WADSWORTH CENTER

CLINICAL LABORATORY EVALUATION PROGRAM

Guidance for completion of the Plan of Correction

This document provides guidance for completion of the Plan of Correction in response to the findings identified in your Laboratory Evaluation Report. The plan of correction is a three-step process to include the performance of a root cause analysis, corrective action or system change to prevent recurrence and, the quality system change made to monitor the effectiveness of the corrective action. **Failure to address all three steps will result in an unacceptable plan of correction and it will be returned for completion.**

I. PERFORM A ROOT CAUSE ANALYSIS

A root cause analysis is a team process to identify the cause of a problem that resulted in a negative outcome. The root cause analysis provides an opportunity to identify why the problem occurred and the actions necessary to prevent similar issues in the future.

1. Investigate to determine what, who, how, why and when the event occurred. Identify the event, select key team member(s) who are knowledgeable about the relevant processes. These team members will collect the information in steps 2 - 5 below.
2. Review the **Quality Management Systems and laboratory practices**, including but not limited to:
   - Audits: Internal systems and process audits, external audits, quality indicators, nonconformances and effectiveness of corrective and/or preventive actions
   - Human Resources: Training and competency assessments
   - Facility Design: Environmental controls
   - Laboratory Safety: Safety procedures and training
   - Laboratory Information Systems: System verification, transcription accuracy and specimen tracking
   - Resource Management: Reagent inventory control and maintenance/verification of instruments and equipment
   - Document Control: Compliance, version control and procedure excerpts
3. Review the elements of the **pre-analytic** systems. Examples include but are not limited to:
   - Test Request: Test request form and verbal test requests
   - Specimen Processing: Submission instructions and monitoring specimen submissions (collection, labeling, transport, required information), accessioning and specimen storage
4. Review the elements of the **analytic** systems. Examples include but are not limited to:
   - Test Procedures: Content (clear and complete instructions)
   - Test Performance Specifications: Analytic records (worksheets), acceptable accuracy, precision, reportable range of results and comparability of test results, if applicable
   - Calibration and Calibration Verification: Appropriate number, type and concentration of calibration materials, acceptable limits for calibration and frequency of calibration
   - Quality Control: Acceptable limits, number, frequency and documentation of quality control
5. Review the elements of the **post-analytic** systems. Examples include but are not limited to:
   - Result Review: Review of analytic record documentation for acceptable test performance
   - Reporting: Verification of accurate transmission and communication of results
   - Patient Impact: Corrected report or testing delays and/or errors

II. CREATE AND IMPLEMENT CORRECTIVE ACTION / SYSTEM CHANGE

The expectation is that all areas overseen by the laboratory and for which the laboratory is responsible have been reviewed for the same or similar nonconformity. Areas include, but are not limited to, transfusion medicine, point of care testing, patient service center, limited laboratory service, respiratory department, oncology unit, etc.

Examples of the questions to ask when creating your corrective action or system change include, but are not limited to, the following:

1. What change is necessary to ensure there will not be a repeat of this deficiency?
2. Do policies, procedures and/or processes need to be revised, amended, or created to ensure there will not be a repeat of this deficiency?
3. Is additional training and competency assessment needed?
4. Should control and feedback loops be created to ensure participants will complete an action?
5. Will simplifying or standardizing tasks improve the process?
6. Is increased supervisor oversight necessary?
7. Should staff increase or staff schedules be revised to provide better coverage for high volume times?
8. Will modification and/or verification of the laboratory information system (LIS) address the issue?
9. Are there distractions that can be reduced or eliminated?
10. Can the communication among laboratory, nursing and medical staff be improved?

III. CREATE QUALITY ASSURANCE (QA) PROCESS(ES) TO FOLLOW THE EFFECTIVENESS OF THE CORRECTIVE ACTION / SYSTEM CHANGE

To ensure the effectiveness of the corrective action or system change, perform audits and/or put quality indicators in place to include the pre-examination, examination and post-examination processes. Examples of quality assurance processes include, but are not limited to, the following:

1. Increase the frequency of Quality Management System (QMS) meetings to provide timely feedback to management and staff
2. Create internal audits and quality indicators
3. Increase the frequency of internal audits and quality indicators
4. Assess specimen transport conditions
5. Assess result turn-around time
6. Increase the frequency of quality control and calibration review
7. Retrain and reassess competency

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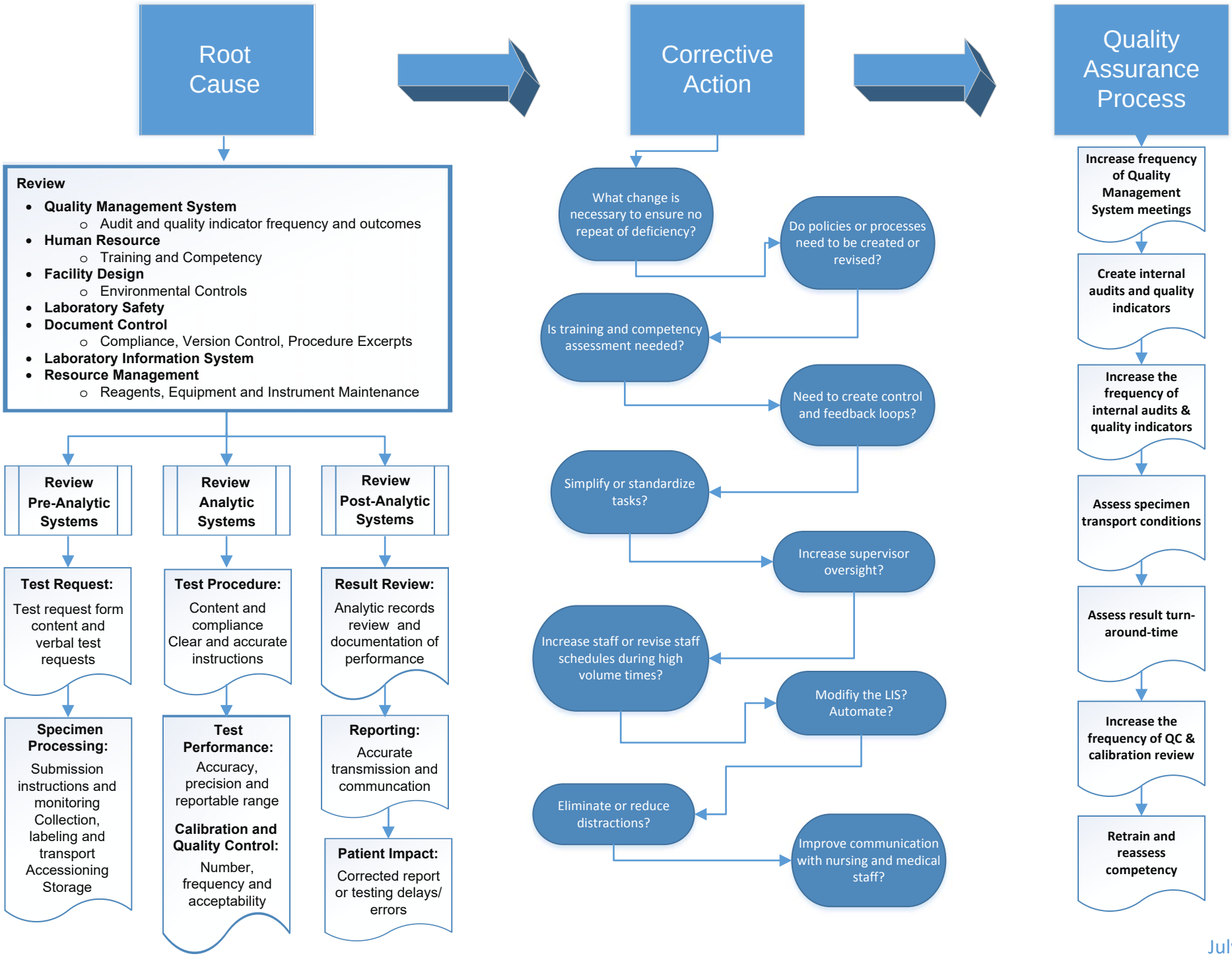
New York State Department of Health
Wadsworth Center



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