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## Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline



This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.





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## Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline

### Abstract

*Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline* (NCCLS document GP27-A) is intended for clinical laboratory managers and testing personnel in both the public and private sectors, from the bedside to large multidisciplinary testing facilities. This guideline approaches proficiency testing from a quality improvement perspective. It includes a suggested classification of unacceptable proficiency testing results and a specific example of an investigation of an unacceptable result.

(NCCLS. *Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline*. NCCLS Document GP27-A [ISBN 1-56238-381-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 1999.)

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## Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline

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## Introduction to the NCCLS Quality Series

This document is one of a series designed for healthcare managers who wish to improve their programs through quality management activities. While three of the documents in this series and several examples apply to clinical laboratory testing, two others are applicable to most healthcare settings. These guidelines were developed independently, but can be used together as a complementary set of resources for facilities beginning to build their quality programs as well as those with mature programs.

A comprehensive program of quality improvement is described in NCCLS publication GP26 *A Quality System Model for Health Care*. This document assists any healthcare organization with the description and analysis of its path of workflow according to the essential elements of each step. A *quality system* builds upon the concepts of quality control and quality assurance to design quality into the organization's product or service. NCCLS document GP26 applies concepts of quality design that are consistent with those described in the ISO 9000 series of standards for quality management.

A well-structured quality system must be managed with a focus on *continuous quality improvement* (CQI) as measured by customer satisfaction. Such management skills are illustrated in NCCLS document GP22— *Continuous Quality Improvement: Essential Management Approaches*. This NCCLS guideline outlines the importance of the synergistic combination of team building, anticipative planning, and quality surveillance. The clinical laboratory is used as the operational model in this document, but its concepts can apply to any healthcare quality system.

NCCLS document C24— *Statistical Quality Control* provides basic statistical fundamentals for the first level of quality management— *quality control* (QC). These are documented procedures to address variation in the testing processes, with a focus on those processes that the laboratory can control. Quality control is fundamental to all aspects of any quality program, and many other NCCLS standards are designed to support a facility's quality control efforts.

An important part of quality management is *external quality assessment*, or proficiency testing (PT). Externally operated programs provide comparisons with other laboratories and with established quality goals. NCCLS document GP27— *Using Proficiency Testing to Improve the Clinical Laboratory* describes one external assessment method to identify and correct significant process variation. This guideline also shows how to fit the review into the laboratory's quality control system.

The NCCLS documents can be used to develop a quality system that could lead to compliance with the draft ISO 15189— *Quality Management in the Medical Laboratory*. This is a draft standard for quality systems in the clinical laboratory, consistent with other international standards such as the ISO 9000 series and ISO 17025 (formerly *ISO/IEC Guide 25*). The draft standard was developed by International Organization for Standardization Technical Committee 212 (ISO/TC 212), for which NCCLS holds the secretariat.

We trust that these documents will prove to be a useful set of tools for quality improvement. Your comments not only on the content of this document but also on its relationship to other NCCLS quality documents are welcome.



## Foreword

Laboratories sometimes view proficiency testing (PT) as a burden imposed by outside regulatory bodies. However, PT is valuable in the quality improvement process. This document provides guidance in using proficiency testing to improve the quality of laboratory results. Proficiency testing should be integrated into the laboratory's quality improvement program. (Refer to the most current edition of NCCLS document [GP22](#)—*Continuous Quality Improvement: Essential Management Approaches*.)

It is important to bear in mind the limitations of proficiency testing. It addresses only the analytic process, not the pre- or postanalytic activities of the laboratory. Proficiency testing results are affected by variables not related to patient testing, including preparation of the proficiency sample, matrix effects, clerical functions, selection of statistical methods of evaluation, and peer group definition. Accordingly, it is not appropriate to use proficiency testing as the sole means for evaluating the quality of a laboratory.

## Key Words

External quality assessment, proficiency testing, quality improvement



# Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline

## 1 Introduction

PT evaluates a laboratory's performance compared to its peers and/or reference laboratories. PT is used not only for analytes measured quantitatively, but also for procedures with qualitative results, such as identification of microorganisms, blood typing, and cell identification.<sup>a</sup>

The purpose of this document is to help clinical laboratories use proficiency testing (PT) as a quality improvement tool.<sup>1,2</sup>

This guideline includes an algorithm for the investigation of unacceptable PT results. Such investigations may yield insights that enable laboratories to implement system changes that prevent recurrence of the unacceptable result.

The use of PT is not limited to investigation of unacceptable results. Monitoring PT results allows the laboratory to identify potential, as of yet asymptomatic problems related to imprecision, systematic error, and human error.

PT evaluates only the analytic phase of patient testing. Other aspects of the laboratory's quality improvement program must address the preanalytic phase (test ordering, specimen acquisition) and the postanalytic phase (patient

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<sup>a</sup> For analytes that are measured quantitatively, PT demonstrates a laboratory's performance relative to other laboratories using similar reagents and instrumentation. The difference between a particular PT result and the target value is an estimate of total error (i.e., analytic bias [calibration and/or interference] plus imprecision), in addition to matrix effects and target value error, if present. Under certain conditions, the laboratory can use this difference as an estimate of accuracy (i.e., true total error). These conditions are: 1) the PT provider can establish the true value by correlation with definitive or reference methods; and, 2) the PT provider can compensate the true value for matrix bias, if present, to establish a sufficiently accurate true target value for the method. Under the same conditions, the laboratory can estimate analytic bias by the average of the differences of a series of singlet results from true target values. Alternatively, the PT provider may supply (after completion of the PT event) additional PT samples with true target values for replicate analysis over several analytic runs at two or more concentrations.<sup>4</sup>

result reporting).<sup>3</sup> (See the most current edition of NCCLS document [GP22—Continuous Quality Improvement: Essential Management Approaches](#).)

PT is also known as external quality assessment (EQA) (see [Section 3](#)).

## 2 Scope

This guideline delineates a systematic approach to monitoring PT, and to investigating and documenting unacceptable PT results, including a classification of their causes. Laboratories may use a similar approach to monitor and investigate unacceptable results from internal quality control programs, (See the most current edition of NCCLS document [C24—Internal Quality Control Testing: Principles and Definitions](#)) as well as "split sample" quality control programs.

This guideline is applicable to any setting in which clinical laboratory testing is performed, from bedside testing to large multispecialty laboratories.

This guideline applies to all kinds of laboratory testing, including detection and quantitation of blood and fluid analytes, morphologic identification, and blood and tissue typing. Some of the discussion applies only to tests with quantitative results.

The procedures in this guideline can help laboratories prepare responses to regulatory and accrediting bodies. Laboratories are cautioned that such bodies may have additional requirements not covered in this document.

This document does not cover use of PT for purposes other than tracking laboratory performance, such as establishment of method characteristics, method comparisons, and continuing education.<sup>5</sup>

This guideline does not prescribe specific corrective/preventive actions.

Proficiency testing is only one component of the determination of laboratory quality, and the

quality of a laboratory should not be judged solely on the results of PT. An unacceptable result does not necessarily indicate that a problem exists in the laboratory. Matrix effects (see the most current edition of NCCLS document [EP14— Evaluation of Matrix Effects](#)) and statistical factors <sup>6-11, b</sup> can cause unacceptable PT results. Investigation fails to reveal the reason for 19.6 - 24.1% of unacceptable PT results. <sup>10,12,13</sup> Conversely, PT will not detect all analytic problems in the laboratory. <sup>6-10</sup>

### 3 Definitions<sup>c</sup>

**Accuracy//Measurement Accuracy//Accuracy of measurement, *n*** - Closeness of the agreement between the result of a measurement and a true value of the measurand {/analyte}. **NOTES:** a) Usually expressed in the same units as the result, as the difference between the true value and the value, or as a percentage of the true value that the difference represents; expressed this way, the quantity is more correctly termed "inaccuracy." b) "Accepted reference value" may be used in place of "true value," c) The difference includes contributions not only from process inaccuracy but also from process imprecision, especially when one determination per specimen is the rule; d) The relevant meaning of the term "accuracy" from the patient's point of view.

**Analytic interference, *n*** - Artifactual increase or decrease in apparent concentration or intensity of an analyte due to the presence of a component or property of the normative clinical sample that reacts nonspecifically with either the detecting reagent or the signal itself.

**Bias, *n*** - The systematic, {signed} deviation of the test results from the accepted reference value. **NOTE:** a) Defined as "the difference between the expectation of the test results and

<sup>b</sup> Examples include: 1) for any quantitative assay, there is a finite probability of exceeding acceptable limits if the imprecision of the assay exceeds zero; 2) inappropriate use of evaluation criteria (e.g., +/- 2 standard deviations) when evaluating skewed or discrete distributions; 3) statistically based acceptable range too narrow relative to precision needed for clinical decision-making; 4) failure to exclude outliers with resultant skewing of mean.

<sup>c</sup> Please see the most current version of NCCLS document NRSL8—*Terminology and Definitions for Use in NCCLS documents*.

an accepted reference value"; b) In general, the deviation/difference is based on replicate measurement using an accepted (definitive, reference, or designated comparison) method and the method being tested, and expressed in the units of the measurement or as a percentage.

**Clerical error, *n*** - An incorrect transcription or improper use of the reporting medium leading to an unacceptable PT result.

**External quality assessment, *n*** - [See definition of proficiency testing.](#)

**Matrix, *n*** - All components of a material system, except the clinically relevant analyte forms.

**Matrix effect, *n*** - The influence of an artificial sample property (i.e., a property that is not part of the normative clinical sample), other than the measurand {/analyte}, on the measurement, and thereby on the value of the measurand.

**Methodologic error, *n*** - A problem in a diagnostic test system or kit, including mechanical difficulties, instrument software problems, erroneous calibration, inadequate reagent performance, or other instrument malfunction, that leads to an unacceptable proficiency testing result.

**Precision, *n*** - The closeness of agreement between independent test results obtained under prescribed {/stipulated} conditions; **NOTE:** Precision is not typically represented as a numerical value but is expressed quantitatively in terms of imprecision—the SD or the CV of the results in a set of replicate measurements.

**Proficiency sample, *n*** - A specimen containing analytes of unknown concentration or identification that is sent to laboratories participating in testing programs in order to independently verify the laboratories' technical competency.

**Proficiency testing//external quality assessment, PT//EQA, *n*** - A program in which multiple specimens are periodically sent to members of a group of laboratories for analysis and/or identification, in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others.

**Quality control, QC,  $n$**  - The operational techniques and activities that are used to fulfill requirements for quality.

**Random error,  $n$**  - The nondirectional, patternless differences between successive results obtained with an analytical process.

**Split-sample testing,  $n$**  - A sample is divided into aliquots. One aliquot is tested on a particular instrument, other aliquot(s) are tested on other instrument(s), and the results are compared.

**Systematic error,  $n$**  - The mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions, minus a true value of the measurand; **NOTES:** a) Systematic error is equal to error minus random error; b) Like the true value, systematic error and its causes cannot be completely known.

**Target value,  $n$**  - *For quantitative tests,* Either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). **NOTE:** The term "target value" is subsumed by the more general term "assigned value," which is defined as the value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose (*ISO Guide 43*).

**Technical error,  $n$**  - An error directly attributable to actions of laboratory personnel that leads to an unacceptable PT result. Examples included mispipetting and morphologic misinterpretation.

## 4 PT: A Tool for Laboratory Improvement

All laboratories will occasionally have an unacceptable PT result. Unacceptable proficiency testing performance may reveal an inadequacy in specimen handling or in analytic processes that is not revealed by other indicators. Each unacceptable result should be investigated thoroughly to maximize the opportunity to correct a problem.

*Whenever possible, the laboratory should use the information gained from investigation of the unacceptable result to prevent similar problems in the future. Laboratory personnel should ask: how can we change our systems so that this problem cannot occur again?*

Thus, the laboratory should integrate PT into its quality improvement program (see the most current version of NCCLS document [GP22—Continuous Quality Improvement: Essential Management Approaches](#)).

Laboratory management should recognize that effective system changes are often suggested by the people directly performing the tests.

Even in the absence of identifiable problems, there always exists a finite probability of an unacceptable PT result for analytes with quantitative results. This probability is a function of the bias and precision of the laboratory's method, relative to the acceptable PT limits prescribed for that analyte by the PT provider. Thus, the laboratory should evaluate the bias and precision of its methods to determine if any of them have an unacceptably high probability of exceeding the PT limits.<sup>d</sup> Unacceptable results can also be observed because of matrix effects associated with the method and the PT material.

Even when PT results are acceptable, laboratories should monitor their results for trends that could signal a developing problem—for example, when all results for an analyte lie on one side of the mean, or when there is an increase in imprecision of results over several PT events. Timely action in this situation may prevent future unacceptable results or inaccuracies in patient testing.

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<sup>d</sup> In the United States, the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) prescribe acceptable limits for certain analytes, known as "regulated" analytes.<sup>14</sup> All PT providers who are approved under CLIA '88 must comply with these limits. Several references provide guidance in evaluating the performance of laboratory tests relative to the CLIA limits.<sup>11,15-20</sup>

## 5 Specimen Handling and Documentation Procedures

Preparation of PT specimens and reporting of PT results often require more manual manipulation than is needed for patient specimens. Thus, detailed procedures for specimen handling and preparation are essential to minimize the possibility of a technical or clerical error. There should be written procedures for delivery of samples to the appropriate analytic areas; reconstitution of samples (including the maximum time interval permitted before testing); analysis of samples; and recording of results on report forms, including verification of clerical accuracy.

It is important that the laboratory retain copies of all documentation submitted to the PT provider.

In order for the laboratory to get the greatest information from PT data, PT specimens should be tested in the same manner as patient specimens, to the extent that it is possible to do so.

## 6 Monitoring PT Results

The procedures described in this section apply to quantitative results.

The specific monitoring scheme can vary by analyte and by the objectives of the laboratory. Ideally, PT monitors will be consistent with other quality monitors used in the laboratory. PT monitoring techniques may be graphical or tabular, depending on the level of detail desired. It is important only that the monitoring technique demonstrates the variability in PT results, identifies trends, and shows the impact of system/process changes.

There are three components to PT performance:

- the actual result
- the target value
- the evaluation interval—or allowed error—for that specimen.

There are also three different types of target values:

- method group ("peer group") means
- means from another group or an all-results mean
- values derived from an external source (for example, reference laboratory consensus or definitive/reference methods).

There are four general types of evaluation intervals:

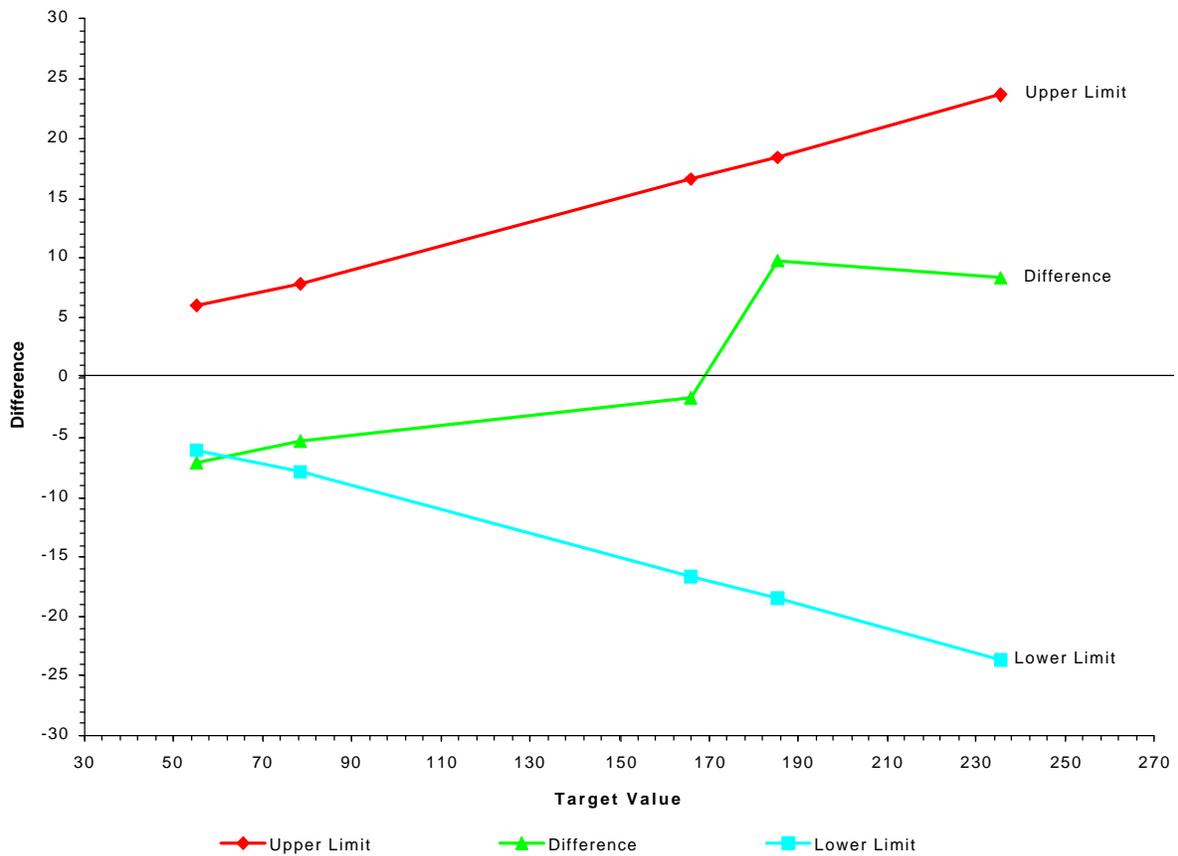
- fixed intervals (e.g.,  $\pm 4$  mmol/L)
- fixed percentages (e.g.,  $\pm 10\%$  of the target value)
- a combination of these two (e.g.,  $\pm 6$  mg/dL or  $10\%$  of the target value, whichever is greater)
- intervals based on the group standard deviation (SD) (e.g.,  $\pm 2$  SD).

For individual PT mailings (for example, five specimens) the simplest way to assess performance is to chart the differences between the submitted PT results and the target value on the vertical (Y) axis against the target value on the horizontal (X) axis, and overlay the evaluation interval. Table 1 shows example data for blood glucose; the data are graphed in [Figure 1](#). This example shows excessive variability of the data relative to the target, great enough to cause an unacceptable result at the lowest level, Specimen 95\_3 E.

**Table 1. Proficiency Test Results for Glucose (single mailing; all values in mg/dL).**

Event and Challenge	Result	Target	Difference	+/- Allowed Difference	Percent of Allowed Difference
95_3 A	195	185.2	9.8	18.5	53
95_3 B	164	165.8	-1.8	16.6	-11
95_3 C	244	235.6	8.4	23.6	36
95_3 D	73	78.3	-5.3	7.8	-68
95_3 E	48	55.0	-7.0	6.0	-117*

\*Unacceptable result



**Figure 1. Proficiency Testing for Glucose - 1995 #3. Difference Between Submitted Results and Target.**

For monitoring results over different PT mailings, a slight modification accommodates the added dimension of time. A general method is suggested below, with a data transformation added to adjust for an evaluation interval that changes at different concentrations.

The laboratory transforms the PT results into "Percentage Allowed Difference." This is the difference between the submitted result and the target value, divided by the amount of error that was allowed for that specimen. For this transformed score, 100% or more (or -100% or less) indicates an unacceptable result; most values will lie between -100% and +100%. The transformed results can then be plotted on traditional "Shewhart" (or Levey-Jennings) charts, with the X-axis designating the PT

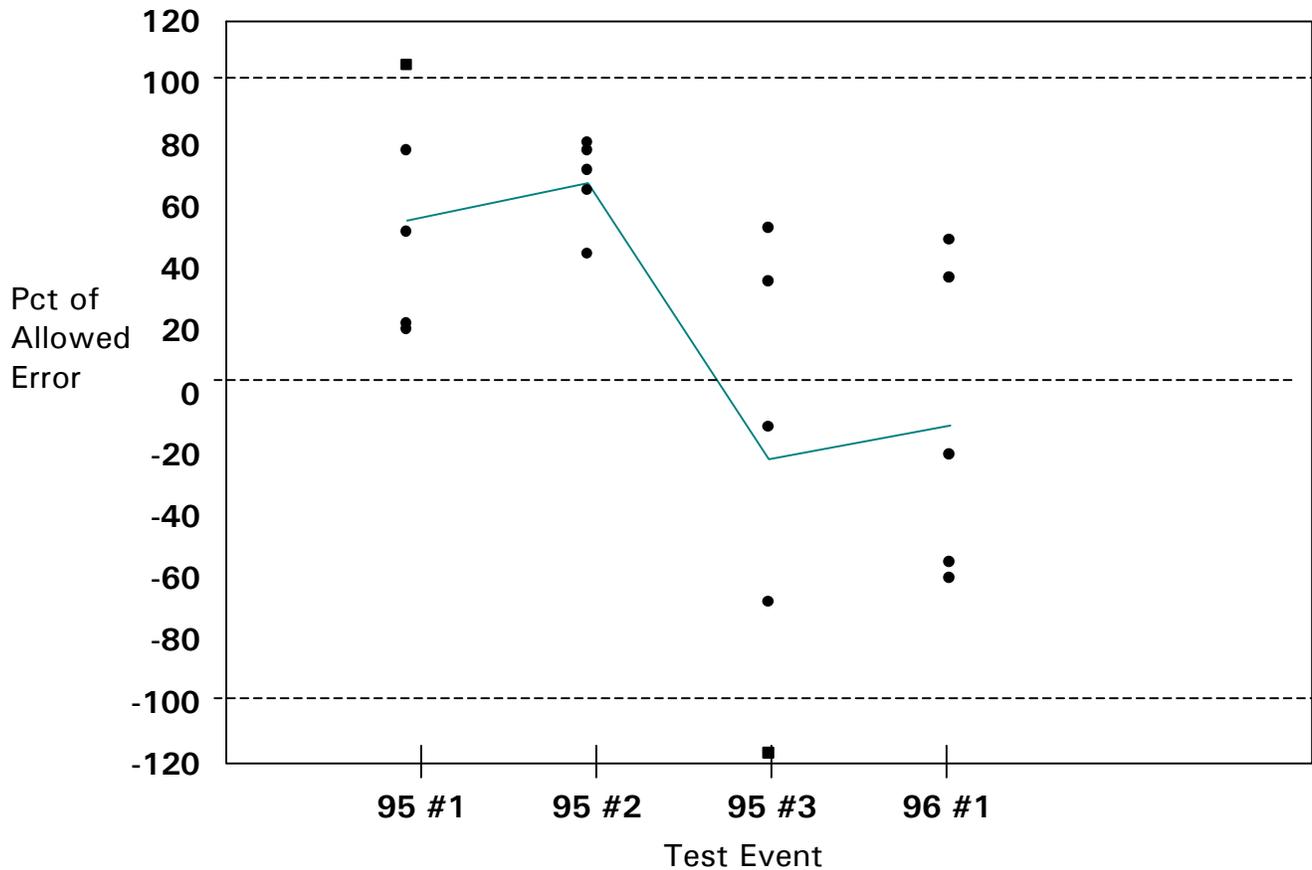
mailing event. To aid interpretation, the means of the transformed results can be connected by lines.

Table 2 and Figure 2 are examples of this procedure. They show results for four consecutive PT events for blood glucose. Events 95\_1 and 95\_2 show a consistent positive bias with one unacceptable result in event 95\_1 (Challenge B). After the 95\_2 event the laboratory recalibrated the instrument and changed reagent lots. The 95\_3 event shows reduced bias but decreased precision, causing another unacceptable result (95\_3 Challenge E). Precision improves in event 96\_1 but is still not as good as in event 95\_2.

**Table 2. Proficiency Test Results for Glucose (four test events; all values in mg/dL).**

Event and Challenge	Result	Target	Difference	+/- Allowed Difference	Percent of Allowed Difference
95_1 A	241	223.6	17.4	22.4	78
95_1 B	289	261.4	27.6	26.1	106*
95_1 C	75	71.3	3.7	7.1	52
95_1 D	76	74.4	1.6	7.4	22
95_1 E	46	44.8	1.2	6.0	20
95_2 A	55	52.3	2.7	6.0	45
95_2 B	260	241.2	18.8	24.2	78
95_2 C	54	49.7	4.3	6.0	72
95_2 D	272	251.5	20.5	25.2	81
95_2 E	85	79.8	5.2	8.0	65
95_3 A	195	185.2	9.8	18.5	53
95_3 B	164	165.8	-1.8	16.6	-11
95_3 C	244	235.6	8.4	23.6	36
95_3 D	73	78.3	-5.3	7.8	-68
95_3 E	48	55.0	-7.0	6.0	-117*
96_1 A	100	96.5	3.5	9.6	36
96_1 B	264	252.1	11.9	25.2	47
96_1 C	43	46.6	-3.6	6.0	-60
96_1 D	169	179.9	-10.0	18.0	-55
96_1 E	93	95.0	-2.0	9.5	-21

\*Unacceptable result.



- Mean % of allowed difference for each PT event
- - - Upper and lower limits of allowed difference
- Corresponds to the result of one challenge
- Refers to unacceptable result

Figure 2. Proficiency Testing for Glucose Percentage Allowed Difference in Submitted Results.

## 7 Procedure for Investigating an Unacceptable PT Result

The laboratory should systematically evaluate every aspect of the testing process. The laboratory should have written procedures detailing the specific steps necessary to identify, understand, and correct any problems identified.

### 7.1 Gathering and Reviewing Data

All documentation (including instrument printouts and worksheets and relevant data stored in electronic form) should be reviewed. Personnel who processed or tested the specimen, and who transcribed results, should

be interviewed. The investigation should include:

- Checks for clerical errors.
- Review of records of quality control, calibration status and instrument function checks.
- Repeat analysis and calculations, when possible. If none of the original sample remains, the laboratory should request an additional aliquot of material from the PT provider, if such material is available.
- Evaluation of the laboratory's historical performance for that analyte.

## 7.2 Classifying the Problem

Unacceptable results may be classified as follows:<sup>12</sup>

- Clerical error
- Methodologic problem
- Technical problem
- Problem with proficiency testing materials
- Problem with evaluation of results
- No explanation after investigation.

Use of this classification (or a similar one<sup>10</sup>) helps to ensure that the investigation does not omit a potential problem area.

Multiple unacceptable results that have shifted in the same direction suggest a systematic error related to a methodologic problem (e.g., incorrect calibration, instrument settings) or a problem with an interfering substance (i.e., matrix effect). A single unacceptable result, or multiple unacceptable results on both sides of the mean, suggests random error. Random errors can arise from technical problems (e.g., imprecision in manual pipetting) or methodologic problems (e.g., unstable assay temperature, specimen carry-over, obstruction of tubing by clot).

Clerical errors can cause single (e.g., miscopying) or multiple (e.g., transposition of results) unacceptable results.

### 7.2.1 Clerical Error

Clerical errors can be further categorized as:

- Result not correctly transcribed from the instrument tape or read-out to the report form (e.g., results for specimens copied in reverse order).
- Incorrect instrument/method indicated on the report form.
- Incorrect units reported or misplaced decimal point.

### 7.2.2 Methodologic Problems

Methodologic problems can be further categorized as:

- Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.
- Scheduled instrument maintenance not performed appropriately.
- Incorrect instrument calibration.
- Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.
- Instrument probes misaligned.
- Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.
- Problem in manufacture of reagents/standards, or with instrument settings specified by manufacturer
- Carry-over from previous specimen.
- Automatic pipettor not calibrated to acceptable precision and accuracy.
- Imprecision from result being close to detection limit of method.
- Instrument problem not detected by quality control:
  - QC material not run within expiration date, or improperly stored.
  - QC material not run at relevant analyte concentration.
- Result not within range of reportable range (linearity) for instrument/reagent system.
- Obstruction of instrument tubing/orifice by clot or protein.
- Incorrect incubation times.

- Microbiology-specific:
  - Inappropriate incubation conditions.
  - Inappropriate identification of organism by computerized database system.

### 7.2.3 Technical Problems

Technical problems can be further categorized as:

- Proficiency testing material improperly reconstituted.
- Testing delayed after reconstitution of PT material (with problem from evaporation or deterioration).
- Sample not placed in proper order on instrument.
- Result released despite unacceptable QC data.
- QC data within acceptable limits, but showed trend suggestive of problem with the assay.
- Inappropriate quality control limits/rules. If the acceptable QC range is too wide, the probability increases that a result will fall within the acceptable QC range, yet exceed acceptable limits for PT (see also Section 4).
- Manual pipetting/diluting performed inaccurately, at an incorrect temperature, or with incorrect diluent.
- Calculation error, or result reported using too few significant digits.
- Secondary specimen tubes incorrectly labeled.
- Morphologic error:
  - Screening error (cytopathology).
  - Misinterpretation (hematology, clinical microscopy, microbiology, surgical pathology, cytopathology).

- Immunohematology-specific error:
  - Inadequate resuspension.
  - ABO discrepancy not resolved.
  - Strength of reaction not defined.
  - Correct reagents not added.
  - Positive direct antiglobulin test.

- Microbiology-specific error:
  - Inappropriate culture media selected.
  - Stain not sufficiently sensitive.
  - Improper plate streaking technique.
  - Misinterpretation of culture plates (selection of colonies for work-up, etc.).
  - Inappropriate culture work-up of particular source; inappropriate antibiotic used for susceptibility test.
  - Result does not reflect up-to-date taxonomy.
  - Responding to the PT challenge is inappropriate since the laboratory routinely does not perform that test for that organism.
- Analysts did not follow laboratory written procedures.

### 7.2.4 Problem with Proficiency Testing Materials

Problems with proficiency testing materials can include:

- Matrix effects. The performance of some instrument/method combinations may be affected by the matrix of the PT sample. This may result in an unacceptable result when laboratories using such instruments/methods are graded against all-method target means or definitive/reference method target means. When an analyte is graded using peer group mean targets, matrix effects can affect grading if few other laboratories use the particular instrument/

method. The laboratory may then be grouped in an "all method group."

- Nonhomogenous test material (from, variability in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens, for example). In this situation there will be unusually high coefficients of variation among participants.
- Bacterial contamination or hemolysis (immunohematology; hematology).
- Microbiology-specific:
  - Nonviable sample.
  - Sample not representative (e.g., stool sample for parasitology).
- Immunohematology-specific:
  - Weak reaction.
  - Antibody detectable but not identifiable.
  - Interference by positive direct antiglobulin test.

### 7.2.5 Problem with Proficiency Testing Evaluation

Problems with proficiency testing evaluations can include:

- Peer group not appropriate.
- Inappropriate target value. Target values developed from participant consensus can be inappropriate from, 1, nonhomogeneous testing material, or 2, lingering ("masked") outliers. PT providers should have procedures to assure homogeneous testing materials,<sup>5</sup> and to prevent or detect outliers (such as robust statistical techniques or procedures for removal of extreme results).<sup>5</sup> However, occasional inappropriate target values occur in every PT program.
- Inappropriate evaluation interval. An evaluation interval may be inappropriately narrow— e.g., if +/- 2 standard deviation units are used with an extremely precise method, the acceptable range may be much

narrower than needed for clinical usefulness.

- Incorrect data entry by PT provider.

### 7.2.6 No Explanation after Investigation

Investigation fails to reveal an explanation for an unacceptable PT result in a significant proportion of unacceptable results (19.6-24.1% in published studies).<sup>10, 12, 13</sup>

When all identifiable sources of error have been excluded, a single unacceptable result may be attributed to random error, particularly when the result of repeat analysis is acceptable. In such cases, no corrective action should be taken, as such an action may actually increase the probability of a future unacceptable result. Deming<sup>21</sup> called such actions "tampering": making changes to a system without understanding the underlying problem. An example would be adjusting calibration for a single low unacceptable result, on the presumption that the problem is bias. This may or may not be true.

If two or more results were unacceptable, with both results shifted in the same direction, then a systematic error (bias) becomes more likely.

Repeated unacceptable results scattered on both sides of the mean suggest that the laboratory's method is not sufficiently precise (also see Section 4 and Section 7.2).

### 7.3 Evaluation of Patient Results

The laboratory should review patient data from the time of the unacceptable PT result, to determine whether the problem could have affected patient care. If so, appropriate follow-up action should be documented.

### 7.4 Conclusions and Actions

The laboratory should make every effort to find the cause(s) of an unacceptable result. In instances where the laboratory can identify an underlying system problem that contributed to the unacceptable result, actions to improve laboratory systems will minimize the risk of recurrence and potentially improve the quality of patient results.

For example: a laboratory submits unacceptable results for a therapeutic drug assay and an investigation reveals that the standards were approaching their expiration date, and that the standard curve had "flattened." Immediate corrective action might be to shorten the time to expiration of the standards for that assay. This action is a "quick fix"; it assumes that the expiration dates given by the manufacturer are not appropriate for this laboratory. The problem may lie elsewhere; for instance, the standards may have been improperly stored. In a laboratory that follows the principles of quality improvement, laboratory personnel would first ask the general question, do our systems adequately evaluate the stability of the standards for this instrument? The laboratory would then proceed with an evaluation of how the standards are handled and stored, and how aging affects standard performance. The laboratory may wish to verify the performance of standards for the other drug assays performed on that instrument.

A second example: if a technologist misidentifies a cell on a projected transparency of a blood film from a PT event, one response might be to review that slide with the technologist. A more effective response— one that aims to improve quality throughout the laboratory— would be to ask if the laboratory's continuing education program in blood morphology is adequate. Perhaps the laboratory

needs to implement a monthly blood morphology review session, or develop a continuing education program with an outside institution.

## 7.5 Documentation

The investigation, conclusions, and corrective action should be thoroughly documented. It is helpful for the laboratory to use a standardized form for recording the results of every unacceptable PT investigation. An example of a standardized form for documenting an investigation can be found in the Appendix.

## 8 Example

[Table 3](#) is an example of documentation of investigation of an unacceptable PT result, using a standardized form. An editorial comment follows.

**Table 3. XYZ Laboratory Unacceptable Proficiency Test Result Record.**

PT Specimen: <u>Proficiency Testing Sample #000</u> Date of Testing: <u>2/2/22</u> Date of investigation: <u>3/3/22</u>				
<b>Unacceptable result.</b> Four of five LD lactate dehydrogenase (LD) results run on Analyzer Z were unacceptable.				
Spec. no.	Original result	Acceptable Range	Specs. reordered	Specs. recalculated
15	159#	522.1-783.1	585	603
16	601#	139.0-208.4	160	165
17	526	477.3-715.9	526	542
18	160#	547.7-821.5	601	619
19	585#	139.2-208.8	159	164
<p><b>Investigation:</b></p> <ol style="list-style-type: none"> <li>No previous problems in PT with LD.</li> <li>Clerical errors: none identified.</li> <li>Instrument calibration/function checks: no problems identified.</li> <li>Quality control data: all acceptable— but review of data showed QC results on Analyzer Z were running lower than on the other chemistry instrument, Analyzer Y. See No. 8 below.</li> <li>Reagents: all within expiration dates. Refrigerator temperature check records all acceptable.</li> <li>Preparation of PT specimens: discussed with personnel who performed reconstitution. No delays after reconstitution; no other problems identified.</li> <li>Discussion with testing personnel: samples were loaded backwards into cassette. Cassette is loaded right to left on Analyzer Z rather than more usual left to right. Sample order is of no importance for patient specimens, which are bar-coded.</li> <li>Although running the specimens in the correct order would have made all results acceptable, it was noted that QC on Analyzer Z was running lower than on Analyzer Y. There was a</li> </ol> <p style="text-align: right;"><i>Continued</i></p>				

**Table 3. (Continued)**

recent change in the photometer mirror on Analyzer Z; afterwards, conversion factor\* was recalculated but evidently did not bring assay within specifications. When conversion factor was readjusted, recalculated LD results moved toward middle of acceptable ranges.

**Conclusion:**

1. Unacceptable results caused by **technical** problem: improper loading of samples into cassettes.
2. **Methodologic** problem—improper setting of conversion factor, which depressed LD results; this alone would not have given unacceptable results.

**Corrective/Preventive action:**

1. Will use bar codes on PT samples in future, or leave one position empty in cassette tray to prevent misloading. All analysts will be given written procedure to read and sign.
2. Conversion factor readjusted. QC being closely monitored.

**Editorial comment:** The actions described above will prevent recurrence of the problem with cassette loading. In this situation, the probability of error is greater for PT samples than for patient samples, because handling of PT samples is less automated.

However, the laboratory did not determine why the initial adjustment of the conversion factor failed to “bring assay within specifications.” To prevent recurrence of the problem, the laboratory must address this issue. The laboratory may need to change its procedure for calibration/calibration verification after changing the photometer mirror.

Also, the laboratory should have reviewed patient results from the period between the photometer mirror change and the readjustment of the conversion factor, to determine if the improper conversion factor setting caused any clinically significant depression in patient results.

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\* The conversion factor is a factor that converts reaction rate to I.U. (International units). In calibrating the instrument, assayed material must be run and the conversion factor adjusted so that the instrument reports the appropriate level of enzyme activity. After adjustment of the conversion factor, the laboratory must re-evaluate the reference range to assure that it is still valid.

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**Appendix. Sample Form for Documenting Unacceptable PT Investigations**

**XYZ Laboratory  
Unacceptable PT Investigation**

**Date of Investigation:** \_\_\_\_\_

<b>PT Set Identification:</b>
<b>Date:</b>
<b>Unacceptable result:</b>
<b>Acceptable result/range:</b>
<b>Previous trends/unacceptable results for this analyte/test:</b>

<b>Clerical/Transcription Review:</b>
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<b>Investigation:</b>
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<b>Conclusions:</b>
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**Appendix. (Continued)**

<b>Was patient data affected?</b>
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<b>Classification of Problem:</b>	
<b>Clerical</b>	<b>Methodologic</b>
<b>Problem with PT material</b>	<b>Technical</b>
<b>Problem with PT evaluation</b>	<b>No explanation</b>

<b>Corrective actions/system change(s) to prevent recurrence:</b>
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**Approved:**

<b>Supervisor</b>	<b>Date</b>
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<b>Director</b>	<b>Date</b>
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## Summary of Comments and Subcommittee Responses

During the advancement of GP22 to the approved stage, the subcommittee recommended that GP22-P should be divided into two separate documents. Subsequently, Part I (CQI) remained GP22 and advanced to the approved level, and Part II (PT) became GP27, and also advanced to the approved level. Below is the Summary of Comments containing the comments regarding Part II of GP22-P.

GP22-P, Part II: *Continuous Quality Improvement: Essential Management Approaches and Their Use in Proficiency Testing; Proposed Guideline*

1. This would make an excellent PC product. Not only should you look into providing templates for the worksheets, but please consider creating an application that would step the user through the process: defining areas of the laboratory to be included, establishing indicators, obtaining benchmarks, etc. It could be very popular.
  - **The subcommittee agrees with the commenter; a personal computer (PC) application is being considered.**
2. The section on working up proficiency testing failures is very well written but it doesn't flow with the rest of the document. I suggest that the Proficiency Testing section be totally removed to another document and combined with suggested procedures and approaches on developing in-house performance assessment programs for tests that have no formal PT.
  - **The subcommittee agrees; Part I and Part II of GP22-P have been divided into two separate documents.**
3. There is a typographical error on page 32. It should read 96A instead of 95D.
  - **The typographical error has been corrected.**
4. Part II should be deleted because it essentially repeats standard CAP processes largely from the cited reference #29.
  - **Reference 29 (new reference 12) proposed a classification for unacceptable PT results. That classification is used in this document. However, reference 29 (new reference 12) does not provide guidance to laboratories in investigation of unacceptable PT results. See Comment 5 below for additional comments.**
5. Part II contains simplistic examples and restates an already well-publicized process to document follow-up to a failed PT result. In practice, PT has only limited value to assess performance of a method on patient specimens. The variable and unpredictable matrix effects make result interpretation difficult at best. Within limits, PT does provide a very valuable external monitor of lab performance relative to a methodological peer group. Accuracy is not evaluated by PT. The treatment here is superficial and needs to be considerably expanded to be useful. The section does not provide a good illustration of a CQI process.
  - **Experience with a proficiency testing monitoring program (College of American Pathologists Laboratory Accreditation Program) shows that, although this "process" may be "well publicized," many laboratories do not know how to investigate PT problems so as to correct/prevent system problems in the laboratory. The subcommittee believes that an easily available, readable consensus document will be valuable to such laboratories. The example of the PT investigation was taken from an actual investigation by a clinical laboratory. The subcommittee could have invented an ideal PT investigation for use as the example, but concluded that there is greater teaching value in showing an imperfect investigation of a PT problem, with comments on how the investigation could be improved. The subcommittee does**

**not believe that the treatment is superficial. Input was solicited from a broad laboratory constituency.**

#### Section 11 (New Section 2)

6. Paragraph 8: The references given should include one related to matrix effects. They are a significant cause of PT failures, and at this point, should be made up-front.
- **The second sentence of the last paragraph of Section 11 (new Section 2) was replaced with the following: An unacceptable result does not necessarily indicate that a problem exists in the laboratory. Matrix effects (see the most current edition of NCCLS document EP14 *Evaluation of Matrix Effects*) and statistical factors<sup>6-11 b</sup> can cause unacceptable PT results. Investigation fails to reveal the reason for 19.6 - 24.1% of unacceptable PT results.<sup>10,12,13</sup> Conversely, PT will not detect all analytic problems in the laboratory.**<sup>6-10</sup>

#### Section 12 (New Section 3)

7. Split-sample testing: We should include here the practice of gathering a second sample at the same time, which is the way "split-sample" testing is usually accomplished (rather than "dividing a sample in half").
- **The subcommittee believes that, to avoid introducing variables related to separately obtained samples, a single original sample should serve as the source for split-sample aliquots.**
8. The definition of accuracy based on average result does not apply to a PT environment since an individual lab makes a singlicate measurement. PT cannot evaluate accuracy as discussed below.
- **The definition of accuracy has been replaced with the following definition which is consistent with NCCLS document NRSL8-A: Accuracy//Measurement Accuracy//Accuracy of measurement,  $n$  - Closeness of the agreement between the result of a measurement and a true value of the measurand {/analyte}.**
9. The definition of external QC "using identical lots"; presumably of QC material not reagents.
- **The definition of external QC has been deleted and the definition for proficiency testing//external quality assessment, from NCCLS document NRSL8-A has been added.**

#### Section 13 (New Section 4)

10. Second Paragraph: Use "not apparent" rather than "inapparent."
- **This section has been revised and inapparent has been replaced with not revealed by.**
11. Last Paragraph: ("If the PT program...). This sentence should be omitted, as it is advice to PT program providers and the federal government rather than the laboratory.
- **The term PT program is misleading; it was intended to refer to the laboratory and not the PT provider. In any case, this paragraph has been deleted (see Comment 12 below).**
12. Last paragraph: "uniformly satisfactory results over a reasonably long time" is a desired state. Tightening PT control limits, etc. is ridiculous. PT control limits must accommodate various sources of imprecision (such as bottle filling imprecision, matrix interaction with different reagent lots) not always found in a lab setting. There is no reason to go looking for "asymptomatic problems." If other monitors ("ancillary control date") show any problems they should be evaluated independently, not triggered by good performance on PT.

- **The subcommittee disagrees that there is no reason to look for "asymptomatic problems." By doing so, the laboratory may be able to find and correct a problem before it becomes large enough to affect patient results. However, this point is made in the previous paragraph; therefore, the last paragraph has been deleted.**

Section 14 (New Section 5)

13. Last paragraph: PT cannot be used "as a marker of accuracy." See Ross, et al. *Archives Pathol Lab Med.* 1993;117:393-400.
- **PT can be used as a marker of accuracy under certain circumstances (see footnote in Section 1). However, this sentence is awkward and has been revised as follows: In order for the laboratory to get the greatest information from PT data, PT specimens should be tested in the same manner as patient specimens, to the extent that it is appropriate to do so.**

Section 15 (New Section 6) and Table 5 (New Table 2)

14. The text commentary on Table 5 and Fig. 7 is improbable. Pipetting systems are typically an integral part of an automated instrument and not introduced by a lab as a process improvement. It is very unlikely that a new pipetting system would affect accuracy since virtually all methods are calibrated with standards which automatically eliminates pipette accuracy as an issue. Precision can be impacted by pipette design or maintenance.
- **The fourth, fifth, and sixth sentences of the last paragraph in Section 15 (new Section 6) have been replaced with: After the 95\_2 event, the laboratory recalibrated the instrument and changed reagent lots. The 95\_3 event shows reduced bias, but decreased precision causing another unacceptable result (95\_3 challenge E). Precision improves in event 96\_1 but is still not as good as in event 95\_2.**

Section 15 (New Section 6), Figure 7 (New Figure 2)

15. We should highlight the unacceptable results by circling the dots and noting this in the legend.
- **The figure has been revised.**

Section 16.1 (New Section 7.1)

16. Bullet three: it is frequently not possible to request an additional aliquot of PT material from the provider.
- **The following has been added to the sentence at the third bullet: "...if such material is available."**

Section 16.2 (New Section 7.2)

17. This section is essentially a paraphrase of reference #29 which itself states the standard follow-up practice recommended by the College of American Pathologists program. CAP is not acknowledged anywhere in the text.
- **The classification is used by the College of American Pathologists, but was first proposed in the cited reference (Reference 12). The subcommittee believes additional acknowledgment here is not necessary.**

Section 16.2.2 (New Section 7.2.2)

18. The first sub-bullet, "QC data not acceptable..." describes a process problem, not a QC problem. The QC System is doing its job.
- **This sub-bullet has been deleted. The following two new bullets have been added under Section 7.2.3 as follows: New bullet 4: Result released despite unacceptable QC data. New bullet 5: QC data within acceptable limits, but showed trend suggestive of problem with the assay.**

Section 17 (New Section 8) and Table 6 (New Table 3)

19. "Survey EC/C" is exact CAP nomenclature. Are there any copyright or trademark issues?
- **In Table 6 (new Table 3), "Survey EC/C" has been replaced with Proficiency Testing Sample #000.**
20. Investigation #8 mentions a K Factor. This is a term unique to Boehringer Mannheim Corporation Hitachi analyzers. The term needs to be defined. Recalculating a K factor then readjusting it sounds like fudging to get the PT results to pass. Is this the recommended procedure? The editorial comment on page 40 addresses this shortcoming in this particular example. Why not make the example the correct procedure for a good lab using good technique?
- **The term K factor has been revised to conversion factor. The conversion factor in Hitachi analyzers is a factor that converts reaction rate to IUs (for reporting enzyme assay results). In calibrating the analyzer, assayed material is run and the conversion factor is adjusted accordingly.**

**In paragraph 8 under "Investigation," the words in parentheses on the third and fourth lines "used to calculate enzyme recovery" have been deleted and the following footnote has been added: The conversion factor is a factor that converts reaction rate to I.U. (international units).**

**In calibrating the instrument, assayed material must be run and the conversion factor adjusted so that the instrument reports the appropriate level of enzyme activity. After adjustment of the conversion factor, the laboratory must re-evaluate the reference range to assure that it is still valid.**

**Also, the second to last paragraph in Section 17 (new Section 8) has been replaced with the following: However, the laboratory did not determine why the initial adjustment of the conversion factor failed to bring assay within specifications. To prevent recurrence of the problem, the laboratory must address this issue. The laboratory may need to change its procedure for calibration/calibration verification after changing the photometer mirror.**

21. Last paragraph: the recommendation to review patient results for "any clinically significant shifts" is difficult and no guidance is provided. One cannot look at individual patient results and tell if they have "shifted." Can one use QC results for this investigation, or the daily mean of patients' results, or what?
- **The subcommittee agrees that the paragraph was not clearly written and has replaced it with the following: Also, the laboratory should have reviewed patient results from the period between the photometer mirror change and the readjustment of the conversion factor, to determine if the improper conversion factor setting caused any clinically significant depression in patient results.**

References

22. Number 14. This citation should include the publisher, The International Organization for Standardization, Geneva, Switzerland.
  - **The publisher has been added to the citation.**
23. The current citation for the AABB Standards is "Standards for Blood Banks and Transfusion Services, 17th ed., Bethesda MD, American Association of Blood Banks, 1996."
  - **The citation has been updated.**
24. Please add the guideline on computer validation to Related NCCLS Publications.
  - **GP19-A *Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline*, has been added to the list of related NCCLS publications.**

**Related NCCLS Publications\***

- C24-A2**      **Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline Second Edition (1998).** This guideline provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.
- EP14-P**      **Evaluation of Matrix Effects; Proposed Guideline (1998).** This document provides guidance for evaluating the error or bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two analytical methods are compared.
- GP2-A3**      **Clinical Laboratory Technical Procedure Manuals Third Edition; Approved Guideline (1996).** Guidelines that address design, preparation, maintenance, and use of technical procedure manuals in the clinical laboratory.
- GP19-A**      **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline (1995).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.
- GP21-A**      **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.
- GP22-A**      **Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (1999).** This guideline considers continuous quality improvement (CQI) as a system of managerial programs addressing team actualization, customer needs anticipation, and quality assessment and improvement.
- GP26-P**      **A Quality System Model for Healthcare; Proposed Guideline (1998).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality systems.
- NRSCL8-A**    **Terminology and Definitions For Use in NCCLS Documents; Approved Standard (1998).** Standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory (NRSCL).

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\* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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