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Vitalant Quality System for Operational Excellence

Serving since 1942 as a steward of the community, Vitalant is committed to producing quality blood and cellular therapy products, and testing services, while at the same time creating an environment and culture dedicated to quality, improvement, and operational excellence. Vitalant maintains a focus on excelling in regulatory compliance and quality. Maintaining this focus on compliance and quality serves as a foundation for continued operational excellence.

Vitalant's focus is further defined in a "Quality System for Operational Excellence" manual. This document describes the 10 chapters that together outline the organization's requirements for quality, compliance and operational excellence. Each chapter includes a policy statement and the components vital for the provision of quality blood and blood products, testing, transfusion, cellular therapy and related services. The 10 chapters include:

- Organization, Leadership, and Customer Focus
- Facilities, Work Environment and Safety
- Human Resources
- Suppliers and Supply Management
- Equipment Management
- Process Management
- Documents, Records, and Information Management
- Nonconforming Events
- Monitoring and Assessment
- Continual Improvement

This is in compliance with applicable Standards and Regulations, including:

- **AABB Standards for Blood Banks and Transfusion Services, 32nd edition**
  - **Standard 1.2 Quality System** – A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.
  - **Standard 1.2.1 Quality Representative** – The quality system shall be under the supervision of a designated person who reports to executive management.

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- **Standard 1.2.2 Management Reviews** – Management shall assess the effectiveness of the quality system through assessments and scheduled management reviews.
- **Standard 5.1.3 Quality Control** – A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Chapter 9, Process Improvement Through Corrective and Preventative Action, applies.
    - **Standard 5.1.3.1** – The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.
    - **Standard 5.1.3.2** – Quality control failures shall be investigated before release of test results, products, or services.
- **Standard 8.3 Quality Monitoring** – The BB/TS shall have a process to collect and evaluate quality indictor data on a scheduled basis, including adverse events.
- **Standard 9.0 Process Improvement Through Corrective and Preventive Action** – The BB/TS shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive action, including near-miss events.
    - **9.1 Corrective Action** – The BB/TS shall have a process for corrective action of deviations, nonconformances, and complaints relating to blood, blood components, tissue, derivatives, critical materials, and services, which includes the following elements, as applicable:
        - Description of the event.
        - Investigation of the event.
        - Determination of the event.
        - Implementation of the event.
        - Determination of the causes(s).
        - Implementation of the corrective action(s).
        - Evaluation to ensure that corrective action is taken and that it is effective.
- **9.2 Preventive Action** – The BB/TS shall have a process for preventive action that includes the following elements:
    - **9.2.1** – Review of information, including assessment results, proficiency testing results, quality control records, and complaints to detect and analyze potential causes of nonconformances.
    - **9.2.2** – Determination of steps needed to respond to potential problems requiring preventive action.
    - **9.2.3** – Initiation of preventive action and application of controls to monitor effectiveness.