TITLE: Individualized Quality Control Plan (IQCP) Program

PURPOSE: The Individual Quality Control Plan Program is to insure that our clients and providers receive analytical data which has accurate, reliable, and appropriate for the intended purpose of quality patient care. The IQCP Program will establish written procedures to be followed to develop a comprehensive program of Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment (QA) required by the Clinical Laboratory Improvement Act [CLIA] and stated by the Centers for Medicare and Medicaid Services. This IQCP provides for continuous monitoring and evaluation of patient care activities within the medical laboratory.

The IQCP is designed to maintain compliance with all federal, state, and local laws and regulations, as well as organizational policies and ethical standards.

SCOPE: All non-waived testing within the laboratory that does not have two or more levels of controls run each day of testing will have an Individual Quality Control Plan made in accordance with CLIA regulations. IQCP considers the entire testing process: pre-analytic, analytic, and post-analytic; thus, the laboratory will consider the corresponding risks in each of these phases and applicable regulatory requirements

POLICY:

1. Each IQCP will have three main components that consist of the following:

* Risk Assessment
  + Identify and evaluate potential failures and sources of error
* Quality Control Plan
  + Consideration is made for how testing, from specimen collection to finalized result, should occur when done properly.
* Quality Assessment
  + Review of how the IQCP is working, to be done on a regular basis as required by each department or semi –annually and annually as required by CMS.

1. It is up to the head of each lab discipline, Lab Manager and Lab Director as to what each finalized QCP will entail in order to meet these requirements.
2. IQCP requires completion of two CAP forms:
   * List of Individualized Quality Control Plans
     + The laboratory has identified all tests using an IQCP
   * Individualized Quality Control Plan Summary
3. The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.

PROCEDURE: This program describes a standardized method of Risk Assessment involving identification and evaluation of potential failure and/or errors in a testing process, including: the specimen, environment, reagent, test system and testing personnel. The risk assessment is followed by a Quality Control Plan (QCP) in which the laboratory’s standard operating procedure is describing the practices and resources to ensure quality for a test system. Finally, the Quality Assessment Plan (QAP) is the laboratory’s policy for monitoring the effectiveness of the IQCP.

Risk Assessment – All of the components of testing including specimen, test system, reagent, environment, and testing personnel need to be researched and reviewed to assess the likelihood and severity an error will be and how it will affect a patient. All phases of testing should be considered including pre-analytical, analytical and post-analytical. For each outcome that has an unacceptable risk level there needs to be an action plan/intervention in place to prevent it from happening.

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| --- | --- | --- | --- | --- | --- |
|  | Severity of harm | | | | |
| Probability of harm | Negligible | Minor | Serious | Major | Catastrophic |
| Frequent | x | x | x | x | x |
| Probable |  | x | x | x | x |
| Occasional |  |  |  | x | x |
| Remote |  |  |  |  | x |
| Improbable |  |  |  |  | x |

Probability terms –

* **Frequent:** Likely to occur immediately or within a short period of time.
* **Probable:** Likelihood of occurrence roughly 2-5 times per year.
* **Occasional:** Probably will occur in time [1-2 years].
* **Remote:** Possible to occur in time [2-5 years].
* **Improbable:** Not likely to occur [5-30 years].

Severity Terms –

* **Negligible:** No harm or injury to patient or increase level of care or hospitalization.
* **Minor:** No increased level of care or hospitalization but adversely affects the labs reputability.
* **Serious**: Increasing length of patients’ hospitalization or increased level of care.
* **Major:** Permanent lessening of bodily functioning not related to the natural course of patients illness.
* **Catastrophic:** Death or permanent loss of function not related to natural cause or illness or underlying condition.

**Risk Assessment** Examples:

*Example Chart:*

Operator Risk Assessment

|  |  |  |  |
| --- | --- | --- | --- |
| Step Where potential Failure could occur | Potential Failure | Potential Cause | Correction/Further education/re-education  Ear cultures |
| Operator training and Capacity | Capacity | Lack of training | Section 2 of General Lab Manual |
| Incompetency | Microbiology SOP: EAR CULTURE M-S-5 |
| Specimen collection manual |
| Personnel training: beginning of employment,  6 months,  yearly |
| Untrained | Personnel Training,  Microbiology SOP: EAR CULTURE M-S-5 |
| No staffing | Not applicable |

Quality Control Plan –The Quality Control Plan - defines all aspects monitored based on risk assessment

* + The number, type (external and internal quality control systems), and frequency of quality control
  + Criteria for acceptable performance
  + Monitoring of other control processes such as:
    - personnel training and competency assessment
    - equipment maintenance and monitoring
    - environment monitoring
    - result reporting error check
    - any other identified risk area
  + Follow manufacturer’s instructions and recommendations for QC at minimum
  + Include the use of external control materials at least every 31 days and with new lots and shipments of reagents

The flow chart or table in the Risk Assessment should outline the process of testing from start to finish. For each step that has an adverse patient outcome, with an unacceptable level of risk, notation should be made and an action plan/suggestion that minimizing that risk by as much as possible is created. This becomes the Quality Control Plan for that analyte/test system.

Quality Assessment – The QA should be able to identify problem areas and find and apply solutions to further *reduce\** the chance of error.This is a continuous monitoring process that includes QC reviews, proficeincy testing reviews, corrected report monitoring, and monitoring of complaints.

If and when error(s) occurs, that is unacceptable, a formal investigation must take place. The investigation should, to the best knowledge of all parties involved, find the origin of the error, determine whether or not the error could have been prevented, delta check the RA, QCP, and QA plans to see if there are any steps that could be either added or change existing ones to better *reduce\** error and suite testing needs.

\*Error can never be totally eliminated and is inherent in any system.

RELATED PROCEDURES:

QM-151 Quality Control Plan (QCP) and Quality Assessment Plan (QAP)

of the Individualized Quality Control Program (IQCP)

SUPPLEMENTAL MATERIALS/ADDENDUM:

Risk Assessment for each test/test system

Individualized Qualy Control Plan Summary for each test/test system

List of Individualized Quality Control Plans

REFERENCES:

Current CAP Checklist

Published Power Point Presentation for CAP by Lyn Wielgos, MT(ASCP), December 8, 2015

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HISTORY PAGE

SOP Number: QM-150

SOP Title: IQCP Program

Written By: Wendy Turner

Manual in which Hard Copy of this SOP is located: Quality Management

Distribution: no other locations

Supersedes Procedure: QM-154 Equivalent QC

SOP CHANGE CONTROL

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