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Document Contact	Brooke Klapatch: Medical Technologist Lead
Area	Laboratory-Blood Bank
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Review of Quality Control - Royal Oak Blood Bank

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies relating to the review of quality control (QC) in the Blood Bank.

II. DEFINITIONS:

A. **Daily**: On a given calendar date.
B. **Monthly**: Within the first two weeks of each calendar month.
C. **Quarterly**: Within the calendar months of January, April, July, and October.
D. **Bi-Annually**: Every 6 months ± 1 month.
E. **Yearly**: Every 12 months ± 1 month.
F. **Biomedical**: Performs repairs and some maintenance of equipment.

III. POLICIES:

A. Frequency of Quality Control Review

1. The frequency at which QC is reviewed is defined on the Quality Control Calendar. This calendar serves as a checklist for the review of QC. It includes a listing of the QC tasks, the forms on which each QC task are documented, and the frequency at which the QC tasks are performed and reviewed. In general the following are reviewed: reactivity of reagents and their controls, instrument function checks, and temperature records. QC data must be reviewed and assessed at least once monthly; however several QC tasks are reviewed at more frequent

intervals as defined on the calendar.

B. Daily Review of QC Tasks Performed by Laboratory Assistants

1. Any QC task that is performed by a Laboratory Assistant, or any other employee who is not a Medical Technologist, must be reviewed by the following day. For example, a Laboratory Assistant may document plasma bath cleanings on the *Daily Temperature and Quality Control Record*; this data is reviewed the following day by a Medical Technologist.

C. Documentation of QC Review

1. QC review is documented on the applicable form (the form on which the QC data is recorded during the course of normal operations). The Medical Technologist Lead (MT Lead) will initial and date the form, along with a notation that the QC has been reviewed.
2. The QC of reagents is documented in the Blood Bank computer using various reagent QC racks; the review of these QC racks is documented as described in the Blood Bank CDM - *Reviewing and Releasing QC Results in SoftBank*.
3. The *Quality Control Calendar* has been fully documented and reviewed for the year, the MT Lead will transfer any applicable information to the *Quality Control Calendar* for the next year, and then discard the completed year.

D. Purpose of MT Lead QC Review

1. Whether QC review is documented on a form or in the computer, the MT Lead's documentation of QC review signifies that the MT Lead has verified the following:
    a. The form or computer record has been documented completely.
    b. All documented data is within the acceptable range, as defined in the corresponding policies and procedures.
    c. All data has been documented in accordance with the applicable policy/procedure.
    d. If any data is not within the acceptable range, a variance report has been submitted.
    e. Corrective action is initiated, when indicated.
    f. Reagents, supplies, and blood components are used within their expiration date.

E. Personnel Responsible to Review Quality Control

1. The Blood Bank Medical Director has designated the MT Leads to review quality control. While it is preferable that a MT Lead does not review one's own QC, it is acceptable for a MT Lead to review one's own QC due to the limited number of MT Leads, scheduling factors, and to ensure that QC is reviewed in a timely manner.
2. The Medical Technologists (MTs) have been designated to review QC of several tasks. For example:
    a. MTs review the QC for unit antigen typing as described in the Blood Bank

CDM - *Antigen Testing: Cosigning Antigen Negative Unit Labels and Review of QC*. MTs review this QC to prevent the unnecessary delay of RBC transfusions.

b. Several MTs have been authorized to perform QC review and supervisory review of antibody problems as described in Transfusion Medicine policy, *Supervisory Review of Antibody Investigations*.

F. Periodic Review by the Blood Bank Medical Director or Manager

1. The Blood Bank Medical Director or Manager may periodically review QC or audit QC related tasks for a variety of reasons including the implementation of new instrumentation, methodologies, or procedures; information obtained from variance reports; process improvement initiatives; concerns raised at staff meetings or daily rounds; changes in regulatory requirements, etc.

G. Variance Reporting

1. A variance is any event detected that may be error, accident, complaint, unplanned deviation, or incident that is documented for review, evaluation, investigation, and correction. A variance report is used to document these issues and the corresponding corrective action. For example, a variance report must be documented when components are prepared that do not meet the QC requirements, or any QC data is outside of the acceptable level as defined in the corresponding policy/procedure. Refer to Transfusion Medicine policy, Variance Reporting for additional information.

IV. REFERENCES:

1. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Attachments

Quality Control Calendar

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	6/21/2023
	Kristina Davis: Staff Physician	6/21/2023

Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	5/11/2023
	Kelly Sartor: Mgr, Division Laboratory	5/11/2023
	Brooke Klapatch: Medical Technologist Lead	5/10/2023