



QSE 1: Organization and Leadership

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| Policy | The laboratory complies with all external requirements and has an organizational structure that ensures quality and meets customer needs. |
| Purpose | This policy provides the effective demonstration of the laboratory's structure and quality management system as it is coordinated with other facility quality management programs. |
| Responsibility | <p>The Laboratory Medical Director is responsible for the allocation of resources so that strategic plans can be executed.</p> <p>The Laboratory Supervisor is responsible for maintaining the organizational chart.</p> <p>The Quality Manager is responsible for developing the laboratory quality management system and coordinating it with other facility quality management programs.</p> |
| Quality Management System | The laboratory quality management system will be developed and linked with other facility quality management systems. |
| Chart of Laboratory Organization | A chart of the organizational structure of the administration and staff of the laboratory will be maintained. |
| Referral Laboratories | A chart identifying all Referral Laboratories is maintained. |
| Supporting Documents | <p>The following processes support this policy:</p> <ul style="list-style-type: none"> • Implementing a Laboratory Quality Management System • Organizational Chart Development and Maintenance • Identification of Referral Laboratories |

Process for Implementing a Laboratory Quality Management System

| What Happens | Who's Responsible | Procedures |
|---|---|--|
| A Quality Manager is designated | <ul style="list-style-type: none"> • Laboratory Director • Human Resources | <ul style="list-style-type: none"> • Personnel Processes/Procedures |
| Internal and external customers' needs are identified | <ul style="list-style-type: none"> • Quality Manager • Laboratory Management | <ul style="list-style-type: none"> • Quality Management |
| The resources needed to meet those needs are identified and obtained | <ul style="list-style-type: none"> • Quality Manager • Laboratory Management | <ul style="list-style-type: none"> • Resource Allocation • Quality Management |
| Policies for each QSE are developed and integrated into a Quality Manual | <ul style="list-style-type: none"> • Quality Manager | <ul style="list-style-type: none"> • Quality Management |
| The processes and procedures needed to implement each policy are developed | <ul style="list-style-type: none"> • Quality Manager | <ul style="list-style-type: none"> • Quality Management |
| The principles in the Quality Manual are communicated to all personnel | <ul style="list-style-type: none"> • Quality Manager • Laboratory Supervisor | <ul style="list-style-type: none"> • Quality Management • Personnel Training Procedures |
| Laboratory leadership reviews the Laboratory Quality Management System at least annually | <ul style="list-style-type: none"> • Quality Manager • Laboratory Management • Laboratory Director | <ul style="list-style-type: none"> • Quality Management |
| Laboratory leadership works with other departments to coordinate the laboratory quality system with other facility quality management systems | <ul style="list-style-type: none"> • Laboratory Management • Laboratory Director • Facility Executive Management | <ul style="list-style-type: none"> • Quality Management • Other Departments' Quality Management Procedures |



Process for Organizational Chart Development and Maintenance

| What Happens | Who's Responsible | Procedures |
|--|---|---|
| The laboratory administration is identified | <ul style="list-style-type: none"> Executive Management Laboratory Director | <ul style="list-style-type: none"> Developing and Maintaining the Organizational Chart |
| The levels of authority and responsibility for all personnel are defined | <ul style="list-style-type: none"> Executive Management Laboratory Director | <ul style="list-style-type: none"> Developing and Maintaining the Organizational Chart |
| The chain of command (reporting relationships among personnel) is identified | <ul style="list-style-type: none"> Executive Management Laboratory Director | <ul style="list-style-type: none"> Developing and Maintaining the Organizational Chart |
| An organizational chart (organogram) is published | <ul style="list-style-type: none"> Executive Management Laboratory Director | <ul style="list-style-type: none"> Developing and Maintaining the Organizational Chart |



Process for Identification of Referral Laboratories

| What Happens | Who's Responsible | Procedures |
|---|---|--|
| The need for referral laboratories is assessed | <ul style="list-style-type: none"> Laboratory Supervisor | <ul style="list-style-type: none"> Use of Referral Laboratories Laboratory Testing Menu Review of Physician Order History |
| Referral laboratory's capabilities are assessed | <ul style="list-style-type: none"> Laboratory Supervisor | <ul style="list-style-type: none"> Use of Referral Laboratories Referral Laboratory Testing Menus |
| A list of Referral Laboratories and the tests that they conduct is maintained | <ul style="list-style-type: none"> Laboratory Supervisor | <ul style="list-style-type: none"> Chart of Referral Laboratories |