Quality Assurance in the Laboratory

This is a primer for Quality Assurance; how to define it, the type of documentation to maintain, what to include in a QA Plan and how to implement it in your laboratory.

PART I
QUALITY ASSURANCE PROCESS

PURPOSE
The purpose of a quality assurance program is to improve the reliability, efficiency, and quality of the laboratory service.

GOALS
The goals of a quality assurance 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 of test results.

DEFINITIONS
The process of Quality Assurance consists of four stages:

1) Planned review of all policies and procedures for their effectiveness.
2) Identification of any problems through this review process.
3) Corrective action taken to prevent future problems.
4) Follow-up review of the effectiveness of corrective actions.

There are three major phases of laboratory testing that a QA program should evaluate:

1) Pre-Analytical — Specimen collection/storage/processing, personnel training, etc.
2) Analytical — Quality control, preventive maintenance, calibrations, etc.
3) Post-Analytical — Result reporting, turn-around times, etc.

The examples listed above are some of the major elements that would be addressed in QA reviews in a laboratory. Refer to the COLA Criteria for Quality Laboratory Performance, question numbers 284-299 for the remaining elements that should be a part of a complete QA Program. A further breakdown of these elements are listed at the end of this LabGuide.

There are two situations that prompt a QA review:

1) Routine, scheduled review of an element.
2) In response to an identified problem or complaint needing immediate attention.

The final essential piece of a QA Program is documentation. All QA activities must be documented completely. This should include:

1) Date of the review or date the problem or complaint was identified.
2) Initials of person performing review.
3) Scope of the review.
4) Results of review and any corrective action taken.
5) Date and description of follow-up review of the effectiveness of corrective action.

PART II
IMPLEMENTATION OF A QUALITY ASSURANCE PLAN

The first step in the QA process is to develop a written QA Program addressing all elements in the phases of testing listed above.

The second step is to schedule the implementation of the plan. Pick an element to evaluate. Decide how the evaluation will be conducted and over what period of time. Determine what is a desirable outcome of the evaluation.

Once the evaluation is complete, determine if any corrective action needs to be taken. If no problems
were identified then the QA review ends here for that element. Schedule the next element to be reviewed.

If a problem was identified, determine the appropriate corrective action to take to attempt to resolve the problem. Institute these corrective actions and schedule a follow-up review. The follow-up is usually a scaled down version of the original review. It is a spot check to verify that the corrective actions taken in response to the problem were effective in preventing the situation from recurring.

The most important step in a QA review is to be sure to document all QA activities. This serves as proof to the surveyors that you in fact have implemented your plan. But more importantly, it provides a mechanism to revisit data from previous reviews that may be helpful with current reviews or problems that arise.

**PART III**

**COLA QUALITY ASSURANCE CRITERIA AND LABORATORY EVALUATION**

279. Have you established a written Quality Assurance Program for your laboratory?
282. Do you document all QA activities?

**Stage One**

280. Do you periodically evaluate the effectiveness of all policies and procedures?

**Stage Two and Stage Three**

281. Does your QA review identify and correct problems?

**Stage Four**

283. Does your QA review also follow-up on corrective actions to ensure their effectiveness so the same problems do not recur?

**PART IV**

**UNDERSTANDING THE QUALITY ASSURANCE PROCESS**

An analogy that might help clarify the QA process:

- Imagine that the written QA Plan is analogous to a physician hanging a diploma on his wall. He is now ready to practice medicine or conduct a QA review. (Criterion #279)
- The documentation of QA activities is equivalent to a physician recording his actions on the patient’s chart. (Criterion #282)
- The QA review is analogous to the patient coming into the office for a routine physical or as a result of some physical ailment or complaint. (Criterion #280)
- Stage Two and Three, problem identification and corrective action, is the diagnosis and treatment phase specified by the physician after results of tests or x-rays are obtained. (Criterion #281)
- Stage Four, follow-up review of corrective action, is analogous to a patient following the prescription of the physician and returning to the office for a follow-up visit. The physician will determine if the protocol was effective or if another treatment should be tried. (Criterion #283)

**PART VI**

**ELEMENTS APPROPRIATE FOR QA REVIEW IN ALL TEST PHASES**

This is a listing of elements that you may elect to review as a part of a comprehensive QA Plan. Laboratory Staff in conjunction with the Laboratory Director are responsible to identify those elements to review and the frequency of performing these reviews.

**Pre-Analytical**

Personnel Training and Evaluation (Criteria #284, #291, and #292)

Requisitions (Criterion #287)

- Name and address of person ordering test
- Name/unique identifier of patient
- Date & time collected
- Appropriateness of testing
- Pertinent patient information (diagnosis, sex, age)

Specimen collection, handling, & labeling (Criterion #286)

- Unique patient ID, labeling of specimen throughout testing process
- Specimen storage/handling/preservation
- Patient preparation (written instructions)
- Unacceptable specimen rejection criteria
- Universal precautions
Complaints  (Criteria # 297 and #298)
Communication breakdowns  (Criterion #293)

Analytical

Records
Correcting laboratory errors (Criterion #285)
Unacceptable specimen rejection records (Criterion #286)
  • Records kept two years
  • Date and time received
  • Testing personnel identified

Instruments
  • Calibration
  • Maintenance

QC corrective actions and follow-up (Criterion #294)

Proficiency testing and split sample testing (Criterion #289)
  • PT or split samples done
  • Review of graded results documented
  • Corrective actions and their effectiveness
  • Evaluate differences in same tests using different instruments or methods every six months (Criterion # 290)

Instrument or kit performance specifications (Criterion # 295)

Reference ranges appropriate for patient population (Criterion # 296)

Post-Analytical

Result Reporting  (Criterion #287)
Procedure for correction of laboratory errors followed
  • Ordering person notified immediately
  • Corrected report provided
  • Both original and corrected reports kept two or five years

Panic values procedure followed and documented
  • Date and time appropriate person notified
  • Name of person notified
  • Patient name and panic values
  • Person who did notification identified

Reports
  • Test name
  • Results, units of measure, normal ranges
  • Testing person identified
  • Patient name
  • Laboratory name and address

Turn-around-time evaluated (Criterion #288)

PART VII
EXAMPLES OF METHODS OF EVALUATION USEFUL FOR QA REVIEWS

Set acceptable criteria for each area: e.g., 95 percent for completeness of documentation.

Perform chart audits: Designate the number of patients’ charts needed to be examined for areas under review. Chart audits are useful when reviewing the completeness of reports, appropriateness of testing, etc.

Review QC, Calibration, and Maintenance records: Look for patterns — same corrective action repeated over and over indicates an underlying problem not being addressed.

Review Test Records (i.e., Logs, Worksheets, Incident reports, Complaints): Suitable for review of specimen rejection (frequency, cause, etc.— looking for patterns/frequency), TAT, completeness of forms, panic value notification, corrective action for lab errors, communication problems, and complaints. (These can be from staff, patients, reference labs, and/or physicians.)

The following form (Figure 1) is adaptable for use to document the QA review of various aspects of your laboratory. It contains headings for all the needed information to be recorded. The format can be modified to represent different elements to be reviewed. Figure 2 is a sample of a completed form.
QUALITY ASSURANCE REVIEW

ELEMENT UNDER REVIEW

FREQUENCY OF REVIEW

METHOD OF REVIEW

MINIMUM ACCEPTABLE SCORE

DATE OF REVIEW  TIME PERIOD COVERED

REVIEWERS

<table>
<thead>
<tr>
<th>MEASURED PARAMETERS</th>
<th>RESULTS</th>
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EVALUATION OF RESULTS

CORRECTIVE ACTION PROPOSED

LABORATORY DIRECTOR CONCURRENCE

FOLLOW-UP REVIEW OF CORRECTIVE ACTION CONDUCTED

RESULTS OF FOLLOW-UP REVIEW

CORRECTIVE ACTION EFFECTIVE?

Figure 1
QUALITY ASSURANCE REVIEW

ELEMENT UNDER REVIEW  Transcription of test results
FREQUENCY OF REVIEW  Quarterly
METHOD OF REVIEW  Review 10 random laboratory requisitions and report forms for each test performed to determine the transcription accuracy of tests ordered, performed, instrument printout or log result, and charted results.
MINIMUM ACCEPTABLE  100% accuracy is expected for this element
DATE OF REVIEW  7/1/95  TIME PERIOD COVERED  4/1/95-7/1/95
REVIEWERS  T. Tech and N. Nurse

<table>
<thead>
<tr>
<th>MEASURED PARAMETERS</th>
<th>TRANSCRIPTION RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># correct</td>
</tr>
<tr>
<td>1. CBC</td>
<td>8</td>
</tr>
<tr>
<td>2. Glucose</td>
<td>9</td>
</tr>
<tr>
<td>3. Cholesterol</td>
<td>9</td>
</tr>
<tr>
<td>4. Rapid Streptococcus</td>
<td>10</td>
</tr>
<tr>
<td>5. Throat culture</td>
<td>10</td>
</tr>
</tbody>
</table>

EVALUATION OF RESULTS — The CBC had the most transcription errors, followed by glucose and cholesterol. All documented errors were caused by misreading of handwritten patient results when charting.

CORRECTIVE ACTION PROPOSED — Use copies of instrument tape printouts for charting results.

LABORATORY DIRECTOR CONCURRENCE — U. B. Good, MD  7/10/95
FOLLOW-UP REVIEW OF CORRECTIVE ACTION CONDUCTED — 8/20/95

RESULTS OF FOLLOW-UP REVIEW — Another 10 results were reviewed for accuracy for CBC’s, glucose and cholesterol. Had instituted the use of copies of instrument printouts. Only tests ordered were reported. All results were accurately reported.

CORRECTIVE ACTION EFFECTIVE? — Corrective action was effective. Next review of this element will be next year.

Figure 2