## Quality Management Program (QMP) – Overview

### Key Elements
- 12 Quality Management Essentials (QME’s) that function as the integrated “building blocks” necessary to support the Laboratory’s pre-, post- and analytic work processes (i.e., path of workflow) so that they function as expected:
  - Organization
  - Facilities and Safety
  - Personnel
  - Equipment
  - Purchasing and Inventory
  - Process Control
  - Documents and Records
  - Information Management
  - Non-conforming Events Management
  - Assessment – External and Internal
  - Customer Service
  - Process Improvement

### Key functions
- Provides an infrastructure to systematically evaluate and improve quality and the appropriateness of laboratory services by:
  - identifying and resolving problems in patient care (i.e., corrective action), including those that may interfere with patient care services
  - identifying opportunities to improve patient care (i.e., preventive action)
  - integrating with the SSR and facility-specific quality initiatives and programs
- Ensures compliance with applicable state and local laws and regulations, which may include:
  - notifiable conditions
  - shipping infectious or diagnostic materials
  - retention of samples and records
  - hazardous waste disposal
  - fire codes
  - confidentiality of test results

### Scope
- Covers the entire scope of acute care and ambulatory laboratory services
- Implemented in all facilities and sections of the Laboratory, including Point-Of-Care testing.

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### Quality Management Program (QMP) – Overview, contd.

| Source model | • Quality Management System Model for Laboratory Services; CLSI GP26-A3  
|             | • A Quality Management System Model for Health Care; CLSI HS1-A2 |
| Quality Manual | • Contains the policies, processes and procedures related to the 12 QME’s  
|               | • Communicates the Laboratory’s intentions and structure for quality management and provides instructions for activities related to each QME |
| QME policies | • Each QME has a policy that states the intent related to that particular QME and becomes the Laboratory’s commitment to adhere to applicable guidelines, standards and requirements and to deliver quality services that meet customer expectations  
|              | • Answer the question, “What does Laboratory intend to do?”  
|              | • The guidance provided can be found in:  
|              |   - international quality standards and guidelines  
|              |   - national, state and local regulations  
|              |   - CAP and JCAHO accreditation requirements  
|              |   - Sutter Health policy |
| QME processes | • Describe the sequence of inter-related activities required to implement the QME policies:  
|               |   - all activities necessary to accomplish the intent of the policy  
|               |   - correct sequencing of the activities for the successful outcome of the process  
|               | • Answer the question, “How does it happen in this Laboratory?”  
|               | • Documented in flowcharts, tables or program descriptions |
| QME procedures | • Provide instructions for how to perform the steps in a given process activity  
|                | • Answer the question, “How do I do this activity?” |

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### Quality Management Program (QMP) – Overview, contd.

| Forms and records | • Forms are used to record data, information or results, including:  
|                   |   - blank pages or templates  
|                   |   - computer screens  
|                   |   - labels  
|                   |   - tags  
|                   | • Records are forms that have had data, information or results entered into/onto them |
| Instructional resource documents | • Provide guidance, reference or instruction to assist in the completion of a procedure |
| QMP Goals | • Optimize customer satisfaction  
|           |   - Physician  
|           |   - Patient  
|           |   - Employee  
|           | • Optimize patient safety  
|           |   - improve patient and sample identification  
|           |     . at the time of specimen collection  
|           |     . at the time of analysis  
|           |     . at the time of results delivery  
|           |   - improve the verification and communication of life threatening or life altering information regarding:  
|           |     . malignancies  
|           |     . HIV and other infections  
|           |     . Cytogenetic abnormalities  
|           |     . Critical (i.e., Alert) values  
|           |   - improve the identification, communication and correction of errors  
|           |   - improve coordination of the laboratory’s role in optimizing patient safety within the Sutter Sac-Sierra Region  
|           | • Accreditation readiness at all times  
|           |   - CAP  
|           |   - JCAHO  
|           |   - AABB (where applicable)  

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### Quality Management Program (QMP) – Overview, contd.

| **QMP Objectives** | • Developed in the form of “Performance Indicators”  
|                    |   - measurable  
|                    |   - dynamic  
|                    |   - meaningful to the customer  
|                    |   - developed for pre-, post- and analytic variables |
| **Linkage to SSR quality initiatives and/or programs** | • The Laboratory QMP links with, and supports, the goals of the Sutter Sac-Sierra Region’s (SSR) “Better, Safer Care” initiative:  
| |   - no needless deaths  
| |   - no needless pain and suffering  
| |   - no needless waste  
| |   - no unwanted or unwarranted delays  
| |   - no helplessness |
| **Quality Report** | • Summarizes performance related to QMP objectives  
| | • Reviewed and assessed by the Medical and Operational Management team  
| | • Is the foundation for:  
| |   - evaluating the effectiveness of the QMP  
| |   - performance improvement |
| **Evaluating Effectiveness** | • Quality is monitored periodically by the Medical and Operational Management (MOM) team  
| | • The MOM Team evaluates the effectiveness of the Quality Management Program by:  
| |   - comparing actual progress to stated goals  
| |   - comparing actual performance to stated objectives (i.e., performance indicators)  
| | • Inability to make progress toward goals and/or consistently achieve objectives will trigger an analysis of the QMP and may result in an action plan for improvement |
| **References** | • CLSI GP26 – A3; Quality Management System Model for Laboratory Services; Approved Guideline – Third Edition (2004)  
| | • CLSI HS1 – A2; A Quality Management System Model for Health Care; Second Edition (2004) |