ARUP® LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

Quality Indicators – What's Required and How to Handle Outliers

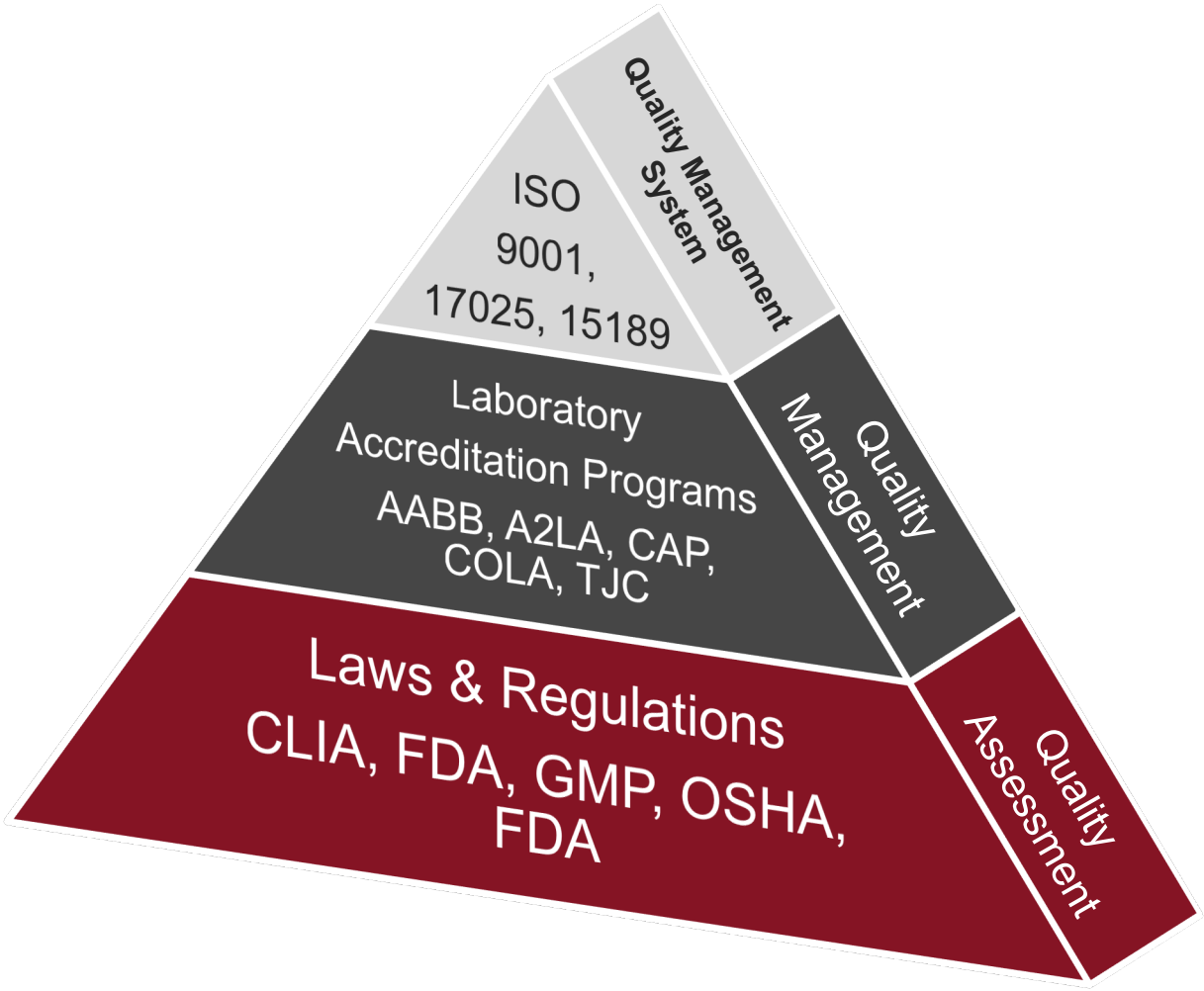
Lab Quality Confab 2019

Presenter: Anne T. Daley, ARUP Quality Officer

Key Learning Objectives

- To expand knowledge of regulatory and accrediting agency requirements regarding the use of quality indicators to monitor performance
- To learn different options on how to respond to unacceptable quality indicator performance
- To develop immediate strategies to address quality indicator issues within the participant's organization.

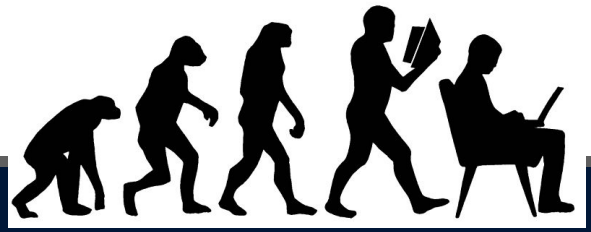
Taking Quality to the Next Level



Evolution of Quality in Medical Laboratories

Elements	QC	QA	QMS
Focus	Method control	Process management	Laboratory-wide system
Scope	Verified examination method controlled to ensure production of correct results by: • Instrument's internal controls • Manufacturer's control materials • Purchased external control materials	Accuracy and efficiency of: • Preexamination processes • Examination processes • Postexamination processes	Effectiveness and sustainability of the management and technical processes that support and move work through the laboratory
Limitations	Does not prevent preexamination or postexamination errors	Does not prevent errors that occur outside the path of workflow processes listed above	No limitations, by including all aspects of laboratory management and technical operations
Evolution of levels	QC was the beginning of quality measures in the medical laboratory.	QA's process focus is broader than QC's method focus.	A QMS's system-wide focus is broader than QC's method focus and QA's process focus.

Resource: CLSI *A Quality Management System Model for Laboratory Services, (Proposed Draft QMS01, 5th ed., 2018)*



What is required?

Interpreting the Standards

- **Needs to / must / shall / is** – explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
- **Require** – represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
- **Should / may be** – describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement

Resource: Modified from CLSI *A Quality Management System Model for Laboratory Services, (Proposed Draft QMS01, 5th ed., 2018)*

CLIA 24CFR §493.1239

§493.1239 Standard: General laboratory systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all general laboratory systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

Same wording for Preanalytic Systems (§493.1249), Analytic Systems (§§493.1289), Postanalytic Systems (§493.1299),

CLIA 24CFR §493.1290

§493.1290 Condition: Postanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

CAP Laboratory General 2019 Checklist

***REVISED** 09/17/2019*

GEN.13806 QM Program **Phase II**

The laboratory has a written quality management (QM) program.

NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program.

The program must ensure quality throughout the pre-analytic, analytic, and post-analytic phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; accurate timely testing/examination; and accurate timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory is expected to develop plans of corrective action based on data from its QM system.

The QM program may be based upon some reference resource such as CLSI QMS01-05; the ISO 9000 series or ISO 15189; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design. If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM program.

GEN.20100 QM Extent of Coverage **Phase II**

The QM program covers all areas of the laboratory and all beneficiaries of service.

CAP Laboratory General Checklist 2018/2019

GEN.20100 QM Extent of Coverage **Phase II**

The QM program covers all areas of the laboratory and all beneficiaries of service.

NOTE: The QM program must be implemented in all areas of the laboratory (eg, chemistry, anatomic pathology, satellite, point-of-care, consultative services). The program must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and referral laboratory services.

CAP Laboratory General Checklist 2018/2019

GEN.16902 QM Program Implementation **Phase II**

For laboratories that have been CAP accredited for more than 12 months, the QM program is implemented as designed and is reviewed annually for effectiveness.

NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM program, as appropriate.

Evidence of Compliance:

✓ Evidence that the QM program has been implemented as designed requires all of the following:

- quality measurements/assessments specified in the program are being substantially carried out;
- there is evidence of active review of quality measurements;
- if target performance levels are specified in the QM program and the targets are not being met, there are records of follow-up action;
- any interventions/changes to operations that are specified in the QM program have been carried out as scheduled, or the reason for delay recorded; **AND**
- any communication of information that is required by the QM program have taken place

CAP Laboratory General Checklist 2019

***REVISED** 09/17/2019*

GEN.20208 QM Patient Care/Client Services **Phase II**

The QM program includes a process to identify and evaluate errors, incidents and other problems that may interfere with patient care/client services.

NOTE: There must be an organized process for recording problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care/client services or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must record investigation and resolution of these problems.

CAP Laboratory General Checklist 2019 - *NEW*

***NEW** 09/17/2019*

GEN.20310 Investigation of Non-conforming Events **Phase II**

The QM program requires a root cause analysis (RCA) when a non-conforming event occurs that results in death, permanent harm or severe temporary harm (eg, sentinel event). For nonconformances that represent a risk to patients, donors, employees, or the health and safety of the general public, but are not sentinel events (eg, near misses), the QM program includes a process to define the scope and extent of the investigation required.

NOTE: An RCA is a systematic process for identifying the causal factor(s) that underlie errors or potential errors in care. By conducting an RCA and addressing root causes, the laboratory may be able to substantially or completely prevent the same or similar incident from recurring. Laboratories must be able to demonstrate appropriate risk-reduction activities based on such RCAs.

Helpful tools on RCA can be found on cap.org on the CAP15189 Accreditation Program landing page.

Evidence of Compliance:

- ✓ Written QM policy and procedure for performing a root cause analysis or investigation of nonconformities **AND**
- ✓ Records of root cause analysis and other nonconformity investigations

CAP Laboratory General Checklist 2018/2019

***REVISED** 08/22/2018*

GEN.20316 QM Indicators of Quality **Phase II**

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

NOTE: Key indicators must monitor activities critical to patient outcome or that may affect many patients. The laboratory must evaluate its indicators by comparing its performance against published benchmarks, or against benchmarks mutually agreed upon by the laboratory and the providers it serves. The laboratory must also evaluate the effectiveness of corrective actions taken to optimize its critical processes. The number of monitored indicators must be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories must monitor multiple aspects of the testing process appropriate to their scope of service.

For laboratories that have implemented one or more individualized quality control plans (IQCPs), the quality management program must include a review of the ongoing monitoring of the effectiveness of each IQCP.

While there is no requirement to monitor any specific laboratory indicator, the following key quality indicators have been commonly used to measure laboratory performance in a consistent manner and are important to clinicians and patients as indices of care.

CAP Laboratory General Checklist 2018/2019

1. *Patient/Specimen Identification: Percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors*
2. *Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer*
3. *Specimen Acceptability: Percent of specimens accepted for testing*
4. *Stat Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority (eg, emergency department or intensive care unit specimens), mean or median turnaround time, or the percent of specimens with turnaround time that falls within an established limit*
5. *Critical Result Reporting: Percent of critical results with written record that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time*
6. *Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents*
7. *Corrected Reports – General Laboratory: Percent of reports that are corrected*
8. *Amended Reports – Anatomic Pathology: Percent of reports that are amended*
9. *Surgical Pathology/Cytology Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type*
10. *Blood Component Wastage: Percent of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue*
11. *Blood Culture Contamination: Percent of blood cultures that grow bacteria that are highly likely to represent contaminants*

CAP Laboratory All Common Checklist 2019

QUALITY MANAGEMENT section, GENERAL ISSUES subsection

***REVISED** 09/17/2019*

COM.04000 QM Program **Phase II**

The laboratory quality management (QM) program is implemented in each section (department) of the laboratory.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, as appropriate for each section (department) of the laboratory. The QM program should address key indicators of quality, in particular those relating to activities that are of high patient impact and/or are of high risk for error.

Evidence of Compliance:

- ✓ Records reflecting conformance with the program as designed **AND**
- ✓ Results of quality surveillance

The Joint Commission July 2019 Standards

Standard Label	Standard Text
PI.01.01.01	The laboratory collects data to monitor its performance.
PI.02.01.01	The laboratory compiles and analyzes data.
PI.03.01.01	The laboratory improves performance.

ISO 15189:2012(E) - 3 Terms and definitions

3.19
quality indicator
measure of the degree to which a set of inherent characteristics fulfils requirements

Note 1 to entry: Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

Note 2 to entry: Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

EXAMPLE If the *requirement* is to receive all urine samples in the laboratory uncontaminated, the number of contaminated urine samples received as a % of all urine samples received (*the inherent characteristic of the process*) is a measure of the quality of the process.

ISO 15189:2012(E) – Quality Indicators

4.14.7 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

EXAMPLE Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports.

The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The indicators shall be periodically reviewed, to ensure their continued appropriateness.

NOTE 1 Quality indicators to monitor non-examination procedures, such as laboratory safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system may provide valuable management insights.

NOTE 2 The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12).

The laboratory, in consultation with the users, shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.

ISO 15189:2012 - Clause 4.15 (Management review), subclause 4.15.2 (Review input)

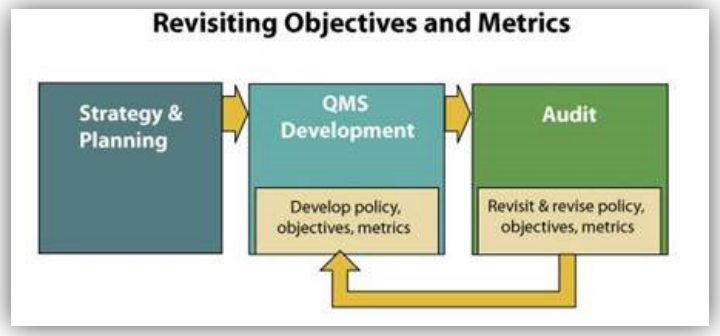
The input to management review shall include information from the results of evaluations of at least the following (note a – o listed):

f) use of quality indicators

l) results of continual improvement including current status of corrective actions and preventive actions

m) follow-up actions from previous management reviews

o) recommendations for improvement, including technical requirements



Resource: CAP ISO 15189, QM*Ed* online course *Quality Manual Development*

How to respond to unacceptable performance?

CAP Laboratory General Checklist 2018/2019

GEN.16902 QM Program Implementation **Phase II**

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CAP Laboratory General Checklist 2018/2019

***REVISED** 08/22/2018*
GEN.20316 QM Indicators of Quality **Phase II**

Performance of indicators should be compared with benchmarks, preferably from multi-institutional studies conducted within ten years of the laboratory's use of the monitor, where such surveys are available.

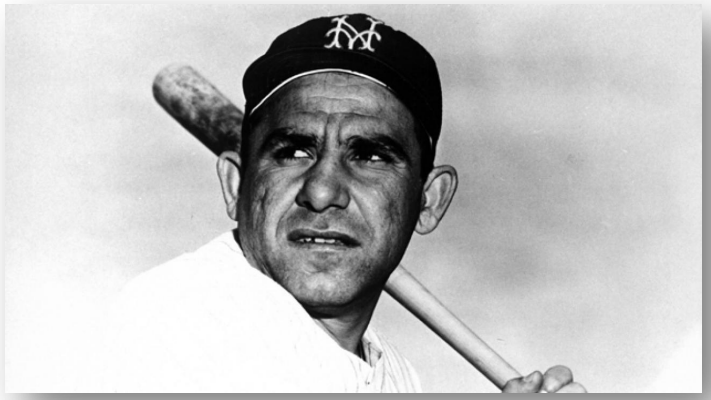
Both the College of American Pathologist's Q-TRACKS Program itself and publications of Q-TRACKS studies in the Archives of Pathology provide information regarding definitions of quality indicators and demonstrate statistically valid peer-group performance standards.

For benchmark information on commonly used quality indicators, please refer to the Quality Management Quality Indicator Monitoring Guidance Document posted on the CAP Website at the following link: http://www.cap.org/apps/docs/laboratory_accreditation/qim.pdf

Evidence of Compliance:

- ✓ Listing of quality indicators that include the following:
  - indicators for pre-analytic, analytic, and post-analytic phases **AND**
  - indicators to address the scope of testing and laboratory services **AND**
  - frequency for monitoring each indicator **AND**
  - defined benchmarks for the performance of each indicator **AND**
- ✓ Quality management data and reports for quality indicator monitoring and evaluation, including comparison against benchmark data, and corrective action when targets are not met

If you don’t know where you’re going, you might not get there.



Yogi Berra
1925 - 2015

Terminology Confusion

Table 6. Important Relationships in Quality Indicator Development

	Purpose	Question	Example
Goal	States how the strategic plan can be accomplished	"What do we do to achieve our strategic plan?"	Improve customer satisfaction
Objective	Specifies an action that, when achieved, will help fulfill a goal	"How will we know if we are achieving our goals?"	Reduce TAT of cardiac markers to the ED by 30% within 4 months
Indicator	Measures performance of the work process involved in the objective	"How close are we in achieving the objective?"	Data measuring time from specimen collection to release of results
Target	Reflects desired performance or expectations	"What performance level are we trying to accomplish?"	25 minutes or less
Threshold	Triggers an improvement action	"What is the poor performance level that, when exceeded, warrants our taking action?"	More than 35 minutes

Abbreviations: ED, emergency department; TAT, turnaround time.

Resource: CLSI, QMS12 *Developing and Using Quality Indicators for Laboratory Improvement,* 2nd Ed., 2019

Corporate Quality Goals & Objectives

Mission: Through excellence in laboratory testing, service, education, and research, ARUP's mission is to continually improve patient care and support the mission of the University of Utah.

Client Commitment Statement: ARUP supports our clients' success by providing excellence and consistency in our delivery of services, by sharing knowledge, and by developing progressive laboratory technology.

GOALS	OBJECTIVES	RELATED METRIC	IMPROVEMENT TARGET	ACTION THRESHOLD
Pre-Examination				
Reduce number of compromised specimens	By June 2020, achieve 5.5σ performance in decreasing compromised specimens	Compromised Specimens	≥5.5σ	5.0σ
Examination				
Reduce turnaround time	Achieve monthly average TAT goal of 95% verified within published TAT throughout the year	Published Turnaround Time (TAT)	≥4.0σ	≤3.5σ
Post-Examination				
Improve critical result notification	By June 2020, achieve 5.0σ performance in calling CF clients within one hour	Critical Result Notification - CF	≥5.0σ	≤4.0σ
	By June 2020, achieve 5.0σ performance in calling CF clients within 15 minutes	Critical Result Notification - UH	≥5.0σ	≤4.0σ
Business Operations				
Reduce employee voluntary turnover	Reduce FY20 employee voluntary turnover percentage rate by 20%	Total Employee Voluntary Turnover Percentage Rate	≤15%	≥20%

Resource: CLSI, QMS25 *Handbook for Developing a Laboratory Quality Manual,* 2017

What is Six Sigma?

A Statistical Measure of a Process's Ability to Meet Customer Requirements

Process Sigma	Process Yield	PPM/DPMO
6	99.9997%	3.4
5	99.98%	233
4	99.4%	6210
3.5	97.7%	22,700
3	93.3%	66,807
2	69.1%	308,537

Healthcare Today?

A "Stretch" Goal
6 Sigma → 3.4 DPMO

6σ Is considered "Virtual Perfection"

Performance Indicators – Data Slicing

Quality Plan - Communication & Tracking Tool

ARUP LABORATORIES

CORP-TEM-5037
Date: July 2018

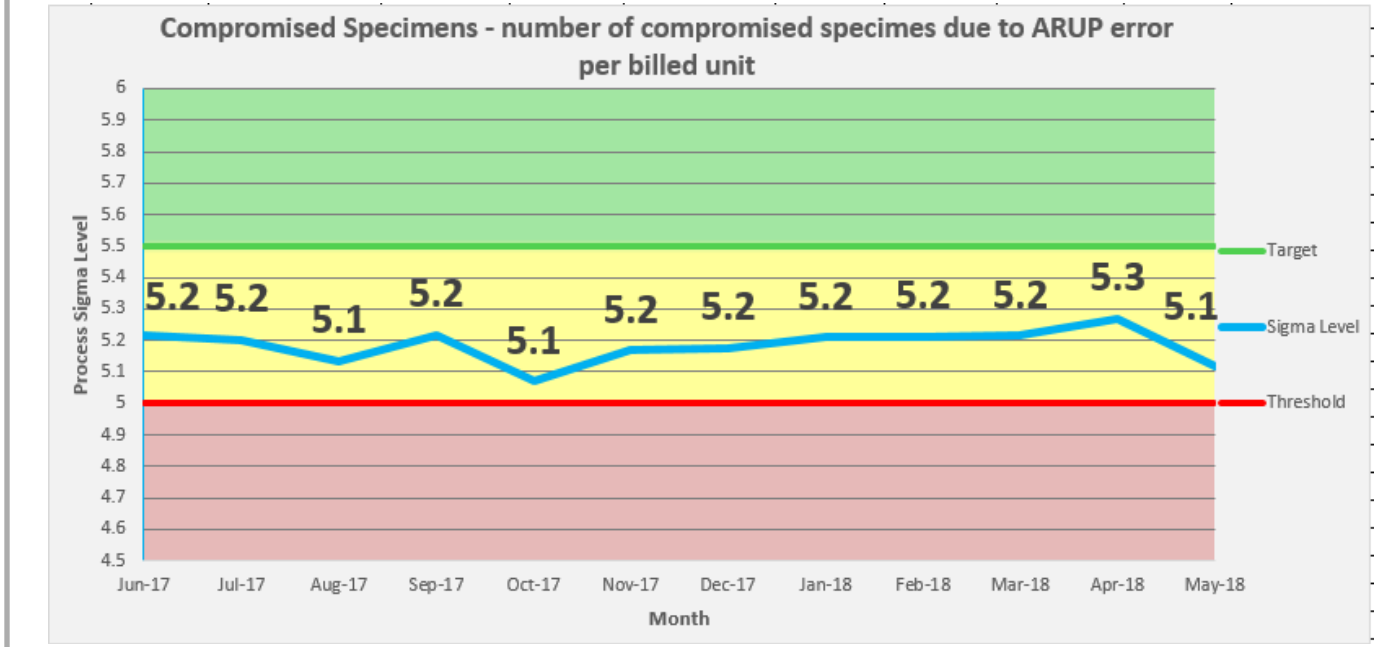
Review of indicators for:		[Dept/Section]	
			Light blue cell = Requires completion
Review of indicators for:	[Month/year]	External corporate indicators (EC)	σ = sigma — add as a cell comment
Meeting date:	[Month/date/year]	Internal corporate indicators (IC)	NR= Not Reported
PREPARED BY:	[Full Name]	Department indicators (DI)	N/A= Not Applicable
		Monitor only	Monitor only thresholds do not require a corrective action and are used while determining thresholds or indicator value
ATTENDING:	[List attendees]		
EXCUSED:	[List absentees. If everyone is present, document N/A.]		
NOTES:	[Optional Field]		

Department indicators are dynamic and evaluated monthly for effectiveness. Performance is evaluated and discussion is documented.
Any changes to indicators are made during monthly review and documented.
Corporate indicators are selected and reviewed at least annually per CORP-PRCS-5037.

Quality Plan - Reporting Indicators

Department Quality Indicators See indicator information tab for Sample and Source, Reporting Details and Rationale for Indicator						Current Month Data ↓	Minutes (Document corrective actions on Corrective. Effectiveness Tab)	Follow-up Items
Indicator Name	**Acceptable Threshold**	**Target**	**Apr-19**	**May-19**	**Jun-19**	**Jul-19**		
Critical Result Notification	**4.8**	**5.8**	6	0	1	3	Three delayed critical calls due to understaffing on shift	Supervisor will review staffing plan and report back at August meeting
	Sigma Value		3.6	>6.0	5.5	4.5		
Department Indicator	**Monitor Only (Use for a limited time while determining thresholds and targets**							
Billed Units (or other defined denominator)	[Denominator]							
The Supervisor and Medical Director signatures recorded in Master Control constitute approval of the plan and recorded corrective actions/Effectiveness checks. Any removal or addition of the Internal QA plan items may be indicated in MasterControl upon approval.								

Performance Indicators – Two Second Review



Above Threshold, below target. Improvement efforts initiated in Chemistry sections

- Red indicates below threshold – corrective action needed
- Yellow indicates above threshold, below target, no corrective action needed. Process improvement indicated.
- Green indicates above target – continue with process improvements as identified

Summary of Trends & Actions

Indicator Trends (changes from previous month)

- Critical Results – CF
- Critical Results – UH
- Compromised
- Corrected
- Lost
- Published TAT
- Excepts
- PSID Errors
- PT Success
- Problem Reports on time

Follow-up Actions

- Unnecessary Except reduction initiative underway
- PT Evaluation process improvement underway. Pilot being conducted at UH and BCG on removing 2.5 SDI criteria.

What resources are available?

Anne's Favorite Resource

Published March, 2019

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Additional Discussion

Anne T. Daley
MS, MT(ASCP)DLM, CSBB(ASQ)CMQOE
ARUP Quality Officer
anne.daley@aruplab.com