TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/9/2014
Department:	Mgmt and QA	**Due Date:**	5/21/2014
		Implementation:	**5/21/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Proficiency Test Results Evaluation GEC / SGAH / WAH.QA21v2

Survey Error Investigation and Corrective Action Report AG.F285.0

Description of change(s):

Section 4:	add SEICAR, graded / ungraded results, near miss
Section 5:	update near miss and ungraded criteria; remove CLIA detail; add detail for SEICAR process; replace Chantilly with Baltimore QA
Section 6:	add updated SEICAR form
Section 9:	update addenda A&B, add C&D

Revised **Survey Error Investigation and Corrective Action Report** attached after SOP

This revised SOP will be implemented on May 21, 2014

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training (version 2)

Non-Technical SOP

Title	**Proficiency Test Results Evaluation**	
Prepared by	Leslie Barrett	Date: 12/29/2009
Owner	Cynthia Bowman-Gholston	Date: 12/29/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. PURPOSE

Proficiency testing results are used to:

- Determine the quality of the laboratory performance
- Compare performance with peer groups
- Utilize the results as an educational and evaluative tool for employees and/or instrument/reagent performance.

2. SCOPE

All clinical laboratory staff involved in specimen testing are required to participate in proficiency testing.

3. RESPONSIBILITY

A. Laboratory Medical Director
Provides final review of all aspects of proficiency testing (PT) in Clinical Laboratory departments.

B. Laboratory Operations Director
Review of PT results and any required follow-up

C. Technical Supervisors
Provide primary review and evaluation of PT results received with investigation and corrective action, as necessary.

D. Quality Assurance staff
Track routing of results to verify timely completion and thoroughness of investigation.

E. Staff technologists and technicians
Review PT evaluation as a mechanism for continuing education.

4. DEFINITIONS

Proficiency Testing (PT) – A means to determine that test methods are performing as expected through outcomes for predetermined standards.

CAP – College of American Pathologists

LAP – Laboratory Accreditation Program of CAP

CAP PT database– Excel spreadsheet utilized to track all aspects of Proficiency Testing materials including:

- **A.** Applicable survey descriptions and codes
- **B.** Ship date
- **C.** Receipt date
- **D.** Due date for results to be submitted
- **E.** Actual date results are submitted
- **F.** Date CAP evaluation of results is received
- **G.** Participating techs
- **H.** Number of results/tests performed
- **I.** Number of results/tests correct
- **J.** Calculated percent of correct results
- **K.** Explanation of variances/failures

CAP Dry Erase Board

- **A.** To be maintained by QA staff
- **B.** Outline of the month's schedule of surveys to include: survey name, ship date, arrival date, due date mailed date.

Survey Error Investigation and Corrective Action Report (SEICAR) – a form used to document the investigation and corrective actions taken to proficiency testing non-conformances and near misses

Graded Result – a result that the proficiency agency has formally evaluated for acceptability against a peer group or all method results using defined evaluation criteria

Near-miss – a statistically improbable graded result that was close to non-conformance but did not actually exceed the proficiency agency's acceptance criteria. Near misses must be investigated to evaluate future risk and to correct existing problems before an actual non-conformance occurs.

Ungraded Result – a result that the proficiency agency has not formally evaluated for acceptability (e.g., lack of participant consensus, peer groups that are too small for statistical evaluation, results reported using '<' or '>', and educational challenges).

5. PROCEDURE

A. Result Communication Prohibition

- **Intra- or inter-laboratory communication regarding PT materials or results is prohibited until the PT provider has formally evaluated the results.** (Questions regarding the administration of the PT program or material integrity may be directed to the Laboratory Director, designee, or PT provider, but communications or discussions concerning PT results are prohibited.)

- Refer to the QA procedure 'Procedure for handling Inappropriate Referral or Proficiency Materials or Inter/Intra laboratory Communication of Proficiency Test Information' for additional details.

B. Routing of Results/Evaluation

Step	Action
1	The College of American Pathologists (CAP) responds to survey input by supplying a critique and summary report of all method groups.
2	The **Technical Supervisor, QA specialist or designee** will route the results and critique to Laboratory leadership (Technical Supervisor, Medical Director, Laboratory Operations Director – see Responsibility section).
3	Results will be reviewed and evaluated as **expeditiously** as possible (within two weeks). Proficiency testing results must be signed by the Technical Supervisor/Manager, Medical Director, Operations Director or designee(s), and the QA specialist or designee.
4	The supervisor will document the investigation of any unsatisfactory PT results or results that do not agree with the majority of respondents on a Survey Error Investigation and Corrective Action Report. (Refer to section E)
5	Corporate Medical Quality also requires that any result deemed "near miss", must be investigated. ~~For evaluated analytes, either:~~ ~~• a result that exceeds ±75% of the acceptable range or~~ ~~• where a consistent positive or negative bias is shown for all samples and at least one result exceeds ±50% of the acceptable range or~~ • Graded results that meet the PT provider's acceptance criteria are evaluated internally to detect "near-misses" for each analyte. Near-misses are opportunities to detect and correct problems before an actual miss occurs. Near-misses are not counted as PT non-conformances. If the test SD is based on zero variation, near miss calculation should not be applied. • If a near-miss is detected, the investigation/corrective actions (if required) must be documented according to local laboratory practice. • If only the 1 75% TEa rule is violated, the laboratory may elect to investigate the near-miss by reviewing previous surveys and monthly QC data for the analyte. • If no misses or near-misses occurred on the previous surveys, QC precision is comparable to peer group survey data, or ≥ 4.0 Sigma, and QC bias is less than TEa/4, the near-miss may be documented as a random event. • A flowchart entitled "Assessing PT Near Misses" (Addendum C) is provided to assist with the near-miss evaluation. • PT results are initially assessed visually, using SDIs, charts or other tools provided on the PT report. It is not necessary to perform near-miss calculations for every PT challenge, just the challenges that visually appear to meet the near-miss criteria.

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6	Refer to Section G if a challenge is ungraded due to one of the following: A. Routinely ungraded analyte/result B. Educational challenge C. Lack of participant consensus D. Results submitted after cut-off date E. Results not submitted F. Appropriate method code was not submitted
7	All documentation is returned to QA staff for filing and database input

C. Staff Feedback/Continuing Education

Step	Action
8	PT materials consisting of photomicrographs are reviewed by the Medical Director and used as a Continuing Education resource.
9	The Analyte Scorecard on the CAP website will be posted quarterly for staff.

D. Proficiency Testing Exception Summary (PTES)

Step	Action
10	A Proficiency Testing Exception Summary (PTES) is issued by CAP if the performance of an analyte falls below the LAP's acceptable criteria for PT.
11	This report is designed to ensure the monitoring of PT performance for purposes of CAP and CLIA certification. PTES notification will be issued for regulated analytes (analytes that CLIA requires PT) that are reported to the Centers for Medicaid Medicare Standards (CMS), regulated analytes that are not reported to CMS; and non-regulated analytes.
12	CAP mails the PTES reports to the Medical Director, who delivers them to the appropriate supervisor for tracking. The PTES packet includes instructions for responding to the PT exception, an exception response form, and a summary of scores for the previous four PT testing events.

E. Survey Error Investigation and Corrective Action Report (SEICAR)

Step	Action
13	~~The State of Maryland guidelines require~~ The process for investigation of PT failures is defined and includes the following analysis: ✓ Assess what went wrong. Is there a problem? ✓ How did we identify the problem or exclude it? ✓ Outline steps followed during investigation. QC review, patient data, technologist performance, etc. ✓ What steps will be taken to prevent a recurrence? ✓ Was patient care affected? The process applies to each analyte missed (graded or ungraded) and for each near-miss. The flowcharts in Addenda B and C may be utilized to assist in the investigation process.

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14	A Survey Error Investigation and Corrective Action Report form is required to document and code this process (Appendices B and C)
15	The QA specialist with the assistance of the technical supervisor or designee will: • Review evaluations on the CAP website, if a failure is identified the investigation process is initiated. • Lead the investigation process. • Interview involved staff members. • Review all records associated with the batch(es) that contained the proficiency testing specimen(s). These records include but are not limited to: test records, worksheets, instrument preventive maintenance records, calibration records (instruments, pipettes, centrifuge, etc.), daily/weekly/monthly QC records, the Survey Companion Form, the proficiency survey result reporting form, participant summary, and previous PT results. • Request retesting the sample, if it's available and document the results on the SEICAR. The proficiency agency may be contacted to obtain additional specimen for evaluation (additional fee may apply). Document on the SEICAR if no specimen is available for retesting. **Note**: In the case of an event failure, the evaluation must include a mechanism to demonstrate the test is currently performing acceptably • List all issues identified during the record review on the SEICAR in the area entitled "Review of Testing Records." Determine if any of the listed issues caused or contributed to the proficiency miss or near-miss. From this information, and using the Survey Error Investigation Flow Charts (Appendix D), assign an error code (Appendix B) to the non-conformance. • Determine the root cause of the non-conformance. • Determine if the PT miss(es) could have any impact on patient samples tested before, during or after the failed PT event. • Define the required corrective action(s) taken to correct the problem and record this information on the SEICAR. The corrective actions must include effective date(s). • Define what steps/actions are required to prevent recurrence of this non-conformance. • Define what monitoring steps/actions may be required to ensure the corrective action is maintained over time. Note: All corrective actions, preventative and monitoring steps will be determined with the assistance of the Technical Supervisor and Operations Director. • Draft the SEICAR **within 5 working days**. The completed form, CAP evaluation report and any accompanying letters and documentation will be given to the Medical Director and Operations Director for review, approval and signature. • If approved by the Medical Director and Operations Director the report will then be signed by the Technical Supervisor. If the report is not approved, QA will make appropriate revisions and return to the Medical and Operations Directors for review and approval.

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	• Completed documentation is ~~forwarded~~ returned to Hospital QA staff for signature and filing.
16	Hospital QA staff will retain a copy of the signed SEICAR with the CAP PT results and submit the completed, signed report to Baltimore QA. Refer to Section H for additional details.

F. Maryland Department of Health

Step	Action
17	A letter may also be received from the Maryland Department of Health requesting documentation/explanation of a proficiency testing failure.
18	The same process, corrective action form, and response will be supplied to the State of Maryland.
19	Written responses are submitted to the Operations Director and the Medical Director for review and signature.
20	Responses are sent to the State of Maryland via certified return receipt requested, US mail. Copy all correspondence to the Baltimore QA department.
21	A copy of the response letter is attached to the proficiency testing results and filed in the appropriate survey notebook. The certified mail receipt is attached to the letter.

G. Ungraded Challenges

Step	Action
22	The QA specialist or Technical supervisor will review the laboratory's result(s) and compare with those provided in the CAP critique or explanation booklet. The following criteria is utilized: Quantitative: For Peer Group Mean: ± 3 SD Near Miss: ± 2.25 SD For All Method Mean: ± 3 SD Near Miss: ± 2.25 SD Semi-Quantitative: Six or fewer possible categories: Most frequent response ± 1 category More than six possible categories: Most frequent response ± 2 categories Qualitative: ~~80% Participant Consensus~~ ~~70-80% - Near Miss~~ Agreement with majority response (>50% consensus) of peer group, all methods, or referee group If the above standards cannot be applied, the Laboratory Director or designee will evaluate the results using clinical judgment, medical usefulness, or equivalency. Results of this alternative evaluation must be explained in writing.
23	The QA specialist or Technical supervisor will document the review and include an assessment of acceptability. For results deemed unacceptable, a SEICAR will be completed following the steps outlined in Section E. All documentation is

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	reviewed by the Operations Director and Medical Director.

H. Records

Step	Action
24	A result summary is maintained in an Excel spreadsheet. The QA staff logs the date results are received, number of results reported and the number correct/accurate. The percentage will be calculated automatically. An additional column is provided to record the reason for variances or outliers.
25	Completed and signed SEICARs are electronically scanned, saved and hyperlinked to the PT Nonconformance database. The report is saved on the G-drive using the following pathway: G:\CHYDept\AHC_Lab\Quality Assurance\Proficiency Testing\Problem Reports_pdf files
26	All survey documentation maintained for the duration outlined in the Quest Diagnostics Record Retention Policy.

6. RELATED DOCUMENTS

- Proficiency Test Handling and Result Submission, QA procedure
- Procedure for handling Inappropriate Referral or Proficiency Materials or Inter/Intra laboratory Communication of Proficiency Test Information, QA procedure
- Internal Proficiency Testing Policy, QA procedure
- Retention of Records and Materials, Laboratory policy
- Survey Error Investigation and Corrective Action Report (AG.F285)

7. REFERENCES

Commission on Laboratory Accreditation Inspection Checklist, Laboratory General, Proficiency Testing section, College of American Pathologists, 325 Waukegan Road, Northfield, Illinois, 60093-2750.

College of American Pathologists website, www.cap.org

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA002.003		
000	5/7/2012	Section 5: B.3 & H.29 revised to match practice; C.9 revised to post CAP Analyte Scorecard Section 9: Update appendix A and addenda B&C	L Barrett	C Bowman

001	4/8/2014	Section 4: add SEICAR, graded / ungraded results, near miss Section 5: update near miss and ungraded criteria; remove CLIA detail; add detail for SEICAR process; replace Chantilly with Baltimore QA Section 6: add updated SEICAR form Section 9: update addenda A&B ,add C&D Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

A. Survey Nonconformance Error Codes
B. Proficiency Testing Result Evaluation Flowchart
C. Assessing PT Near Misses Flow Chart
D. Approved Proficiency Testing Agencies

Addendum A

Survey Non-conformance Error Key

Error Category	Error Description	Error Code
Method Issues	Survey agency uses 'all methods mean' to grade our results. Our method has bias to agency criteria used.	M-1
	Survey specimen beyond method linearity (either low or high).	M-5
	Method used lacks precision (at least 3 sigma).	M-6
	Sensitivity inadequate for the survey.	M-7
Reagent Issues	Reagent used deteriorated due to either improper storage or deterioration near expiration date (e.g. based on shift in QC not observed at time of testing).	R-1
	Assay bias caused by specific lot of reagent.	R-2
	Reagent improperly stored (temperature, light sensitivity, etc.).	R-3
Quality Control Issues	QC material used deteriorated due to either improper storage or deterioration near expiration date.	Q-1
	Established QC range does not properly control the assay.	Q-2
Calibration Issues	Standard/Calibrator used deteriorated due to either improper storage or deterioration near expiration date.	C-1
	Calibration not performed correctly (e.g., incorrect frequency, factors, set points, etc.).	C-2
	Bias attributed to Calibration.	C-3
Instrument Issues	Instrument linearity problem.	I-1
	Instrument sensitivity problem.	I-2
	Instrument specificity/interference problem.	I-3
	Carryover from previous specimen (carryover issue with instrument not identified during original validation).	I-4
	Instrument part(s) failed during survey specimen analysis.	I-5
	Instrument maintenance was not performed at the required interval(s).	I-6
	Required maintenance frequency not adequate for volume on instrument.	I-7
	Instrument/method environment issues (humidity, temperature, sunlight, etc.).	I-8
Technologist Issue	The technologist did not follow the Quest Diagnostics testing procedure. (use T-14 if the survey agency instructions for testing were not followed)	T-1
	Survey specimen(s) mishandled prior to testing (not reconstituted according to agency instructions, survey specimen(s) not adequately mixed, mislabeled, or contaminated).	T-2
	Pipetting error made during the test process (wrong type of pipette used, wrong volume used, etc.)	T-3

Error Category	Error Description	Error Code
	Manual calculations not performed as directed in SOP (includes failure to correct for dilution or wrong factor used).	T-5
	Wrong dilution performed.	T-6
	Delay in testing (time between reconstitution or opening of survey specimen and performance of test).	T-7
	Technologist assayed wrong survey specimen for required test (includes sequence problems).	T-9
	Batch containing survey specimen(s) had significant bias (shift and/or trend) that was not identified.	T-10
	Technologist misidentified cell/organism on photomicrograph or slide.	T-11
	Technologist misinterpreted reaction or data.	T-12
	Technologist missed carryover issue defined in test SOP.	T-13
	Survey agency instructions for specimen testing not followed.	T-14
Non-Testing (Clerical) Issues	Results entered incorrectly on-line or onto the survey result form.	NT-1
	Incorrect method code used in reporting results.	NT-2
	Incorrect instrument code used in reporting results.	NT-3
	Incorrect units of measure used in reporting results (survey agency requires different units of measure versus Quest Diagnostics and conversion was not performed correctly).	NT-4
	Laboratory failed to report survey results by agency deadline (failed to mail, fax or release results on-line).	NT-5
	Not all results submitted because pages of the survey result form were not sent or faxed to agency.	NT-7
Survey Specimen Issues	Survey specimen was compromised prior to receipt by laboratory.	SS-2
	Survey specimen integrity in question.	SS-3
	Survey specimen matrix issue.	SS-4
Survey Agency Issues	Survey agency does not have peer group for method used (evaluated against different agency selected method).	SA-3
	Data entry error made by the agency.	SA-4
Random Error	After thorough review of testing records (QC, Instrument PM, Calibration, Reagent Checks, etc.) and retesting of survey specimen (if material is available, no root cause for the non-conformance could be identified). Potential random error.	E
Other	Other – Must detail investigation findings in the Comments section.	F

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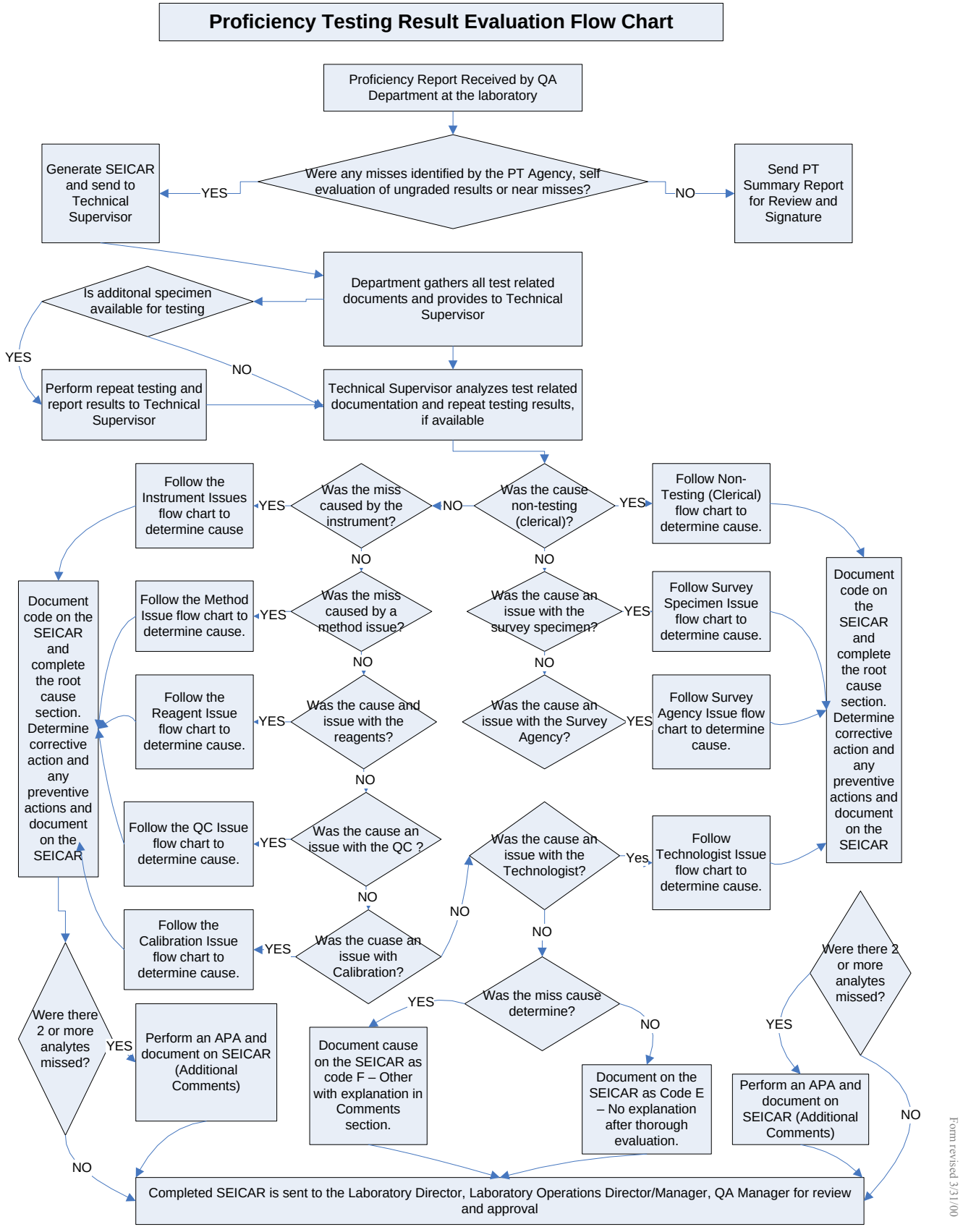
Addendum B


Proficiency Testing Result Evaluation Flow Chart
Proficiency Report Received by QA Department at the laboratory
Were any misses identified by the PT Agency, self evaluation of ungraded results or near misses?
YES
Generate SEICAR and send to Technical Supervisor
NO
Send PT Summary Report for Review and Signature
Department gathers all test related documents and provides to Technical Supervisor
Is additonal specimen available for testing
YES
Perform repeat testing and report results to Technical Supervisor
NO
Technical Supervisor analyzes test related documentation and repeat testing results, if available
Was the cause non-testing (clerical)?
YES
Follow Non-Testing (Clerical) flow chart to determine cause.
NO
Was the miss caused by the instrument?
YES
Follow the Instrument Issues flow chart to determine cause
NO
Was the cause an issue with the survey specimen?
YES
Follow Survey Specimen Issue flow chart to determine cause.
NO
Was the miss caused by a method issue?
YES
Follow the Method Issue flow chart to determine cause.
NO
Was the cause an issue with the Survey Agency?
YES
Follow Survey Agency Issue flow chart to determine cause.
NO
Was the cause and issue with the reagents?
YES
Follow the Reagent Issue flow chart to determine cause.
NO
Was the cause an issue with the Technologist?
Yes
Follow Technologist Issue flow chart to determine cause.
NO
Was the cause an issue with the QC ?
YES
Follow the QC Issue flow chart to determine cause.
NO
Was the cuase an issue with Calibration?
YES
Follow the Calibration Issue flow chart to determine cause.
NO
Was the miss cause determine?
YES
Document cause on the SEICAR as code F – Other with explanation in Comments section.
NO
Document on the SEICAR as Code E – No explanation after thorough evaluation.
Were there 2 or more analytes missed?
YES
Perform an APA and document on SEICAR (Additional Comments)
NO
Were there 2 or more analytes missed?
YES
Perform an APA and document on SEICAR (Additional Comments)
NO
Document code on the SEICAR and complete the root cause section. Determine corrective action and any preventive actions and document on the SEICAR
Document code on the SEICAR and complete the root cause section. Determine corrective action and any preventive actions and document on the SEICAR
Completed SEICAR is sent to the Laboratory Director, Laboratory Operations Director/Manager, QA Manager for review and approval
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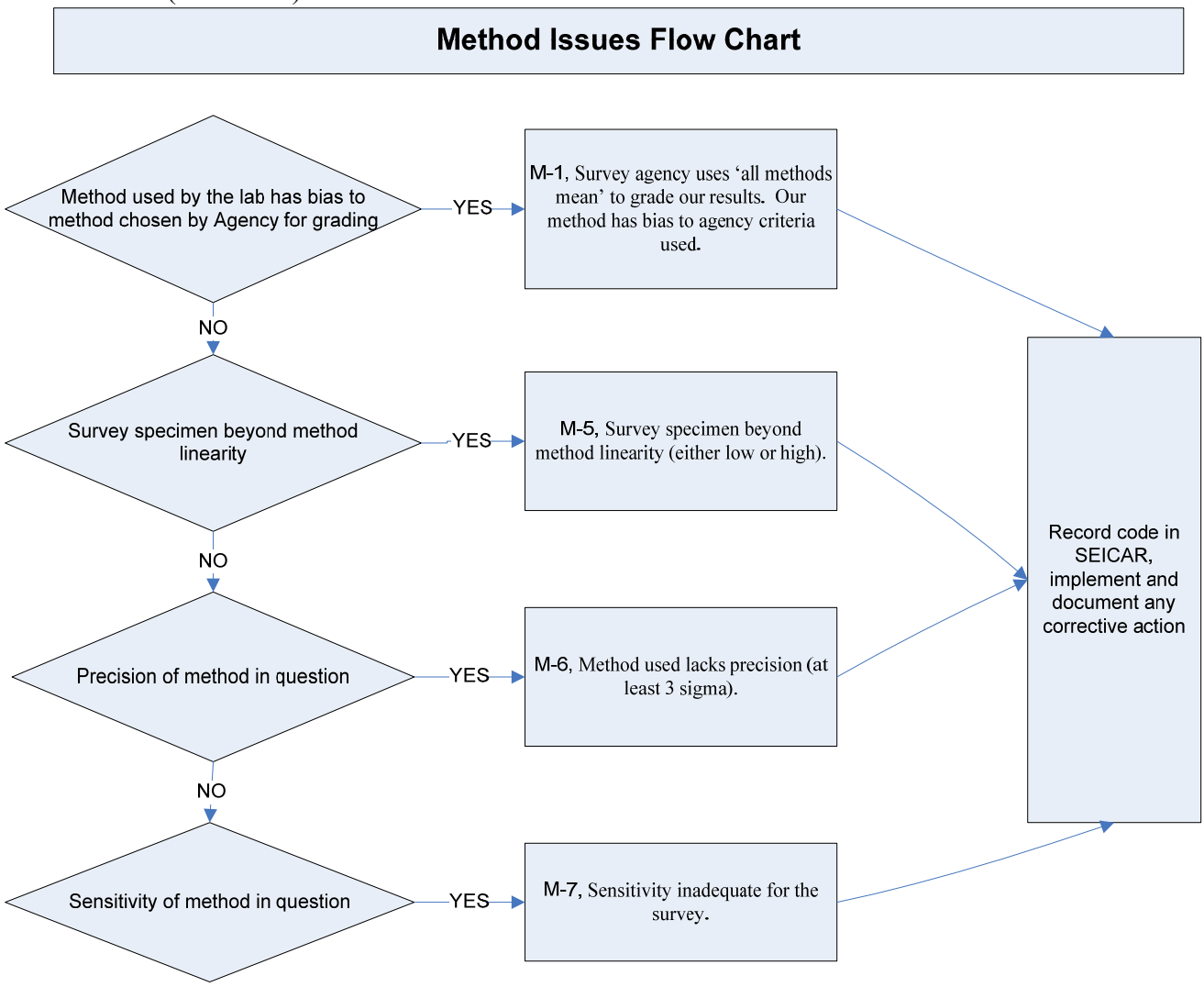
Addendum B (continued)



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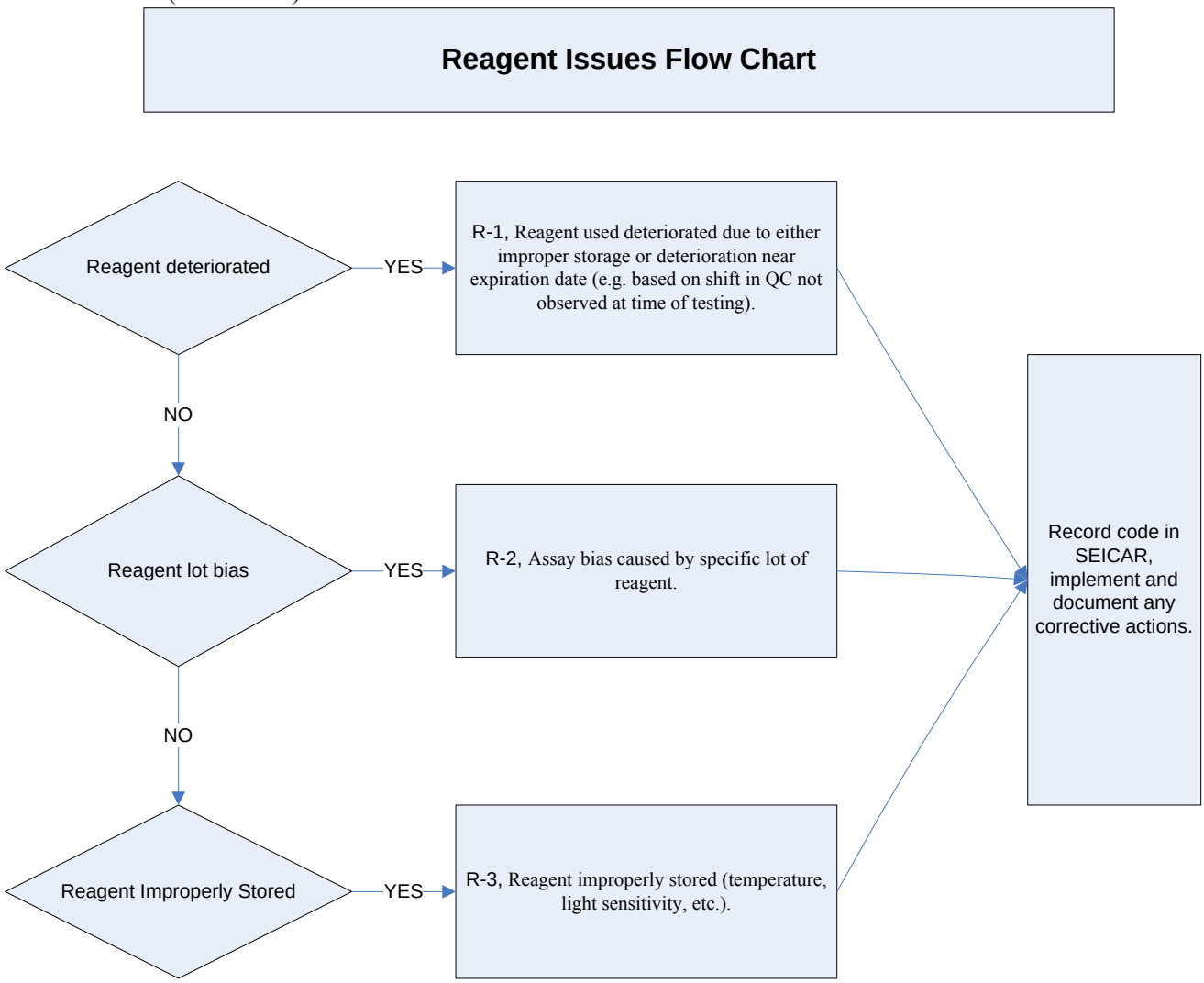

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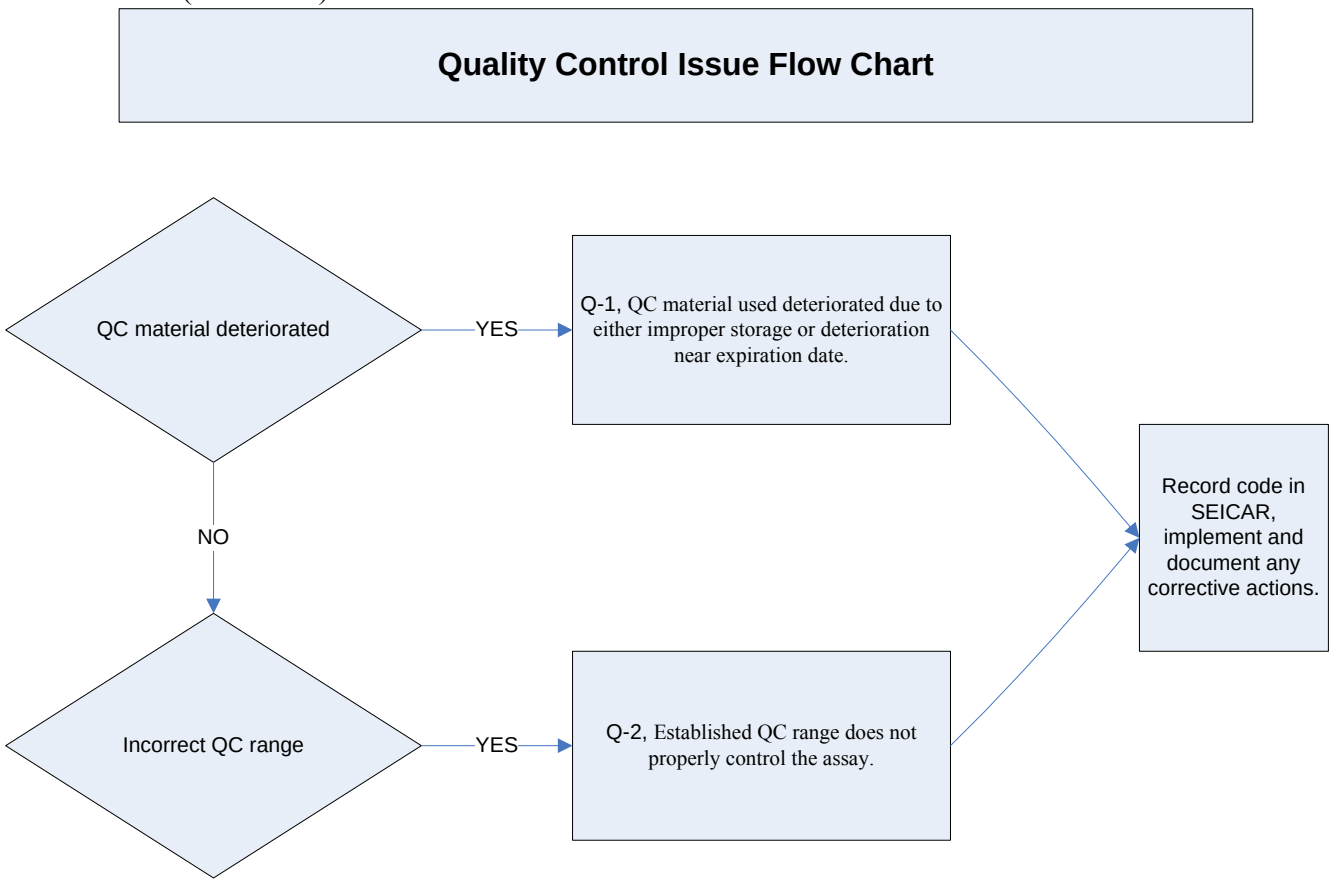

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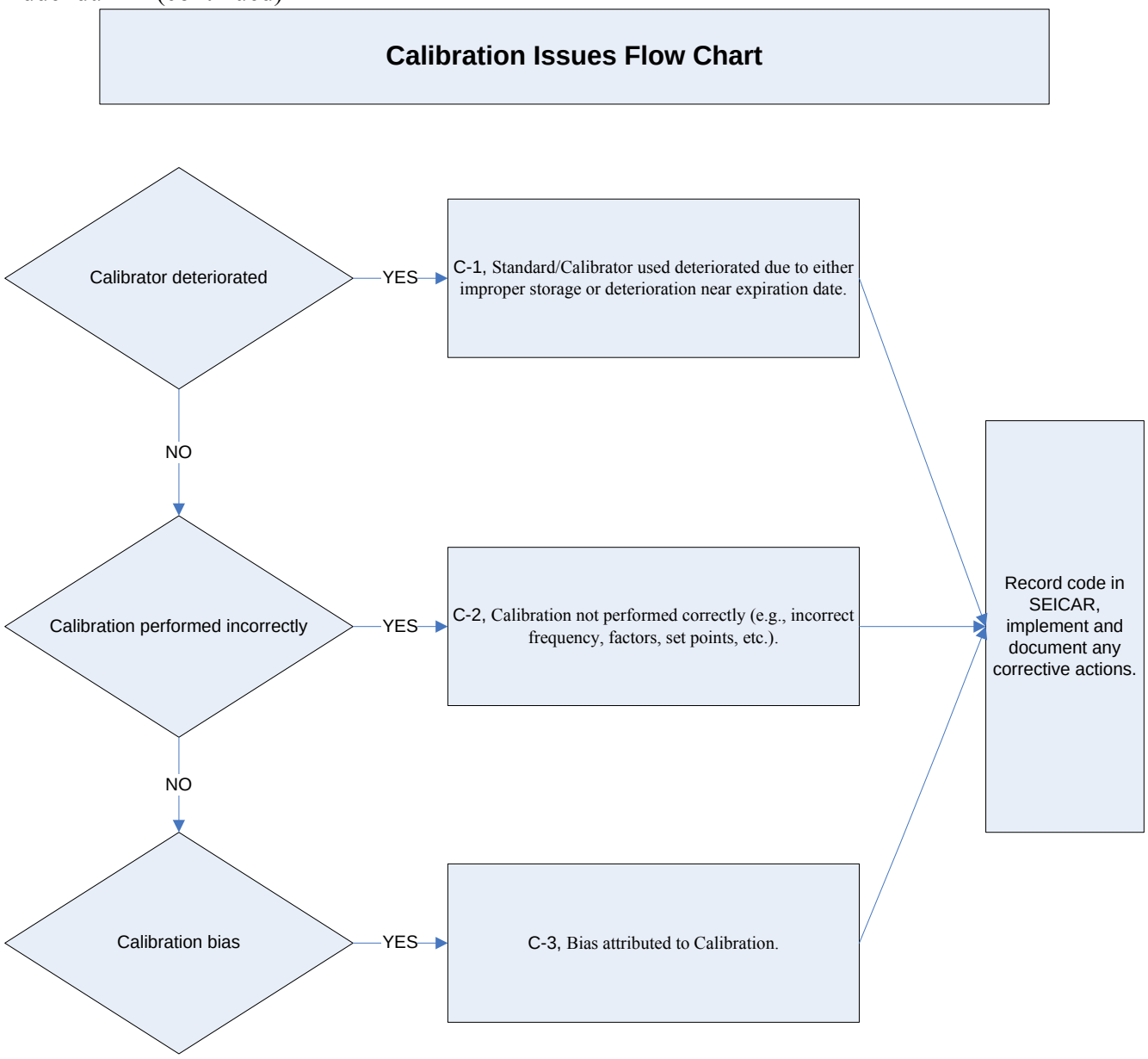

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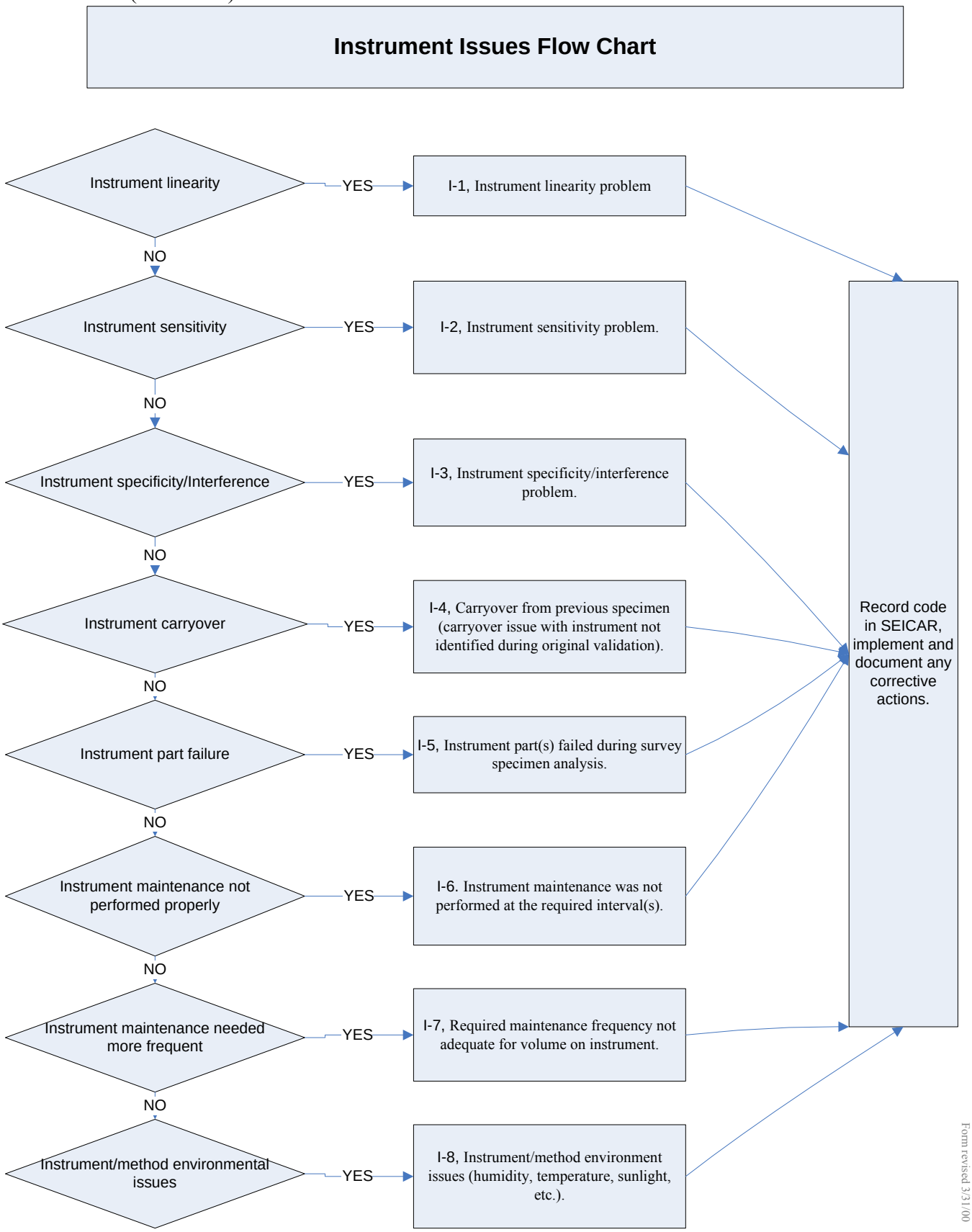
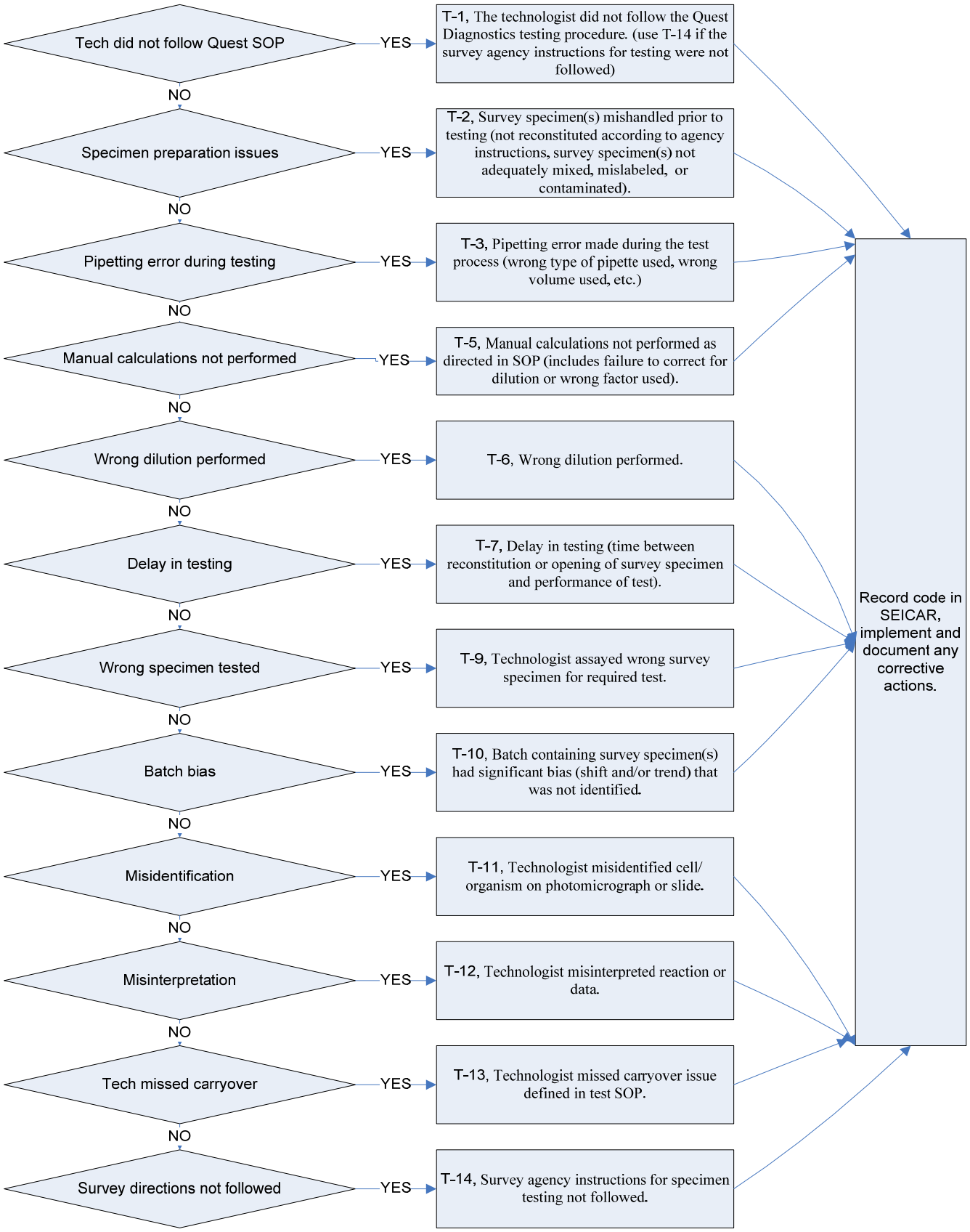


Technologist Issues Flow Chart



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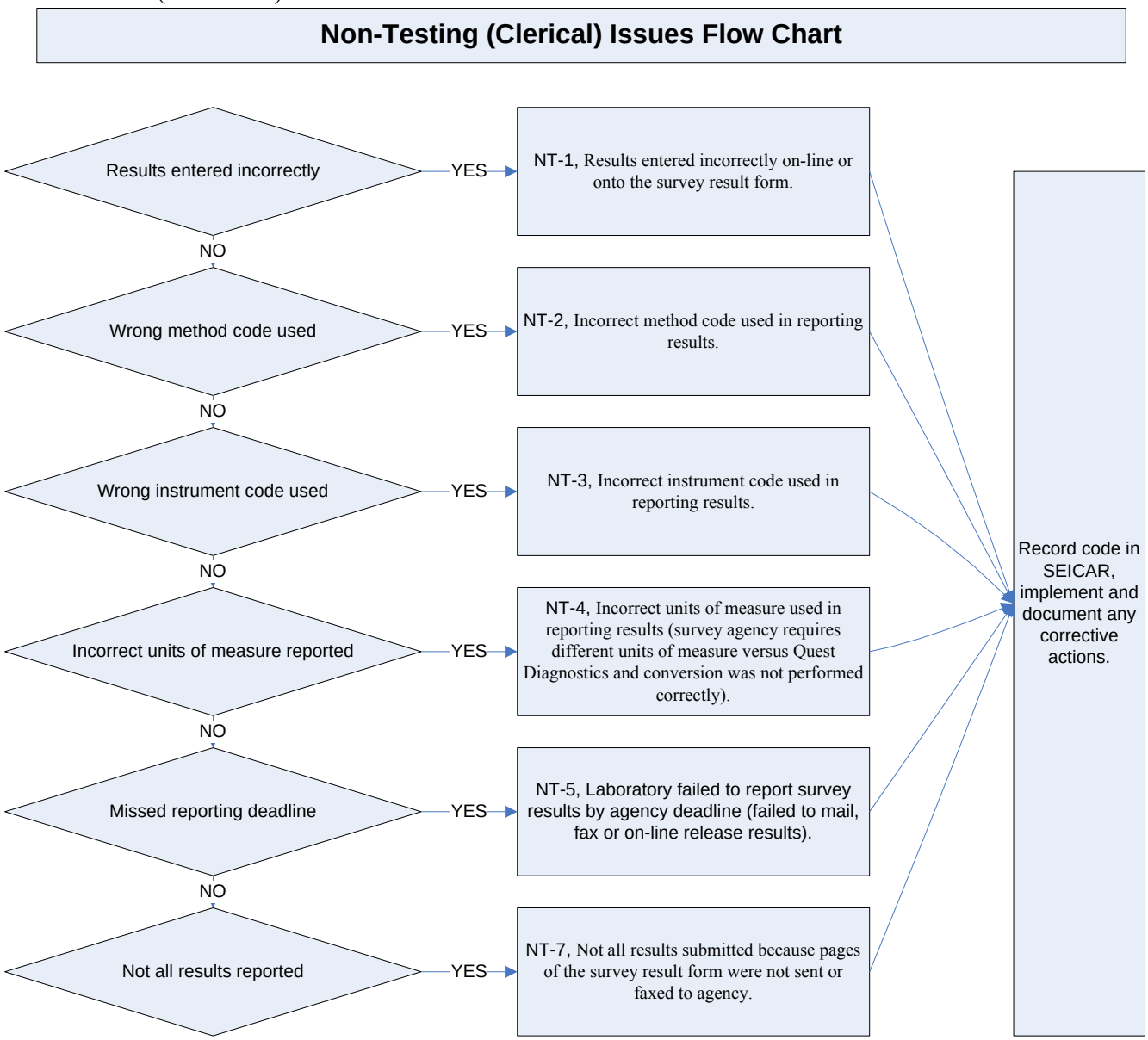

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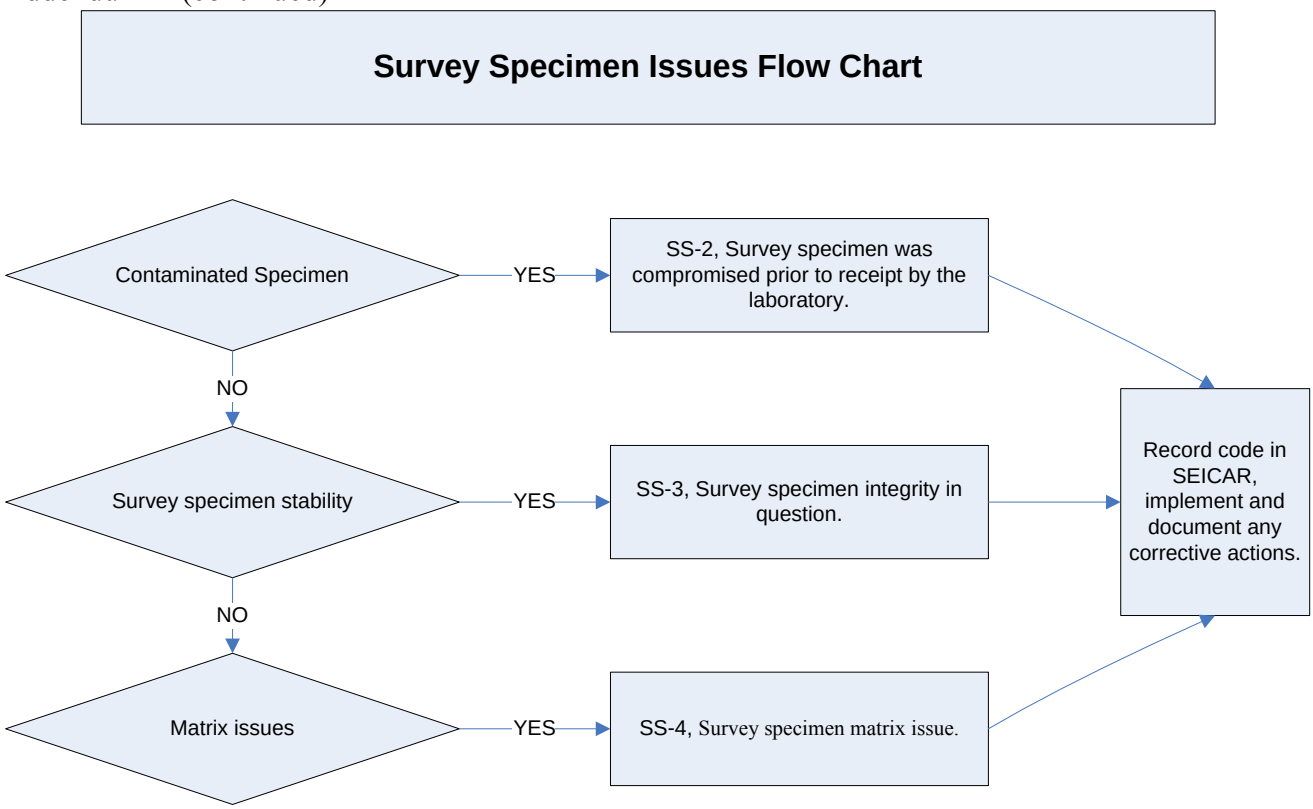

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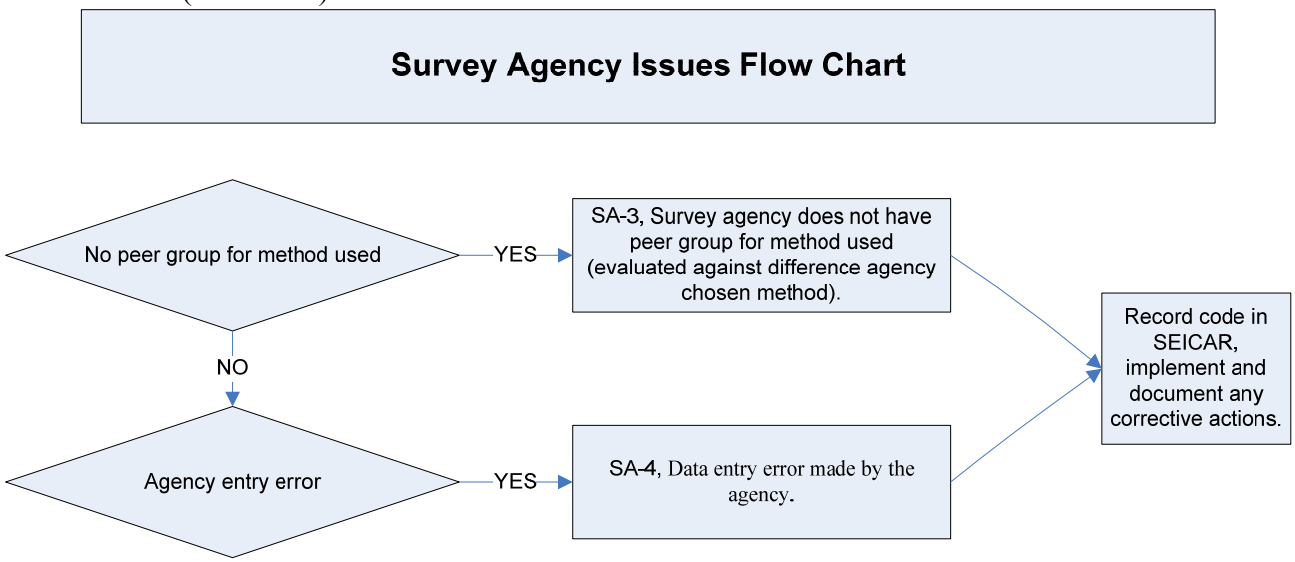

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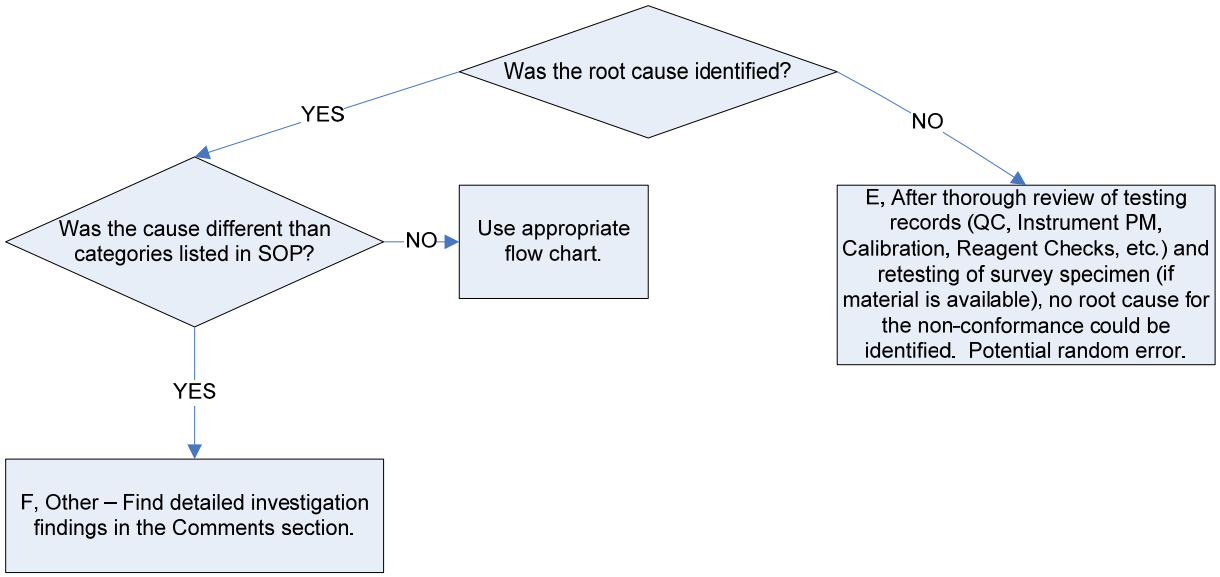
Addendum B (continued)

No Root Cause or Other Issues Flow Chart



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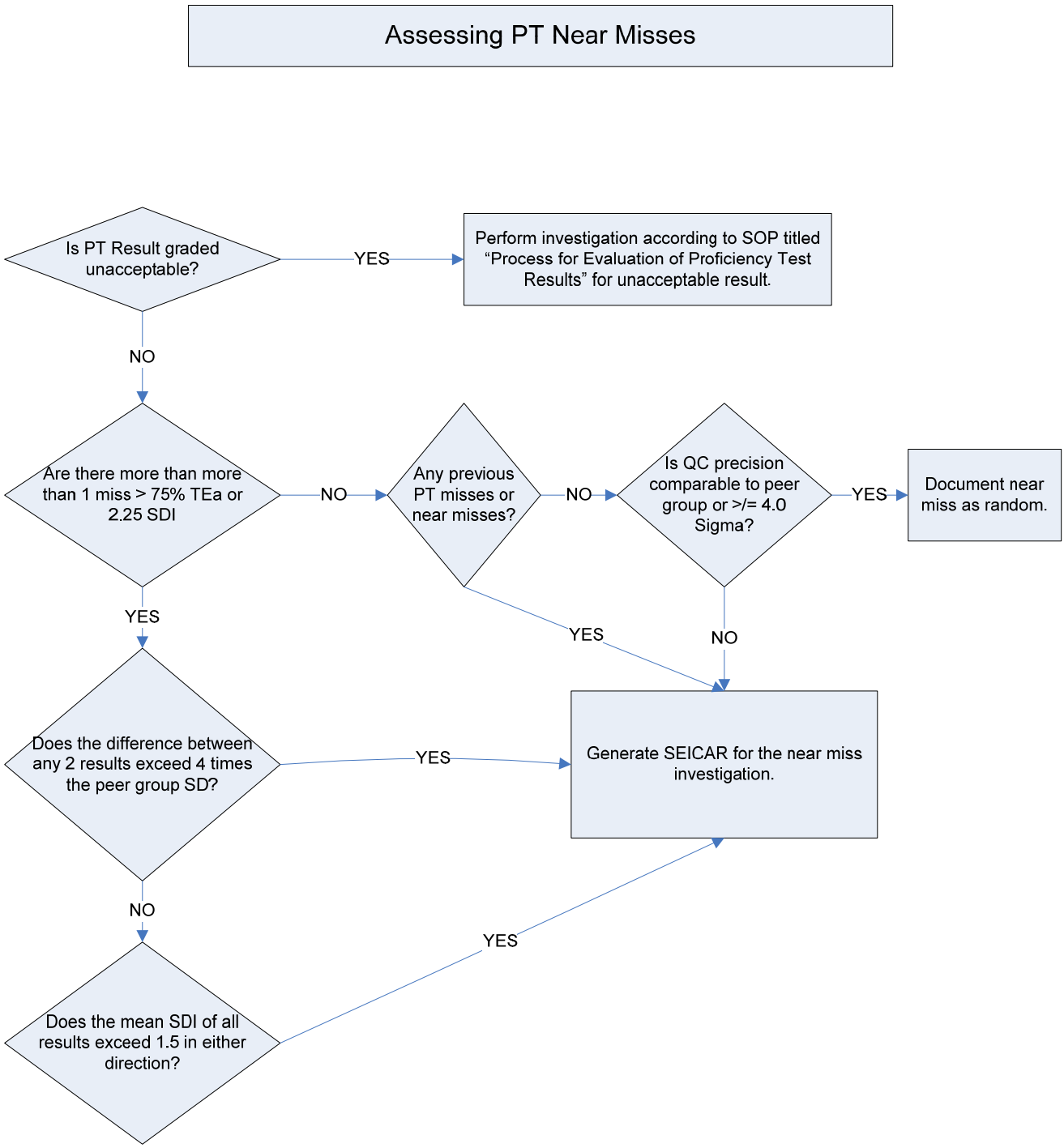
Addendum C



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Addendum D

External Proficiency Programs

Approved for Accuracy Evaluations by Alternative Performance Assessment

Agency	Telephone Number
College of American Pathologists (CAP)	(800) 323-4040
Accutest, Inc.	(800) 665-2575
American Association of Bioanalysts (AAB)	(800) 234-5315
American Proficiency Institute (API)	(800)333-0958
New York State Department of Health	(518) 474-8739
Puerto Rico Proficiency Testing Service	(787) 274-6827
WSLH	(800) 462-5261

Other CLIA Approved Proficiency Programs

Agency	Telephone Number
American Academy of Family Physicians (AAFP)	(800) 274-7911
California Thoracic Society (CTS)	(714) 730-1944
Medical Laboratory Evaluation Program (MLE)	(800) 338-2746
Commonwealth of Pennsylvania	(610) 280-3464

Quest Diagnostics

☐ Germantown Emergency Center
☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

QUEST DIAGNOSTICS
SURVEY ERROR INVESTIGATION AND CORRECTIVE ACTION REPORT (SEICAR)

Department: _____ Test Name: _____
Survey Agency: _____ Survey Name: _____
Date Issued: _____ Response Due Date: _____
Test At Risk: Yes or No (circle one)

Non-conformance Type: __ Graded __ Ungraded __ Near Miss __ D/Dmax (NY)

Proficiency ID #	Internal ID	Original Date Assayed	Original Result	Mean	SDI	Acceptance Range	Repeat Result(s)	Repeat Assay Date

Review of testing records (Findings from review of worksheets, QC results, maintenance records, procedural steps, patient reports, Survey Companion Document, etc.): _____
_____
_____
_____

Describe any previous proficiency testing issues with this test in the last year: _____
_____
_____
_____

Error code (from Survey Non-conformance Error Key List):_____

Root cause of non-conformance:_____
_____
_____
_____

Assessment of the impact of root cause on patient results (Patient results may be affected before, during or after the PT event). Describe how the conclusion of impact was made and any corrective actions made to the patient result(s):
_____
_____
_____

Corrective action (include effective dates):_____
_____
_____
_____
_____

Preventive action(s): _____
_____
_____
_____

Follow-up needed (if Yes, describe and include responsibility and frequency required)?
_____
_____

Additional comments: _____
_____
_____

If additional space is needed for documenting the response for the above, attach separate sheet(s) if necessary.

Reviews:
Technical Supervisor: _____ Date: _____

Department Manager: _____ Date: _____

QA Director/Manager: _____ Date: _____

Laboratory Director: _____ Date: _____

Other Reviewer (include title):
Name: _____ Date: _____

Title: _____