

## RT's Commitment to Quality The Fundamentals

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The Quality Management System (QMS) provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.

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Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction.
Quality Cost Management	Includes the stages below and also the economic aspects of the "cost of quality."
<b>Quality Management System</b>	<b>Systematic process-oriented approach to quality objectives.</b>
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality.
Quality Control	Operational process control techniques to fulfill requirements for quality and governmental compliance.




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### **Why Quality Systems?**

- Consistent, high quality services
- Enhance employee potential
- Business advantage
  - Streamline processes
  - Increase productivity and efficiency
  - Cost-effective

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### **Why Quality Systems?**

- Reduce or eliminate medical errors
  - Patient safety
- Meeting customer requirements
- Potential for successful governmental and accreditation assessments

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### **Current Quality Models**

- CLSI HS1-A2 Quality System Model for Healthcare (2004)
- ISO 9001 Quality System Model
  - Healthcare Application 2001 and update
  - 15189 Clinical Laboratory specific
  - CLSI GP26-A3 Application of a Quality System Model for Laboratory Services

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## Current Quality Models

- Malcolm Baldrige Award for Healthcare, Education, Business
- CLSI HS4-A2 Application of a Quality System Model to Respiratory Services

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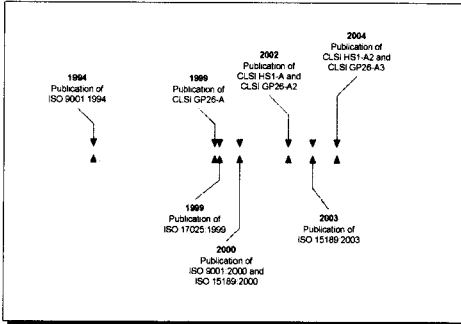
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## QMS Guidance - A Timeline




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## QSEs and ISO9001

CLSI	ISO
Organization	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 6.1 Provision of resources
Personnel	6.2 Human resources
Equipment	7.6 Control of measuring and monitoring devices
Documents and records	4.2 Documentation requirements
Purchasing and inventory	7.4 Purchasing
Customer service	6.2 Customer focus
Process improvement	8.5 Improvement

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## QSEs and ISO9001

Process Control	7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.5 Production and service provision
Occurrence management	8.3 Control of nonconforming product
Assessments—external and internal	8.1 General 8.2 Monitoring and measurement 8.4 Analysis of data
Information Management	Not addressed
Facilities and safety	6.3 Infrastructure 6.4 Work environment

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## Critical Requirements

**Commitment to quality**  
from senior management  
and throughout the organization

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## Model Structure For a Quality System

### Quality System Essentials

- Organization
  - Personnel
  - Equipment
  - Purchasing and Inventory
  - Process Control
  - Documents/Records
  - Occurrence Management
  - Assessment- internal and external
  - Process Improvement
  - Customer Service and Satisfaction
  - Information Management
  - Facilities and Safety

CLSI Document HS1-A2, 2004

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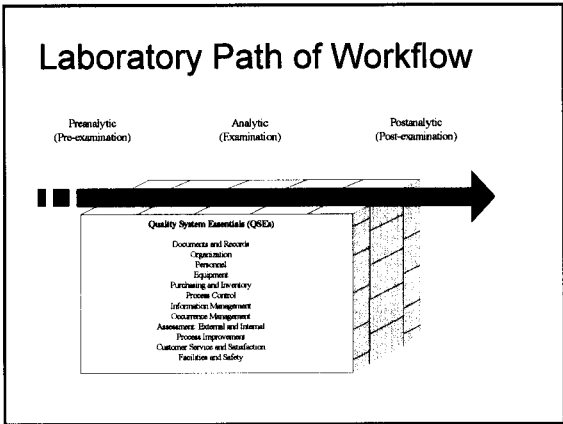
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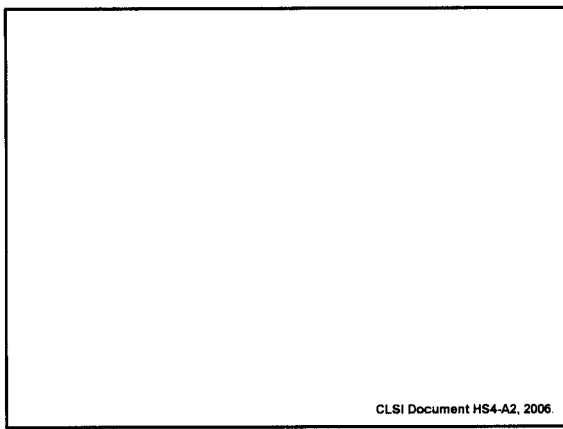
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CLSI Document HS4-A2, 2006.

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### PF Lab: Pretest Phase

- Patient Assessment
  - clinical history
  - patient signs and symptoms
  - other indicators that guide the physician or practitioner to make recommendations related to appropriate testing
  - standardized ordering format may guide the process

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### Pretest Phase

- Test Request Process
  - generating the order
  - patient instructions
  - scheduling
  - sequencing of test performance may impact test results

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### Pretest Phase

- Patient Preparation
  - specific demographic and history information from the patient (e.g., questionnaires, height and weight)
  - assessing patient compliance with pretest instructions
  - verifying the clinical indication or contraindications for testing
  - consent forms when appropriate

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### Pretest Phase

- Equipment Preparation
  - calibration and gathering equipment and supplies
  - selection of reference values

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## Testing Session

- Patient training
- Test performance
- Results review and selection
- Patient assessment for further testing

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## Post-test Phase

- Results report
- Interpretation
- Clinical consultation

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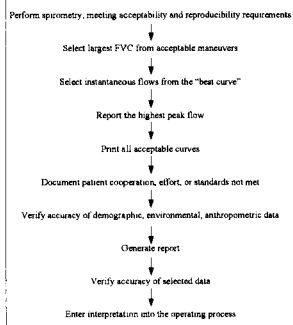
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### Operating Process: Spirometry Test Result Selection and Reporting



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## Definitions

- Policies
  - What do we do?
- Processes
  - How does it happen in this organization?
- Procedures
  - How do I do this activity?
- Forms and Records
  - Documents/files to record data, information or results

CLSI Document HS1-A2, 2004

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## Quality System Essentials (QSEs)

12 fundamental components for building a quality management system. Each QSE encompasses **policies**, **processes**, and **procedures** necessary to manage and improve work practices that will ultimately lead to better patient care

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## CLSI Quality System Essentials (QSEs)

- Documents and Records
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Occurrence Management
- Assessments: Internal and External
- Process Improvement
- Customer Satisfaction
- Facilities and Safety

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## Documenting the System

- Organization's quality policy
- The Quality Manual  
QSE: Organization
- Quality Management System  
QSE: Documents and Records
- Document structure  
QSE: Documents and Records

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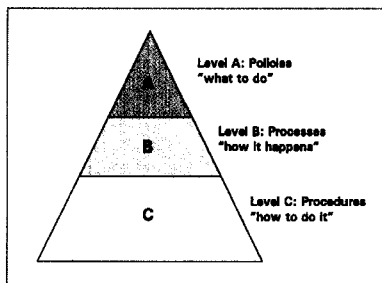
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## Quality System Documentation Hierarchy



CLSI Document HS2-A, 2004

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## QSE: Documents & Records

- Development of the system for controlling documents and records
- Analysis and validation of processes, development of SOPs and implementation of process controls

CLSI Document HS1-A2, 2004

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## QSE: Documents and Records

- System for controlling documents
  - Creation, identification, revision, review, distribution, and archiving
- System for controlling records
  - Identification, collection, review, indexing, accessing, storage, retention, and disposal

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## Documents and Records

- Policies, processes, and procedures
- Retention Schedule
- Master Index

Master Index			
Document Identification	Document Name	Effective Date	Location(s)

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## QSE: Organization

- Establishment of management commitment
  - Quality planning
  - Quality officer/staff
- Identification of the service's path of workflow
- Development of the quality manual

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<b>XYZ Service Quality Manual</b>	
Section 1	Purpose
Section 2	Scope
Section 3	Quality Policy Statement
Section 4	Quality Goals and Objectives
Section 5	Polices for Quality System Essentials
5.1	Documents and Records
5.2	Organization
5.3	Personnel
5.4	Equipment
5.5	Purchasing and Inventory
5.6	Process Control
5.6.1	Pre-service
5.6.2	Service
5.6.3	Post-service
5.7	Information Management
5.8	Occurrence Management
5.9	Assessments: Internal and External
5.9.1	Findings From Occurrences
5.9.2	Findings From Customer Satisfaction Surveys
5.9.3	Findings From Complaints
5.9.4	Findings From Internal Quality Indicators
5.9.5	Findings From Internal Audits
5.9.6	Findings From External Assessments
5.10	Process Improvement
5.11	Customer Service
5.12	Facilities and Safety
Document number/version	Facility Name/Location
Page 1 of 1	
Effective Date	

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**QSE: Personnel**

- Job descriptions
- Orientation
- Training
- Competency assessment
- Continuing education and professional development

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**QSE : Personnel**

- Job qualifications and descriptions
  - ATS
  - ERS
  - AARC
- Training and Competence Assessment Programs

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## **Training and Competence Assessment Programs**

- Orientation and Training
- Training Guides
- Competence Assessment
- Documentation of Training and Competence Assessment

CLSI Document HS4-A2, 2005.

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## **QSE: Equipment**

- Acquisition, installation, and identification
- Validation
- Calibration, maintenance, and use
- Troubleshooting, service, and repair
- Equipment records

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## **QSE : Equipment**

- The Equipment Management Plan
- Equipment Selection
- Equipment Installation

CLSI Document HS4-A2, 2005

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## Equipment Selection

- Management Plan
  - List of acceptable vendors
  - Develop product-evaluation matrix
  - Evaluate equipment
  - Determine acceptable limits of accuracy and precision

CLSI Document HS4-A2, 2005

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## Equipment Selection

- Management Plan
  - Consider database options
  - Consider quality control and calibration routines
  - Consider computer standards
  - Identify warranty and service agreements
  - Perform on-site evaluation
  - Correlate old and new equipment

CLSI Document HS4-A2, 2005

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## Equipment Installation

- Develop installation manual
- Validate equipment function
- Perform biomedical checks
- Validate reference values selected

CLSI Document HS4-A2, 2005

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### **QSE: Purchasing and Inventory**

- Purchasing
  - Critical supplies and service
  - Vendor qualification and evaluation
  - Contract review
  
- Inventory

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### **QSE : Process Control**

- Develop flowcharts for processes
- Process Validation
- Identify and Write Standard Operating Procedures
- Process Control
  - Quality Control
  - Proficiency Testing

CLSI Document HS1-A2, 2004

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### **Process Flowchart Examples**

- Data management
- Guideline/standards development
- Meeting management
- Project development
- Interpretation of data
- Request For Proposal (RFP) process

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## **QSE: Information Management**

- Commitment to quality in the flow of information between service units
  - Ingoing and outgoing information
  - Computer access and security
  - Data integrity
  - Information system “downtime”
  - Information requests (external, internal)

CLSI Document HS1-A2, 2004.

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## **QSE: Occurrence Management**

- Capturing information
  - Uniform formats and forms
- Report forms
- Immediate action and investigation
- Occurrence analysis
- Corrective action

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## **QSE: Occurrence Management**

Policy for

- Identification, documentation and investigation of nonforming events
- Classification, analysis, and data trending
- Identification of need for root cause analysis

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POCA	
<b>Plan: a mission-consistent, customer-oriented action plan</b>	
<ul style="list-style-type: none"> <li>• Identify opportunities for improvement from data sources.</li> <li>• Prioritize improvement activities.</li> <li>• Develop an action plan for the selected activity:               <ul style="list-style-type: none"> <li>- selecting a new process, and</li> <li>- improving an existing process.</li> </ul> </li> <li>• Identify               <ul style="list-style-type: none"> <li>- customer needs,</li> <li>- participants,</li> <li>- time frame,</li> <li>- outcome measurements, and</li> <li>- success criteria.</li> </ul> </li> </ul>	
<b>Do: Put the plan into action.</b>	
<ul style="list-style-type: none"> <li>• Implement the action plan:               <ul style="list-style-type: none"> <li>- pilot project first, and</li> <li>- broaden only after success.</li> </ul> </li> <li>• Collect performance data.</li> </ul>	
<b>Check: Has the planned and implemented change created intended improvement?</b>	
<ul style="list-style-type: none"> <li>• Analyze collected data.</li> <li>• Compare performance data to established success targets and original performance data to determine if improvement was achieved.</li> <li>• Identify any unexpected peripheral benefits.</li> <li>• Identify unanticipated problems in other areas.</li> </ul>	
<b>Act: Decide what to do next.</b>	
<ul style="list-style-type: none"> <li>• Determine if customer needs were met.</li> <li>• Take action based on the results:               <ul style="list-style-type: none"> <li>- Success:                   <ul style="list-style-type: none"> <li>• Review the processes for further improvements (optional).</li> <li>• Assess again to determine if improvement is maintained.                       <ul style="list-style-type: none"> <li>- if a pilot project, standardize to the bigger group.</li> </ul> </li> </ul> </li> <li>- Lack of success:                   <ul style="list-style-type: none"> <li>• revise the action plan and repeat.</li> </ul> </li> </ul> </li> </ul>	

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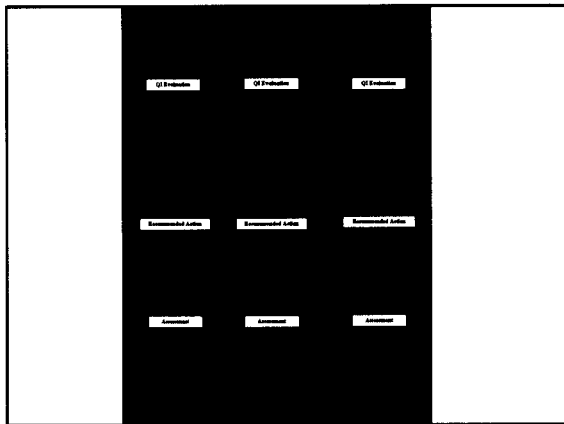
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## QSE: Customer Service

- Identifying the customer
- Identifying customer needs
- Customer feedback
- Mechanisms to respond to input

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## QSE : Service and Satisfaction

- Internal (Division or Agency)
  - Physicians
  - Staff
  - Other therapists
  - Nurses
  - Other caregivers
  - Leadership team

CLSI Document HS4-A2, 2005.

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## QSE : Service and Satisfaction

- External
  - Public
  - Patients
  - Physicians
  - Clinics
  - Accrediting bodies (JCAHO, CAP)
  - Regulatory groups (CLIA)
  - Laboratories (state lab directors)
  - Other agencies (CMS, FDA)

CLSI Document HS1-A2, 2004.

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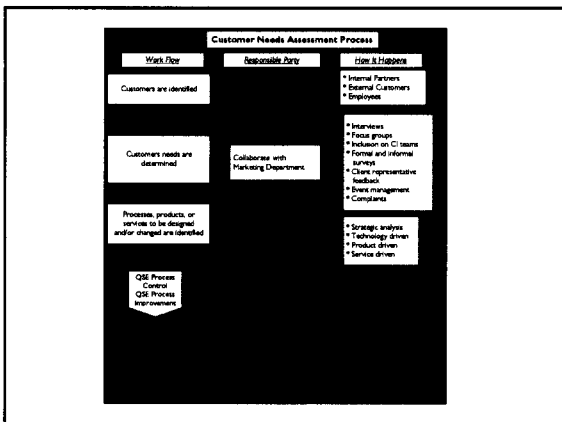
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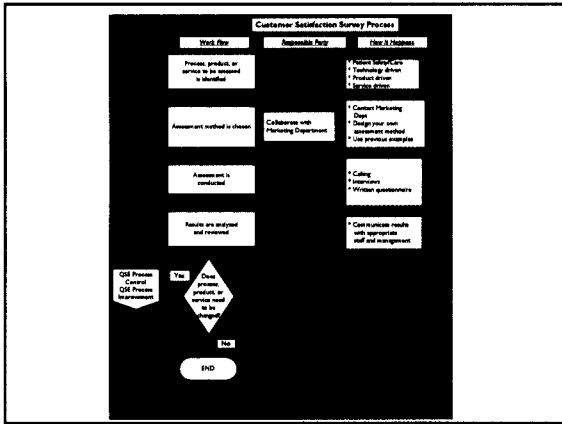
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## QSE: Facilities and Safety

- Facilities
  - Design
  - Environment
- Safety
  - Safety requirements and programs

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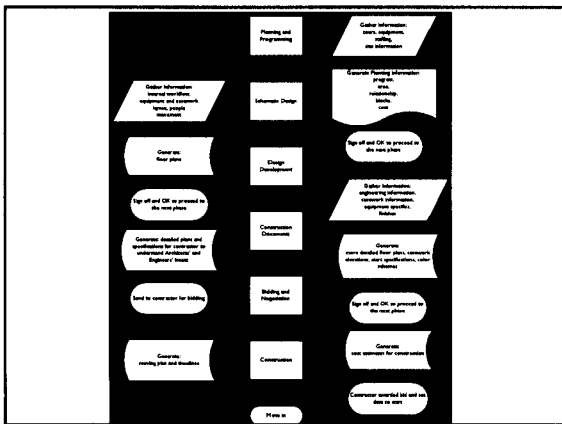
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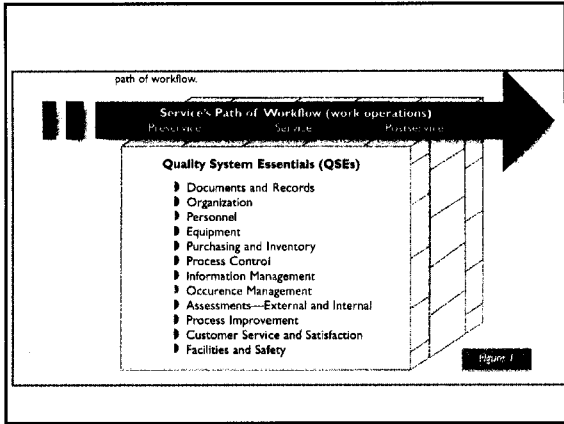
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## How to Begin

- Planning
  - Gap analysis
- Initial Phases
  - Documents and records
  - Process controls
  - Occurrence control
- Continuing implementation

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## Resources

- ATS Pulmonary Function Laboratory management and procedure manual second edition
- ATS/ERS statements
- AARC CPGs
- CLSI documents
- ISO documents

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## Staff Benefits

- Staff are more process focused (think globally)
- Increased accountability (clear definitions)
- Improved training (customer/employee satisfaction)
- Develops team attitude (removes departmental barriers)

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## Keys to Success

- Ability
- Agility
- Skating to where the puck is going to be

*Wayne Gretzky  
Hockey Star  
New York Rangers*

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## CLSI Documents

- Clinical and Laboratory Standards Institute:
- 940 West Valley Road  
Suite 1400  
Wayne, PA 19087-1898  
610-688-0100

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**Thank You!**

Any Questions?

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