Writing Quality Assurance Plans
&
Conducting Written Quality Assurance Reviews

An effective quality assurance (QA) plan addresses the entire laboratory process, from the time a patient or sample arrives in your facility, to the moment results are recorded on patient charts and reported to the appropriate health care provider. The steps listed in this packet will assist you in writing and implementing a QA plan.

Writing Quality Assurance Plans

When writing a QA plan , it should begin with your laboratory's **Purpose** and **Goal** for QA. For each element to be reviewed always indicate **what** will be reviewed, **when** reviews will be conducted, **how** the review will be conducted, and an **acceptable threshold**. QA plans should also include a provision to **follow-up** on corrective actions taken. By implementing routine follow-up procedures you can ensure problems are corrected, and if not, take further action to resolve the problem. A calendar should be established identifying when system reviews are to be performed. Every system in the laboratory should be thoroughly evaluated over the course of one year. See the sample pages for examples of a QA plan, completed QA review, and annual calendar of reviews.

Elements Appropriate for QA Review

There are three phases of laboratory testing. Under each testing phase the bold items listed are the elements (items to review) that should be addressed in your written QA plan.

? **Pre-analytical (before testing) phase**
1. **Personnel training and evaluation – Ensure each employee's personnel folder includes:**
   a. Documentation of an evaluation every six months during the first year of employment and annually thereafter.
   b. Continuing education (must be specifically documented).
   c. Proof of education.
   d. Annual safety and OSHA training.
   e. Evidence of Hepatitis B vaccine options.

2. **Test tracking (requisitions) – Ensure the following are noted on each requisition:**
   a. Name and address of healthcare provider ordering tests.
   b. Patient name or identifier.
   c. Date and time of collection.
   d. Pertinent patient information (sex, date of birth, diagnosis, etc).

3. **Specimen handling, collection, and labeling – Ensure the following:**
   a. The unique patient identifier used when labeling the specimen remains with the sample throughout the testing process.
   b. Specimens are collected, handled, stored, and preserved as appropriate.
   c. A written mechanism is in place to inform patients of special requirements for testing (i.e. fasting, 24-hour urine collection).
   d. Written instructions are in place to identify unacceptable samples and if necessary, to contact the patient for recollection.
   e. All staff are following universal precautions.

? **Analytical (during testing) phase**
    1. Instruments:
      a. Verify calibrations are performed at frequency indicated by the manufacturer or every six months, whichever is more frequent.
      b. Ensure daily, weekly, and monthly maintenance is performed and documented as indicated by manufacturer instructions.
      c. Check quality control (QC) results, graphs, and corrective actions by ensuring that:
        ? QC is performed according to written policies and procedures.
        ? QC is performed at the proper frequency (e.g., Hematology QC is required every eight hours).
        ? QC graphs are reviewed at least weekly for shifts and trends.
        ? Corrective actions are documented for any out-of-range results.
      d. Verify patient results are not reported until QC is within expected ranges.
      e. Verify Laboratory Director or Technical Consultant has reviewed and signed QC charts monthly.

    2. Check instrument or kit performance specifications:
      a. Evaluate corrective actions taken when instruments or kits do not meet performance specifications.

    3. Proficiency testing (PT) and split sample testing:
      a. Verify PT and/or split sampling is performed in accordance with CLIA guidelines. (Refer to *COLA Lab Guides 8* and *9* in your *COLA Accreditation Manual*).
      b. Ensure PT is performed in the same manner as patient testing.
      c. Ensure a review of graded results is conducted and documented.
      d. Verify unsuccessful or unsatisfactory PT events are investigated and corrective actions taken. Document findings and actions.
      e. If two methods are used to perform the same test, evaluate the difference between the two methods at least twice per year. (e.g., spun hematocrit versus Coulter hematology analyzer).

    4. Check reference ranges are appropriate for patient population:
      a. Perform periodic reviews of reference ranges for patient population.

? **Post-analytical (after testing) phase**
    1. Result reporting - Verify reports contain the following information:
      a. Name of test.
      b. Results, units of measure, and normal ranges.
      c. Testing person is identified.
      d. Patient name.
      e. Laboratory name and address**.**

    2. Records:
      a. Verify lab records and final results on patient chart are the same.
      b. Inspect unacceptable specimen rejection logs.
      c. Ensure records are maintained for at least two years. (Immunohematology five years and pathology testing 10 years.)

    3. Verify procedure for correction of laboratory results is established and followed:
      a. Ensure ordering physician is notified immediately.
      b. Ensure a corrected report is provided.
      c. Ensure both original and corrected copies are retained for 2 years (Immunohematology five years).

4. **Ensure critical (panic) value procedures are followed and documented:**
   a. Verify date and time healthcare provider is notified.
   b. Verify patient name and critical values are documented.
   c. Verify person who notified healthcare provider is documented.

5. **Turn-around-time evaluation:**
   a. Verify results are reported to the healthcare provider in a clinically useful time.
   b. Verify STAT and critical values are reported within specified turn-around-time.
   c. Verify documentation of reporting of STAT and critical values.
   d. Verify turn-around-times for samples sent to reference laboratories are acceptable.

6. **Communication and complaints:**
   a. Ensure communication is evaluated to avoid breakdowns between laboratory staff, physicians and other personnel.
   b. Verify communication breakdown is documented along with possible solutions.
   c. Ensure complaints are promptly recorded and evaluated between staff, patients, and other health care providers.
   d. Ensure remedial action is documented for all valid complaints.

There are many other elements for review that your laboratory may want to include in the plan (e.g., overall QA plan, policy/procedure manual, vendor/reference lab relationships).

Conducting Written Quality Assurance Reviews

QA is an ongoing process, not just a response to problems. There are two situations that prompt a QA review:
? Routine scheduled evaluations of specific elements.
? Responses to identified laboratory problems or complaints that require immediate attention.

The first step in conducting a QA review should be to accumulate supporting data. Developing checklists specific for each element of review is a convenient way to accumulate the supporting data. Your laboratory should develop checklists specifically tailored to your needs. Upon review, if a problem is identified, documentation should include:
  ? supporting data
  ? description of the problem
  ? corrective action taken
  ? date corrective action taken
  ? date of review of corrections (follow-up)
  ? results of corrective actions
  ? who conducted the review

Prepare a yearly calendar and specify which elements will be reviewed each month. The *Quality Assurance Review Form* at the end of this packet may be used in documenting the QA review of various aspects of your laboratory. It contains headings to record all necessary information. The format can be modified to accommodate your laboratory's QA plan.

Reference: *Quality Assurance in the Laboratory, COLA Lab Guide 70*, revised 5/99.

Sample Written Quality Assurance (QA) Plan

Only two elements are detailed in this example. Your QA plan should address all elements previously noted. (COLA criteria questions 279-299 address QA. Refer to your *COLA Accreditation Manual*). Additional topics for review may be added as appropriate for your laboratory.

Purpose:

The purpose of our QA program is to improve the reliability, efficiency, and quality of laboratory services.

Goals:

The Goals of our QA program are to:
? **Improve the overall quality and efficiency of the laboratory service.**
? **Evaluate the effectiveness of the laboratory's policies and procedures.**
? **Identify problems and make corrections.**
? **Assure accurate, reliable and prompt performance of tests and reporting results.**

Implementation:

Our QA program will be implemented as indicated:

1. **Personnel Training and Evaluation** will be reviewed annually. All employee files will be screened for evidence of performance reviews, proof of education, continuing education, OSHA training, safety training, and Hepatitis B vaccine options. Should omissions be found, corrective actions will be developed and implemented. Follow up reviews shall be conducted in three months to ensure that all required documentation is in place. 100 percent compliance is expected.

2. **Test Tracking - Requisitions** will be reviewed quarterly by randomly selecting 10 requisitions. Requisitions will be checked for name and address of person ordering tests, patient name or identifier, date and time of collection, and pertinent patient information (sex, date of birth, diagnosis, etc). Compliance is expected to be 100 percent. If our minimal acceptable limits are not met, corrective actions will be implemented and followed up with an additional review within 30 days.

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Here is an example of how to design the written statement for each element for review.

WHAT:	Personnel Training and Evaluation
WHEN:	Annual Review
HOW:	All employee files will be screened for evidence of performance reviews, proof of education, documentation of continuing education, OSHA and safety training, and Hepatitis B vaccine options.
Acceptable Threshold:	100 percent compliance is expected.
Follow-up:	If omissions are found, corrective action will be developed and implemented with a follow-up review performed in three months.

Reference: *Quality Assurance in the Laboratory, COLA Lab Guide 70*, revised 5/99.

Sample Quality Assurance Review

Element Under Review: Test Tracking - Requisitions

Frequency of Review: Quarterly

Method of Review: Randomly check 10 requisitions to ensure all necessary data is noted.

Minimum Acceptable Score: 100 percent

Date of Review: 1 April 2000   Time Period Covered: 1-31 March 2000

Reviewer: _____

Measured Parameters	# correct	# incorrect	% correct
Ordering Person Name and Address	10	0	100%
Patient Identification	10	0	100%
Date and Time of Collection	5	5	50%
Pertinent Patient Information	9	1	90%

Evaluation of Results: Only 50 percent of requisitions reviewed had date and time of collection indicated. Pertinent patient information is at 90 percent compliance.

Corrective Action Proposed: Counsel laboratory staff on importance of date and time of collection. In addition, a date/ time stamp will be purchased and placed in the phlebotomy area. When a patient initially enters the phlebotomy area they will stamp the date and time on the requisition. Continue to monitor pertinent patient information, no corrective action at this time.

Signature of Reviewer: _____   Date: _____

Laboratory Director Concurrence: _____   Date: _____

Follow-up Review of Corrective Action: To be conducted 1 May 2000.

Results of Follow-up Review:

Corrective Action Effective?

Reference: *Quality Assurance in the Laboratory, COLA Lab Guide 70*, revised 5/99

Sample
Annual Calendar of Reviews
NOTE: The calendar should be set up specifically for your laboratory activities.

Instructions:
1. Review the element (s) assigned for each month. Document the review and attach all supporting data and information.

2. Each month, complete the Monthly Checklists** performed as part of routine laboratory operation for:
   - ✐ Maintenance, Calibration, and Quality Control
   - ✐ Communications, Complaints, and Problems

3. Proficiency Testing * review should be scheduled for the months that the proficiency testing results are received.

January
QA Plan

Personnel Training and Evaluation

Monthly Checklists **

February
Test Tracking (Requisitions)

Communication, Complaints, and Problems Checklist

Monthly Checklists **

March
Specimen Handling

Proficiency Testing*

Monthly Checklists **

April
Maintenance / Calibration

Monthly Checklists **

May
Turn-Around Time Evaluation

Monthly Checklists **

June
Quality Control

Monthly Checklists **

July
Test Menu / Methods

Monthly Checklists **

August
Proficiency Testing*

Monthly Checklists **

September
Vendor / Reference Lab Relationships

Monthly Checklists **

October
Policy / Procedure Manuals

Monthly Checklists **

November
Safety

Monthly Checklists **

December
Quality Control

Proficiency Testing*

Monthly Checklists **

SAMPLE CALENDAR

Reference: Quality Assurance in the Laboratory, COLA Lab Guide 70, revised 5/99

Your Letterhead Here

Quality Assurance Review Form

Element Under Review: _____

Frequency of Review: _____

Method of Review: _____

_____

Minimum Acceptable Score: _____

Date of Review: _____   Time Period Covered: _____

Reviewer: _____

Measured Parameters	Results		

Evaluation of Results:

Corrective Action Proposed:

Signature of Reviewer: _____   Date: _____

Laboratory Director Concurrence: _____   Date: _____

Follow-up Review of Corrective Action:

Results of Follow-up Review:

Corrective Action Effective?

Reference: Quality Assurance in the Laboratory, COLA Lab Guide 70, revised 5/99

PATIENT TEST MANAGEMENT -- MONTHLY CHART AUDIT RECORD

Date Of Review:_____ **Time Period Covered by Review:** _____

Reviewer(s: _____

Criteria	Patient Identifier or Chart Number					# Discrepant	Action?
Test requisition:							
? written requisition received w/in 30 days							
? MD name/address							
? patient name							
? specifies the tests ordered							
? date & time of collection							
? pertinent info is present							
Specimen collection:							
? pt. prep noted (i.e., fasting)							
? label legible and complete							
? unaccept. spec. reject/doc							
? logged w/ name/date/time							
Test Records:							
? retained for 2/5/10 years							
? acceptable turnaround time							
Test Reports:							
? are all reports present							
? are accurate and legible							
? have lab name and address							
? have patient name							
? have result/units of measure							
? have normal ranges							
? have ID of testing person							
? abn. results rechecked							
? alert values reported & doc							
? if errors = corrected report							
? results OK w/pts. history							
Reference Laboratory:							
? send-out log accurate							
? acceptable turnaround time							

Problem areas: _____

_____

Corrective action: _____

_____

Director review: **Date:**

Staff review/Implementation: **Date:**

Follow-up to be done: **Date:**

Document follow-up on another form and attach.

PROFICIENCY TESTING -- QA TRACKING SHEET

Month/Year>							
Criteria Event/Specialty>							Action Needed
For PT specimens received this month:							
? who performed testing							
? were they processed in a timely manner							
? were they perf. the same as patient spec.							
? were they submitted before cut-off date							
? were PT specimens retained for follow-up							
? were copies kept of processing instructions, testing records, attestation statement/report							
If any PT reports were received this month:							
? were scores of <80% thoroughly investigated and corrective action taken							
? were any ungraded results reviewed based on information provided in the PT booklet							
? were corrective actions taken and effective							
? lab dir. doc. rev. of results & corr. act. taken							
? have the reviewed reports been retained							
? do PT scores qualify you to continue testing							
? Was corrective action doc. sent to COLA							
For unregulated analytes on your test menu not enrolled in PT:							
? was split-specimen testing performed and documented this month? [5 spec. 2x/yr]							
? did the results fall within your set limits							
? was corr. action taken/doc for those outside limits							
If you do a test by more than one method:							
? has a comparison been done between them							
? were results of the comparison satisfactory							
? if not, has corrective action been taken							
DATE and INITIALS>							

Problem areas: _____

_____

_____

Corrective action: _____

_____

_____

Director review: **Date:**

Staff review/Implementation: **Date:**

Follow-up to be done: **Date:**

Document follow-up on another form and attach.

MAINTENANCE, CALIBRATION, AND QUALITY CONTROL -- QA TRACKING SHEET

Criteria	Instrument/Test Method						#Discrepant	Action
General								
? are QC, calib.& reagents stored OK								
? are any QC, calib.& rgts. expired								
Maintenance								
? do maint logs follow manuf. req.								
? are maint. logs complete & retained								
? are temps. recorded each day for:								
? refrigerator(s)								
? freezer(s)								
? incubator(s)								
? heat block(s)								
? water bath(s)								
? room temperature								
? temp. dependent equip.								
? accept. ranges established								
? humidity recorded daily, if needed								
? annual maintenance performed:								
? thermometers calibrated								
? microscopes serviced								
? centrifuges maintained								
? pipettes, etc. calibrated								
Calibration								
? done at req. freq. & doc kept								
? records have lot # & exp. dates								
Quality Control								
? proper type QC material used								
? req. # done prior to testing patients								
? QC done at req. freq. & doc kept								
? QC range established if unassayed								
? doc has lot # /exp.date/acc.ranges								
? quantitative results graphed								
? reviewed for shifts/trends								
? corrective action taken								
? patient tests repeated								
? lab director review of all QC results								

Problem areas: _____

_____

Corrective action: _____

_____

Director review: **Date:**

Staff review/Implementation: **Date:**

Follow-up to be done: **Date:**

Document follow-up on another form and attach.

COMMUNCATIONS, COMPLAINTS, PROBLEMS AND PERSONNEL -- QA TRACKING SHEET

Criteria	Month						#Discrepant	Action
Communication breakdowns								
? # noted this month								
? promptly & thoroughly investigated								
? corr. action taken and doc kept								
Complaints								
? # noted this month								
? promptly & thoroughly investigated								
? corr. action taken and doc kept								
Problems/Incidents								
? # noted this month								
? promptly & thoroughly investigated								
? corr. action taken and doc kept								
Personnel								
? # new lab staff hired this month								
? personnel file info:								
? doc of qualifying educ/training								
? doc hepatitis vaccine status								
? doc of orientation completed								
? copy Personnel Form to COLA								
? # lab staff pass anniversary date								
? doc annual perf. evaluation								
? include doc of Cont. Ed.								
? include doc OSHA Training/yr								
Date/Initials								

Problem areas: _____

_____

_____

Corrective action: _____

_____

_____

Director review: **Date:**

Staff review/Implementation: **Date:**

Follow-up to be done: **Date:**

<u>Document follow-up on another form and attach.</u>