

## QSE 1: Organization and Leadership

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"> <li>• Implementing a Laboratory Quality Management System</li> <li>• Organizational Chart Development and Maintenance</li> <li>• Identification of Referral Laboratories</li> </ul>

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



## Process for Organizational Chart Development and Maintenance

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



## 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"> <li>• Laboratory Supervisor</li> </ul>	<ul style="list-style-type: none"> <li>• Use of Referral Laboratories</li> <li>• Laboratory Testing Menu</li> <li>• Review of Physician Order History</li> </ul>
Referral laboratory's capabilities are assessed	<ul style="list-style-type: none"> <li>• Laboratory Supervisor</li> </ul>	<ul style="list-style-type: none"> <li>• Use of Referral Laboratories</li> <li>• Referral Laboratory Testing Menus</li> </ul>
A list of Referral Laboratories and the tests that they conduct is maintained	<ul style="list-style-type: none"> <li>• Laboratory Supervisor</li> </ul>	<ul style="list-style-type: none"> <li>• Chart of Referral Laboratories</li> </ul>