Benefits of Implementing an Effective ISO 15189-based Quality Management System: A 4-year Retrospective

**Abstract**

In 2009, Blanchard Valley Hospital Laboratory accepted the challenge of obtaining ISO 15189 accreditation, and, true, four years later, continue to reap the benefits of an effective ISO 15189-based Quality Management System (QMS). The initial goal of attaining ISO 15189 accreditation was to challenge our Laboratory to "rise to the occasion" on its existing quality operation.

The benefits of the QMS surpassed our expectations and were more extensive than first envisioned. Tangible results include improvement in both turnaround times and percentage of outliers for several of our Quality Assurance Performance Improvement studies. Evaluation of our pre-analytic processes resulted in increased efficiencies with our outreach specimens and improved relationships with our clients. Additional benefits include an engaged staff equipped to be part of the solution, increased influence on the organization, structured occurrence management and problem solving, and sustained continual improvement. All of these advancements translate into improved patient care.

**Methods**

Organization of the QMS and structured management review was centered around the twelve quality system essentials: Organization, Documents and Records, Personnel, Equipment, Purchasing and Inventory, Process Control and Workflow, Information System, Occurrence Management, Process Improvement, Assessment, Customer Service, Facilities and Safety. The following were of particular importance to our success.

1. **DOCUMENT CONTROL**
   - Maintaining written policies and procedures for all laboratory activity is the first step in standardization.

2. **OCCURRENCE MANAGEMENT and PERFORMANCE IMPROVEMENT**
   - Effective occurrence management depends on documentation of occurrences from all job classifications and is only possible as a culture conducts to performance improvement.

3. **ASSESSMENT**
   - Systematic evaluation of laboratory processes is essential to developing an effective QMS with the capacity to continually improve patient care.

4. **PERSONNEL**
   - Compliance with the ISO 15189 standard requires buy-in from all job classifications.

5. **PROCESS CONTROL**
   - Effective monitoring of QMS decisions and improved processes enhances performance.

6. **PREVENTIVE MEASURES**
   - Communicating clear performance expectations and making data relevant to associates is essential to performance improvement.

**Conclusion**

The journey to ISO 15189 compliance resulted in development of an effective quality management system with sustained and continual performance improvement. The laboratory culture has maintained a mature thinking, driven by evidence-based problem solving, systematic evaluation of laboratory processes, and an engaged and informed staff.

*"Quality is never an accident. It is always the result of intention. Love the plan. Work the plan. Vary the plan."* - Will Power

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