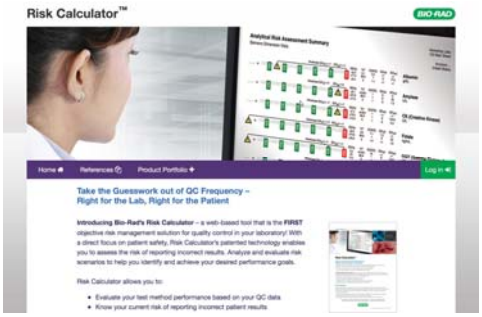
We're now living in a time when sophisticated automated systems continuously produce patient test results. Yet typical QC practices are based around a batch of patient samples, or are set by default to a once daily, regulatory minimum. Take your laboratory into the era of patient risk management – with Bio-Rad as your partner.

In this article you will learn about building a QC system based around patient risk management. Related articles in the appendices provide more detail on key concepts.

evaluation of QC materials. For more information on the extent of the window of vulnerability see the related article *Expected Number of Patients Compromised by Failure* (Appendix II).

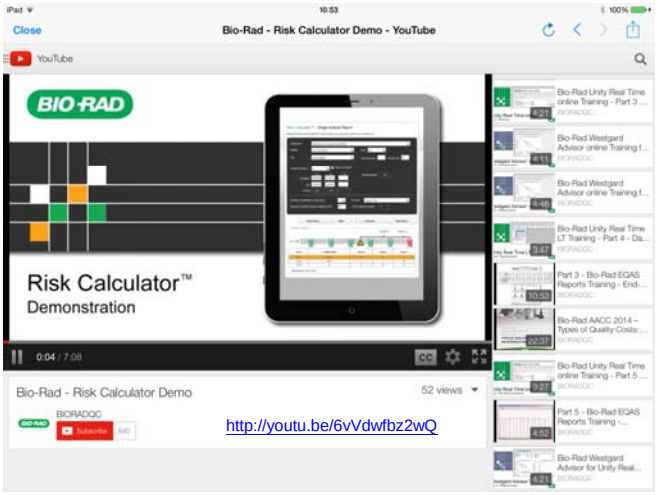
Since the expectation is that on average half the number of patient specimens tested between QC evaluations will be affected in the event of an undetected test system failure [3], the question becomes how often should QC materials be run? Typically, analyzer performance is verified with QC

http://www.qcnet.com/QCDocuments/PatientRiskManagement/tabid/7546/language/en-US/Default.aspx



Bio-Rad is completing development of an IQCP-oriented software tool to complement its Unity program. "This tool will allow labs to look at the performance of the test along with their QC rules and their risk comfort level and give a recommendation for QC frequency. If a lab says it is more comfortable with more patients being tested between QC events, for example, that's taken into account. We do this on an analyte-by-analyte basis, because different analytes have different risk levels associated with them."

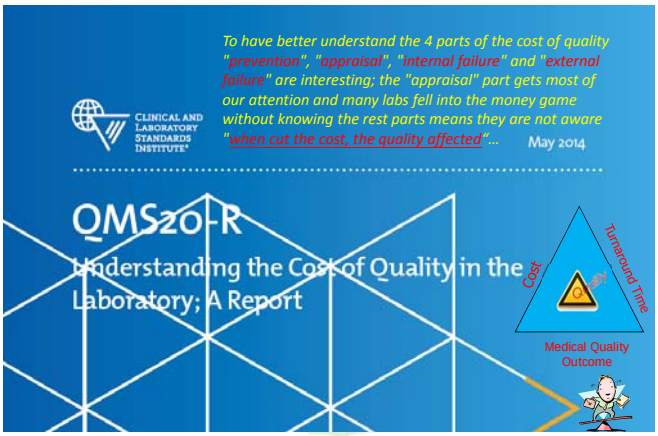
Called Risk Calculator, the Bio-Rad software is slated for release in early 2015. Other programs designed to help laboratories with IQCP include Carepoint Solutions' EZ-QCP and a software package available from CRI, the educational arm of COLA, called IQCP E-Optimizer.



http://youtu.be/6vVdwfbz2wQ

Minimum Requirement

現今很多實驗室主管都有一種心態：認可要求的一定做，沒要求的，就（可以）不做！不要忘記：CAP/ISO 認可只是最低要求（Minimum Requirement）啊！



http://clsi.org/blog/2014/05/22/qms20-r/

Time Flies…

An Era of Risk Management

Acknowledgements

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- Curtis Parvin
- Andy Quintenz
- Alan Wu
- …

**Personal Communications*

Quality Cocktail
The Solution?

Be it Lean, Six Sigma, CLSI/Risk Management, CAP and/or ISO 15189?

ISO Guidelines for Risk-Based QC

- *ISO 14971:2007* Medical Devices – Applications of Risk Management to Medical Devices
- *ISO 15198:2004* Validation of User Quality Control Procedures by the Manufacturer
- *ISO 15189:2012* Medical Laboratories – Requirements for Quality and Competence

CLSI Guidelines for Risk-Based QC

- *CLSI EP18-A3:2009* Risk Management Techniques to Identify and Control Laboratory Error Sources
- *CLSI C24-A3:2006* Statistical Quality Control for Quantitative Measurement Procedures
- *CLSI EP23-A:2011* Laboratory Quality Control Based on Risk Management

Bring Home Messages

- *Quality Management System* (QMS) requires application of preventive measures to reduce the opportunity for significant error. Laboratories can develop strategies to incorporate patient safety goals and risk management techniques within the QMS to prevent error.
- *Traditional QC* is a powerful technique for managing the analytical quality of laboratory testing processes, but it must be implemented properly to provide the potential benefits.
- *Individualized QC plan* based on the identified risk(s), is a comprehensive strategy that includes flexibility in customizing QC policies and procedures depending on the test systems used and the individual characteristics of the laboratory.

Frank Sinatra

I Did It …

Individualized QC Plan

- *Regrets, I've had a few; but then again, too few to mention.*
- *I did what I had to do and saw it through without exemption.*
- *I planned each charted course; each careful step along the byway,*
- *But more, much more than this, I did it my way. ..*

http://iamzeeshan.blogspot.hk/2011/12/as-frank-sinatra-said-my-way.html#sthash.e50VnAJU.dpuf

常餐，特餐，快餐，午餐，晚餐

參兜：麻煩，我要一個常餐呀
參太：常餐？常餐有什麼吃的呀？
伙記：跟特餐一樣囉
參太：那特餐是什麼東西呀？
伙記：跟快餐差不多囉
參太：那快餐又是什麼呀？
伙記：切，快餐不就是午餐
參太：午餐吃什麼呀？
伙記：午餐同晚餐一樣啊
參太：那晚餐又吃什麼呀？
伙記：晚餐也就是常餐囉
參太：這樣呀，我要兩個常餐呀
伙記：好東西呀，我們今天的常餐。。。。。不好意思，常餐賣完了

參兜：恩，那改要特餐呀
參太：特餐？特餐有什麼吃呀？
伙記：特餐也就是午餐囉
參太：午餐吃什麼的呀？
伙記：都是晚餐那些東西呀
參太：那什麼是晚餐呀？
伙記：同快餐一樣囉
參太：那快餐吃什麼的？
伙計：恩，快餐也就是常餐囉。。。。。

https://www.youtube.com/watch?v=bjsjSLYDEWg

ISO 15189 : 2012/2017

- **5.5.1 Selection, verification and validation of examination procedures**
- **5.5.1.1 General**
- The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination.
- **5.6.2 Quality control**
- **5.6.2.1 General**
- The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.
  - *NOTE In several countries, quality control, as referred to in this subclause, is also named "internal quality control."*

Medical Laboratories - Requirements for Quality and Competence

What Does P Stand for?

Policy?
Process?
Protocol?
Plan?
Procedure?
Program?
Practice?
Placebo?
Or just
Problem..?

Questions…